Atlas Medical

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PRODUCT CATALOGUE

2022-2023

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INTRODUCTION

Atlas Medical GmbH was established in 1996 as a manufacturer and supplier of quality Diagnostic Reagents and Kits. Our products are sold in over 80 countries worldwide.

The company is located at the Cambridge Science Park, Cambridge, UK. In addition to the UK site, the company has offices in Germany and Turkey as well as two purpose-built modern facilities in both Jordan and Malaysia. We take quality assurance very seriously and strive to produce goods to the highest standards known in the industry, including, ISO13485 & CE mark and US FDA standards. Our R&D team constantly develops and innovates novel products that significantly contribute to the advancement of the Diagnostic Industry.

Vision

To be a major provider of quality medical diagnostic products to local, regional and international markets.

Mission

Our mission is to develop, produce and provide our customers with high quality products and excellent customer services through deep understanding of customers' needs and perception, recruitment of high caliber professionals & technicians, adopting strict quality assurance and control procedures and embracing new scientific advancements in the medical lab diagnostic field.

Objectives

- *High and Consistent Quality*
- *Satisfied Customer*
- *Continuous Improvement & Innovation*
- *Care for the Environment & Working Conditions*

Sites

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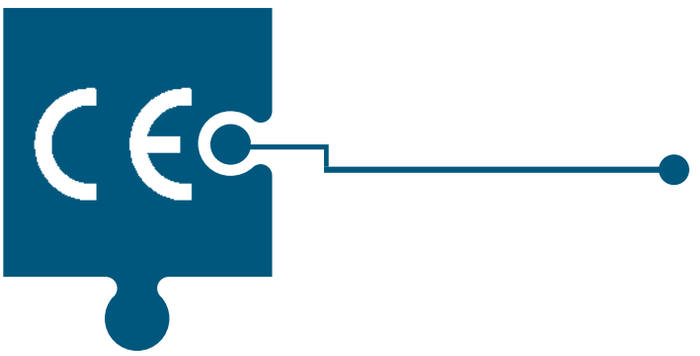
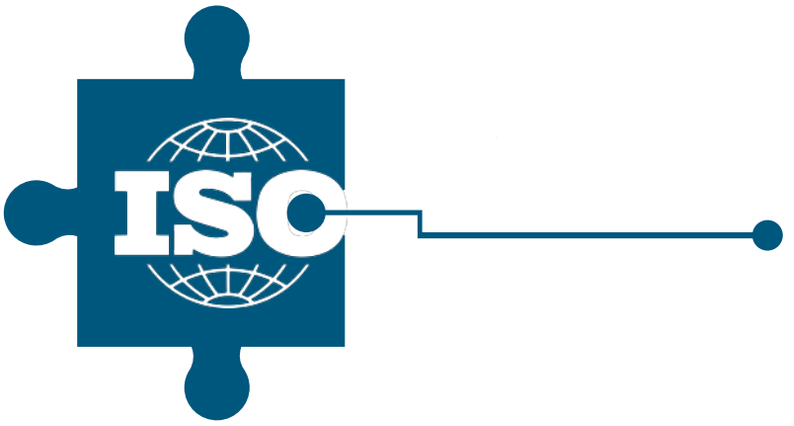
Our Markets

Atlas Medical enjoys a good presence in many international markets. We take pride in our export activities through our dedicated export department. We actively participate in major industry-related exhibitions seeking keen representatives around the globe to sell and distribute our products in their respective countries. We are internationally repre - sented in more than 80 of countries spanning in five continents: Europe, North America, South America, Africa and Asia. Our efforts will continue to increase our representation to include most markets around the globe.

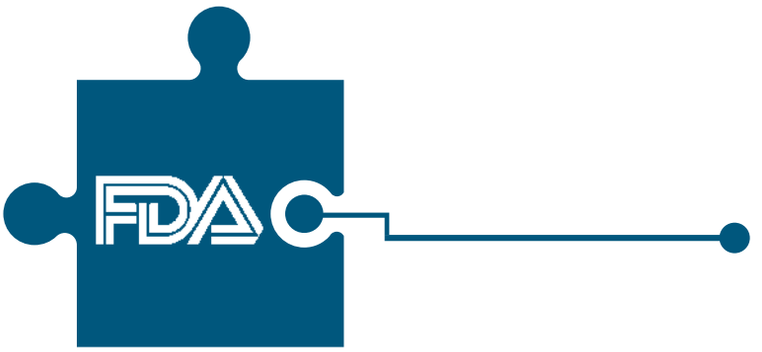
Standards



Our products are manufactured in accordance to the standards as set in the European In-Vitro Diagnostic Directive 98/79/EC. This has led to the successful attainment of Annex IV Full Quality Assurance Certification and the declaration of conformity for CE marking purposes for many of our IVD products, either self-declared or through our Notified Body LNE/G-MED

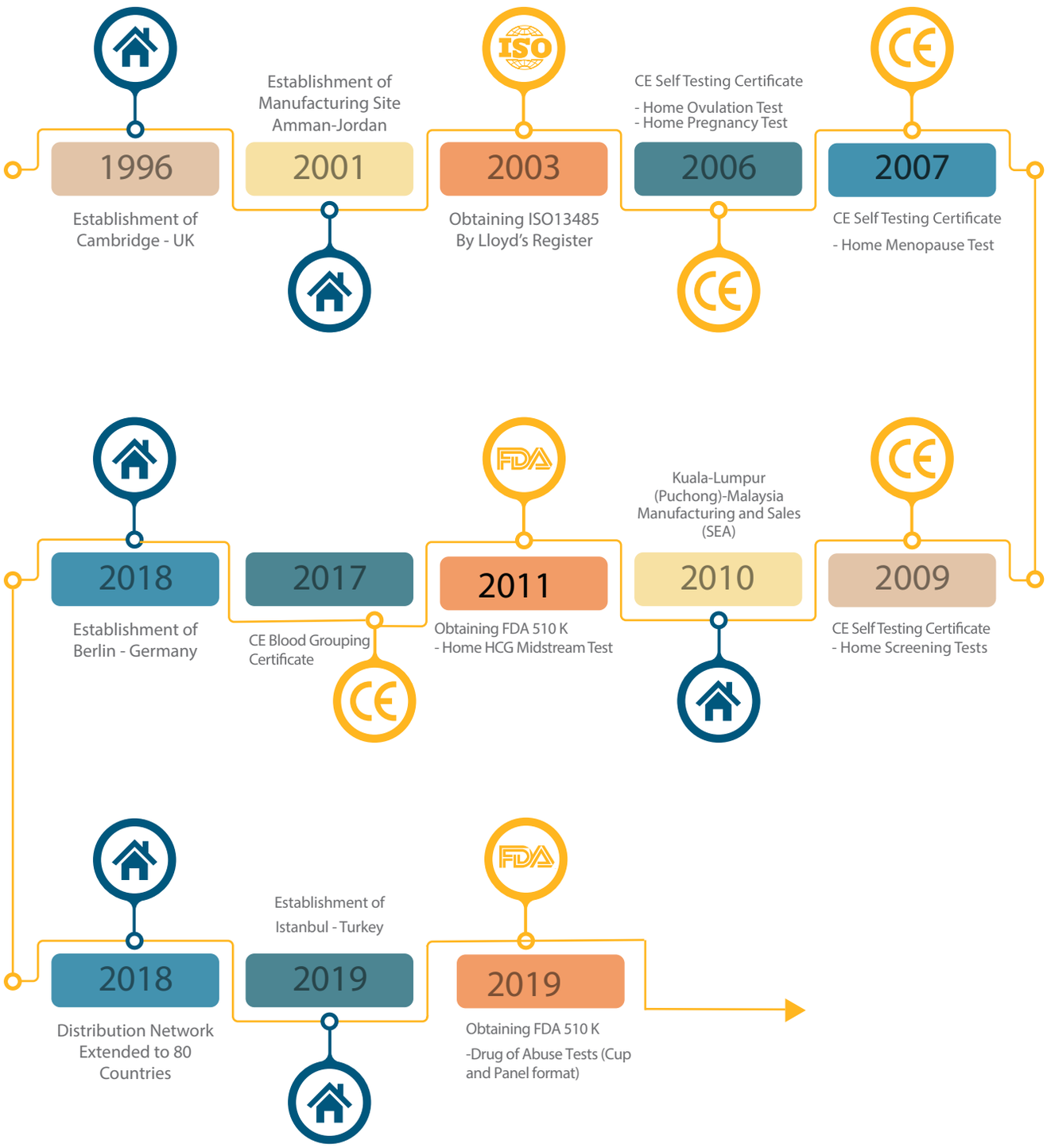


To complete the quality assurance scheme the company has put in place a robust Quality Management and Enhancement System that has concluded in the successful attainment of ISO13485: 2016 certificate



the company also adheres to the US-FDA regulations and had already FDA-cleared few products for the US market. Our products are registered in numerous countries.

MILESTONES


1996
Establishment of Cambridge - UK
2001
Establishment of Manufacturing Site Amman-Jordan
2003
Obtaining ISO13485 By Lloyd's Register
2006
CE Self Testing Certificate
- Home Ovulation Test
- Home Pregnancy Test
2007
CE Self Testing Certificate
- Home Menopause Test
2009
CE Self Testing Certificate
- Home Screening Tests
2010
Kuala-Lumpur (Puchong)-Malaysia Manufacturing and Sales (SEA)
2011
Obtaining FDA 510 K
- Home HCG Midstream Test
2017
CE Blood Grouping Certificate
2018
Establishment of Berlin - Germany
2018
Distribution Network Extended to 80 Countries
2019
Establishment of Istanbul - Turkey
2019
Obtaining FDA 510 K
-Drug of Abuse Tests (Cup and Panel format)

COVID-19 TESTING KITS

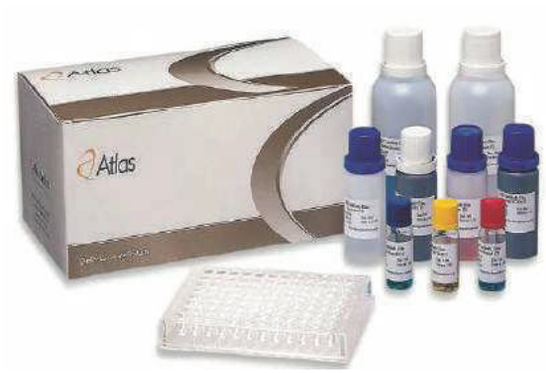
Overview

Atlas medical is introducing COVID-19 Real Time RT-PCR kit for the amplification and detection of the viral genetic material in patient specimen ,In addition Atlas Medical had introduced three new kits using the ELISA technique to detect the antibody response to COVID-19 infection. Detecting antibodies to SARS-CoV-2 virus could tell if a patient has been infected with COVID-19, either currently or in the past.

Item Code	Item Description	Sizes
8.14.45.0096	COVID-19 Real Time RT-PCR Test	96 Tests /Kits
8.14.45.0096	COVID-19 Total Ab Elisa Kit	96 Tests /Kits
8.14.46.0096	COVID-19 IgM Elisa Kit	96 Tests /Kits
8.14.47.0096	COVID-19 S1-RBD IgG Elisa Kit	96 Tests /Kits

Features

- Reverse-Transc RT-PCR is a special version used when RNA is being detected
- Atlas RT-PCR testing kits are fairly quick, sensitive ,reliable and can detect current infections of disease.
- Atlas ELISA kits are based on a simple and high sensitive laboratory technique, results can typically be produced within 1 to 2 hours from the moment of collecting the nasal swab sample .



COVID-19 RAPID TESTING KITS

Overview

Atlas Medical offers COVID-19 Rapid Test as a quick screening tool for the detection of the presence of SARS-CoV-2 virus in Nasopharyngeal swabs,"COVID-19 Antigen testing kit" , in addition Atlas medical offers" COVID-19 IgG/IgM Antibody Testing kit " as a screening tool for the human body response to the infection with the virus .

Item Code	Item Description	Sizes
8.66.00.0.0001 8.66.00.0.0020	COVID-19 IgM /IgG Test Cassette, Whole Blood/ Serum/Plasma ,Individually Pouched	Bulk 20 Tests/Box
8.66.01.0.0001 8.66.01.0.0020	COVID-19 Antigen Test Cassette, Nasal Swab, Individually Pouched	Bulk 20 Tests/Box
8.66.02.0.0001 8.66.02.0.0020	COVID-19 Combo Antigen & Influenza, A+B Test Individually Pouched	Bulk 20 Tests/Box
8.66.04.0.0020	COVID-19 Neutralizing Antibody Rapid Test Cassette ,Whole Blood /Serum/Plasma, Individually Pouched	20 Tests/Box

Features

- COVID-19 rapid test kits are based on Lateral Flow Immuno-Chromatographic Assay.
- Reliable ,easy to use with a short testing time of 10-15 minutes per each sample.
- The kits are conveniently packed in different sizes of 20,25 or 100 tests per kit including the necessary test accessories to perform the assay .

VIRAL TRANSPORT MEDIUM KITS

Overview

As a result of the current worldwide crises such as the COVID-19 pandemic and other worldwide health pandemic that are caused from malaria , Influenza and chlamydia ,Atlas medical had come up with Viral transport media ,The Media is used for facilitating the testing procedures by preserving the sample through the collection and transport process of the clinical samples containing viruses; including SARS-CoV-2 (COVID-19) and other viruses, in active form from collection site to the testing laboratory.

Features

- Atlas Medical offers VTM that allows the safe transfer of viruses for further research, including diagnostic tests, and molecular biology techniques
- Atlas VTM can come either as a biological format "activated product (VTM) " or in a chemical format "In Activated product (IVTM)" .
- Atlas VTM maintain the viral structure and activity over a wide temperature range and suppress "
- Atlas viral transport medium is stable at room temperature

- Atlas VTM kits are conveniently packed in different sizes of 50 ,100 tube per kit with flocked swabs

Item Code	Item Description	Sizes
8.64.02.0.0050 8.64.02.0.0100	Viral Transport Medium (VTM) with Flocked , Swab ,Individually Pouched	50 Tube/Kit 100 Tube/Kit
8.64.03.0.0050 8.64.03.0.0100	Viral Transport Medium (In Activating) with Flocked Swab ,(3 ml /vial)	50 Tube/Kit 100 Tube/Kit

LATEX KITS

Overview

Latex kits offer a quick and simple assay to diagnose a range of pathogens and medical conditions. The assay is based on an immunological reaction between the detected analyte in the sample and its corresponding antibody or antigen already coated on latex particles.

Features

- They cover a selection of routine tests in serology and microbiology.
- They are conveniently packed in sizes of 50 or 100 tests and includes all the necessary reagents, controls, stirrers and slides to conduct the test.
- Affordable, easy to use, dependable and offer a clear and visible agglutination for doubt-free results.
- Some Latex Kits come with a Buffer.

Item Code	Item Description	Sizes
8.00.00.0.0050 8.00.00.0.0100	CRP Latex Kit	50 Tests 100 Tests
8.00.01.0.0050 8.00.01.0.0100	CRP Latex Kit with Buffer	50 Tests 100 Tests
8.00.02.0.0050 8.00.02.0.0100	ASO Latex Kit	50 Tests 100 Tests
8.00.03.0.0050 8.00.03.0.0100	ASO Latex Kit with Buffer	50 Tests 100 Tests
8.00.04.0.0050 8.00.04.0.0100	RF Latex Kit	50 Tests 100 Tests
8.00.05.0.0050 8.00.05.0.0100	RF Latex Kit with Buffer	50 Tests 100 Tests
8.00.07.0.0050 8.00.07.0.0100	hCG Latex Kit	50 Tests 100 Tests
8.00.11.0.0050 8.00.11.0.0100	SLE Latex Kit	50 Tests 100 Tests
8.00.16.0.0050 8.00.16.0.0100	Rota Virus Latex Kit	50 Tests 100 Tests
8.00.17.0.0050 8.00.17.0.0100	D-Dimer Latex Kit	50 Tests 100 Tests
8.00.21.0.0050 8.00.21.0.0100	Waaler Rose Kit	50 Tests 100 Tests
8.00.08.0.0050 8.00.08.0.0100	IM Latex Kit	50 Tests 100 Tests
8.00.12.0.0050 8.00.12.0.0100	Staphylococcus Latex Kit	50 Tests 100 Tests
8.00.13.0.0300	Streptococcus Latex Kit	50 Tests

Item Code	Item Description	Sizes
8.00.09.0.0050 8.00.09.0.0100	Toxo Latex Kit	50 Tests 100 Tests
8.00.10.0.0050 8.00.10.0.0100	Toxo Latex Kit with Buffer	50 Tests 100 Tests
8.00.14.0.0100	Rubella Latex Kit	100 Tests

TURBIDIMETRIC LATEX KITS

Overview

The turbidimetric assay is based on the agglutination reaction between latex particles coated with antibody and the antigen in solution. The intended use for Turbilatex products is to detect and quantify the antigen present in human serum or plasma samples.

Features

- Atlas Medical offers a dynamic range of Turbidimetric Latex Kits which are conveniently packed in sizes of 50, 100 and 250 tests and include all the necessary accessories.

Item Code	Item Description	Sizes
8.44.00.0.0050 8.44.00.0.0250	RF Turbidimetric Latex Kit	50 Tests 250 Tests
8.44.01.0.0050 8.44.01.0.0100 8.44.01.0.0250	CRP Turbidimetric Latex Kit	50 Tests 100 Tests 250 Tests
8.44.02.0.0050 8.44.02.0.0100 8.44.02.0.0250	ASO Turbidimetric Latex Kit	50 Tests 100 Tests 250 Tests
8.44.03.0.0050 8.44.03.0.0100 8.44.03.0.0250	D-Dimer Turbidimetric Latex Kit	50 Tests 100 Tests 250 Tests
8.44.04.0.0050	Microalbumine Turbilatex	50 Tests
8.44.05.0.0050	Ferritin Turbilatex	50 Tests
8.44.06.0.0050	Transferrin Turbilatex (TRF)	50 Tests

SYPHILIS KITS

Overview

Atlas Medical offers a number of assays to detect Syphilis that include: TPHA kits which are used for the detection of antibodies to Treponema pallidum in human Serum or plasma using micro haemagglutination ; VDRL and RPR kits which are based on non-Treponemal floccuation to detect reagin antibodies in serum or plasma .

Item Code	Item Description	Sizes
8.00.18.0.0100 8.00.18.0.0250 8.00.18.0.0500	RPR Carbon Antigen Kit	100 Tests 250 Tests 500 Tests
8.00.19.0.0050 8.00.19.0.0100 8.00.19.0.0200	TPHA Kit	50 Tests 100 Tests 200 Tests
8.00.20.0.0250 8.00.20.0.0500 8.00.20.0.2500	VDRL Kit	250 Tests 500 Tests 2500 Tests
8.00.20.1.0250 8.00.20.1.2500	VDRL Kit with controls	250 Tests 2500 Tests

Features

- Easy to use, affordable and conveniently packed in different sizes to suit all needs.
- They include all the necessary reagents/devices, controls, stirrers and slides to conduct the test

FEBRILE ANTIGENS

Overview

Febrile antigen kits are based on bacterial suspensions that agglutinate in the presence of antibodies formed in human infection by certain fever-causing microbial agents. In positive samples, the agglutination is macroscopically visible at certain antibody levels in serum. These antigen reagents are used for the qualitative and semi quantitative febrile screening purposes.

Features

- Atlas Medical Febrile Antigen kits contain various types of antigens for Brucella, Proteus, Salmonella typhi and paratyphi, and their controls as needed.

- Atlas Medical Febrile Antigen kits are competitively priced and easy to use, and give clear results within 2 minutes

Item Code	Item Description	Sizes
8.01.17.0.0050	Febrile Antigen Set (10 Antigens: Salmonella OA, OB, OC, OD, HA, HB, HC, HD, Brucella abortus, melitensis)	10x5 ml
8.01.17.1.0050	Febrile Antigen Set (10 Antigens: Salmonella OA, OB, OC, OD,HA, HB, HC, HD, Brucella abortus, melitensis) with 3x1.0ml Controls	10x5 ml
8.01.18.0.0030	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD,HA, HB, HD)	6x5 ml
8.01.18.1.0030	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD) with 2x1.0ml Controls	6x5 ml
8.01.19.0.0001 8.01.19.0.0005	Febrile Antigens Positive Control	1 ml/vial 5 ml/vial
8.01.20.0.0001 8.01.20.0.0005	Febrile Antigen Negative Control	1 ml/vial 5 ml/vial

Item Code	Item Description	Sizes
8.01.00.0.0005 8.01.00.0.0050 8.01.00.0.0100	Brucella Rose Bengal Kit	5ml/vial 50 Tests 100 Tests
8.01.01.0.0005 8.01.01.1.0040 8.01.01.0.0050	Salmonella OA Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.02.0.0005 8.01.02.1.0040 8.01.02.0.0050	Salmonella OB Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.03.0.0005 8.01.03.1.0040 8.01.03.0.0050	Salmonella OC Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.04.0.0005 8.01.04.1.0040 8.01.04.0.0050	Salmonella OD Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.05.0.0005 8.01.05.1.0040 8.01.05.0.0050	Salmonella HA Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.06.0.0005 8.01.06.1.0040 8.01.06.0.0050	Salmonella HB Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.07.0.0005 8.01.07.1.0040 8.01.07.0.0050	Salmonella HC Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.08.0.0005 8.01.08.1.0040 8.01.08.0.0050	Salmonella HD Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.10.0.0005 8.01.10.1.0040	Brucella Abortus Reagent	5 ml/vial 8x5 ml
8.01.11.0.0005 8.01.11.1.0040	Brucella Melitensis Reagent	5 ml/vial 8x5 ml
8.01.12.0.0005 8.01.12.1.0040	Proteus OX2 Reagent	5 ml/vial 8x5 ml
8.01.13.0.0005 8.01.13.1.0040	Proteus OX19 Reagent	5 ml/vial 8x5 ml
8.01.14.0.0005 8.01.14.1.0040	Proteus OXK Reagent	5 ml/vial 8x5 ml
8.01.15.0.0010	Brucella Antigen Kit (Brucella melitensis, Brucella abortus)	2 vials/Box
8.01.15.1.0010	Brucella Antigen Kit with Controls (Brucella melitensis, Brucella abortus, 2x1.0 ml Controls)	2 vials/Box
8.01.15.2.0010	Brucella Antigen Kit with Controls, (5ml Brucella melitensis, 5ml Brucella abortus, 2x0.5 ml Controls)	2 vials/Box
8.01.16.0.0040	Salmonella Antigen Set (8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD)	8x5 ml
8.01.16.1.0040	Salmonella Antigen Set (8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD) with 2x1.0 ml Controls	8x5 ml
8.01.16.2.0040	Salmonella Antigen set (8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD) with 2x0.5ml Controls	8x5 ml

BLOOD GROUPING REAGENTS

Overview

Blood Grouping reagents are used for the identification of blood types. The test procedure is based on the agglutination principle, where red cells possessing the typing antigen agglutinate in the presence of the corresponding antibody in the testing reagent indicating the presence of the tested antigen. No agglutination indicates the absence of the tested antigen.

Features

- Atlas Medical ABO reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines.
- The reagents are formulated and optimized for use in tube and slide methods.
- Atlas Medical provides high quality blood grouping reagents that are accurate, easy to use, competitively priced, and conveniently packed in different sizes and options.

Item Code	Item Description	Sizes
8.02.14.0.0010	Anti-D Monoclonal (IgM), Clone 1, 10ml/vial	10 ml/vial
8.02.15.0.0010	Anti-D Monoclonal (IgM), Clone 2, 10ml/vial	10 ml/vial
8.02.16.0.0005	Anti-A1, Lectin (Dolichosbiflorus), 5ml/vial	5 ml/vial
8.02.17.0.0005	Anti-H, Lectin (Ulexeuropaeus), 5ml/vial	5 ml/vial
8.02.18.0.0005	Anti-C Monoclonal, 5ml/vial	5 ml/vial
8.02.19.0.0005	Anti-c Monoclonal, 5ml/vial	5 ml/vial
8.02.20.0.0005	Anti-E Monoclonal, 5ml/vial	5 ml/vial
8.02.21.0.0005	Anti-e Monoclonal, 5ml/vial	5 ml/vial
8.02.22.0.0005	Anti-C+D+E Monoclonal, 5ml/vial	5 ml/vial
8.02.27.0.0002	Anti-Fya, Human, 2ml/vial	2 ml/vial
8.02.28.0.0002	Anti-Fyb, Human, 2ml/vial	2 ml/vial
8.02.29.0.0002	Anti-k, Human, 2ml/vial	2 ml/vial
8.02.30.0.0002	Anti-Kpa, Human, 2ml/vial	2 ml/vial
8.02.31.0.0002	Anti-Kpb, Human, 2ml/vial	2 ml/vial
8.02.32.0.0002	Anti-Jka, Human, 2ml/vial	2 ml/vial
8.02.35.0.0002	Anti-Lub, Human,2 ml/vial	2 ml/vial
8.02.36.0.0005	Anti-K Monoclonal, 5ml/vial	5 ml/vial
8.02.54.0.0002	Anti-Cw,2 ml/vial	2 ml/vial

Item Code	Item Description	Sizes
8.02.00.0.0010 8.02.00.1.0100	Anti-A Monoclonal reagent (titer: 1/512)	10 ml/vial 10x10 ml
8.02.01.0.0010 8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512)	10 ml/vial 10x10 ml
8.02.02.0.0010 8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512)	10 ml/vial 10x10 ml
8.02.03.0.0010 8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128)	10 ml/vial 10x10 ml
8.02.04.0.0010 8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256	10 ml/vial 10x10 ml
8.02.05.0.0010 8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256)	10 ml/vial 10x10 ml
8.02.06.0.0010 8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256)	10 ml/vial 10x10 ml
8.02.07.0.0010 8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64)	10 ml/vial 10x10 ml
8.02.08.0.0010 8.02.08.1.0100	Bovine Albumin 22%	10 ml/vial 10x10 ml
8.02.09.0.0010 8.02.09.1.0100	Bovine Albumin 30%	10 ml/vial 10x10 ml
8.02.10.0.0010 8.02.10.1.0100	Anti-Human Globulin (Green) (Titer 1/512)	10 ml/vial 10x10 ml
8.02.11.0.0010 8.02.11.1.0100	Anti-Human Globulin (Green) (Titer 1/256)	10 ml/vial 10x10 ml
8.02.47.0.0030	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128))	3x10 ml
8.02.47.1.0030	ABO Set (Anti-A (1/265), Anti-B (1/265), Anti-D (1/64))	3x10 ml
8.02.49.0.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/64))	4x10 ml
8.02.53.0.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128))	4x10 ml
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64))	3x10ml
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1/256)	2x10ml
8.02.52.0.0010 8.02.52.0.0100	Rh-D Negative Control	10 ml/vial 10x10 ml
8.02.63.1.0010 8.02.63.0.0100	Antibody Enhancement Solution (LISS)	10 ml/vial 10x10 ml
8.02.23.0.0002	Anti-M, Human, 2ml/vial	2 ml/vial
8.02.24.0.0002	Anti-N, Lectin (Viciagraminea), 2ml/vial	2 ml/vial
8.02.25.0.0002	Anti-S, Human, 2ml/vial	2 ml/vial
8.02.26.0.0002	Anti-s, Human, 2ml/vial	2 ml/vial
8.02.34.0.0002	Anti-Lua, Human, 2ml/vial	2 ml/vial
8.02.37.0.0002	Anti-Lea, Monoclonal, 2ml/vial	2 ml/vial
8.02.38.0.0002	Anti-Leb, Monoclonal, 2ml/vial	2 ml/vial
8.02.39.0.0002	Anti-P1, Monoclonal, 2ml/vial	2 ml/vial

HEMATOLOGY TESTS

Overview

Atlas Medical supplies coagulation reagents.
The coagulation regents include PT,PTT and fibronogen in liquid formats and in various sizes to suit most lab applications.
The range also includes normal and abnormal coagulation controls.

Features

- Some kits includes normal and abnormal controls .
- The Kit comes in sizes of 50 and 100 tests.
- Atlas Medical provides high quality coagulation reagents that are accurate, easy to use, competitively priced, and conveniently packed in different sizes and options.

Co-aggulation Reagents

Item Code	Item Description	Sizes
8.02.40.1.0010 8.02.40.1.0050 8.02.40.1.0100	PT Calcium Rabbit Brain Thromboplastin, Liquid	2ml (20 Tests) 5ml (50 Tests) 10ml (100 Tests)
8.02.41.1.0040 8.02.41.1.0050 8.02.41.1.0100	APTT (PTT) Micronised Silica Platelet Substitute	2ml (40 Tests) 2.5ml (50 Tests) 5ml (100 Tests)
8.02.44.0.0040 8.02.44.0.0100	PT Kit with Normal Control	2x2ml + 1ml 2x10ml + 1ml
8.02.45.0.0080 8.02.45.0.0200	APTT (PTT) Kit with Normal Control	2x2ml + 1ml 2x10ml + 1ml
8.02.48.0.0010 8.02.48.0.0100	Calcium Chloride, 25 mM	10ml/vial 10ml/vial / 10 Vials / Box
8.02.60.0.0006	Normal Coagulation Control	6x1ml
8.02.61.0.0006	Abnormal Coagulation Control	6x1ml
8.02.69.0.0005	Fibrinogen Reagent	5ml/vial
8.02.45.1.0080	APTT (PTT) Kit (Calcium Chloride reagent + Normal Control)	80 Tests
8.02.64.0.0006	Normal & Abnormal Coaggulation Control	3x1ml
8.02.69.0.0100	Fibronogen Test kit KIT	100 Tests

Hemoglobin Reagents

Item Code	Item Description	Sizes
8.02.46.1.0500 8.02.46.1.1000 8.02.46.1.3000	Drabkins Reagent, 40x (White Plastic Bottle)	50ml/Bottle 2x50ml 6x50ml
8.02.50.0.0010 8.02.50.0.0050	Haemoglobin Standard	10ml/vial 50ml/Bottle

SICKLE CELL KITS

Overview

Sickle cell disease (also called sickle cell anemia) is an inherited blood disorder that affects red blood cells. The sickle cell gene causes the body to produce abnormal hemoglobin.

Features

- Atlas Sickle Cell Kits is a qualitative solubility test for Sickle Haemoglobin.
- The test can be performed in two ways:
  1. A screening test to detect sickle haemoglobin (HbS)
  2. A centrifugation test to differentiate the sickle cell trait (AS) from sickle cell anaemia (SS).

Item Code	Item Description	Sizes
8.02.67.0.0050	Sickle Cell Kit, 50 Tests	2x50ml Buffer + 2 vials of Sodium Dithionate
8.02.67.0.0100	Sickle Cell Kit, 100 Tests	4x50ml Buffer, 4 vials of Sodium Dithionate
8.02.68.0.0001 8.02.68.1.0001	Sickle Cell positive & negative control set	1ml each 0.5 ml each

INFECTIOUS DISEASE RAPID TESTS

ANTIBODY TESTING

Overview

Atlas Medical offers an extensive range of lateral flow immunoassay tests for the rapid detection of antibodies and antigens in human samples (blood, serum, plasma, urine, oral swabs, nasal swabs, and feces). This range includes tests to detect a wide variety of viruses, microorganisms and parasites.

Features

- Atlas Medical infectious disease rapid tests are reliable, accurate and supplied in both cassette and strip formats.
- The kits are conveniently packed in different sizes of 20, 25, 30, 40, 50 and 100 tests per kit and include the necessary test accessories to perform the assay.

RAPID TESTS

Item Code	Item Description	Sizes
8.04.27.0.0001 8.04.27.0.0020	HIV 1/2 Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.28.0.0001 8.04.28.0.0020	HIV 1/2 Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.29.0.0001 8.04.29.0.0100	HIV 1/2 Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.30.0.0001 8.04.30.0.0020	HCV Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.31.0.0001 8.04.31.0.0020	HCV Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.32.0.0001 8.04.32.0.0100	HCV Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.35.0.0001 8.04.35.0.0020	HBs Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.36.0.0001 8.04.36.0.0100	HBs Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.107.0.0040	Toxo IgG test cassette indiviually packed	40 Tests/Box

Item Code	Item Description	Sizes
8.04.20.0.0001 8.04.20.0.0020	H.pylori Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.21.0.0001 8.04.21.0.0020	H.pylori Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.22.0.0001 8.04.22.0.0100	H.pylori Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.41.0.0001 8.04.41.0.0020	Syphilis Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.42.0.0001 8.04.42.0.0020	Syphilis Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.43.0.0001 8.04.43.0.0100	Syphilis Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.16.16.0.0001 8.16.16.0.0020	TB Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.16.16.1.0020 8.16.16.1.0025	TB Test Cassette, Whole Blood, Individually Pouched	20 Tests/Box 25 Tests/Box

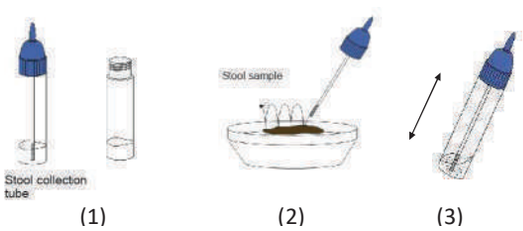
Item Code	Item Description	Sizes
8.42.47.0.0020	HAV IgM Test Cassette, Individually Pouched	20 Tests/Box
8.04.44.0.0001 8.04.44.0.0020	Dengue IgG/IgM Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box

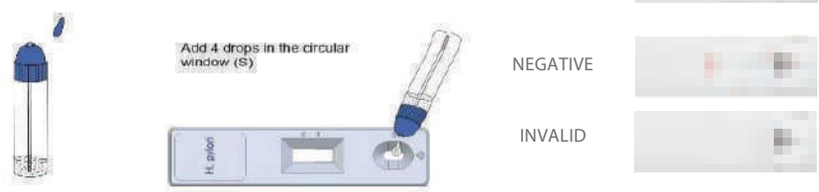
INFECTIOUS DISEASE RAPID TESTS

ANTIGEN TESTING

STOOL SAMPLE

Item Code	Item Description	Sizes
8.04.23.1.0020	H.pylori Antigen Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.04.24.1.0025	H.pylori Antigen Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.04.69.0.0020	Rotavirus Antigen Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.04.70.0.0025	Rotavirus Antigen Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.04.71.0.0020	Adenovirus Antigen Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.04.72.0.0025	Adenovirus Antigen Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.04.73.0.0020	Rota-Adeno Antigens Combo test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.04.74.0.0025	Rota-Adeno Antigens Combo test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.16.01.0.0020	Crypto Virus Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.16.02.0.0025	Crypto Virus Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.16.31.0.0020	Giardia Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.16.30.0.0025	Giardia Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.16.33.0.0020	Crypto-Giardia Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.16.32.0.0025	Crypto-Giardia Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.16.41.0.0020	E.coli Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.16.40.0.0025	E.coli Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.16.82.0.0025	Salmonella typhi Antigen Test Cassette, Stool Sample, Individually Pouched	25 Tests/Box
8.16.85.0.0025	Salmonella paratyphi Antigen Test Cassette, Stool Sample, Individually Pouched	25 Tests/Box
8.16.80.0.0020	Clostridium difficile Antigen Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.16.81.0.0025	Clostridium difficile Antigen Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.16.86.0.0025	C.Difficle Toxin A+B, Test Cassette, Stool Sample, Individually Pouched	25 Tests/Box
8.16.91.0.0025	Norovirus Genogroups I & II Ag, Test Cassette, Stool Sample, Individually Pouched	25 Tests/Box





SWAB & NASAL SAMPLE

Item Code	Item Description	Sizes
8.04.25.0.0020	Strep A Test Cassette, Swab Sample	20 Tests/Box
8.45.00.0.0020	Strep B Test Cassette, Swab Sample	20 Tests/Box
8.45.01.0.0020	Strep A+B Test Cassette, Swab Sample	20 Tests/Box
8.04.86.0.0020	Influenza A+B Test Cassette, Nasal Sample	20 Tests/Box
8.04.96.0.0025	Influenza A+B Test Strip, Nasal Sample	25 Tests/Box
8.16.20.0.0020	RSV Test Cassette, Swab Sample	20 Tests/Box
8.16.22.0.0025	RSV Test Strip, Swab Sample	25 Tests/Box
8.16.37.0.0020	Adeno Respiratory Antigen Test Cassette, Swab Sample	20 Tests/Box
8.16.36.0.0025	Adeno Respiratory Antigen Test Strip, Swab Sample	25 Tests/Box
8.16.39.0.0020	Adeno - RSV Respiratory Test Cassette, Swab Sample	20 Tests/Box
8.16.38.0.0025	Adeno - RSV Respiratory Test Strip, Swab Sample	25 Tests/Box

BLOOD SAMPLE

Item Code	Item Description	Sizes
8.04.37.0.0020	Malaria Pf. Test Cassette, Whole Blood, Individually Pouched	20 Tests/Box
8.16.14.0.0020	Malaria Pf/Pv. Test Cassette, Whole Blood, Individually Pouched	20 Tests/Box

Item Code	Item Description	Sizes
8.16.24.0.0001 8.16.24.0.0020	HBsAg Test Cassette (Whole Blood/Serum/ Plasma), Individually Pouched	Bulk 20 Tests/Box
8.04.33.0.0001 8.04.33.0.0020	HBsAg Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.34.0.0001 8.04.34.0.0100	HBsAg Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.26.0.0020	Chlamydia Test Cassette, Urine or Swab	20 Tests/Box
8.63.00.0.0025	Chlamydia + Gonorrhea Rapid Test Cassette (Cervical/Urethral swab)	25 Tests/Box

URINE REAGENT STRIPS

Overview

Urine Reagent Strips (URS) are widely used in Urinalysis to determine pathological changes in urine. The strips contain dry-chemistry pads that, when dipped in urine, change their colors. The color change allows for the semi-quantitative measurement of various urine parameters. The strips are suitable for lab, point-of-care and even home use.

Features

- Atlas Medical Urine Reagent Strips can be used to detect up to 14 urine parameters.
- They are simple to use and the results are visually read within a minute.
- The strips are packed in desiccated bottles of 50 or 100 strips.
- Atlas Medical can also provide suitable readers to read the strip colors and document the results.

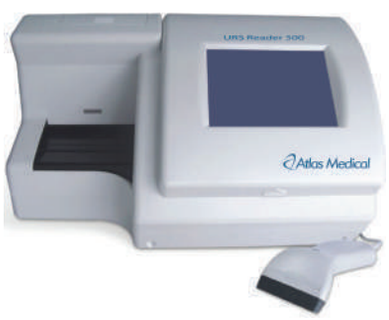
Item Code	Item Description	Sizes
8.03.00.0.0050 8.03.00.0.0100	URS 1 Parameter: Glucose	50 Strips 100 Strips
8.03.01.0.0050 8.03.01.0.0100	URS 1 Parameter: Protein	50 Strips 100 Strips
8.03.02.0.0050 8.03.02.0.0100	URS 1 Parameter: Ketone	50 Strips 100 Strips
8.03.45.0.0050	URS 1 Parameter Blood, (5mm)	50 Strips
8.03.03.0.0050 8.03.03.0.0100	URS 2 Parameters: Glucose, Ketone	50 Strips 100 Strips
8.03.04.0.0050 8.03.04.0.0100	URS 2 Parameters: Glucose, Protein	50 Strips 100 Strips
8.03.05.0.0100	URS 2 Parameters: Sample end: Urobilinogen, Bilirubin	100 Strips
8.03.19.0.0050 8.03.19.0.0100	URS 2 Parameters(5mm): Sample End: Creatinine, pH	50 Strips 100 Strips
8.03.06.0.0050 8.03.06.0.0100	URS 3 Parameters: Protein, pH, Glucose	50 Strips 100 Strips
8.03.07.0.0100	URS 3 Parameters: Glucose, Protein, Ketone	100 Strips
8.03.08.0.0100	URS 3 Parameters: Sample end:pH, Ketone, Glucose	100 Strips
8.03.09.0.0100	URS 3 Parameters: Sample end:Leukocytes, Nitrite, Blood	100 Strips
8.03.10.0.0050 8.03.10.0.0100	URS 3 Parameters: Sample end:Protein, Specific Gravity, Creatinine	50 Strips 100 Strips
8.03.11.0.0100	URS 4 Parameters: Protein, pH, Specific Gravity, Glucose	100 Strips
8.03.12.0.0100	URS 4 Parameters: Protein, pH, Blood, Glucose	100 Strips
8.03.13.0.0050 8.03.13.0.0100	URS 5 Parameters: Glucose, Protein, Ketone, pH, Blood	50 Strips 100 Strips
8.03.25.0.0100	URS 5 Parameters(5mm): Blood, Glucose, Protein, Nitrite, Leucocytes	100 Strips
8.03.14.0.0100	URS 6 Parameters: Leukocytes, Nitrite, Protein, pH, Blood, Glucose	100 Strips
8.03.44.0.0100	URS 7 Parameter: Glucose, Ketone, Protien, PH, Blood, Bilirubin, Urobilinogen	100 Strips
8.03.23.0.0100	URS 8 Parameters: Glucose, Protein, pH, Ketone, Urobilinogen, Bilirubin, Blood, Nitrite	100 Strips
8.03.15.0.0100	URS 9 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose	100 Strips
8.03.16.0.0100	URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose	100 Strips
8.03.17.0.0050 8.03.17.0.0100	URS 10 Parameters: Sample end: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone,Bilirubin, Glucose, Ascorbic Acid	50 Strips 100 Strips
8.03.18.0.0100	URS 11 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid	100 Strips
8.03.47.0.0100	URS 14 Parameters (ASC, GLU, BIL, KET, SG, BLO, PH, PRO, URO, NIT, LEU, ALB, CRE, CA)	100 Strips

URINE ANALYZER

Atlas Urine Analyzer is a manual analyzer that detects Photosensitive Diode using the method of Reflectance Photometry. Test Categories include Routine, STAT and QC. Atlas Urine Analyzer has an Automatic calibration for accurate results and easy operation. It can read strips with up to 14 parameters, including Microalbumin/Creatininenine/Calcium. It has an option to print results for quick and simple record management.

- Accurate.
- Reliable.
- Convenient.
- Easy Data Management.

Item Code	Item Description	Sizes
8.001.U120	Urine Analyzer For Clinics, U120	1 Unit
8.002.U500	Urine Analyzer For Hospitals, U500	1 Unit



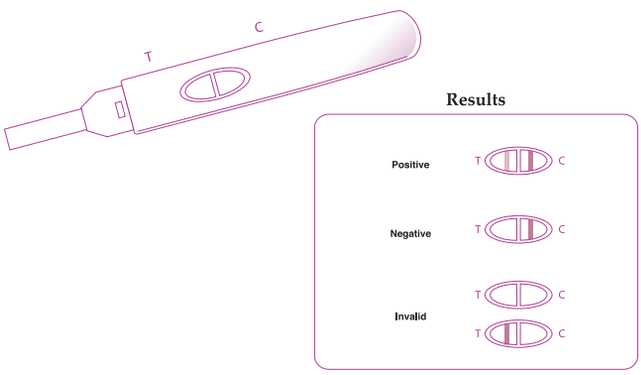
FERTILITY RAPID TESTS

Overview

Atlas Medical Fertility Rapid Tests are based on lateral flow immunoassay for the detection of human chorionic gonadotropin (hCG), Ovulation (LH), and Human Follicular Stimulating Hormone (FSH) in urine. Each of the three tests comes in strip, cassette, or midstream formats and are conveniently packed in sizes to suit lab, point-of-care and home uses.

Features

- Accurate.
- Convenient.
- Easy to use (add or dip in urine).
- Competitively priced.
- Results are obtained in 1 to 5 minutes.
- Different strip sizes are available.



Item Code	Item Description	Sizes
8.04.00.0.0001 8.04.00.0.0020	hCG Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.01.0.0001 8.04.01.0.0020	hCG Test Cassette, Urine/Serum, Individually Pouched	Bulk 20 Tests/Box
8.04.04.0.0001 8.04.04.0.0100	hCG Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.10.0.0001 8.04.10.0.0100	hCG Test Strip, Urine/Serum, Individually Pouched	Bulk 100 Tests/Box
8.04.13.0.0001 8.04.13.0.0015	hCG Midstream Test, Individually Pouched	Bulk 15 Tests/Box
8.04.14.0.0001 8.04.14.0.0020	LH Test Cassette, Urine, Individually pouched	Bulk 20 Tests/Box
8.04.15.0.0001 8.04.15.0.0100	LH Test Strip, Urine, Individually pouched	Bulk 100 Tests/Box
8.04.16.0.0001 8.04.16.0.0015	LH Midstream Test, Individually Pouched	Bulk 15 Tests/Box
8.04.17.0.0001 8.04.17.0.0020	FSH Test Cassette, Urine, Individually pouched	Bulk 20 Tests/Box
8.04.18.0.0001 8.04.18.0.0100	FSH Test Strip, Urine, Individually pouched	Bulk 100 Tests/Box
8.04.19.0.0001 8.04.19.0.0015	FSH Midstream Test, Individually Pouched	Bulk 15 Tests/Box

Item Code	Item Description	Sizes
8.59.00.0.0001	Vaginal PH strips with handle , Individually Pouched	Bulk

KIDNEY FUNCTION RAPID TESTS

Overview

Atlas Medical Microalbumin Rapid Test is a rapid visual immunoassay used for the qualitative detection of microalbumin in human urine samples. This kit is intended for use as an aid in the diagnosis of renal dysfunction.

Features

- The test comes in cassette and Strip formats.

Item Code	Item Description	Sizes
8.16.52.0.0001 8.16.52.0.0020	Microalbumin Test Cassette ,Individually Pouched	Bulk 20 Tests/Box
8.16.53.0.0030 8.16.53.0.0100	Microalbumin Test Strip ,Individually Pouched	30 Tests/Box 100 Tests/Box

INFLAMMATION AND CANCER MARKERS

Overview

All the tests in this group are qualitative and based on lateral flow immunoassay for the detection of various inflammation and cancer markers.

Item Code	Item Description	Sizes
8.04.38.0.0020	Fecal Occult Blood Test (FOB) Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.04.85.0.0050	Fecal Occult Blood Test (FOB) Test Strip Stool Sample, Individually Pouched	50 Tests/Box
8.04.109.0.0020	Procalcitonin Test Cassette (PCT), (Serum/Plasma)	20 Tests/Box
8.48.00.0.0020	Procalcitonin Test Cassette (PCT), (Whole Blood / Serum/ Plasma)	20 Tests/Box
8.16.78.0.0025	Calprotectin Test Cassette	25 Tests/Box

Features

- Atlas Medical inflammation and cancer markers rapid tests are supplied in both cassette and strip formats.
- The kits are conveniently packed in different kit sizes of 20, 25, 30 and 100 tests per kit.

Item Code	Item Description	Sizes
8.16.28.0.0001 8.16.28.0.0020	PSA Test Cassette, Whole Blood/Serum/Plasma), Individually Pouched	Bulk 20 Tests/Box
8.04.39.0.0001 8.04.39.0.0020	PSA Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.40.0.0001 8.04.40.0.0100	PSA Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box

CARDIAC MARKERS RAPID TESTS

Overview

Atlas Medical offers lateral flow immunoassay rapid tests to detect the three major cardiac markers namely: Troponin I, Myoglobin and CK-MB, as an aid in the diagnosis of myocardial infarction (MI).

Item Code	Item Description	Sizes
8.04.45.0.0001 8.04.45.0.0020	Troponin I Test Cassette, Whole Blood/Serum/ Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.46.0.0001 8.04.46.0.0020	Myoglobin Test Cassette, Whole Blood/Serum/ Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.47.0.0001 8.04.47.0.0020	CK-MB Test Cassette, Whole Blood/Serum/ Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.48.0.0001 8.04.48.0.0020	Cardiac Triple Test Cassette (Troponin I, CK-MB, Myoglobin), Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box

Features

- They can be used on whole blood (in addition to serum/plasma) making them ideal for emergency rooms.
- They come in single test or triple combo test cassette formats.
- The kits are conveniently packed in different kit sizes of 20, 25, 30 tests per kit.

DOA RAPID TESTS

Overview

All the tests in this group are qualitative and based on lateral flow immunoassay for the detection of various Drug of Abuse .

Features

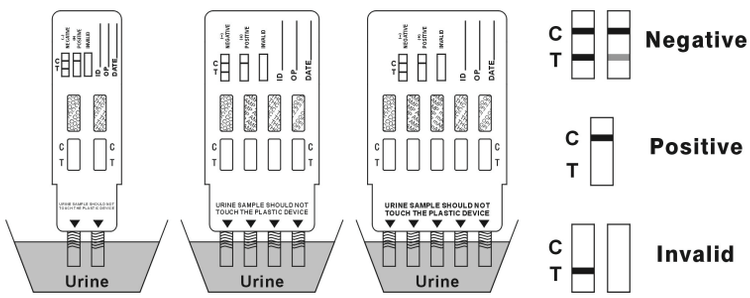
- Atlas Medical DOA rapid tests are supplied in cassette , strip, panel and cup formats.
- The kits are conveniently packed in different kit sizes of 20, 25, 30, 50 and 100 tests per kit.

STRIP AND CASSETTE FORMAT

Item Code	Item Description	Sizes
8.04.49.0.0001 8.04.49.0.0020	Morphine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.50.0.0001 8.04.50.0.0100	Morphine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.51.0.0001 8.04.51.0.0020	Marijuana (THC) Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.52.0.0001 8.04.52.0.0100	Marijuana (THC) Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.53.0.0001 8.04.53.0.0020	Amphetamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.54.0.0001 8.04.54.0.0100	Amphetamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.55.0.0001 8.04.55.0.0020	Barbiturates Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.56.0.0001 8.04.56.0.0100	Barbiturates Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.57.0.0001 8.04.57.0.0020	Benzodiazepines Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.58.0.0001 8.04.58.0.0100	Benzodiazepines Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.59.0.0001 8.04.59.0.0020	Cocaine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.60.0.0001 8.04.60.0.0100	Cocaine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.61.0.0001 8.04.61.0.0020	Methamphetamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.62.0.0001 8.04.62.0.0100	Methamphetamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.63.0.0001 8.04.63.0.0020	Methadone Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.64.0.0001 8.04.64.0.0100	Methadone Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.65.0.0001 8.04.65.0.0020	Phencyclidine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.66.0.0001 8.04.66.0.0100	Phencyclidine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.67.0.0001 8.04.67.0.0020	Tricyclic Anti-Depressants Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.68.0.0001 8.04.68.0.0100	Tricyclic Anti-Depressants Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.99.0.0001 8.04.99.0.0020	Buprenorphine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.23.0.0001 8.16.23.0.0100	Buprenorphine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.68.0.0001 8.16.68.0.0020	Tramadol Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.44.0.0001 8.16.44.0.0100	Tramadol Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.15.0.0001 8.16.15.0.0020	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Cassette,Urine,Individually Pouched	Bulk 20 Tests/Box
8.16.05.0.0001 8.16.05.0.0100	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Strip, Urine,Individually Pouched	Bulk 100 Tests/Box
8.16.06.0.0001 8.16.06.0.0020	Opiates Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.07.0.0001 8.16.07.0.0100	Opiates Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.58.0.0001 8.16.58.0.0020	Cotinine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.59.0.0001 8.16.59.0.0100	Cotinine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.62.0.0001 8.16.62.0.0020	Oxycodone Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.63.0.0001 8.16.63.0.0100	Oxycodone Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.64.0.0001 8.16.64.0.0020	Ketamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.65.0.0001 8.16.65.0.0100	Ketamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.66.0.0001 8.16.66.0.0020	Proxyphene Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.67.0.0001 8.16.67.0.0100	Proxyphene Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.68.0.0001 8.16.68.0.0020	Tramadol Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.69.0.0001 8.16.69.0.0020	EDDP Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.70.0.0001 8.16.70.0.0100	EDDP Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.60.0.0001 8.16.60.0.0020	Dolantin Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.61.0.0001 8.16.61.0.0100	Dolantin Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box

DOA RAPID TESTS

Item Code	Item Description	Sizes
8.04.93.0.0001 8.04.93.0.0025	DOA Panel: 2 Drugs (Combination of any 2 drugs) Urine, Individually Pouched	Bulk 25 Tests/Box
8.04.94.0.0001 8.04.94.0.0025	DOA Panel: 3 Drugs (Combination of any 3 drugs) Urine, Individually Pouched	Bulk 25 Tests/Box
8.04.95.0.0001 8.04.95.0.0025	DOA Panel: 4 Drugs (Combination of any 4 drugs) Urine, Individually Pouched	Bulk 25 Tests/Box
8.04.79.0.0001 8.04.79.0.0025	DOA Panel: 5 Drugs (Combination of any 5 drugs) Urine, Individually Pouched	Bulk 25 Tests/Box
8.04.80.0.0001 8.04.80.0.0025	DOA Panel: 6 Drugs (Combination of any 6 drugs) Urine, Individually Pouched	Bulk 25 Tests/Box
8.04.81.0.0001 8.04.81.0.0025	DOA Panel: 7 Drugs (Combination of any 7 drugs) Urine, Individually Pouched	Bulk 25 Tests/Box
8.04.82.0.0001 8.04.82.0.0025	DOA Panel: 8 Drugs (Combination of any 8 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box
8.04.83.0.0001	DOA Panel: 9 Drugs (Combination of any 9 drugs) Urine, Individually Pouched	Bulk
8.04.84.0.0001 8.04.84.0.0025	DOA Panel: 10 Drugs (Combination of any 10 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box
8.16.03.0.0001 8.16.03.0.0025	DOA Panel: 11 Drugs (Combination of any 11 drugs),Urine, Individually Pouched	Bulk 25 Tests/Box
8.16.04.0.0001 8.16.04.0.0025	DOA Panel: 12 Drugs (Combination of any 12 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box



Item Code	Item Description	Sizes
8.42.43.0.0001	Drug Of Abuse Cup, 7 parameters (Combination of any 7 drugs), Urine, Individually Pouched	Bulk
8.42.50.0.0001	Drug Of Abuse Cup, 8 parameters (Combination of any 8 drugs), Urine, Individually Pouched	Bulk
8.16.71.0.0001	Drug Of Abuse Cup, 10 parameters (Combination of any 10 drugs), Urine, Individually Pouched	Bulk

Item Code	Item Description	Sizes
8.16.87.0.0001	DOA Multiscreen Cassette: 3 Drugs (Combination of any 3 drugs), Urine, Individually Pouched	Bulk
8.16.88.0.0001	DOA Multiscreen Panel 7 Drugs (Combination of any 7 drugs), Urine, Individually Pouched	Bulk
8.16.89.0.0001	DOA Multiscreen Cassette: 8 Drugs (Combination of any 8 drugs), Urine, Individually Pouched	Bulk

CLINICAL CHEMISTRY KITS

Overview

Kits in this group measure concentrations of electrolytes , hormones, proteins, and other metabolic products in human blood , serum,plasma, CSF and urine .
Clincal Chemistry tests are indicated to assess systemic functions such liver function , kidney function , and endocrine and metabolic function .
Methods commonly used are colormetric and kinetic.

Features

- The kits are conveniently packed in different kit sizes of 20, 30, 60, 75,100, 150, 200, 250, 500, and 1000 tests per kit.

Item Code	Item Description	Sizes
8.05.00.0.0250 8.05.00.0.0500	Albumin Bromocresol Green	2x125ml 4x125ml
8.05.01.0.0030 8.05.01.0.0060	Amylase	3x10ml 6x10ml
8.05.02.0.0020 8.05.02.0.0040	Acid Phosphatase Kinetic, Hilmann Method (Tablets)	10x2ml 20x2ml
8.05.03.0.0030 8.05.03.0.0060	Alkaline Phosphatase Kinetic, DGKC Method (Tablets)	10x3ml 20x3ml
8.05.04.0.0250 8.05.04.0.0500	Alkaline Phosphatase Kinetic, DGKC Method (Liquid)	5x50ml 5x100ml
8.05.05.0.0250 8.05.05.0.0500	Bilirubin Total (DMSO Method)	2x125ml 4x125ml
8.05.06.0.0250 8.05.06.0.0500	Bilirubin Direct (DMSO Method)	2x125ml 4x125ml
8.05.07.0.0250 8.05.07.0.0500	Bilirubin Total & Direct (DMSO Method)	2x125ml 4x125ml
8.05.08.0.0250 8.05.08.0.0500	Calcium Arsenazo III	2x125ml 4x125ml
8.05.09.0.0250 8.05.09.0.0500	Calcium O-Cresolphthalein	2x125ml 4x125ml
8.05.10.0.0250 8.05.10.0.0500	Chloride Thiocyanate Colorimetric	2x125ml 4x125ml
8.05.11.0.0250 8.05.11.0.0500	Cholesterol Liquid (CHOD-POD)	2x125ml 4x125ml
8.05.12.0.0025 8.05.12.0.0050	CK-MB Kinetic (Tablets)	10x2.5ml 20x2.5ml
8.05.13.0.0050 8.05.13.0.0100	CK-MB Kinetic (Liquid)	5x10ml 5x20ml
8.05.14.0.0025 8.05.14.0.0050	CK-NAC Kinetic (Tablets)	10x2.5ml 20x2.5ml
8.05.15.0.0050 8.05.15.0.0100	CK-NAC Kinetic (Liquid)	5x10ml 5x20ml

Item Code	Item Description	Sizes
8.05.16.0.0250 8.05.16.0.0500	Creatinine Jaffe Color-Kinetic	2x125ml 4x125ml
8.05.17.0.0250 8.05.17.0.0500	Glucose GOD-POD (Liquid)	2x125ml 4x125ml
8.05.18.0.0020 8.05.18.0.0040	GOT (AST) IFCC Kinetic (Tablets)	10x2ml 20x2ml
8.05.19.0.0250 8.05.19.0.0500	GOT (AST) IFCC Kinetic (Liquid)	5x50ml 5x100ml
8.05.20.0.0250 8.05.20.0.0500	GOT (AST) Reitman-Frankel Colorimetric	2x125ml 2x250ml
8.05.21.0.0020 8.05.21.0.0040	GPT (ALT) IFCC Kinetic (Tablets)	10x2ml 20x2ml
8.05.22.0.0250 8.05.22.0.0500	GPT (ALT) IFCC Kinetic (Liquid)	5x50ml 5x100ml
8.05.23.0.0200 8.05.23.0.0250	GPT (ALT) Reitman-Frankel Colorimetric	2x100ml 2x125m
8.05.24.0.0020 8.05.24.0.0040	Gamma GT Kinetic, Carboxy Substrate (Tablets)	10x2ml 20x2ml
8.05.25.0.0250 8.05.25.0.0500	Gamma GT Kinetic, Carboxy Substrate (Liquid)	5x50ml 5x100ml
8.05.26.0.0100 8.05.26.0.0200	HDL Cholesterol Precipitating Reagent	2x50ml 2x100ml
8.05.27.0.0200	Iron Ferrozine Colorimetric	4x50ml
8.05.28.0.0030 8.05.28.0.0060	LDH IFCC Kinetic (Tablets)	10x3ml 20x3ml
8.05.29.0.0250 8.05.29.0.0500	LDH Pyruvate Kinetic UV DGKC (Liquid)	5x50ml 5x100ml
8.05.30.0.0060	Lipase Kinetic (Liquid)	6x10ml
8.05.31.0.0250 8.05.31.0.0500	Magnesium Calmagite Colorimetric	2x125ml 4x125ml
8.05.32.0.0250 8.05.32.0.0500	Phosphorus Phosphomolybdate UV	2x125ml 4x125ml
8.05.33.0.0050 8.05.33.0.0100	Potassium Colorimetric	50 Tests 100 Tests
8.05.34.0.0050 8.05.34.0.0100	Sodium Colorimetric	50 Tests 100 Tests
8.05.35.0.0100	TIBC (Total Iron Binding Capacity)	100 Tests
8.05.36.0.0250 8.05.36.0.0500	Total Lipids Phosphovainilline Colorimetric	2x125ml 4x125ml
8.05.37.0.0250 8.05.37.0.0500	Total Protein Biuret Colorimetric	2x125ml 4x125ml
8.05.38.0.0250 8.05.38.0.0500	Total Protein in CSF	2x125ml 4x125ml

CLINICAL CHEMISTRY KITS

Item Code	Item Description	Sizes
8.05.39.0.0250 8.05.39.0.0500	Triglycerides GPO-POD Colorimetric	2x125ml 4x125ml
8.05.40.0.0250 8.05.40.0.0500	Urea Urease-GLDH Kinetic (UV)	5x50ml 5x100ml
8.05.41.0.0250 8.05.41.0.0500	Urea Berthelot Colorimetric	2x125ml 4x125ml
8.05.42.0.0250 8.05.42.0.0500	Uric Acid Uricase-PAP Colorimetric (Two Reagents)	2x125ml 4x125ml
8.05.45.0.0250 8.05.45.0.0500	G6PD Deficiency Qualitative Kit	250 Tests 500 Tests
8.05.45.1.0250 8.05.45.1.0500	G6PD Deficiency Qualitative Kit, (with Filter Cards)	250 Tests 500 Tests
8.05.46.0.0075 8.05.46.0.0150	G6PD Deficiency Quantitative Kit	75 Tests 150 Tests
8.05.46.1.0075 8.05.46.1.0150	G6PD Deficiency Quantitative Kit, (with Filter Cards)	75 Tests 150 Tests

Item Code	Item Description	Sizes
8.05.71.0.0250 8.05.71.0.0500	Uric Acid Enzymatic Colorimetric (Mono Reagents)	2x125ml 4x125ml
8.05.43.1.0005	Pathological Control for Clinical Chemistry, Lyophilized, Human Source	5ml/vial
8.05.44.1.0005	Normal Control for Clinical Chemistry, Lyophilized, Human Source	5ml/vial
8.05.47.0.0003	G6PD Control, Normal Level, (Lyophilized)	6x0.5ml
8.05.51.0.0100	HDL Choelsterol, Enzymatic Colorimetric Direct Method	100 Tests
8.05.52.0.0100	LDL Cholesterol, Enzymatic Colorimetric Direct Method	100 Tests
8.40.00.1.0100	HbA1c Direct Enzymatic Colorimetric Kit	100 Tests
8.05.73.0.0020 8.05.73.0.0050	Electrolytes Kit (Sodium, Potassium, Chloride)	20 Tests for each 50 Tests for each

ALCOHOL TESTS

Overview

Atlas Medical supplies kits to test for alcohol in urine, saliva and breath. The urine alcohol test is based on the detection of EtG (Ethyl Glucuronide) in urine using a rapid lateral flow immunoassay. Whereas the saliva alcohol test uses a strip with dry chemistry pad that changes color to indicate the level of alcohol in the saliva. The alcohol breath test is a tube with crystals that change color as the subject blows through when alcohol level in breath exceeds a certain limit.

Item Code	Item Description	Sizes
8.25.01.0.0001 8.25.01.0.0025	Saliva Alcohol Test Strip, Individually Pouched	Bulk 25 Tests/Box
8.25.02.0.0001 8.25.02.0.0020	Breath Alcohol Test (0.02%), Individually Pouched	Bulk 20 Tests/Box
8.25.03.0.0001 8.25.03.0.0025	Breath Alcohol Test (0.05%), Individually Pouched	Bulk 25 Tests/Box
8.25.04.0.0001 8.25.04.0.0025	Breath Alcohol Test (0.08%), Individually Pouched	Bulk 25 Tests/Box
8.25.05.0.0001 8.25.05.0.0020	Ethyl Glucuronide (ETG) Urine Strip, Individually pouched	Bulk 20 Tests/Box

Features

- The kits are conveniently packed in different kit sizes of 20, 25, 50 and 100 tests per kit.

STAINS FOR HISTOLOGY & MICROBIOLOGY

Overview

Atlas Medical is well known for its range of lab stains for histology and microbiology applications.
Atlas Medical stains are made of the highest quality ingredientsto ensure good quality and vivid staining.

Features

- The stains come in convenient sizes, but custom sizes are also available.

STAIN PACKS FOR HISTOLOGY

Item Code	Item Description	Sizes
8.17.003.0300	Periodic Acid Schiff (PAS) Stain Kit	3x100ml
8.17.004.0300	Iron Stain Kit - Perl	3x100ml
8.17.009.1000	Gram Stain Pack	4x250ml
8.17.010.0750	Cold ZN - Kinyoun Stain Pack	3x250ml
8.17.011.0750	ZN Pack Standard	3x250ml
8.17.015.0500	Diff-3 Stain Pack	4x125ml
8.17.016.1000	Papanicolaou Stain Pack (EA35, EA50, EA65, OG6)	4X250ml

STAINS FOR HISTOLOGY

Item Code	Item Description	Sizes
8.15.017.0250	Carbol Fuchsin (Gram)	250ml/Bottle
8.15.019.0250	Carbol Fuchsin (Ziehl-Neelsen)	250ml/Bottle
8.15.032.0250	Crystal Violet (for Gram Stain)	250ml/Bottle
8.15.037.0250	Eosin Y (1% Aqueous)	250ml/Bottle
8.15.038.0250	Eosin Y (5% Aqueous)	250ml/Bottle
8.15.039.0250	Eosin Stain (diff 3)	250ml/Bottle
8.15.041.0250	Field Stain (Solution A)	250ml/Bottle
8.15.042.0250	Field Stain (Solution B)	250ml/Bottle
8.15.043.0750	Field Stain (Fixing Reagent, Eosin Reagent, Methylene Blue Reagent	3x250ml
8.15.044.0500	Field Stain (Solution A+B)	2x250ml
8.15.047.0250	Giemsa Stain (Modified-Glycerol/Methanol)	250ml/Bottle
8.15.049.0250	Gram's Iodine	250ml/Bottle
8.15.051.0250	Gram's Decolouriser	250ml/Bottle
8.15.059.0250	Haematoxylin Harris (no Acetic Acid)	250ml/Bottle
8.15.069.0250	Leishman Stain	250ml/Bottle
8.15.074.0250	Lugol's Iodine	250ml/Bottle
8.15.076.0250	Malachite Green (Aqueous)	250ml/Bottle
8.15.078.0250	May Grunwald Stain (Modified)	250ml/Bottle
8.15.105.0250	New Methylene Blue for Reticulocytes	250ml/Bottle
8.15.110.0250	Papanicolaou Stain EA35	250ml/Bottle
8.15.111.0250	Papanicolaou Stain EA36	250ml/Bottle
8.15.112.0250	Papanicolaou Stain EA65	250ml/Bottle
8.15.114.0250	Papanicolaou Stain EA50	250ml/Bottle
8.15.115.0250	Papanicolaou Stain OG6	250ml/Bottle
8.15.126.0250	Safranin (1% Aqueous)	250ml/Bottle
8.15.143.0250	Wright's Stain (Modified)	250ml/Bottle
8.15.144.0250	ZN Decolouriser	250ml/Bottle
8.15.146.0100	Immersion Oil	100ml/Bottle
8.15.150.1000	Mayers haematoxylin	1 L/Bottle
8.15.152.0500	Field Stain (Solution B)+Methanol	2X250 ml

MICROBIOLOGY

Item Code	Item Description	Sizes
8.38.00.0.0025	Blood Culture Bottles, Pediatric Size	25ml/Bottle
8.38.00.0.0050	Blood Culture Bottles, Adult Size	50ml/Bottle
8.36.00.0.0020	Mycoplasma Culture, Identification, Enumeration and Susceptibility Kit	20 Tests/Box

ANTIBIOTIC SENSITIVITY DISCS

Overview

Antibiotic sensitivity is a term used to describe the susceptibility of bacteria to antibiotics. Antibiotic susceptibility testing (AST) is usually carried out to determine which antibiotic will be most successful in treating a bacterial infection in vivo.

Small discs containing antibiotics are placed onto a plate upon which bacteria are growing. If the bacteria are sensitive to the antibiotic, a clear ring, or zone of inhibition, is seen around the disc indicating poor growth.

Features

- Atlas Medical offers a wide range of antibiotics discs at competitive prices.
- Easy to use.
- The kit comes with a Cartridge Applicator.
- Reliable quality.
- Comprehensive range of antibiotics at different concentrations.

Item Code	Item Description	Sizes
8.39.48.0.0250	NORFLOXACIN (10 µg) - NX	5x50 Discs
8.39.49.0.0250	OFLOXACIN (5 µg) - OF	5x50 Discs
8.39.50.0.0250	PEFLOXACIN (5 µg) – PF	5x50 Discs
8.39.51.0.0250	PENICILLIN –G (10 IU) – P	5x50 Discs
8.39.52.0.0250	PIPERACILLIN (100 µg) – PI	5x50 Discs
8.39.53.0.0250	PIPERACILLIN / TAZOBACTAM (100 µg + 10 µg) - PTZ	5x50 Discs
8.39.54.0.0250	RIFAMPIN (5 µg) – RIF	5x50 Discs
8.39.55.0.0250	ROXITHROMYCIN (30 µg) – RO	5x50 Discs

Item Code	Item Description	Sizes
8.39.01.0.0250	AMIKACIN (30 µg) – AK	5x50 Discs
8.39.02.0.0250	AMOXICILLIN (10 µg) – AX	5x50 Discs
8.39.03.0.0250	AMOXICILLIN / CLAVULANATE (20 µg + 10 µg) - AMC	5x50 Discs
8.39.04.0.0250	AMPICILLIN (10 µg) – AMP	5x50 Discs
8.39.05.0.0250	AMPICILLIN / SULBACTAM (10 µg - 10 µg) – AS	5x50 Discs
8.39.06.0.0250	AZITHROMYCIN (15 µg) – AZM	5x50 Discs
8.39.07.0.0250	AZTREONAM (30 µg) – AT	5x50 Discs
8.39.08.0.0250	CEFACLOR (30 µg) - CF	5x50 Discs
8.39.09.0.0250	CEFADROXIL (30 µg) - CD	5x50 Discs
8.39.10.0.0250	CEFAZOLIN (30 µg) - CZ	5x50 Discs
8.39.11.0.0250	CEFDINIR (5µg) - CDR	5x50 Discs
8.39.12.0.0250	CEFIXIME (5 µg) - CFM	5x50 Discs
8.39.13.0.0250	CEFOPERAZONE (75 µg) - CPZ	5x50 Discs
8.39.14.0.0250	CEFOPERAZONE / SULBACTUM (75 µg + 30 µg) - CS	5x50 Discs
8.39.15.0.0250	CEFOTAXIME (30 µg) - CTX	5x50 Discs
8.39.16.0.0250	CEFPIROME (30 µg) - CE	5x50 Discs
8.39.17.0.0250	CEFPODOXIME (10 µg) – CPD	5x50 Discs
8.39.18.0.0250	CEFPROZIL (30 µg) - CPR	5x50 Discs
8.39.19.0.0250	CEFTAZIDIME (30 µg) – CAZ	5x50 Discs
8.39.20.0.0250	CEFTIZOXIME (30 µg) - CZX	5x50 Discs
8.39.21.0.0250	CEFTRIOXONE (30 µg) - CTR	5x50 Discs
8.39.22.0.0250	CEFUROXIME (30 µg) - CXM	5x50 Discs
8.39.23.0.0250	CEPHALEXIN (30 µg) - CN	5x50 Discs
8.39.24.0.0250	CEPHALORIDINE (30 µg) - CH	5x50 Discs
8.39.25.0.0250	CEPHALOTHIN (30 µg) - CEP	5x50 Discs
8.39.26.0.0250	CHLORAMPHENICOL (30 µg) - C	5x50 Discs
8.39.27.0.0250	CIPROFLOXACIN (5 µg) - CIP	5x50 Discs
8.39.28.0.0250	CLARITHROMYCIN (15 µg) - CLR	5x50 Discs
8.39.29.0.0250	CLINDAMYCIN (2 µg) - CD	5x50 Discs
8.39.30.0.0250	CLOXACILLIN (5 µg) - COX	5x50 Discs
8.39.32.0.0250	DOXYCYCLINE (30 µg) - DOX	5x50 Discs
8.39.33.0.0250	ERYTHROMYCIN (15 µg) - E	5x50 Discs
8.39.34.0.0250	FURAZOLIDONE (100 µg) - FZ	5x50 Discs
8.39.35.0.0250	GATIFLOXACIN (5 µg) - GAT	5x50 Discs
8.39.36.0.0250	GENTAMYCIN (10 µg) - GEN	5x50 Discs
8.39.38.0.0250	KANAMYCIN (30 µg) - K	5x50 Discs
8.39.39.0.0250	LEVOFOLXACIN (5 µg) - LE	5x50 Discs
8.39.40.0.0250	LINCOMYCIN (15 µg) - LN	5x50 Discs
8.39.41.0.0250	LINEZOLID (30 µg) - LZ	5x50 Discs
8.39.42.0.0250	LOMEFLOXACIN (10 µg) - LOM	5x50 Discs
8.39.43.0.0250	MEROPENEM (10 µg) - MRP	5x50 Discs
8.39.44.0.0250	MINOCYCLINE (30 µg) - MI	5x50 Discs
8.39.45.0.0250	MOXIFLOXACIN (5 µg) - MXF	5x50 Discs
8.39.46.0.0250	NALIDIXIC ACID (30 µg) - NA	5x50 Discs
8.39.47.0.0250	NITROFURANTOIN (300 µg) - NIT	5x50 Discs

ANTIBIOTIC SENSITIVITY DISCS

Item Code	Item Description	Sizes
8.39.56.0.0250	SPARFLOXACIN (5 µg) – SPX	5x50 Discs
8.39.57.0.0250	STREPTOMYCIN (10 µg) – S	5x50 Discs
8.39.58.0.0250	SULFADIAZINE (300 µg) - SD	5x50 Discs
8.39.59.0.0250	TEICOPLANIN (30 µg) – TEI	5x50 Discs
8.39.60.0.0250	TETRACYCLINE (30 µg) – TE	5x50 Discs
8.39.61.0.0250	TICARCILLIN / CLAVULANATE (75 µg + 10 µg)-TCC	5x50 Discs
8.39.62.0.0250	TOBRAMYCIN (10 µg) – TOB	5x50 Discs
8.39.63.0.0250	TRIMETHOPRIM (5 µg) – TR	5x50 Discs
8.39.64.0.0250	VANCOMYCIN (30 µg) – VA	5x50 Discs
8.39.65.0.0250	POLYMYXIN-B (300 UNITS) -PB	5x50 Discs
8.39.66.0.0050	CEFOXITIN (30 µg) - CX	1x50 Discs
8.39.67.0.0250	CEFEPIME (30 µg) - CPM	5x50 Discs
8.39.69.0.0050	NOVOBIOCIN (5 µg) -NV	1x50 Discs

Item Code	Item Description	Sizes
8.39.70.0.0050	CARBENICILLIN (100 µg) - CB	1x50 Discs
8.39.71.0.0050	BACITRACIN - B (10 Unit)	1x50 Discs
8.39.72.0.0050	CEFOXITIN (30 µg) - CX	20x50 Discs
8.39.76.0.0250	COLISTIN -CL (10 µg)	5x50 Discs
8.39.77.0.0250	IMIPENEM-IPM (10 µg)	5x50 Discs
8.39.78.0.0250	OXACILLIN -OX (1 µg)	5x50 Discs

ELISA KITS

Features

- The kits feature high sensitivities, simple and robust methods, breakable well strips, quantitative results, ready-to use liquid reagents, and reasonable assay time.
- The assays can be used on most open ELISA manual readers and washers as well as open ELISA auto-analyzers.
- Kits are packed in sizes of 96 tests.

Overview

Atlas Medical offers a range of Enzyme Linked Immunosorbent Assay (ELISA or EIA) to detect major hormones in the fields of thyroids and fertility in serum.

HORMONE ELISA KITS

Item Code	Item Description	Sizes
8.07.02.0.0096	PSA Elisa Kit	96 Tests
8.07.10.0.0096	Free PSA Elisa Kit	96 Tests

HORMONE ELISA KITS

Item Code	Item Description	Sizes
8.10.01.0.0096	hCG Elisa Kit	96 Tests
8.10.03.0.0096	FSH Elisa Kit	96 Tests
8.10.04.0.0096	LH Elisa Kit	96 Tests
8.10.05.0.0096	Prolactin Elisa Kit	96 Tests
8.12.00.0.0096	T3 Elisa Kit	96 Tests
8.12.01.0.0096	T4 Elisa Kit	96 Tests
8.12.02.0.0096	TSH Elisa Kit	96 Tests
8.12.03.0.0096	Free T4 Elisa Kit	96 Tests
8.12.04.0.0096	Free T3 Elisa Kit	96 Tests
8.11.03.0.0096	Progesterone Elisa kit	96 Tests
8.11.04.0.0096	Testosterone Elisa Kit	96 Tests

ELISA KITS

Overview

Atlas Medical offers a range of Enzyme Linked Immunosorbent Assay (ELISA or EIA) to detect IgG and IgM antibodies against ToRCH (Toxoplasmosis, Rubella, CMV and Herpes I & II) in serum.

* Different Packaging sizes.
* Easy to Use
* High Quality

Item Code	Item Description	Sizes
8.13.10.0.0096	Herpes Simplex 2 IgM (HSV2 IgM) Elisa Kit	96 Tests
8.13.11.0.0096	Herpes Simplex 1,2 IgG (HSV1,2 IgG) Elisa Kit	96 Tests
8.13.12.0.0096	Herpes Simplex 1,2 IgM (HSV1,2 IgM) Elisa Kit	96 Tests

TORCH ELISA KITS

Item Code	Item Description	Sizes
8.13.00.0.0096	Toxo Plasma Gondii IgG (Toxo IgG) Elisa kit	96 Tests
8.13.01.0.0096	Toxoplasma gondii IgM (Toxo IgM) Elisa kit	96 Tests
8.13.02.0.0096	Rubella IgG Elisa Kit	96 Tests
8.13.03.0.0096	Rubella IgM Elisa Kit	96 Tests
8.13.05.0.0096	Cytomegalovirus IgG (CMV IgG) Elisa Kit	96 Tests
8.13.06.0.0096	Cytomegalovirus IgM (CMV IgM) Elisa Kit	96 Tests
8.13.07.0.0096	Herpes Simplex 1 IgG (HSV1 IgG) Elisa Kit	96 Tests
8.13.08.0.0096	Herpes Simplex 1 IgM (HSV1 IgM) Elisa Kit	96 Tests
8.13.09.0.0096	Herpes Simplex 2 IgG (HSV2 IgG) Elisa Kit	96 Tests

Overview

Atlas Medical offers a range of Enzyme Linked Immunosorbent Assay (ELISA or EIA) to detect a series of infection diseases such as HIV, Hepatitis (A, B, C, D and E) and H. pylori (antigens in feces).

INFECTIOUS DISEASES ELISA KITS

Item Code	Item Description	Sizes
8.14.19.1.0096	Helicobacter Pylori Antigen Elisa Kit	96 Tests

INFECTIOUS DISEASES ELISA KITS

Item Code	Item Description	Sizes
8.14.28.0.0096	HBsAg Elisa Kit	96 Tests
8.14.29.0.0096	HBsAb Elisa Kit	96 Tests
8.14.30.0.0096	HBcAb Elisa Kit	96 Tests
8.14.31.0.0096	HBeAg Elisa Kit	96 Tests
8.14.32.0.0096	HBeAb Elisa Kit	96 Tests
8.14.35.0.0096	HEV IgM Elisa Kit	96 Tests
8.14.38.0.0096	HCV Ab Elisa Kit	96 Tests
8.14.39.0.0096	HAV IgM Elisa Kit	96 Tests
8.14.40.0.0096	HIV 1,2 Antibody Elisa Kit	96 Tests
8.14.43.0.0096	Syphilis Antibody total (IgG,IgA,IgM) Elisa Kit	96 Tests
8.14.44.0.0096	HIV Ag/Ab Elisa Kit	96 Tests

OTHER ELISA KITS

Item Code	Item Description	Sizes
8.07.03.0.0096	Alpha Feto Protein (AFP) Elisa Kit	96 Tests
8.07.08.0.0096	Ferritin Elisa Kit	96 Tests
8.08.00.0.0096	Troponin I Elisa Kit	96 Tests
8.09.00.0.0096	IgE Elisa Kit	96 Tests
8.51.00.0.0096	25-OH Vitamin D Elisa Kit	96 Tests
8.57.00.0.0096	Vitamin B12 Elisa Kit	96 Tests
8.58.00.0.0096	Folic Acid Elisa Kit	96 Tests
8.06.32.0.0096	Anti-CRA Elisa Kit	96 Tests

HOME TESTS

CE 0459

Overview

Atlas Medical provides a range of home tests that have been specifically CE marked for OTC use. The range includes fertility tests (Pregnancy, Ovulation and Menopause). The home tests range also includes other medical conditions such as liver function, kidney function, diabetes and urine tract infection. These tests are based on urine reagent strips.

Screening Kits

Item Code	Item Description	Sizes
70004001	Atlas Home Diabetes Test	2 Tests/Box
70021001	Atlas Home Urinary Tract Infection Test	2 Tests/Box
70022001	Atlas Home Kidney Function Test	2 Tests/Box
70023001	Atlas Home Liver Function Test	2 Tests/Box

Features

- These tests come in cassette, midstream and strip formats.
- The screening kits come with 2 individually pouched strips and easy to read instructions for use.
- All kits are packed in attractively designed boxes with various languages.
- Atlas Medical also supplies these kits under OEM arrangements.
- Screening bundle including (UTI, Kidney, Liver, Diabetes) is available , Family planning kit (Pregnancy and Ovulation) is also available .

- Simply dip the test strip in urine for one second.
- Wait for 30 - 60 seconds.
- Compare the colors on the strip to the color chart on the box.

CE 0459

Fertility Kits

Item Code	Item Description	Sizes
70171001	Atlas Home Pregnancy Test Cassette	1 Test/Box
70172001	Atlas Home Pregnancy Test Midstream	1 Tests/Box
70174001	Atlas Home Ovulation Test Cassette	5 Tests/Box
70175001	Atlas Home Ovulation Test Midstream	3 Tests/Box
70177001	Atlas Home Menopause Test Cassette	1 Test/Box
70178001	Atlas Home Menopause Test Midstream	1 Test/Box
70180001	Atlas Home Pregnancy Test Strip (With Handle)	1 Test/Box
70170001	Atlas Home Pregnancy Test Strip	1 Test/Box

BLOOD GLUCOSE MONITORING SYSTEMS

Overview

Testing your blood glucose regularly helps you better manage your diabetes. Reliance ™ by Atlas Medical, uses the latest blood glucose sensor technologies to offer you the most accurate and reliable results for the peace of mind you need. Atlas Medical offers these systems in strips which includes Gold Electrodes.

Features

- Reliance Gold ™ by Atlas Medical, uses the latest blood glucose gold sensor technology to offer the most accurate and reliable results.
- Test time required is 5 Seconds.
- Required sample volume is 0.9µl
- Test result range is between 10 - 600 mg/dl (0.6 -33.3 mmol/L)

Reliance Gold

Item Code	Item Description	Sizes
8.52.00.0.0001	Reliance Gold Glucometer Pack	1 Pack
8.52.00.0.0025 8.52.00.0.0050	Strips for Reliance Gold Glucometer	25 Strips/Bottle 50 Strips/Bottle
8.52.00.1.0001	Reliance Gold Glucometer (Divce only)	1 Divce only

CERTIFICATES

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.1

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro ;

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum
See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité / *Effective date* : October 9th, 2020 (included)
Valable jusqu'au / *Expiry date* : October 8th, 2023 (included)
Etabli le / *Issued on* : October 8th, 2020

On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

ISO 13485

ATTESTATION/ *CERTIFICATE* N° 33544 rev. 2
Délivrée à Paris le 19 mars 2026
Issued in Paris on March 19th, 2020

ATTESTATION CE / *EC CERTIFICATE*
Examen CE de la Conception (du produit) / *EC Design Examination (of the product)*
ANNEXE IV point 4 Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro
ANNEX IV section 4 DIRECTIVE 98/79/EC concerning in vitro diagnostic medical devices

Fabricant / *Manufacturer*

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

Catégorie du(des) dispositif(s) / *Device(s) category*

Développement, production, et commercialisation de dispositifs médicaux destinés au diagnostic in vitro.
Annexe II liste A : détermination des groupes sanguins.
Design, production and sales of medical devices for in vitro diagnostic
Annex II list A : blood grouping determination.

Identification du(des) dispositif(s) / *Identification of device(s)*

ATLAS Anti-A, Anti-B, Anti-AB, Anti-D Monoclonal Reagents
See addendum

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P172375, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 98/79/CE.
GMED certifies that, on the basis of the results contained in the file referenced P172375, the product(s) complies(s) with the requirements of the directive 98/79/EC, annex I.

Début de validité / *Effective date* : March 18th, 2020 (included)
Valable jusqu'au / *Expiry date* : October 8th, 2022 (included)

On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Blood Grouping CE Certificate

ATTESTATION / *CERTIFICATE* N° 33540 rev. 3
Délivrée à Paris le 08 octobre 2020
Issued in Paris on October 8th, 2020

ATTESTATION CE / *EC CERTIFICATE*
Approbation du Système Complet d'Assurance Qualité / *Approval full Quality Assurance System*
Annexe IV excluant les points 4 et 6 Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro
Annex IV excluding sections 4 & 6 Directive 98/79/EC concerning in vitro diagnostic medical devices
Pour les dispositifs de la liste A IVD, un certificat CE de la conception est requis
For list A IVD devices, a EC design certificate is required

Fabricant / *Manufacturer*

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

Catégorie du(des) dispositif(s) / *Device(s) category*

Annexe II liste A : Détermination des groupes sanguins : système ABO et rhésus D.

Annex II list A : Blood grouping determination : ABO system and rhesus D.

Voir détails sur addendum
See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P501408, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe IV excluant les points 4 et 6 de la Directive 98/79/CE.

GMED certifies that, on the basis of the results contained in the file referenced P501408, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 98/79/EC, annex IV excluding sections 4 & 6.

La validité du présent certificat est soumise à une vérification périodique ou imprévue.
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date* : October 9th, 2020 (included)
Valable jusqu'au / *Expiry date* : October 8th, 2023 (included)

On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Full Quality Assurance Certificate.

OTHER CERTIFICATES

- FDA 510k Atlas Drug of Abuse Tests (Cup & Panel Format)
- GMP Certificate
- FDA 510k Atlas Home Pregnancy Test (Midstream Format)
- FDA 510k Atlas Home Ovulation Test (Midstream Format)
- hCG Test Strip CE certificate
- hCG Test Cassette CE certificate
- hCG Midstream Test CE certificate
- Ovulation Test Midstream CE certificate
- Ovulation Test Cassette CE certificate
- Menopause Test Midstream CE certificate
- Menopause Test Cassette CE certificate
- Liver Function Test CE certificate
- Diabetes Test CE certificate
- UTI Test CE certificate
- Kidney function Test CE certificate

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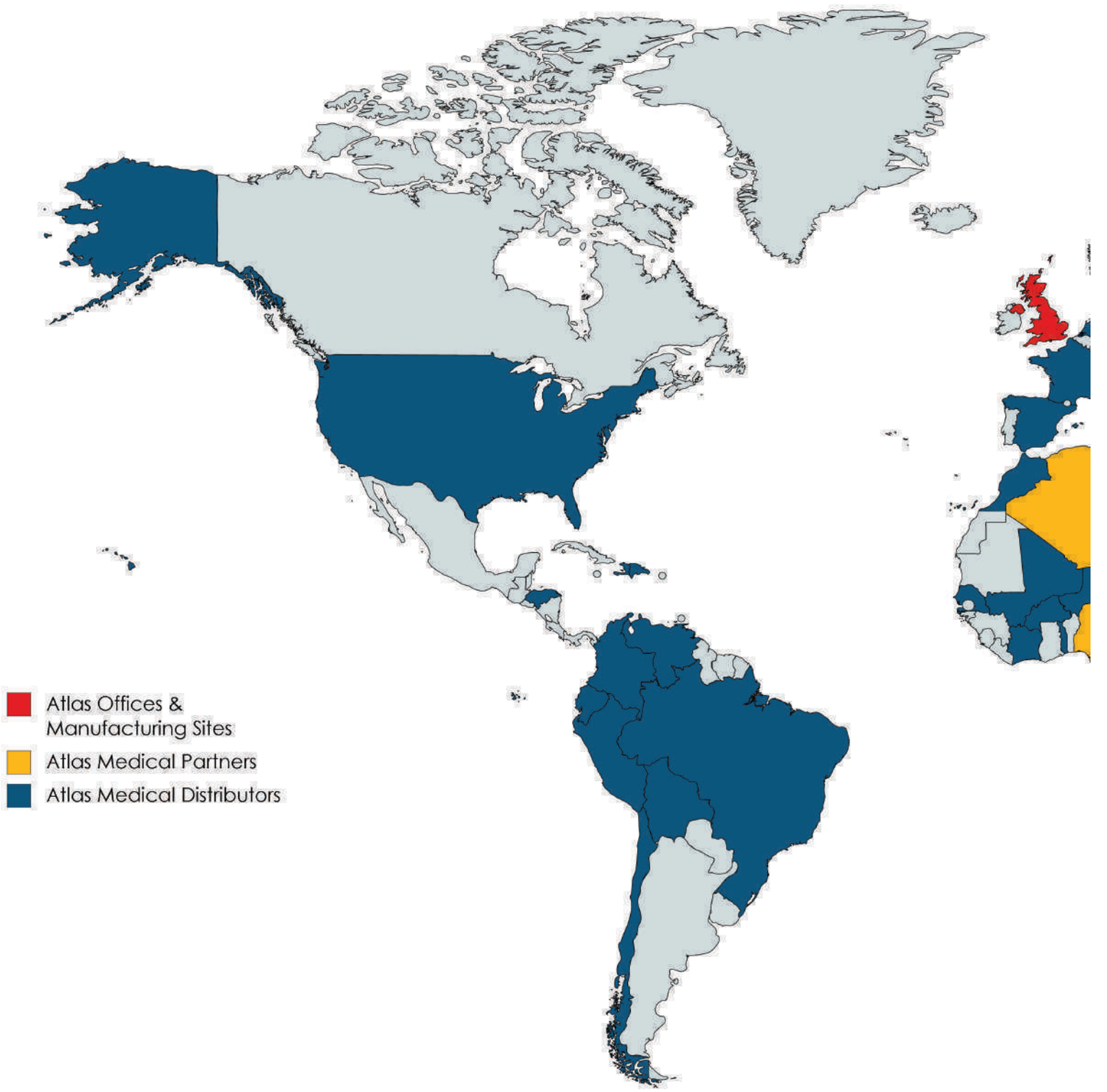
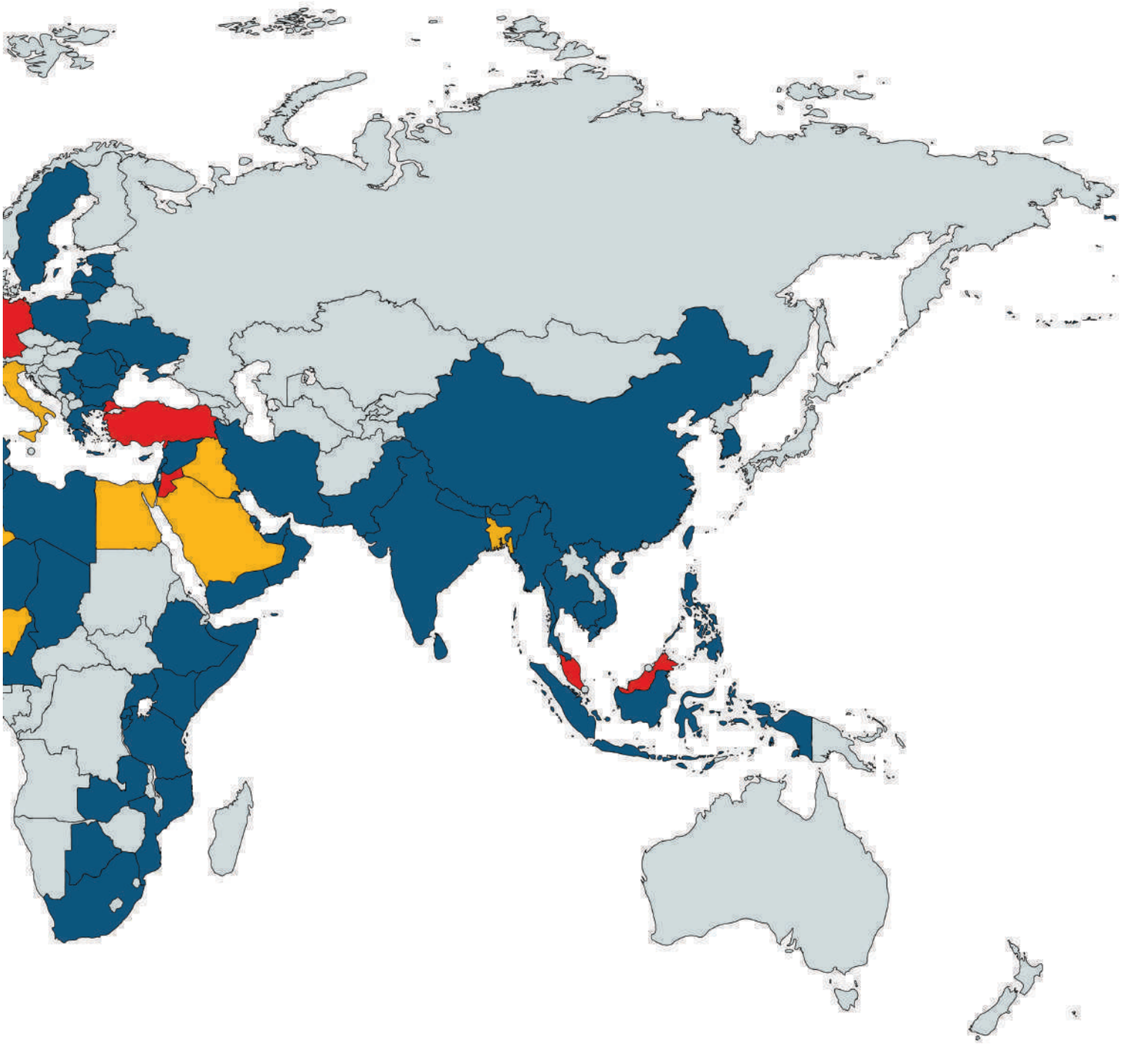
Amazon.co.uk/Atlas Medical

Email: Info@atlas-medical.com

INTERNATIONAL PRESENCE



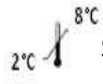


Atlas Medical CE

STREPTOCOCCAL GROUPING SLIDE
LATEX TEST

A qualitative latex agglutination test for the Detection of
Streptococcal groups A, B, C, D, F and G

IVD *For In-Vitro diagnostic and professional use only*



Store at 2° to 8° C

INTENDED USE

For the qualitative detection of streptococcal groups A, B, C, D, F and G based on latex agglutination.

INTRODUCTION & PRINCIPLES

ATLAS Streptococcal test uses an enzyme extraction procedure to release Carbohydrate antigen from Streptococcal cell walls.

The antigens are detected using specific antibodies to groups A, B, C, D, F and G Lancefield. These antibodies are coated on latex particles. When the antigen extract is mixed with the latex reagent, agglutination will occur. The agglutination appears as a visible clumping and can be seen macroscopically.

MATERIALS

MATERIALS PROVIDED

- Group A, B, C, D, F and G latex reagents.
- Extraction Enzyme dried.
- Positive control.
- Test slide.
- Stirring Sticks.
- Package Insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Water bath.
- Pipette to deliver 50ul.
- Timer and test tubes.

PRECAUTIONS:

1. Prior to use, the Latex reagent should be mixed well to obtain a uniform suspension of the Latex.
2. This kit should be stored in an upright position and refrigerated between 2 to 8ºC. Never Freeze.
3. Use a fresh disposable slide and mixer for each test.
4. Always ensure an acceptable performance of the kit by performing the test on the negative and the Positive controls before using the kit.
5. The extraction procedure may not kill all organisms; therefore carefully dispose the materials into disinfectant or by autoclaving.

PREPARING THE EXTRACTION ENZYME

The Extract enzyme in this kit comes in two vials dried.Reconstitute with 10ml distilled or deionized water. Once reconstituted store at 2-8°C for a maximum of 3 months or a liquot in 0.4ml volumes and store at -20°C for up to a year.

SAMPLE PREPARATION

Cultures

Note colonial characteristics, hemolysis, and cell morphology before starting the test. Ensure that the organisms to be tested are Gram-positive and catalase-negative. Any blood agar plate culture yielding 2-6 well-separated colonies maybe used, they should have been inoculated from a pure culture of the organism.

PROCEDURES

1. Using a sterile bacteriological loop, pick no more than 6 colonies of streptococci (avoiding other types of colony on the plate) and emulsify them in 0.4 ml extraction enzyme. (If a broth culture is to be grouped, pipette 0.1ml of an overnight culture into 0.4ml extraction enzyme).
2. Incubate the mixture in a water bath at 37ºC for 10 minutes. Shake the tubes vigorously after 5 minutes incubation. Longer incubation period may lead to false positive results.
3. Re-suspend the latex reagents by gentle agitation.
4. Dispense 1 drop of each latex into the appropriate labeled circle on the test slide.
5. Using a pipette, place 50ul of the extract to each drop of latex reagent, and mix the contents of each circle with a separate mixing stick.
6. Gently rock the slide for one minute.
7. Read the result in normal light and observe for any agglutination.

READING THE RESULT

POSITIVE: If Agglutination appears within one minute.
NEGATIVE: If Agglutination does not appear within one minute.

PROCEDURE LIMITATION

- This test provides a presumptive diagnosis. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
- Faint granularity may be seen in some negative patterns, this should be disregarded.

PERFORMANCE CHARACTERISTICS

		Test reagent	
		+	-
Reference method	+	607	55
	-	0	24

Sensitivity 607/662 = 92%
Specificity 24/24 = 100%

INTERNAL QUALITY CONTROL

A positive control is provided and should be used to verify that the latex reagents are working satisfactorily under test conditions.

Periodically check the following:

1. The test reagents agglutinate with a known reference Streptococcus strain
2. The test reagents do not auto agglutinate in normal saline solution.

REFERENCES

1. Lancefield, R.c., (1938)Proc. Soc.Exp. Bio. Med. 38, 473

2. Harvey,C.L.,Mcillmurray, M.B. (1984) Eur.J. Clin. Microbiol, 3.6,526
3. Facklam,R.R., (1980) “Manual of Clinical Microbiology” 3 Edn., American Society for Microbiology, Washington, DC, pp 88-110.

ATLAS Medical
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Cowley Rd, Cambridge, CB4 0WX
Tel: ++44 (0) 1223 858 910
Fax: ++44 (0) 1223 858 524
PPI082A01
Rev C (09.09.2015)

REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
Σ	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if
	Manufacturer telephone number		

Clostridium difficile Antigen GDH Rapid Test Cassette (Feces)

CE

INTENDED USE

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) a rapid visual immunoassay for the qualitative, presumptive detection of Clostridium difficile Glutamate Dehydrogenase (GDH) in human fecal specimens, as a screening test and as an aid in the diagnosis of Clostridium difficile infection.

INTRODUCTION

Clostridium difficile (C.difficile), a Gram-positive spore bearing anaerobic bacterium is the major aetiological agent of diarrhoea and colitis associated with antibiotics. C. difficile is the most common cause of health care-associated diarrhoea in developed countries and is a major source of nosocomial morbidity and mortality worldwide

Disease due to C. difficile develops when the organism is allowed to proliferate in the colon, most commonly after antibiotic use has eliminated competing flora. C.difficile can release two high-molecular-weight toxins, toxin A and toxin B, which are responsible for the clinical manifestations, which range from mild, self-limited watery diarrhoea to fulminant pseudomembranous colitis, toxic megacolon and death.

Clostridium difficile Glutamate Dehydrogenase (GDH) is an enzyme produced in large quantities by all toxigenic and non-toxigenic strains,making it an excellent marker for the organism.

The toxigenic culture (TC) is used as the gold standard technique to determine Clostridium difficile infection. This method consists in culture and isolation of C. difficile from faeces, followed by toxin testing of the isolate, a labour-intensive assay to obtain a result.

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) is a rapid test to qualitatively detect Clostridium difficile Glutamate Dehydrogenase (GDH) in human feces in 10 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) is a qualitative lateral flow immunoassay for the detection of Clostridium difficile GDH in human feces samples. The membrane is pre-coated with monoclonal antibodies against GDH on the test line region. During testing, the sample reacts with the particle coated with anti-GDH antibodies, which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. If there is sufficient Clostridium difficile GDH in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) containing Clostridium difficile GDH-specific antibodies coated particles and GDH-specific antibodies coated on the membrane.

MATERIALS SUPPLIED

20 Test cassettes
20 Extraction tubes with buffer
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test Cassette is stable through the expiration date printed on the sealed pouch. The test Cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged.
3. Test is for single use only. Do not re- use under any circumstances.
4. Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
5. Read the entire procedure carefully prior to testing.
6. Do not eat, drink or smoke in any area where specimens and kits are handled.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
8. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

SPECIMEN COLLECTION AND PREPARATION

- The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) is intended for use with human fecal specimens only.
- Stool samples should be collected in clean containers. The samples can be stored in the refrigerator (2-8℃) for 7 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen a-20℃. In this case, the sample will be totally thawed and brought to room temperature before testing. Ensure only the amount needed is thawed because of freezing and defrosting cycles are not recommended. Homogenise stool samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

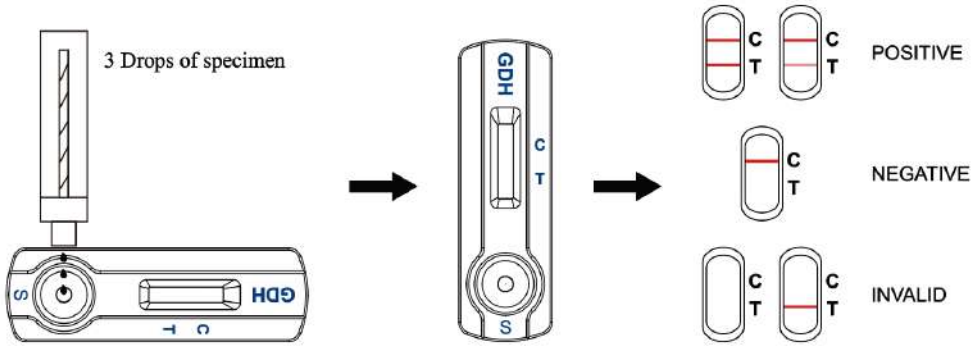
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1. Collect a random sample of feces in a clean, dry receptacle. Best results will be obtained if the assay is performed within 6 hours after collection.
2. Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 5 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
3. **For liquid specimens:** Hold the pipette vertically, aspirate fecal specimens, and then transfer 3 drops (approximately 80μL) into the specimen collection tube containing the extraction buffer.
4. Replace the stick in the tube and tighten securely.
5. Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20° C if not tested within 1 hour after preparation.

TEST PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (15-30°C) prior to testing.

1. Remove the test from the sealed pouch and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed immediately after opening the foil pouch.
2. Holding the sample collection device upright, carefully break off the tip of collection device.
3. Squeeze 3 drops (~90μL) of the sample solution in the sample well of the device and start the timer.
4. Wait for the colored line(s) to appear. Read results in 10 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of Clostridium difficile GDH in faeces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) should be used only with samples from human faeces. The use of other samples has not been established. The quality of the test depends on the quality of the sample; proper faecal specimens must be obtained
4. Positive results determine the presence of Clostridium difficile in faecal samples; never the less it can be due to toxigenic or non-toxigenic strains of Clostridium difficile. A positive result should be flowed up with additional laboratory techniques (toxigenic culture) to determine the strain.
5. A negative result is not meaningful because of it is possible the antigen concentration in the stool samples is lower than the detection limit value. If the symptoms or situation still persist, a Clostridium difficile determination should be carried out, on a sample from an enrichment culture.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity, Specificity and Accuracy

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) has been evaluated with specimens obtained from patients. ELISA method was used as the reference method. The results show that the Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) has a high overall relative accuracy.

Table 1: The Clostridium difficile Antigen GDH Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Antigen GDH Rapid Test Cassette	Results	Positive	Negative	
	Positive	62	1	63
	Negative	0	50	50
Total Results		62	51	113

Relative Sensitivity: 100%
Relative Specificity: 98.0%
Accuracy: 99.1%

2. Analytical Sensitivity

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) was determined by testing serial dilutions of recombinant antigen. The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) can detect the levels of Clostridium difficile GDH recombinant antigen as low as 1ng/mL.

3. Cross-Reactivity

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative: *Campylobacter*

Campylobacter coli	*Salmonella enteritidis*	*Shigella dysenteriae*
Campylobacter jejuni	*Salmonella paratyphi*	*Shigella flexneri*
E. Coli O157: H7	*Salmonella typhi*	*Shigella sonnei*
H. Pylori	*Salmonella typhimurium*	*Staphliococcus aureus*
Listeria monocytogenes	*Shigella boydii*	*Yersinia enterocolitica*

REFERENCE

1. Knoop, F.C. et al.: Clostridium difficile: Clinical disease and diagnosis. Clin.Microbiol. Rev. (1993); 6: 251-265.
2. Kelly, C.P. et al.: Clostridium difficile Colitis. New Engl. J. Med. (1994); 330: 257-262.
3. Sullivan, N.M. et al.: Purification and characterization of toxins A and B of Clostridium difficile. Infect. Immun. (1982); 35: 1032-1040.
4. McDonald, L.C. et al.: An epidemic, toxin gene-variant strain of Clostridium difficile.N. Engl. J. Med. (2005); 353: 23.
5. Loo, V.G. et al.: A predominantly clonal multi-institutional outbreak of Clostridium difficile-associated diarrhea with high morbidity and mortality. N. Engl. J. Med. (2005); 353.23.
6. Bartlett, J.G., Gerding, D.N.: Clinical recognition and diagnosis of Clostridium difficile infection. CID (2008); 46(Suppl. 1): 12-18.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
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Anji 313300, Huzhou, Zhejiang, China
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REF GCCD(GDH)-602a

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Clostridium difficile Toxin A&B Rapid Test Cassette (Feces)

CE

INTENDED USE

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) a rapid visual immunoassay for the qualitative, presumptive detection of Clostridium difficile Toxin A&B in human fecal specimens, as a screening test and as an aid in the diagnosis of Clostridium difficile infection.

INTRODUCTION

Clostridium difficile (C. difficile), a Gram-positive spore bearing anaerobic bacterium is the major aetiological agent of diarrhoea and colitis associated with antibiotics. C. difficile is the most common cause of health care-associated diarrhoea in developed countries and is a major source of nosocomial morbidity and mortality worldwide.

Disease due to C. difficile develops when the organism is allowed to proliferate in the colon, most commonly after antibiotic use has eliminated competing flora. C. difficile can release two high-molecular-weight toxins, toxin A and toxin B, which are responsible for the clinical manifestations, which range from mild, self-limited watery diarrhoea to fulminant pseudomembranous colitis, toxic megacolon and death.

Clostridium difficile Glutamate Dehydrogenase (GDH) is an enzyme produced in large quantities by all toxigenic and non-toxigenic strains, making it an excellent marker for the organism.

The toxigenic culture (TC) is used as the gold standard technique to determine Clostridium difficile infection. This method consists in culture and isolation of C. difficile from feces, followed by toxin testing of the isolate, a labor-intensive assay to obtain a result.

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) is a rapid test to qualitatively detect Clostridium difficile Toxin A&B in human feces in 10 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) is a qualitative lateral flow immunoassay for the detection of Clostridium difficile Toxin A&B in human feces samples. The membrane is pre-coated with monoclonal antibodies against Toxin A on the A test line region and monoclonal antibodies against Toxin B on the B test line region. During testing, the sample reacts with the particle coated with anti-Toxin A and anti-Toxin B antibodies, which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. If there is sufficient Clostridium difficile Toxin or Toxin B in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) containing Clostridium difficile Toxin A and Toxin B antibodies coated particles and Toxin A-specific antibodies and Toxin B-specific antibodies coated on the membrane.

MATERIALS SUPPLIED

20 Test cassettes
20 Extraction tubes with buffer
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30℃). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged.
3. Test is for single use only. Do not re-use under any circumstances.
4. Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
5. Read the entire procedure carefully prior to testing.
6. Do not eat, drink or smoke in any area where specimens and kits are handled.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
8. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

SPECIMEN COLLECTION AND PREPARATION

- The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) is intended for use with human fecal specimens only.
- Stool samples should be collected in clean containers. The samples can be stored in the refrigerator (2-8℃) for 7 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen a-20℃. In this case, the sample will be totally thawed and brought to room temperature before testing. Ensure only the amount needed is thawed because of freezing and defrosting cycles are not recommended. Homogenise stool samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

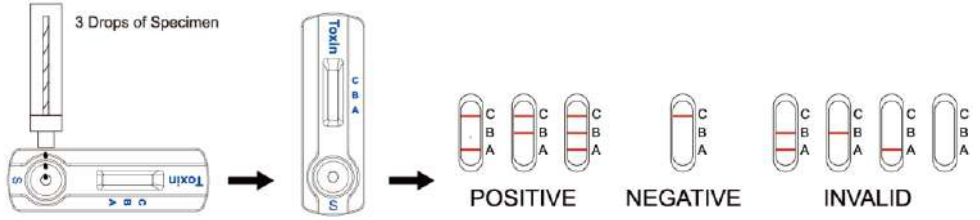
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1. Collect a random sample of feces in a clean, dry receptacle. Best results will be obtained if the assay is performed within 6 hours after collection.
2. Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 5 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
3. **For liquid specimens:** Hold the pipette vertically, aspirate fecal specimens, and then transfer 3 drops (approximately 80 μL) into the specimen collection tube containing the extraction buffer.
4. Replace the stick in the tube and tighten securely.
5. Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20℃ if not tested within 1 hour after preparation.

TEST PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (15-30℃) prior to testing.

1. Remove the test from the sealed pouch and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed immediately after opening the foil pouch.
2. Holding the sample collection device upright, carefully break off the tip of collection device.
3. Squeeze 3 drops (~90 μL) of the sample solution in the sample well of the device and start the timer.
4. Wait for the colored line(s) to appear. Read results in 10 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

1. Positive:

1.1 Toxin A Positive:

The presence of two lines as control line (C) and A test line within the result window indicates a positive result for Toxin A.

1.2 Toxin B Positive:
The presence of two lines as control line (C) and B test line within the result window indicates a positive result for Toxin B.
1.3 Toxin A& B Positive:
The presence of three lines as control line (C), A test line and B test line within the result window indicates a positive result for both Toxin A and Toxin B.
2. Negative:
One colored line appears in the control line region (C). No line appears in the test line region (T).
3. Invalid:
If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of Clostridium difficile Toxin A&B in feces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) should be used only with samples from human feces. The use of other samples has not been established. The quality of the test depends on the quality of the sample; proper fecal specimens must be obtained.
4. A negative result is not meaningful because of it is possible the antigen concentration in the stool samples is lower than the detection limit value. If the symptoms or situation still persist, a Clostridium difficile determination should be carried out, on a sample from an enrichment culture.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity, Specificity and Accuracy

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) has been evaluated with specimens obtained from patients. ELISA method was used as the reference method. The results show that the Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) has a high overall relative accuracy.

Table 1: The Clostridium difficile Toxin A Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Toxin A&B Rapid Test Cassette	Results	Positive	Negative	
	Positive	43	1	44
	Negative	0	69	69
Total Results		43	70	113

Relative Sensitivity: 100%
Relative Specificity: 98.6%
Accuracy: 99.1%

Table 2: The Clostridium difficile Toxin B Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Toxin A&B Rapid Test Cassette	Results	Positive	Negative	
	Positive	36	1	37
	Negative	0	76	76
Total Results		36	77	113

Relative Sensitivity: 100%
Relative Specificity: 98.6%
Accuracy: 99.1%

2. Analytical Sensitivity

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) was determined by testing serial dilutions of recombinant antigen. Detection limit values of Clostridium difficile Toxin A&B are 2 ng/mL for Toxin A and 1 ng/mL for Toxin B.

3. Cross-Reactivity

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative:

Campylobacter coli	*Salmonella enteritidis*	*Shigella dysenteriae*
Campylobacter jejuni	*Salmonella paratyphi*	*Shigella flexneri*
E. Coli O157: H7	*Salmonella typhi*	*Shigella sonnei*
H. pylori	*Salmonella typhimurium*	*Staphliococcus aureus*
Listeria monocytogenes	*Shigella boydii*	*Yersinia enterocolitica*

REFERENCE

1. Knoop, F.C. et al.: Clostridium difficile: Clinical disease and diagnosis. Clin. Microbiol. Rev. (1993); 6: 251-265.
2. Kelly, C.P. et al.: Clostridium difficile Colitis. New Engl. J. Med. (1994); 330: 257-262.
3. Sullivan, N.M. et al.: Purification and characterization of toxins A and B of Clostridium difficile. Infect. Immun. (1982); 35: 1032-1040.
4. McDonald, L.C. et al.: An epidemic, toxin gene-variant strain of Clostridium difficile. N. Engl. J. Med. (2005); 353: 23.
5. Loo, V.G. et al.: A predominantly clonal multi-institutional outbreak of Clostridium difficile-associated diarrhea with high morbidity and mortality. N. Engl. J. Med. (2005); 353.23
6. Bartlett, J.G., Gerding, D.N.: Clinical recognition and diagnosis of Clostridium difficile infection. CID (2008); 46 (Suppl. 1): 12-18.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

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REF GCCD(Toxin A&B)-602a

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Optochin Discs

DD009

Optochin Discs are used for identification and differentiation of *Streptococcus pneumoniae* and Viridans Streptococci.

Directions

Prepare Soyabean Casein Digest Agar (M290) w/blood or Blood Agar Base (M073) plates and streak pure culture of organism to be tested across one half of the plate. Streak a known Pneumococcus culture across the other half of the plate as positive control. Immediately place Optochin discs in the centre of the two halves of the plate and incubate at 35-37°C for 18-24 hours. Observe for zone of inhibition around the discs.

Principle And Interpretation

Alpha haemolytic (viridans) streptococci and Pneumococcus (*Streptococcus pneumoniae*) cannot be easily distinguished on Blood Agar plates as pneumococci strain shows partial clearing of blood and greenish discolouration (a-hemolysis). Optochin is inhibitory for pneumococcal growth whereas other streptococci strains show good growth or a very small zone of inhibition. Bowers and Jeffries have shown a correlation between bile solubility and full Optochin susceptibility for the differentiation of Streptococcus pneumoniae from other streptococci (1).

Hence optochin test is a useful diagnostic aid for identification / differentiation of pneumococci and viridans Streptococci.

Optochin discs are filter paper discs impregnated with optochin. The test is based on the property of viridans streptococci to grow in the presence of Optochin (ethyl hydrocuprein hydrochloride) which inhibits pneumococci. This test is performed for the diagnosis of penumococcal infections. Specimens of sputum, lung aspirate, pleural fluid, CSF, urine or blood are first examined by Gram's stain, cultured and the isolates are then subjected to Optochin Sensitivity Test.

Quality Control

Appearance

Filter paper discs of 6 mm diameter bearing letters "Op" in continuous printing style.

Cultural response

Cultural response observed after an incubation at 35-37°C for 18-24 hours at on seeded Soyabean Casein Digest Agar (M290) with added sterile defibrinated blood, using Optochin discs.

Organism	**Zone of inhibition**
Streptococcus pneumoniae *ATCC 6303*	More than or equal to 15mm

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Reference

1.Bowers E.F. and Jeffries L.R., 1995, J. Clin. Path., 8:58.

Revision : 1 / 2011

CE

Oxidase Discs

DD018

Oxidase Discs are used for detection of oxidase production by microorganisms like Neisseria, Alcaligenes, Aeromonas, Vibrio's, Campylobacter and Pseudomonas, which give positive reactions and for excluding Enterobacteriaceae, which give negative reactions.

Directions

Oxidase reaction is carried out by touching and spreading a well isolated colony on the oxidase disc. The reaction is observed within 5-10 seconds at 25-30°C. A change later than 10 seconds or no change at all is considered negative reaction.

Precautions

1. ,,Do not use stainless steel or nichrome inoculating wires, as false positive reaction may result from surface oxidation products formed during flame sterilization.

2. ,,Growth from media containing dyes is not suitable for testing.

3. ,,Timing is critical (5-10 sec) for interpretation of results.

4. ,,Perform oxidase test on all gram-negative bacilli.

5. ,,Cytochrome oxidase production may be inhibited byacid production. False negative reactions may be exhibited by Vibrio, Aeromonas and Plesiomonas species when grown on a medium containing fermentable carbohydrate e.g. MacConkey Agar (M081). Colonies taken from media containing nitrate may give unreliable results. The loss of activity of the oxidase reagent is caused by auto-oxidation which may be avoided by adding 0.1% ascorbic acid (3).

Principle And Interpretation

Certain bacteria posses either cytochrome oxidase or indophenol oxidase (an iron-containing haemoprotein), which catalyzes the transport of electrons from donor compounds (NADH) to electron acceptors (usually oxygen). In the oxidase test, a colourless dye such as N, N-dimethy-p-phenylenediamine serves as an artificial electron acceptor for the enzyme oxidase. The dye is oxidized to form indophenol blue, a coloured compound. The test is useful in the initial characterization of aerobic gram-negative bacteria of the genera Aeromonas, Plesiomonas, Pseudomonas, Campylobacter and Pasteurella.

Oxidase discs are sterile filter paper discs impregnated with N, N-dimethyl-p-phenylenediamine oxalate, ascorbic acid and a-naphthol. These discs overcome the neccessity of daily preparation of fresh reagent. Gordon and McLeod (1) introduced oxidase test for identifying gonococci based upon the ability of certain bacteria to produce indophenol blue from the oxidation of dimethyl-p-phenylenediamine and a-naphthol. Gaby and Hadley (2) introduced a more sensitive method by using N, N-dimethyl-p-phenylenediamine oxalate where all staphylococci were oxidase negative. In a positive reaction the enzyme cytochrome oxidase combines with N,N-dimethyl-p-phenylenediamine oxalate and a-naphthol to form the dye, indophenol blue.

Quality Control

Appearance

Filter paper discs of 10 mm diameter

Cultural response

Typical oxidase reaction given by 18-48 hour culture observed within 5-10 seconds at 25-30°C.

Organism	Reaction Observed
Pseudomonas aeruginosa ATCC 27853	positive : deep purplish blue colouration of disc

Neisseria gonorrhoeae ATCC 19424	positive : deep purplish blue colouration of disc
Escherichia coli ATCC 25922	negative : purplish blue colouration after 10 sec/ no colour change
Staphylococcus aureus ATCC 25923	negative : no colour change

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Reference

1.Gordon J. and Mcleod J.W., 1928, J. Path. Bact., 31:185
2.Gaby W.L and Hadley C., 1957. J. Bact., 74:356
3.Steel. K.J. 1962. J. Appl. Bact. 25:445

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X Factor discs

DD020

Used for the presumptive identification of *Haemophilus* species on the basis of their requirements for X or V factors or both.

Directions

Inoculate the surface of a Blood Agar (M073) plate or Brain Heart Infusion Agar (M211) plate with the test organisms by either streaking or surface spreading. Aseptically place the X (DD020), V (DD021) and X+V (DD022) factor discs on the plate, in the following positions:

Disc Position on the Agar plate

X factor disc 12 O' clock

V factor disc 4 O' clock

X+V factor disc 8 O' clock

Incubate the plates at 35 - 37°C for 24 - 48 hours. Observe for the growth in the neighbourhood of the discs.

Principle And Interpretation

Both X and V factors are growth factors that are essential for certain organisms like *Haemophilus* species and also enhance growth of organisms like *Neisseria* species.

X-factor discs are the sterile filter paper discs impregnated with growth factor X which are used for differentiating *Haemophilus* species in conjuction of V factor & X+V factor discs. *Bordetella* and *Haemophilus* species can also be identified on the basis of the requirement of X and V growth factors in the basal medium.

The X factor (hemin) and V factor (Coenzyme- Nicotinamide adenine dinucleotide NAD+) are impregnated on the sterile filter paper discs of diameter 6 mm.

The test organism requiring X factor alone, grows only in the vicinities of X and X+V factor discs. Those which require V factor alone grow in the vicinities of V and X+V factor discs. If both X and V factors are required, then the organism will grow only in the vicinity of the X+V factor discs. This satellite growth is seen around the disc promoting growth (1).

Quality Control

Appearance

Filter paper discs of 6 mm diameter bearing letters "X" in continuous printing style.

Cultural response

Cultural characteristics observed on Brain Heart Infusion Agar (M211)or Blood Agar Base (M073) after an incubation of 24-48 hours at 35-37°C.

Cultural Response

Organism	Growth with X factor	Growth without growth factor
Cultural response		
Bordetella pertussis ATCC 8467	Positive(initial isolation on Bordet Gengou Agar (M175))	Positive(initial isolation on Bordet Gengou Agar (M175))
Haemophilus influenzae ATCC 35056	Negative	Negative
Haemophilus parainfluenzae ATCC 7901	Negative	Negative

Haemophilus haemoglobinophilus ATCC19416	Positive	Negative
Haemophilus ducreyi	Positive	Negative

Storage and Shelf Life

Store between 2-8°C. For prolonged use store at -20°C. Use before the expiry date on the label.

Reference

1.Murray PR, Baron EJ, Jorgensen J.H., Pfaller M A, Yolken R.H(Eds.),8th ed, 2003, Manual of Clinical Microbiology, ASM, Washington D.C.

Note:
Use known strains of *Haemophilus influenzae* to monitor the performance of the differentiation discs and the medium.
Do not use too heavy suspension of the test organisms as X or V factor carryover from the primary growth medium may take place

Revision : 1 / 2011

V Factor Discs

DD021

Used for the presumptive identification of *Haemophilus* species on the basis of their requirements for X or V factors or both.

Directions

Inoculate the surface of a Blood Agar (M073) plate or Brain Heart Infusion Agar (M211) plate with the test organisms by either streaking or surface spreading. Aseptically place the X (DD020), V (DD021) and X+V (DD022) factor discs on the plate, in the following positions:

Disc Position on the Agar plate

X factor disc 12 O' clock

V factor disc 4 O' clock

X+V factor disc 8 O' clock

Incubate the plates at 35 - 37°C for 24 - 48 hours. Observe for the growth in the neighbourhood of the discs.

Principle And Interpretation

Both X and V factors are growth factors that are essential for certain organisms like *Haemophilus* species and also enhance growth of organisms like *Neisseria* species.

V-factor discs are the sterile filter paper discs impregnated with growth factor V which are used for differentiating *Haemophilus* species in conjuction of X factor & X+V factor discs. *Bordetella* and *Haemophilus* species can also be identified on the basis of the requirement of X and V growth factors in the basal medium.

The X factor (hemin) and V factor (Coenzyme- Nicotinamide adenine dinucleotide NAD+) are impregnated on the sterile filter paper discs of diameter 6 mm.

The test organism requiring X factor alone, grows only in the vicinities of X and X+V factor discs. Those which require V factor alone grow in the vicinities of V and X+V factor discs. If both X and V factors are required, then the organism will grow only in the vicinity of the X+V factor discs. This satellite growth is seen around the disc promoting growth (1).

Quality Control

Appearance

Filter paper discs of 6 mm diameter bearing letters "V" in continuous printing style.

Cultural response

Cultural characteristics observed on Brain Heart Infusion Agar (M211)or Blood Agar Base (M073) after an incubation of 24-48 hours at 35-37°C.

Organism	Growth with V factor	Growth without growth factor
Bordetella pertussis ATCC 8467	Positive(initial isolation on Bordet Gengou Agar (M175))	Positive(initial isolation on Bordet Gengou Agar (M175))
Haemophilus influenzae ATCC 35056	Negative	Negative
Haemophilus parainfluenzae ATCC 7901	Positive	Negative

Haemophilus haemoglobinophilus ATCC19416	Negative	Negative
Haemophilus ducreyi	Negative	Negative

Storage and Shelf Life

Store below -10°C. Use before the expiry date on the label.

Reference

1.Murray PR, Baron EJ, Jorgensen J.H., Pfaller M A, Yolken R.H(Eds.),8th ed, 2003, Manual of Clinical Microbiology, ASM, Washington D.C.

Note:
Use known strains of *Haemophilus influenzae* to monitor the performance of the differentiation discs and the medium.
Do not use too heavy suspension of the test organisms as X or V factor carryover from the primary growth medium may take place

Revision : 1 / 2011

X+V Factor discs

DD022

Used for the presumptive identification of *Haemophilus* species on the basis of their requirements for X or V factors or both.

Directions

Inoculate the surface of a Blood Agar (M073) plate or Brain Heart Infusion Agar (M211) plate with the test organisms by either streaking or surface spreading. Aseptically place the X (DD020), V (DD021) and X+V (DD022) factor discs on the plate, in the following positions:

Disc Position on the Agar plate

X factor disc 12 O' clock

V factor disc 4 O' clock

X+V factor disc 8 O' clock

Incubate the plates at 35 - 37°C for 24 - 48 hours. Observe for the growth in the neighbourhood of the discs.

Principle And Interpretation

Both X and V factors are growth factors that are essential for certain organisms like *Haemophilus* species and also enhance growth of organisms like *Neisseria* species.

X+V factor discs are the sterile filter paper discs impregnated with growth factors x <(>&<)> V which are used for differentiating *Haemophilus* species in conjuction of X factor & V factor discs. *Bordetella* and *Haemophilus* species can also be identified on the basis of the requirement of X and V growth factors in the basal medium.

The X factor (hemin) and V factor (Coenzyme- Nicotinamide adenine dinucleotide NAD+) are impregnated on the sterile filter paper discs of diameter 6 mm.

The test organism requiring X factor alone, grows only in the vicinities of X and X+V factor discs. Those which require V factor alone grow in the vicinities of V and X+V factor discs. If both X and V factors are required, then the organism will grow only in the vicinity of the X+V factor discs. This satellite growth is seen around the disc promoting growth (1).

Quality Control

Appearance

Filter paper discs of 6 mm diameter bearing letters "X+V" in continuous printing style.

Cultural response

Cultural characteristics observed on Brain Heart Infusion Agar (M211)or Blood Agar Base (M073) after an incubation of 24-48 hours at 35-37°C.

Organism	Growth with X +V factor	Growth without growth factor
Bordetella pertussis ATCC 8467	Positive(initial isolation on Bordet Gengou Agar (M175))	Positive(initial isolation on Bordet Gengou Agar (M175))
Haemophilus influenzae ATCC 35056	Positive	Negative
Haemophilus parainfluenzae ATCC 7901	Positive	Negative

Haemophilus haemoglobinophilus ATCC19416	Positive	Negative
Haemophilus ducreyi	Positive	Negative

Storage and Shelf Life

Store below -10°C. Use before the expiry date on the label.

Reference

1.Murray PR, Baron EJ, Jorgensen J.H., Pfaller M A, Yolken R.H(Eds.),8th ed, 2003, Manual of Clinical Microbiology, ASM, Washington D.C.

Note:
Use known strains of *Haemophilus influenzae* to monitor the performance of the differentiation discs and the medium.
Do not use too heavy suspension of the test organisms as X or V factor carryover from the primary growth medium may take place

Revision : 1 / 2011

Bile Esculin Discs

DD024

Bile Esculin Discs are used for detection of esculin hydrolysis in the presence of bile, for differentiating Group D streptococci from other Streptococcal groups.

Directions

Esculin impregnated disc is placed on the seeded Bile Esculin Agar Base (M340) plate and is incubated at 35-37°C for 18-24 hours.

Principle And Interpretation

Group D streptococci hydrolyze esculin to esculetin and dextrose. Esculetin reacts with an iron salt such as ferric citrate to form a blackish brown coloured complex (4).

Rochaix found that esculin hydrolysis is an important criteria in the identification of enterococci (1). Meyer and Schonfeld (2) observed that when bile was added to esculin medium, around 60% enterococci were able to grow and split the esculin while other streptococci could not. When a comparative study was performed by Facklam and Moody (3) for presumptive identification of Group D streptococci, they found the bile esculin test as a reliable means of identifying Group D streptococci and differentiating them from other streptococci groups.

Quality Control

Appearance

Plain filter paper discs of 6mm diameter

Cultural response

Cultural response observed by placing Bile Esculin disc (DD024) on seeded Bile Esculin Agar Base(M340) plate, incubated at 35-37°C for 18-24 hours.

Organism	Growth	Esculin hydrolysis
Enterococcus faecalis ATCC 29212	luxuriant	positive: blackening of media around the disc.
Streptococcus agalactiae ATCC 13813	luxuriant	negative: no blackening
Listeria monocytogenes ATCC 19118	luxuriant	positive: blackening of media around the disc.
Streptococcus pyogenes ATCC 19615	luxuriant	negative: no blackening

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Reference

1. Rochaix, 1924, C. R. Soc. Biol., 90:771.
2. Meyer and Schonfeld, 1926, Zentralbl. Bacteriol. Parasitenkd. Infectionskr. Hyg. Abt. I Orig., 99:402.
3. Facklam and Moody, 1970, Appl. Microbiol., 20:245.
4.MacFaddin J. F., 2000, Biochemical Tests for Identification of Medical Bacteria, 3rd ed., Philadelphia: Lippincott. Williams and Wilkins.

Revision : 1 / 2011

CE

Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

DMACA Indole Discs

DD040

The DMACA Indole Discs are used for Indole test to determine the ability of an organism to split indole from the tryptophan molecule, and thus to aid differentiation between *Escherichia coli* from *Klebsiella.*

Directions

Place the DMACA Indole Disc on suspected colony from HiCrome UTI Agar (M1353) or HiCrome UTI Agar, Modified (M1418) plate. Observe for appearance of blue-purple colour within 10 - 30 seconds.

Principle And Interpretation

In the presence of oxygen, some bacteria are able to split tryptophan into indole and alpha-aminopropionic acid. The presence of indole can be detected by the addition of DMACA (p-Dimethylaminocinnamaldehyde) reagent indicated by formation of bluish-purple colour (1).

Quality Control

Appearance

Filter paper discs of 6 mm diameter bearing letters 'Dm' in continuous printing style.

Cultural response

The indole production by organisms was tested after an incubation of 18-24 hours at 35-37°C, using HiCrome UTI Agar (M1353).

Cultural Response

Organism	**Indole production**
Cultural response	
Escherichia coli ATCC 25922	Positive reaction, blue-purple colour formation
Klebsiella pneumoniae ATCC 13883	Negative reaction.
Pseudomonas aeruginosa ATCC 27853	Negative reaction.

Storage and Shelf Life

Store at 2-8°C. Use before the expiry date on the label.

Reference

1.MacFaddin J. F., 1980, Biochemical Tests for Identification of Medical Bacteria, 2nd ed., Williams and Wilkins, Baltimore.

Revision : 1 / 2011

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Colistin Ezy MIC™ Strip (CL) (0.016-256 mcg/ml) EM020

Antimicrobial Susceptibility Testing

For *In Vitro* Diagnostic use Not for Medicinal Use

It is a unique MIC determination paper strip which is coated with Colistin on a single paper strip in a concentration gradient manner, capable of showing MICs in the range of 0.016mcg/ml to 256 mcg/ml, on testing against the test organism.

Introduction

Ezy MIC™ strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MIC™ Strip Features and Advantages

Ezy MIC™ strip exhibits several advantages over existing plastic strip.

1) Ezy MIC™ strip is made up of porous paper material unlike plastic non-porous material.
2) Ezy MIC™ strip has MIC values printed on both sides identically.
3) The antimicrobial agent is evenly distributed on either side of the Ezy MIC™ strip and hence it can be placed by any side on the agar surface.
4) For Ezy MIC™ strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar is employed.
5) Once placed, Ezy MIC™ strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
6) Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.

METHOD AND USE OF EZY MIC™ STRIPS

- **Type of specimen**

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1, 3).

- **Clinical specimen collection, handling and processing**

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1, 3).

- **Guidelines for preparation of the medium**

Prepare the medium of choice from dehydrated powder according to the directions specified on the label. Cool the sterilized molten medium to 45-50°C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2 mm and allow to solidify. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

- **Preparation of Inoculum**

Use only pure cultures. Confirm by Gram-staining before starting susceptibility test. Transfer 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 620 nm).
Also direct colony suspension method can be used. Prepare a direct colony suspension, from 18-24 hour old non-selective media agar plate in broth or saline. Adjust the turbidity to that of standard 0.5 McFarland .This method is recommended for testing fastidious organisms like *Haemophilus* spp., *Neisseria* spp, streptococci and for testing staphylococci for potential Methicillin or Oxacillin resistance.

- **Test Procedure**

1. Prepare plates with suitable make of Mueller Hinton Agar. For fastidious organisms such as Streptococci, Mueller Hinton Agar is supplemented with 5% sterile, defibrinated blood is recommended.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking.
3. Remove Ezy MIC™ strip container from cold and keep it at room temperature for 15-30 minutes before opening.
4. Remove one applicator from the self-sealing bag stored at room temperature.
5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC™ strip.
6. Lift the applicator along with attached Ezy MIC™ strip.
7. Place the strip at a desired position on agar plate pre-spread with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
8. DO NOT PRESS EZY MIC™ STRIP. Within 60 seconds, Ezy MIC™ strip will be adsorbed and will firmly adhere to the agar surface.
9. Ezy MIC™ strip should not be repositioned or adjusted once placed.
10. Transfer plates in the incubator under appropriate conditions.

Warning and Precautions:

1. Ezy MIC™ Strip is intended for *In vitro* diagnostic use only.
2. Although based on simple procedure, Ezy MIC™ Strip should only be used by at least semi-trained personnel.
3. This strip is intended only for agar diffusion method and not for broth dilution method.
4. Ezy MIC™ Strip should be used strictly according to procedures described herein.
5. Performance of Ezy MIC™ Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
6. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
7. Before using Ezy MIC™ Strips, ensure that the strip is at room temperature.
8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
9. Place the unused strips back to recommended temperature.

INTERPRETATION & QUALITY CONTROL (As per CLSI):

Table 1: Use following interpretive criteria for susceptibility categorization as per CLSI.

When testing	**Incubation**	**Interpretative Criteria**		
		≤ S	**I**	**≥ R**
Other non-*Enterobacteriaceae*	35-37°C for 18 hrs.	2	4	8
Acinetobacter spp, *P.aeruginosa*	35-37°C for 18 hrs.	2	-	4

Table 2: Quality Control for EUCAST Recommended MCR4 E. coli

Method	**MIC (mcg/ml)**
EUCAST Recommended MIC	4
In-house broth Dilution method	4 (mode value)
MIC with Ezy MIC ™ strips	4 (mode value) MIC Range : 2-4-8

Table 3: In-house Quality Control for Colistin Resistant Clinical Isolates

Organisms	Mode MICs (mcg/ml) obtained by micro-broth dilution method N=10	Mode MICs (mcg/ml) obtained by Ezy MIC ™ strips N=20	Recommended MIC (mcg/ml) range
Isolate- 1	32	32	16-32-64
Isolate- 2	16	16	8-16-32
Isolate- 3	8	8	4-8-16

Table 4: Following are the reference MIC values (mcg/ml) range for Colistin as per CLSI and EUCAST.

Organism	Medium used	Incubation	Std. Quality Control limits (mcg/ml)
E.coli ATCC 25922	Mueller Hinton Agar	35-37°C for 18 hrs.	0.25 - 0.5 – 1.0 - 2.0
P. aeruginosa ATCC 27853	Mueller Hinton Agar	35-37°C for 18 hrs.	0.5 -1.0 - 2.0 - 4.0
E. coli NCTC 13846	Mueller Hinton Agar	35-37°C for 18 hrs.	2.0 - 4.0 – 8.0

Storage & Shelf Life:

1. Once the consignment is received, store applicators at Room Temperature and Ezy MIC™ strips container at -20°C or below.
2. Use before expiry date on the label.
3. Ezy MIC™ Strip left over from opened package must be kept dry.
4. Moisture should be prevented from penetrating into or forming within the package or storage container.
5. Check whether the batch number and expiry date are marked on the storage container.
6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal

After use, Ezy MIC™ Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Limitation of Test

Ezy MIC™ Strips provides *In vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

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References:

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
3. Jorgensen,J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
4. Performance standards of Antimicrobial Susceptibility Testing; Twenty Ninth Informational Supplement. M100-S29, Vol. 39, No.1, Jan 2019.
5. Performance standards of Antimicrobial Susceptibility Testing; Twenty Sixth Informational Supplement. M100-S26, Vol. 36, No.1, Jan 2016.
6. European Committee on Antimicrobial Susceptibility Testing: Breakpoint tables for interpretation of MICs and zone diameters. Version 9.0, valid from 2019-01-01.
7. European Committee on Antimicrobial Susceptibility Testing:Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST., Version 9.0, valid from 2019-01-01.

Packing:

Each Pack contains following material packed in air-tight plastic container with a desiccator capsule.

1) Colistin Ezy MIC™ strips (10/30/60/90/120/150 Strips per pack)
2) Applicator sticks
3) Package insert

Vancomycin Ezy MIC™ Strip (VAN) (0.016-256 mcg/ml) EM060

Antimicrobial Susceptibility Testing
For *In Vitro* Diagnostic use Not for Medicinal Use

It is a unique MIC determination paper strip which is coated with Vancomycin in a concentration gradient manner, capable of showing MICs in the range of 0.016mcg/ml to 256 mcg/ml, on testing against the test organism.

Introduction

Ezy MIC™ strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MIC™ Strip FEATURES AND ADVANTAGES

Ezy MIC™ strip exhibits several advantages over existing plastic strip.

1. Ezy MIC™ strip is made up of porous paper material unlike plastic non-porous material
2. Ezy MIC™ strip has MIC values printed on both sides identically.
3. The antimicrobial agent is evenly distributed on either side of the Ezy MIC™ strip and hence it can be placed by any side on the agar surface.
4. For Ezy MIC™ strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar is employed.
5. Once placed, Ezy MIC™ strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.

CLSI RECOMMENDATION FOR VANCOMYCIN SENSITIVITY TEST

High molecular weight antibiotics such as Vancomycin, polymyxin B and colistin do not diffuse in concentration gradient manner while diffusing through the agar medium when the disc susceptibility test is employed. The Antimicrobial Susceptibility Testing using disc diffusion test does not differentiate vancomycin-susceptible isolates of *S.aureus* from Vancomycin intermediate isolates, nor does the test differentiates among Vancomycin–susceptible, intermediate, and resistant isolates of coagulase-negative staphylococci, all of which may give similar size zones of inhibition.

CLSI therefore recommends that MIC test should be performed to determine the susceptibility of all isolates of staphylococci to Vancomycin .[1]

Usefulness of Vancomycin Ezy MIC™ strip

1) Besides obtaining accurate MIC values for Gram- positive cultures, VISA (Vancomycin Intermediate *Staphylococcus aureus*) can be detected when isolated colonies appear within the zone of inhibition of Vancomycin particularly when 1.0 McFarland inoculum is used and MIC is read on full 48 hrs incubation. The sensitivity of the method can be further enhanced for better detection of VISA/ VRSA (Vancomycin Resistant *Staphylococcus aureus* / hVISA (Hetro Vancomycin Intermediate *Staphylococcus aureus*) using BHI agar with higher inoculum and 48 hr incubation.

METHOD AND USE OF EZY MIC™ STRIPS

- **Type of specimen**

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1,3).

- **Clinical specimen collection, handling and processing**

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1, 3).

- **Guidelines for preparation of the medium**

Prepare the medium of choice from dehydrated powder according to the directions specified on the label. Cool the sterilized molten medium to 45-50°C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2 mm and allow to solidify. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

- **Preparation of Inoculum**

Use only pure cultures. Confirm by Gram-staining before starting susceptibility test. Transfer 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 620 nm yields 10^5 - 10^6 cells/ml).
Also direct colony suspension method can be used. Prepare a direct colony suspension, from 18-24 hour old non-selective media agar plate in broth or saline. Adjust the turbidity to that of standard 0.5 McFarland .This method is recommended for testing fastidious organisms like *Haemophilus* spp., *Neisseria* spp, and streptococci and for testing staphylococci for potential Methicillin or Oxacillin resistance.

- **Test Procedure**

1. Prepare plates with suitable make of Mueller Hinton Agar for rapidly growing aerobic organisms as mentioned above. For fastidious organisms such as Streptococci, Mueller Hinton Agar supplemented with 5% sterile, defibrinated blood is recommended.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking.
3. Remove Ezy MIC™ strip container from cold and keep it at room temperature for 15 minutes before opening.
4. Remove one applicator from the self sealing bag stored at room temperature.
5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC™ strip.
6. Lift the applicator along with attached Ezy MIC™ strip.
7. Place the strip at a desired position on agar plate swabbed with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
8. DO NOT PRESS EZY MIC™ STRIP. Within 60 seconds, Ezy MIC™ strip will be adsorbed and will firmly adhere to the agar surface.
9. Ezy MIC™ strip should not be repositioned or adjusted once placed.
10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

1. Read the plates only when sufficient growth is seen.
2. Read the MIC where the ellipse intersects the MIC scale on the strip.
3. For bactericidal drugs such Vancomycin, Gentamicin, Amikacin, and members of β-lactams class of drugs, always read the MIC at the point of completion inhibition of all growth, including hazes, microcolonies and isolated colonies. If necessary, use magnifying glass.
4. Isolated colonies, microcolonies and hazes appearing in the zone of inhibition are indicative of hetero nature of the culture having resistant subpopulation in it. In such cases, consider reading for MIC determination at a point on the scale above which no resistant colonies are observed close to MIC strip (within 1-3 mm distance from the strip).
5. Since Ezy MIC™ strip has continuous gradient, MIC values “in-between” two fold dilutions can be obtained.
6. Always round up these values to the next two-fold dilution before categorization. For example: Vancomycin showing reading of 0.75 mcg/ml should be rounded up to next concentration i.e. 1.0 mcg/ml.
7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
8. When growth occurs along the entire strip, report the MIC as $\geq$ the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC < the lowest value on the MIC scale.

Warning and Precautions:

1. Ezy MIC™ Strip is intended for *In vitro* diagnostic use only.
2. Although based on simple procedure, Ezy MIC™ Strip should only be used by at least semi-trained personnel.
3. This strip is intended only for agar diffusion method and not for broth dilution method.
4. Ezy MIC™ Strip should be used strictly according to procedures described herein.
5. Performance of Ezy MIC™ Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
6. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
7. Before using Ezy MIC™ Strips, ensure that the strips is at room temperature.
8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
9. Place the unused strips back to recommended temperature.

INTERPRETATION & QUALITY CONTROL (As per CLSI Guidelines):

Interpretation

Table 1: Use following interpretive criteria for susceptibility categorization as per CLSI.

When testing	**Interpretative Criteria**		
	≤ S	**I**	**≥ R**
Staphylococcus spp	2	4-8	16
Coagulase negative *Staphylococci* spps. and *Enterococcus*	4	8-16	32
S.pneumoniae, Streptococcus spps. Beta haemolytic group, *Streptococcus* spps. Viridans group	1	-	-

QUALITY CONTROL

Quality control of Ezy MIC™ Strip is carried out by testing the strips with standard ATCC Cultures recommended by CLSI on suitable medium incubated appropriately.
Following are the reference MIC values (mcg/ml) range for Vancomycin.

Organism	**Medium used**	**Incubation**	**Std. Quality Control limits (mcg/ml)**
S.aureus ATCC 29213	Mueller Hinton Agar	35-37°C for 18 hrs.	0.5 – 1.0 – 2.0
E.faecalis ATCC 29212	Mueller Hinton Agar	35-37°C for 18 hrs.	1.0 – 2.0 – 4.0
S. pneumoniae ATCC 49619	Mueller Hinton Agar w/ 5% Sheep Blood	35-37°C for 20-24hrs at 5% CO_2	0.12– 0.25 – 0.5

Storage & Shelf Life:

1. Once the consignment is received, store applicators at Room Temperature and Ezy MIC™ strips container at 2-8°C, for prolonged use store below -20°C.
2. Use before expiry date on the label.
3. Ezy MIC™ Strip left over from opened package must be kept dry.
4. Moisture should be prevented from penetrating into or forming within the package or storage container.
5. Check whether the batch number and expiry date are marked on the storage container.
6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal:
After use, Ezy MIC™ Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Limitation of Test

Ezy MIC™ Strips provides *In vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
3. Jorgensen,J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
4. Performance standards of Antimicrobial Susceptibility Testing; Twenty Ninth Informational Supplement. M100-S29, Vol. 39, No.1, Jan 2019.

Packing:
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1) Vancomycin Ezy MIC™ strips (10/30/60/90/120/150 Strips per pack)
2) Applicator sticks
3) Package insert

Penicillin Ezy MIC™ Strip (PEN) (0.002-32 mcg/ml) EM084

Antimicrobial Susceptibility Testing
For *In Vitro* Diagnostic use Not for Medicinal Use

It is a unique MIC determination paper strip which is coated with Penicillin on a single paper strip in a concentration gradient manner, capable of showing MICs in the range of 0.002 mcg/ml to 32 mcg/ml, on testing against the test organism.

Introduction:
Ezy MIC™ strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MIC™ Strip FEATURES AND ADVANTAGES

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3. The antimicrobial agent is evenly distributed on either side of the Ezy MIC™ strip and hence it can be placed by any side on the agar surface.
4. For Ezy MIC™ strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar is employed.
5. Once placed, Ezy MIC™ strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.

METHOD AND USE OF EZY MIC™ STRIPS

- **Type of specimen**

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1, 3).

- **Clinical specimen collection, handling and processing**

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1, 3).

- **Guidelines for preparation of the medium**

Prepare the medium of choice from dehydrated powder according to the directions specified on the label. Cool the sterilized molten medium to 45-50°C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2 mm and allow to solidify. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

- **Preparation of Inoculum**

Use only pure cultures. Confirm by Gram-staining before starting susceptibility test. Transfer 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 620 nm).
Also direct colony suspension method can be used. Prepare a direct colony suspension, from 18-24 hour old non-selective media agar plate in broth or saline. Adjust the turbidity to that of standard 0.5 McFarland .This method is recommended for testing fastidious organisms like *Haemophilus* spp., *Neisseria* spp, streptococci and for testing staphylococci for potential Methicillin or Oxacillin resistance.

Please refer disclaimer Overleaf

- **Test Procedure**

1. Prepare plates with suitable make of Mueller Hinton Agar for rapidly growing aerobic organisms as mentioned above. For fastidious organisms such as Streptococci, Mueller Hinton Agar is supplemented with 5% sterile, defibrinated blood and for *Neisseria gonorrhoeae*, GC Agar Base (M434) with 1% defined growth supplement (FD025) is recommended.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking.
3. Remove Ezy MIC™ strip container from cold and keep it at room temperature for 15 minutes before opening.
4. Remove one applicator from the self sealing bag stored at room temperature.
5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC™ strip.
6. Lift the applicator along with attached Ezy MIC™ strip.
7. Place the strip at a desired position on agar plate swabbed with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
8. DO NOT PRESS EZY MIC™ STRIP. Within 60 seconds, Ezy MIC™ strip will be adsorbed and will firmly adhere to the agar surface.
9. Ezy MIC™ strip should not be repositioned or adjusted once placed.
10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

1. Read the plates only when sufficient growth is seen.
2. Read the MIC where the ellipse intersects the MIC scale on the strip.
3. For bactericidal drugs such as Penicillin and other members of β-lactams class of drugs, Amikacin, Vancomycin, Gentamicin, always read the MIC at the point of complete inhibition of all growth, including hazes, microcolonies and isolated colonies. If necessary, use magnifying glass.
4. Isolated colonies, microcolonies and hazes appearing in the zone of inhibition are indicative of hetero nature of the culture having resistant subpopulation in it. In such cases, consider reading for MIC determination at a point on the scale above which no resistant colonies are observed close to MIC strip (within 1-3 mm distance from the strip).
5. Since Ezy MIC™ strip has continuous gradient, MIC values “in-between” two fold dilutions can be obtained.
6. Always round up these values to the next two-fold dilution before categorization. For example: Penicillin showing reading of 0.75 mcg/ml should be rounded up to next concentration ie. 1.0 mcg/ml.
7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
8. When growth occurs along the entire strip, report the MIC as $\geq$ the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC < the lowest value on the MIC scale.

Warning and Precautions:

1. Ezy MIC™ Strip is intended for *In vitro* diagnostic use only.
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7. Before using Ezy MIC™ Strips, ensure that the strip is at room temperature.
8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
9. Place the unused strips back to recommended temperature.

INTERPRETATION:

Use following interpretive criteria for susceptibility categorization.

When testing	Incubation	Interpretive Criteria		
		≤ S	I	≥ R
Staphylococcus spp	35-37°C for 18 hrs.	0.12	-	0.25
Enterococcus spp	35-37°C for 18 hrs.	8	-	16
S.pneumoniae (Non Meningitis)	35-37°C for 20-24hrs with 5% CO_2	2	4	8
S.pneumoniae (Meningitis)	35-37°C for 20-24hrs with 5% CO_2	0.06	-	0.12
Streptococcus spps. Beta haemolytic group	35-37°C for 20-24hrs with 5% CO_2	0.12	-	-
Streptococcus spps. Viridans group	35-37°C for 20-24hrs with 5% CO_2	0.12	0.25-2	4
N. gonorrhoeae	35-37°C for 20-24hrs with 5% CO_2	0.06	0.12-1	2
N. meningitidis	35-37°C for 20-24hrs with 5% CO_2	0.06	0.12-0.25	0.5
Anaerobes	35-37°C for 24-48hrs under anaerobic condition.	0.5	1	2

QUALITY CONTROL

Quality control of Ezy MIC™ Strip is carried out by testing the strips with standard ATCC cultures recommended by CLSI on suitable medium incubated appropriately.

Following are the reference MIC values (mcg/ml) range for Penicillin

Organism	Medium used	Incubation	Std. Quality Control limits (mcg/ml)
S. aureus ATCC 29213	Mueller Hinton Agar	35-37°C for 18 hrs.	0.25-0.5-1.0-2.0
E. faecalis ATCC 29212	Mueller Hinton Agar	35-37°C for 18 hrs.	1.0 - 2.0 - 4.0
S. pneumoniae ATCC 49619	Mueller Hinton Agar w/ 5% Sheep Blood	35-37°C for 20-24hrs at 5% CO_2	0.25 - 0.5 - 1.0
Neisseria gonorrhoeae ATCC 49226	GC Agar Base (M434) with 1% defined growth supplement (FD025)	35-37°C for 20-24hrs at 5% CO_2	0.25 - 0.5 - 1.0

Storage & Shelf Life:

1. Once the consignment is received, store applicators at Room Temperature and Ezy MIC™ strips container at -20°C or below.
2. Use before expiry date on the label.
3. Ezy MIC™ Strip left over from opened package must be kept dry.
4. Moisture should be prevented from penetrating into or forming within the package or storage container.
5. Check whether the batch number and expiry date are marked on the storage container.
6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal

After use, Ezy MIC™ Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Limitation of Test

Ezy MIC™ Strips provides *In vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
3. Jorgensen,J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
4. Performance standards of Antimicrobial Susceptibility Testing; Twenty Ninth Informational Supplement. M100-S29, Vol. 39, No.1, Jan 2019.

Packing:

Each Pack contains following material packed in sealed glass vial with a desiccator capsule.

1) Penicillin Ezy MIC™ strips (30/60/90/120/150 Strips per pack)
2) Applicator sticks
3) Package insert

Egg Yolk Emulsion (50 ml/100 ml per vial)

FD045

Sterile stabilized emulsion of egg yolk recommended for use in various culture media.

Composition

Ingredients	Concentration (100 ml per vial)	Concentration (50 ml per vial)
Egg yolk	30ml	15ml
Sterile saline	70ml	35ml

Directions:

Warm up the refrigerated egg yolk emulsion to room temperature. Shake well to attain uniform emulsion. (Since on refrigeration emulsion has a tendency to form layers or small lumps). Aseptically add 50 ml emulsion in 950 ml of sterile, molten, cooled (45-50°C) Baird Parker Agar Base M043/ Baird Parker Agar Base M043S/ Baird Parker HiVeg™ Agar Base MV043/ Baird Parker HiCynth™ Agar MCD043/ Baird Parker Agar (Agar Medium O) ME043/ Baird Parker Agar (Agar Medium O) M043B/ Baird Parker Agar Base, Granulated GM043I/ Baird Parker Agar Base, Granulated GM043/ Baird Parker Agar Medium (In accordance with IP 1996) MM043/ Baird Parker Agar Medium MU043/ Baird Parker Agar Base M043I / Mannitol Salt Agar Base M118/Mannitol Salt Agar Base, Granulated GM118/Mannitol Salt HiCynth™ Agar Base MCD118 / Mannitol Salt HiVeg™ Agar Base MV118/ Baird Parker Agar Base w/Sulpha M1140.

Aseptically add in 475 ml of sterile, molten, cooled (45-50°C) Bacillus Cereus Agar Base M833/ Bacillus Cereus HiVeg™ Agar Base MV833/ Bacillus Cereus HiCynth™ Agar Base MCD833

OR

Aseptically add 100 ml emulsion in 900 ml of sterile, molten, cooled (45-50°C) McClung Toabe Agar Base M387/ McClung Toabe HiVeg™ Agar Base MV387/K.R.A.N.E.P. Agar Base M583/K.R.A.N.E.P. HiVeg™ Agar Base MV583 / MYP Agar Base (Phenol Red Egg Yolk Polymyxin Agar Base) M636/ M636S/ MYP HiVeg™ Agar Base (Phenol Red Egg Yolk Polymyxin HiVeg™ Agar Base MV636/ MYP Agar Base, Granulated (Phenol Red Egg Yolk Polymyxin Agar Base, Granulated) GM636 / MYP HiCynth™Agar Base (Phenol Red Egg Yolk Polymyxin HiCynth™ Agar Base) MCD636/ KG Agar Base M658/KG HiVeg™ Agar Base MV658/ L.D. Egg Yolk Agar Base M744/ Egg Yolk Agar Base M808 / Egg Yolk Agar Base, HiVeg™ MV808/ Egg Yolk Agar Base, Modified M1043 / Modified MYP Agar Base M1139/ Bacillus cereus Selective Agar Base (MYP) ISO 7932 M1139I /Modified MYP HiVeg™ Agar Base MV1139. Aseptically add in 890 ml of sterile, molten, cooled (45-50°C) TPEY Agar Base M402/ TPEY HiVeg™ Agar Base MV402.

Aseptically add 450 ml of sterile, molten, cooled (45-50°C) in C. botulinum Isolation Agar Base M911/ C. botulinum Isolation HiVeg™ Agar Base MV911

OR

Aseptically add 25 ml emulsion in 475 ml of sterile, molten, cooled (45-50°C) Perfringens Agar Base T.S.C./S.F.P.AgarBase) M837/ Perfringens Agar Base, Granulated (Tryptose Sulphite Cycloserine Agar Base, Granulated) (T.S.C./S.F.P. Agar Base, Granulated) GM837/ Perfringens HiCynth™ Agar Base (T.S.C/S.F.P HiCynth™ Agar Base) MCD837/ Perfringens HiVeg™ Agar Base (T.S.C. / S.F.P. HiVeg™ Agar Base) MV837/ S.F.P. Agar Base M1005/ S.F.P. HiVegTM Agar Base MV1005.

OR

Aseptically add 80 ml emulsion in 920 ml of sterile, molten, cooled (45-50°C) Anaerobic Egg Agar Base M902 / Anaerobic Egg HiVeg™ Agar Base MV902.

OR

Aseptically add 20 ml emulsion in 90 ml of sterile, molten, cooled (45-50°C) Polymyxin Pyruvate Egg Yolk Mannitol Bromothymol Blue Agar Base (PEMBA) M1484.

OR

Aseptically add 15 ml emulsion in 420 ml of sterile, molten, cooled (45-50°C) Willis and Hobb's Medium Base M1375.

OR

Aseptically add 7ml of Emulsion in 93ml of sterile, molten, cooled (45-50°C) Lipovitellin Salt Mannitol Agar Base M627.

OR

Aseptically add 2 vials of Clostridium Difficile Supplement (FD010), 40 ml of Egg Yolk Emulsion (FD045) together with 10 ml lysed horse blood in 1000 ml of sterile, molten, cooled (45-50°C) Clostridium Brazier Agar Base M1803

OR

Aseptically add 50ml of concetrated Egg yolk emulsion (FD045) and rehydrated contents of 1 vial of LM Selective Supplement (FD330) in 950 ml of sterile, molten, cooled (45-50°C) L.mono Selective Agar Base (LM Selective Agar Base) M1994.

Mix well and pour into sterile petri plates.

Type of specimen

Clinical samples - faeces, urine etc. ; Food samples

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2).
For Food samples follow appropriate techniques for handling specimens as per established guidelines (3).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

Reference

1. Isenberg (Ed.),2004, Clinical Microbiology Procedures Handbook, Vol.3, American Society for Microbiology, Washington. D.C.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology,11th Edition. Vol. 1.
3. Salfinger Y., and Tortorello M.L. Fifth (Ed.), 2015, Compendium of Methods for the Microbiological Examination of Foods, American Public Health Association, Washington, D.C.

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IVD ***In vitro* diagnostic medical device**

CE Marking

2°C 8°C **Storage temperature**

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Technical Data

Tinsdale Selective Supplement (Part A & Part B) FD073

A selective supplement recommended for the isolation and presumptive identification of *Corynebacterium diphtheriae*.

Composition

Per vial sufficient for 1000 ml medium

Ingredients	Concentration
Part A	
Horse serum	100ml
Part B	
Potassium tellurite	1ml

Directions:

Warm up the refrigerated contents of Part B vial and aseptically add 29 ml sterile distilled water. Mix thoroughly. Aseptically add warmed up (to 50°C) contents of Part A and B vials to sterile, molten, cooled (45-50°C) Tinsdale Agar Base M314 / Tinsdale HiVeg™ Agar Base MV314 as required. Mix well and pour into sterile petri plates.

For 10 ml of M314 : 1.0 ml of Part A and 0.3 ml of Part B, is recommended.

Type of specimen

Clinical samples- Throat swab, nasal swab, wound swab, pus, etc.; Food samples

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2).
For food samples follow appropriate techniques for handling specimens as per established guidelines (3).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

Reference

1.Isenberg (Ed.),2004, Clinical Microbiology Procedures Handbook, Vol.3, American Society for Microbiology, Washington. D.C.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology,11th Edition. Vol. 1.

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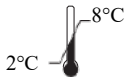

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Vitamin K1 Supplement

FD114

A vitamin growth supplement used for the isolation of anaerobic organisms.

Composition

Per vial sufficient for 1000 ml medium

Ingredients	Concentration
Vitamin K1	10mg

Directions:

Rehydrate the content of 1 vial aseptically with 5 ml sterile distilled water. Mix well and aseptically add it to 1000 ml sterile, molten, cooled (45-50ºC) Anaerobic Blood Agar Base M975A.
If desired add rehydrated contents of 1 vial each of Vitamin K1 Supplement FD114 to Schaedler Broth M291/ Schaedler HiVeg™ Agar MV291 for preparing Schaedler Agar w/Vitamin K1 or Schaedler HiVeg™ Agar w/Vitamin K1 or Schaedler CNA Agar or Schaedler CNA HiVeg™ Agar along with CNA Supplement FD115 or Schaedler KV Agar or Schaedler KV HiVeg™ Agar along with KV Supplement FD116. Add 50 ml sterile defibrinated sheep blood to all the above media. Mix well and pour into sterile petri plates.

Type of specimen

Clinical samples : stool, abscess, genital specimen, upper respiratory swab, endotracheal aspiration swab,etc.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

Reference

1. Isenberg (Ed.),2004, Clinical Microbiology Procedures Handbook, Vol.3, American Society for Microbiology, Washington. D.C.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology,11th Edition. Vol. 1.

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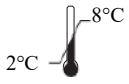

Storage temperature

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Technical Data

Coagulase Plasma (0.1gm per vial) FD248

It is recommended for studying coagulase reaction in diagnosis of Staphylococci.

Composition

Per vial sufficient for 6 tests medium

Ingredients	Concentration
Coagulase Plasma	0.100g

Directions:

Rehydrate the contents of one vial aseptically with 3 ml sterile distilled water. Add 0.5 ml of rehydrated FD248 in a tube. To this add approximately 0.05 ml of overnight broth culture of test organisms or 2-3 pure colonies picked from a non-inhibitory agar plate. Mix gently & incubate at 37°C in incubator or water bath for up to 4 hours. Observe for clot formation in the tube at regular intervals. Any degree of clotting within 4 hours is considered as positive results.

Type of specimen

Clinical- skin, throat samples etc; Food samples

Specimen Collection and Handling

For Clinical & Food samples follow appropriate techniques for handling specimens as per established guidelines (1,2,3). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Storage and Shelf Life

Store at 2-8°C. For unopened vial, use before the expiry date on the label. The rehydrated solution can be stored for up to 2 weeks at 2-8°C

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

Reference

1. Isenberg (Ed.),2004, Clinical Microbiology Procedures Handbook, Vol.3, American Society for Microbiology, Washington. D.C.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology,11th Edition. Vol. 1.
3. Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.

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IVD ***In vitro* diagnostic medical device**

2°C 8°C **Storage temperature**

CE Marking

Do not use if package is damaged

Sabouraud Dextrose Agar, Granulated

GM063

Intended Use:

Recommended for the cultivation of yeasts, moulds and aciduric microorganisms from clinical and non-clinical samples.

Composition**

Ingredients	Gms / Litre
Dextrose (Glucose)	40.000
Mycological, peptone	10.000
Agar	15.000
Final pH (at 25°C)	5.6±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 65.0 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Sabouraud Dextrose Agar is Carlier's modification (1) of the formulation described by is a modification of Sabouraud Dextrose Agar which is described by Sabouraud (2) for the cultivation of fungi (yeasts, moulds), particularly useful for the fungi associated with skin infections. This medium is also employed to determine microbial contamination in food, cosmetics, and clinical specimens (3). Mycological Peptone provides nitrogenous compounds. Dextrose provides an energy source. High dextrose concentration and low pH favors fungal growth and inhibits contaminating bacteria from test samples (4).

Type of specimen

Food and dairy samples ; Clinical samples: skin scrapings

Specimen Collection and Handling

For food and dairy samples follow appropriate techniques for handling specimens as per established guidelines (5,6,7).
For clinical samples, follow appropriate techniques for sample collection and processing as per guidelines (8,9). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions:

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. For heavily contaminated samples, the plate must be supplemented with inhibitory agents for inhibiting bacterial growth with lower pH.
2. Some pathogenic fungi may produce infective spores which are easily dispersed in air, so examination should be carried out in safety cabinet
3. Further biochemical tests should be carried out for confirmation.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Cream to yellow coloured granular media.
Gelling
Firm, comparable with 1.5% Agar gel.
Colour and Clarity of prepared medium
Light yellow to amber coloured clear to slightly opalescent gel forms in Petri plates.

Reaction
Reaction of 6.5% w/v aqueous solution at 25°C (after sterilization). pH : 5.6±0.2
pH
5.40-5.80
Cultural Response
Cultural response was observed after an incubation at 20-25°C for 24-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery
Candida albicans ATCC 10231 (00054*)	50 -100	Luxuriant (white colonies)	>=70 %
#*Aspergillus brasiliensis* ATCC 16404 (00053*)	50 -100	luxuriant	>=70 %
Candida albicans ATCC 2091 (00055*)	50 -100	luxuriant	>=70 %
Saccharomyces cerevisiae ATCC 9763 (00058*)	50 -100	luxuriant	>=70 %
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant	>=70 %
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant	>=70 %
Escherichia coli NCTC 9002	50 -100	luxuriant	>=70 %
Lactobacillus casei ATCC 334	50 -100	luxuriant	>=70 %
Trichophyton rubrum ATCC 28191		luxuriant	

Key : (*) - Corresponding WDCM numbers. (#) - Formerly known as *Aspergillus niger*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (8,9).

Reference

1.Carlier G. I. M., 1948, Brit. J. Derm. Syph., 60:61.
2.Sabouraud K., 1892, Ann. Dermatol. Syphilol, 3:1061.
3.Bacteriological Analytical Manual, 8th Edition, Revision A, 1998. AOAC, Washington D.C.
4. Murray PR, Baren EJ, Jorgensen JH, Pfaller MA, Yolken RH (editors) 2003, Manual of clinical Microbiology, 8th ed., ASM, Washington, D.C.
5. American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.
6.Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
7. Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.8.
8.Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
9.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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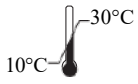

Storage temperature

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CE **CE Marking**

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Fluid Thioglycollate medium (Thioglycollate medium Fluid) M009

Intended use

Recommended for sterility testing of biologicals and for cultivation of aerobes, anaerobes and microaerophiles.

Composition**

Ingredients	Gms / Litre
Tryptone	15.000
Yeast extract	5.000
Dextrose (Glucose)	5.500
Sodium chloride	2.500
L-Cystine	0.500
Sodium thioglycollate	0.500
Resazurin sodium	0.001
Agar	0.750
Final pH (at 25°C)	7.1±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 29.75 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 25°C and store in a cool dark place preferably below 25°C. Note : If more than the upper one-third of the medium has acquired a pink-purple colour, the medium may be restored once by heating in a water bath or in free flowing steam until the pink-purple colour disappears.

Principle And Interpretation

Brewer (1) formulated Fluid Thioglycollate Medium for rapid cultivation of aerobes as well as anaerobes including microaerophiles by adding a reducing agent and small amount of agar. The BP (2), EP (3), USP (4), and AOAC (5) have recommended the media for sterility testing of antibiotics, biologicals and foods and for determining the phenol coefficient and sporicidal effect of disinfectants. However, it is intended for the examination of clear liquid or water-soluble materials. Fluid Thioglycollate Medium is also routinely used to check the sterility of stored blood in blood banks (6). Dextrose, tryptone, yeast extract, L-cystine provide the growth factors necessary for bacterial multiplication. L-cystine and sodium thioglycollate allows Clostridium to grow in this medium even under aerobic conditions (7). Also the small amount of agar used in the medium favors the growth of aerobes as well as anaerobes in the medium, even if sodium thioglycollate is deleted from the medium(1). Sodium thioglycollate act as a reducing agent and neutralizes the toxic effects of mercurial preservatives and peroxides formed in the medium, thereby promoting anaerobiosis, and making the medium suitable to test materials containing heavy metals. (8,9). Any increase in the oxygen content is indicated by a colour change of redox indicator, resazurin to red (6,10,11). The small amount of agar helps in maintaining low redox potential for stabilizing the medium (9).

Type of specimen

Pharmaceutical samples for sterility testing, clinical samples- pus, wounds

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (12,13).
For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per guidelines (2,3,4) After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic Use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. It is intended for the examination of clear liquid or water-soluble materials.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Light straw coloured, clear to slightly opalescent solution with upper 10% or less medium pink-purple on standing.

Reaction

Reaction of 2.97% w/v aqueous solution at 25°C. pH : 7.1±0.2

pH

6.90-7.30

Cultural Response

Cultural characteristics observed after an incubation at 30-35°C for not more than 3 days.

Organism	Inoculum (CFU)	Growth
Clostridium sporogenes ATCC 19404 (00008*)	50 -100	luxuriant
Clostridium sporogenes ATCC 11437	50 -100	luxuriant
Clostridium perfringens ATCC 13124 (00007*)	50 -100	luxuriant
Bacteroides fragilis ATCC 23745	50 -100	luxuriant
Bacteroides vulgatus ATCC 8482	50 -100	luxuriant
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50 -100	luxuriant
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50 -100	luxuriant
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant
Pseudomonas aeruginosa ATCC 9027 (00026*)	50 -100	luxuriant
Micrococcus luteus ATCC 9341	50 -100	luxuriant
Streptococcus pneumoniae ATCC 6305	50 -100	luxuriant
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant
Escherichia coli NCTC 9002	50 -100	luxuriant
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant

Bacillus subtilis subsp. *spizizenii* ATCC 6633 (00003*)	50 -100	luxuriant

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (12,13).

Reference

1. Brewer, 1940, J. Am. Med. Assoc., 115:598.
2. The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
3. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
4. The United States Pharmacopoeia-National Formulatory (USP-NF), 2022
5. Williams H., (Ed.), 2005, Official Methods of Analysis of the Association of Official Analytical Chemists, 19th Ed., AOAC,Washington, D.C
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7. Portwood, 1944, J. Bact., 48:255.
8. Federal Register, 1992, Fed. Regist., 21:640.
9. Quastel and Stephenson, 1926, J.Biochem., 20
10. Marshall, Gunnison and Luxen, 1940, Proc. Soc. Exp. Biol. Med., 43:672.
11. MacFaddin J.F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams and Wilkins, Baltimore.
12. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
13. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

Revision : 06/2022

HiMedia Laboratories Pvt. Limited,
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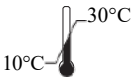
MIDC, Wagle Industrial Area,
Thane (W) -400604, MS, India

IVD ***In vitro* diagnostic medical device**



Storage temperature

EC REP CEpartner4U, Esdoornlaan 13,
3951DB Maarn, NL
www.cepartner4u.eu

CE **CE Marking**

Do not use if package is damaged

Triple Sugar Iron Agar

M021

Intended Use:

Recommended for the identification of gram-negative enteric bacilli on the basis of dextrose, lactose and sucrose fermentation and hydrogen sulphide production.

Composition**

Ingredients	Gms / Litre
Peptone	10.000
Tryptone	10.000
Yeast extract	3.000
HM Peptone B#	3.000
Lactose	10.000
Sucrose	10.000
Dextrose (Glucose)	1.000
Sodium chloride	5.000
Ferrous sulphate	0.200
Sodium thiosulphate	0.300
Phenol red	0.024
Agar	12.000
Final pH (at 25°C)	7.4±0.2

**Formula adjusted, standardized to suit performance parameters

Equivalent to Beef extract

Directions

Suspend 64.52 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Mix well and distribute into test tubes. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Allow the medium to set in sloped form with a butt about 1 inch long.

Note: For better results, the medium can be sterilized by autoclaving at 10 lbs pressure (115°C) for 15 minutes.

Principle And Interpretation

Triple Sugar Iron Agar was originally proposed by Sulkin and Willett (1) and modified by Hajna (2) for identifying *Enterobacteriaceae*. This medium complies with the recommendation of APHA, for the examination of meat and food products (3), for the examination of milk and dairy products (4) and for microbial limit test for confirming the presence of *Salmonellae* (5,6) and in the identification of gram-negative bacilli (5,7).

Tryptone, peptone, yeast extract and HM peptone B provide nitrogenous compounds, sulphur, trace elements and vitamin B complex etc. Sodium chloride maintains osmotic equilibrium. Lactose, sucrose and dextrose are the fermentable carbohydrates. Sodium thiosulphate and ferrous ions make H_2S indicator system. Phenol red is the pH indicator. Organisms that ferment glucose produce a variety of acids, turning the colour of the medium from red to yellow. More amount of acids are liberated in butt (fermentation) than in the slant (respiration). Growing bacteria also form alkaline products from the oxidative decarboxylation of peptone and these alkaline products neutralize the large amounts of acid present in the butt. Thus the appearance of an alkaline (red) slant and an acid (yellow) butt after incubation indicates that the organism is a glucose fermenter but is unable to ferment lactose and/or sucrose. Bacteria that ferment lactose or sucrose (or both), in addition to glucose, produce large amounts of acid enables no reversion of pH in that region and thus bacteria exhibit an acid slant and acid butt. Gas production (CO_2) is detected by the presence of cracks or bubbles in the medium, when the accumulated gas escapes. Thiosulphate is reduced to hydrogen sulphide by several species of bacteria and H_2S combines with ferric ions of ferric salts to produce the insoluble black precipitate of ferrous sulphide. Reduction of thiosulphate proceeds only in an acid environment and blackening usually occurs in the butt of the tube. Triple Sugar Iron Agar should be used in parallel with Urea Agar/Broth (M112/M111) to distinguish between *Salmonella* and *Proteus* species. The reactions can be summarized as follows:

Alkaline slant / acid butt-only glucose fermented
Acid slant / acid butt-glucose and sucrose fermented or glucose and lactose fermented or all the three sugars, glucose, lactose and sucrose fermented.
Bubbles or cracks present-gas production
Black precipitate present-H_2S gas production

Type of specimen
Pure bacterial isolate from water, food, or clinical sample.

Specimen Collection and Handling:
For clinical samples follow appropriate techniques for handling specimens as per established guidelines (8,9).
For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (3,4). For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards (5). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions
In Vitro diagnostic Use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :
1.Some members of the *Enterobacteriaceae* and H_2S producing *Salmonella* may not be H_2S positive on TSI Agar. Some bacteria may show H_2S production on Kligler Iron Agar but not on TSI Agar. This can happen because utilization of sucrose in TSI Agar suppresses the enzymic pathway that result in H_2S production.

Performance and Evaluation
Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control
Appearance
Light yellow to pink homogeneous free flowing powder
Gelling
Firm, comparable with 1.2% Agar gel.
Colour and Clarity of prepared medium
Pinkish red coloured clear to slightly opalescent gel forms in tubes as slants.
Reaction
Reaction of 6.45% w/v aqueous solution at 25°C. pH : 7.4±0.2
pH
7.20-7.60
Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours.

Organism	Inoculum (CFU)	Growth	Slant	Butt	Gas	H_2S
Citrobacter freundii ATCC 8090	50-100	luxuriant	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium	positive reaction	positive, blackening of medium
# *Klebsiella aerogenes* ATCC 13048 (00175*)	50-100	luxuriant	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium	positive reaction	negative, no blackening of medium
Escherichia coli ATCC 25922 (00013*)	50-100	luxuriant	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium	positive reaction	negative, no blackening of medium
Klebsiella pneumoniae ATCC 13883 (00097*)	50-100	luxuriant	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium	positive reaction	negative, no blackening of medium

Proteus vulgaris ATCC 13315	50-100	luxuriant	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium	negative reaction	positive, blackening of medium
Salmonella Paratyphi A ATCC 9150	50-100	luxuriant	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium	positive reaction	negative, no blackening of medium
Salmonella Typhi ATCC 6539	50-100	luxuriant	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium	negative reaction	positive, blackening of medium
Salmonella Typhimurium ATCC 14028 (00031*)	50-100	luxuriant	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium	positive reaction	positive, blackening of medium
Shigella flexneri ATCC 12022 (00126*)	50-100	luxuriant	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium	negative reaction	negative, no blackening of medium
Escherichia coli ATCC 8739 (00012*)	50-100	luxuriant	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium	positive reaction	negative, no blackening of medium
Escherichia coli NCTC 9002	50-100	luxuriant	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium	positive reaction	negative, no blackening of medium
Klebsiella pneumoniae ATCC 10031	50-100	luxuriant	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium	positive reaction	negative, no blackening of medium

Key : (*) Corresponding WDCM numbers.
(#) Formerly known as Enterobacter aerogenes

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (8,9).

Reference

1.Sulkin E.S. and Willett J.C., 1940, J. Lab. Clin. Med., 25:649.

2.Hajna A.A., 1945, J. Bacteriol, 49:516.

3.Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.

4.Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.

5.Baird R.B., Eaton A.D., and Rice E.W., (Eds.), 2015, Standard Methods for the Examination of Water and Wastewater, 23rd ed., APHA, Washington, D.C.

6.Finegold S. M. and Baron E. J., 1986, Bailey and Scotts Diagnostic Microbiology, 7th Ed., The C.V. Mosby Co., St. Louis.

7.MacFaddin J., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams and Wilkins, Baltimore.

8.Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.

9.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

Revision : 03/ 2022

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IVD ***In vitro*** **diagnostic medical device**

10°C – 30°C **Storage temperature**

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CE Marking

Do not use if package is damaged

Disclaimer :

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Endo Agar, Special

M029R

Endo Agar, Special is recommended for the detection of coliform and other enteric organisms.

Composition**

Ingredients	Gms / Litre
Peptone, special	11.500
Lactose	12.900
Dipotassium phosphate	0.480
Monopotassium phosphate	0.220
Sodium chloride	3.600
Sodium sulphite	0.860
Sodium lauryl sulphate	0.010
Basic fuchsin	0.830
Agar	9.600
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 40.0 grams in 1000 ml distilled water. Boil to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Caution: Basic Fuchsin is a potential Carcinogen and care should be taken to avoid inhalation of the powdered dye and contamination of the skin.

Principle And Interpretation

Endo (1) had first developed a culture medium for differentiation of lactose fermentors and non-fermenters and further developed as todays Endo Agar (2). Endo agar is used for microbiological examination of potable water and waste water, dairy products and food (3,4,5).

Sodium sulphite and basic fuchsin has inhibitory effect on gram-positive microorganisms. Sodium Lauryl sulphate inhibits many organisms other than coliforms. Lactose fermenting coliforms produce aldehyde and acid. The aldehyde in turn liberates fuchsin from the fuchsin-sulphite complex, giving rise to a red colouration of colonies. With *Escherichia coli* this reaction is very pronounced that the fuchsin crystallises, exhibiting to the colonies a permanent greenish metallic lustre (fuchsin lustre). The phosphates buffer the medium. Peptone special provides essential nutrients especially nitrogenous for the coliforms.

Quality Control

Appearance
Light pink to purple homogeneous free flowing powder

Gelling
Firm,comparable with 0.96% Agar gel.

Colour and Clarity of prepared medium
Pink Clear to slightly opalescent gel with a slight precipitate forms in Petri plates.

Reaction
Reaction of 4.0% w/v aqueous solution at 25°C. pH : 7.3±0.2

pH
7.10-7.50

Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours.

Cultural Response

Organism	Growth	Inoculum (CFU)	Recovery	Colour of Colony
Cultural Response				
Bacillus subtilis ATCC 6633	inhibited	>=10^3	0%	
Enterobacter aerogenes ATCC 13048	good-luxuriant	50-100	>=50%	pink
Enterococcus faecalis ATCC 29212	none-poor	50-100	<=10%	pink, small
Escherichia coli ATCC 25922	good-luxuriant	50-100	>=50%	pink to rose red with metallic sheen
Klebsiella pneumoniae ATCC 13883	good-luxuriant	50-100	>=50%	pink, mucoid
Salmonella Typhi ATCC 6539	good-luxuriant	50-100	>=50%	colourless to pale pink
Staphylococcus aureus ATCC 25923	inhibited	>=10^3	0%	
Pseudomonas aeruginosa ATCC 27853	good-luxuriant	50-100	>=50%	colourless, irregular
Proteus vulgaris ATCC 13315	good-luxuriant	50-100	>=50%	colourless to pale pink
Shigella sonnei ATCC 25931	good-luxuriant	50-100	>=50%	colourless to pale pink

Storage and Shelf Life

Store below 30°C in tightly closed container and prepared medium at 2 – 8°C away from light to avoid photo-oxidation. Use before expiry date on the label.

Reference

1.Endo, 1904, Zentralbl. Bakteriol., Abt. 1., Orig., 35:109.
2.Levin and Schoenlein, 1930, A Compilation of Culture Media for the Cultivation of Microorganisms, Williams and Wilkins, Baltimore.
3.Greenberg, Trussell and Clesceri (ed.), 1998, Standard Methods for the Examination of Water and Wastewater, 20th ed., APHA, Washington, D.C.
4.Richardson (ed.), 1992, Standard Methods for the Examination of Dairy Products, 16th ed., APHA, Washington, D.C.
5.Speck M., 1984, Compendium of Methods for the Microbiological Examination of Foods, 3rd ed., APHA, Washington, D.C.

Revision : 01 / 2014

Kligler Iron Agar

M078

Intended Use:

Recommended for differential identification of gram-negative enteric bacilli from clinical and non-clinical samples on the basis of the fermentation of glucose (dextrose), lactose and hydrogen sulphide production.

Composition**

Ingredients	Gms / Litre
Peptone	15.000
HM Peptone B #	3.000
Yeast extract	3.000
Proteose peptone	5.000
Lactose	10.000
Dextrose	1.000
Ferrous sulphate	0.200
Sodium chloride	5.000
Sodium thiosulphate	0.300
Phenol red	0.024
Agar	15.000
Final pH (at 25°C)	7.4±0.2

**Formula adjusted, standardized to suit performance parameters

- Equivalent to Beef extract

Directions

Suspend 57.52 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Mix well and distribute into tubes. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Allow the tubes to cool in slanted position to form slopes with about 1 inch butts. Best reactions are obtained on freshly prepared medium. Do not use screw capped tubes or bottles.

Note: *Avoid overheating otherwise it may produce precipitate in the medium.*

Principle And Interpretation

Kligler Iron Agar is a combination of the lead acetate medium described by Kligler (1,2) and Russels Double Sugar Agar (3) and is used as a differentiation medium for typhoid, dysentery and allied bacilli (4). Bailey and Lacey substituted phenol red for andrade indicator previously used as pH indicator (4). Kligler Iron Agar differentiates lactose fermenters from the non-fermenters. It differentiates *Salmonella* Typhi from other Salmonellae and also *Salmonella* Paratyphi A from *Salmonella* Scottmuelleri and *Salmonella* Enteritidis (5). Fermentation of dextrose results in production of acid, which turns the indicator from red to yellow. Since there is little sugar i.e. dextrose, acid production is very limited and therefore a reoxidation of the indicator is produced on the surface of the medium, and the indicator remains red. However, when lactose is fermented, the large amount of acid produced, avoids reoxidation and therefore the entire medium turns yellow. Kligler Iron Agar, in addition to Peptone, HM peptone B and yeast extract, contains lactose and glucose (dextrose), which enables the differentiation of species of enteric bacilli. Phenol red is the pH indicator, which exhibits a colour change in response to acid produced during the fermentation of sugars. The combination of ferrous sulphate and sodium thiosulphate enables the detection of hydrogen sulfide production, which is evidenced by a black color either throughout the butt, or in a ring formation near the top of the butt. Lactose non-fermenters (e.g., *Salmonella* and *Shigella*) initially produce a yellow slant due to acid produced by the fermentation of the small amount of glucose (dextrose). When glucose (dextrose) supply is exhausted in the aerobic environment of the slant, the reaction reverts to alkaline (red slant) due to oxidation of the acids produced. The reversion does not occur in the anaerobic environment of the butt, which therefore remains acidic (yellow butt). Lactose fermenters produce yellow slants and butts because of lactose fermentation. The high amount of acids thus produced helps to maintain an acidic pH under aerobic conditions. Tubes showing original colour of the medium indicates the fermentation of neither glucose (dextrose) nor lactose. Gas production (aerogenic reaction) is detected as individual bubbles or by splitting or displacement of the agar by the formation of cracks in the butt of the medium.

Pure cultures of suspected organisms from plating media such as MacConkey Agar (M081), Bismuth Sulphite Agar (M027) or Deoxycholate Citrate Agar (M065), SS Agar (M108) etc. are inoculated on Kligler Iron Agar for identification.

Type of specimen

Isolated microorganism from clinical, food, dairy and water samples.

Specimen Collection and Handling

For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards (6). For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (7,8,9). For clinical samples follow appropriate techniques for handling specimens as per established guidelines (10,11). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Results should be noted after 18-24 hours to avoid erroneous results.
2. Straight wire loop should be used for inoculation.
3. Pure isolates should be used to avoid erroneous results.
4. Other biochemical and serological tests must be performed for complete identification

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Light yellow to pink homogeneous free flowing powder
Gelling
Firm, comparable with 1.5% Agar gel
Colour and Clarity of prepared medium
Red coloured, clear to slightly opalescent gel forms in tubes as slants
Reaction
Reaction of 5.75% w/v aqueous solution at 25°C. pH : 7.4±0.2
pH
7.20-7.60
Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 18 - 48 hours.

Organism	Inoculum (CFU)	Growth	Gas	H2S	Slant	Butt
Escherichia coli ATCC 25922 (00013*)	50-100	luxuriant	positive reaction	negative reaction, no blackening of medium	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium
#*Klebsiella aerogenes* ATCC 13048 (00175*)	50-100	luxuriant	positive reaction	negative reaction, no blackening of medium	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium
Citrobacter freundii ATCC 8090	50-100	luxuriant	positive reaction	positive reaction, blackening of medium	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium
Proteus vulgaris ATCC 6380	50-100	luxuriant	negative reaction	positive reaction, blackening of medium	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium
Klebsiella pneumoniae ATCC 13883 (00087*)	50-100	luxuriant	positive reaction	negative reaction,no blackening of medium	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium
Salmonella Paratyphi A ATCC 9150	50-100	luxuriant	positive reaction	negative reaction,no blackening of medium	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium

Salmonella Schottmuelleri ATCC 10719	50-100	luxuriant	positive reaction	positive reaction, blackening of medium	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium
Salmonella Typhi ATCC 6539	50-100	luxuriant	negative reaction	positive reaction, blackening of medium	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium
Salmonella Enteritidis ATCC 13076 (00030*)	50-100	luxuriant	positive reaction	positive reaction, blackening of medium	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium
Shigella flexneri ATCC 12022 (00126*)	50-100	luxuriant	negative reaction	negative reaction,no blackening of medium	alkaline reaction, red colour of the medium	acidic reaction, yellowing of the medium
Pseudomonas aeruginosa ATCC 27853 (00025*)	50-100	luxuriant	negative reaction	negative reaction, blackening of medium	alkaline reaction, red colour of the medium	alkaline reaction,red colour of the medium
Yersinia enterocolitica ATCC 27729	50-100	luxuriant	variable reaction	negative reaction,no blackening of medium	alkaline reaction,red colour of the medium	acidic reaction, yellowing of the medium
Enterobacter cloacae ATCC 13047 (00083*)	50-100	luxuriant	positive reaction	negative reaction,no blackening of medium	acidic reaction, yellowing of the medium	acidic reaction, yellowing of the medium

Key :* Corresponding WDCM numbers

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (10,11).

Reference

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7.American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.
8.Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
9.Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed.,APHA Inc., Washington, D.C.
10.Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
11.Jorgensen,J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1

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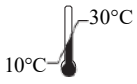

Storage temperature

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Simmons Citrate Agar

M099

Intended Use:

Recommended for differentiation the members of *Enterobacteriaceae* on the basis of citrate utilization from clinical and non clinical samples.

Composition**

Ingredients	Gms / Litre
Magnesium sulphate	0.200
Ammonium dihydrogen phosphate	1.000
Dipotassium phosphate	1.000
Sodium citrate	2.000
Sodium chloride	5.000
Bromothymol blue	0.080
Agar	15.000
Final pH (at 25°C)	6.8±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 24.28 grams in 1000 ml purified/ distilled water. Heat, to boiling, to dissolve the medium completely. Mix well and distribute in tubes or flasks. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.
Precaution: Before using water, ensure pH of water is 6.5 to 7.0. Initial colour of the medium may deviate from expected colour, if the above precaution is ignored.

Principle And Interpretation

These media are used for the differentiation between *Enterobacteriaceae* and the members of aerogenes group on the basis of citrate utilization as sole carbon source. Initially the citrate medium was developed by Koser (1) containing ammonium salt as the only nitrogen source and citrate as the only carbon source for differentiating *Escherichia coli* and *Enterobacter aerogenes* by IMViC tests. Later on Simmons (2) modified Kosers formulation by adding agar and bromothymol blue (3). It is recommended by APHA (4).
Ammonium dihydrogen phosphate and sodium citrate serve as the sole nitrogen and carbon source respectively. Microorganisms also use inorganic ammonium salts as their sole nitrogen source. Metabolism of these salts causes the medium to become alkaline, indicated by a change in colour of the pH indicator from green to blue. Bromothymol blue is the pH indicator. The medium should be freshly prepared because in dry conditions, changes in colour may appear even before inoculation, especially at the bottom of the slant.

Type of specimen

Isolated microorganism from clinical and non clinical samples.

Specimen Collection and Handling

For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards (5). For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (6,7,8). For clinical samples follow appropriate techniques for handling specimens as per established guidelines (9,10).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1.Before using water, ensure pH of water is 6.5 to 7.0.Initial colour of the medium may deviate from expected colour, if the above precaution is ignored.

2.The pH affects the performance of the medium and must be correctly monitored.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Cream to yellow homogeneous free flowing powder.
Gelling
Firm, comparable with 1.5% Agar gel
Colour and Clarity of prepared medium
Forest green coloured slightly opalescent gel forms in tubes as slants.
Reaction
Reaction of 2.43% w/v aqueous solution at 25°C. pH : 6.8±0.2.
pH
6.60-7.00
Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours.

Organism	Inoculum (CFU)	Growth	Citrate utilisation
# *Klebsiella aerogenes* ATCC 13048 (00175*)	50-100	good-luxuriant	positive reaction, blue colour
Escherichia coli ATCC 25922 (00013*)	>=10^4	inhibited	
Salmonella Typhi ATCC 6539	50-100	fair-good	negative reaction, green colour
Salmonella Typhimurium ATCC 14028 (00031*)	50-100	good-luxuriant	positive reaction, blue colour
Shigella dysenteriae ATCC 13313	>=10^4	inhibited	
Salmonella Choleraesuis ATCC 12011	50-100	good-luxuriant	positive reaction, blue colour
Salmonella Enteritidis ATCC 13076 (00030*)	50-100	good-luxuriant	positive reaction, blue colour

Key: * Corresponding WDCM numbers
Formerly known as *Enterobacter aerogenes*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 2 - 8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (9,10).

Reference

1. Koser, 1923, J. Bact., 8:493.
2. Simmons, 1926, J. Infect. Dis., 39:209.
3. MacFaddin J., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams and Wilkins, Baltimore.
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5. Lipps WC, Braun-Howland EB, Baxter TE,eds. Standard methods for the Examination of Water and Wastewater, 24th ed. Washington DC:APHA Press; 2023.
6. American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.

7. Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
8. Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.
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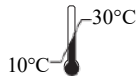

Storage temperature

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SS Agar (Salmonella Shigella Agar)

M108

Intended Use:

Recommended for the isolation of *Salmonella* and some *Shigella* species from pathological specimens, suspected foodstuffs etc.

Composition**

Ingredients	Gms / Litre
Peptone	5.000
HM peptone B #	5.000
Lactose	10.000
Bile salts mixture	8.500
Sodium citrate	10.000
Sodium thiosulphate	8.500
Ferric citrate	1.000
Brilliant green	0.00033
Neutral red	0.025
Agar	15.000
Final pH (at 25°C)	7.0±0.2

**Formula adjusted, standardized to suit performance parameters

- Equivalent to Beef extract

Directions

Suspend 63.02 grams in 1000 ml purified /distilled water. Boil with frequent agitation to dissolve the medium completely. DO NOT AUTOCLAVE OR OVERHEAT. Overheating may destroy selectivity of the medium. Cool to about 50°C. Mix and pour into sterile Petri plates.

Principle And Interpretation

SS Agar medium is recommended as differential and selective medium for the isolation of *Salmonella* and *Shigella* species from pathological specimens (1) and suspected foodstuffs (2,3,4,5) and for microbial limit test (6). SS Agar is a moderately selective medium in which gram-positive bacteria are inhibited by bile salts, brilliant green and sodium citrate.

Peptone, HM peptone B provides nitrogen and carbon source, long chain amino acids, vitamins and essential growth nutrients. Lactose is the fermentable carbohydrate. Brilliant green, bile salts and thiosulphate selectively inhibit gram-positive and coliform organisms. Sodium thiosulphate is reduced by certain species of enteric organisms to sulphite and H_2S gas and this reductive enzyme process is attributed by thiosulphate reductase. Production of H_2S gas is detected as an insoluble black precipitate of ferrous sulphide, formed upon reaction of H_2S with ferric ions or ferric citrate, indicated in the center of the colonies.

The high selectivity of Salmonella Shigella Agar allows the use of large inocula directly from faeces, rectal swabs or other materials suspected of containing pathogenic enteric bacilli. On fermentation of lactose by few lactose-fermenting normal intestinal flora, acid is produced which is indicated by change of colour from yellow to red by the pH indicator-neutral red. Thus these organisms grow as red pigmented colonies. Lactose non-fermenting organisms grow as translucent colourless colonies with or without black centers. Growth of *Salmonella* species appears as colourless colonies with black centers resulting from H_2S production. *Shigella* species also grow as colourless colonies which do not produce H_2S.

Type of specimen

Clinical: faeces, rectal swabs; Suspected food stuffs.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (8,9).

For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (2,3,4,5).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1.The medium is highly selective and may be toxic to certain *Salmonella* or *Shigella* species. Hence it is recommended to use to inoculate plates of less inhibitory media parallel to SS Agar, such as Hektoen Enteric Agar (M467) or Deoxycholate Citrate Agar (M065) for easier isolation of *Shigella* species (9).

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Light yellow to pink homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Reddish orange coloured clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 6.3% w/v aqueous solution at 25°C. pH : 7.0±0.2

pH

6.80-7.20

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of colony
# *Klebsiella aerogenes* ATCC 13048 (00175*)	50-100	fair	20-30%	cream pink
Escherichia coli ATCC 25922 (00013*)	50-100	fair	20-30%	pink with bile precipitate
Salmonella Choleraesuis ATCC 12011	50-100	good-luxuriant	>=50%	colourless with black centre
Salmonella Typhi ATCC 6539	50-100	good-luxuriant	>=50%	colourless with black centre
Enterococcus faecalis ATCC 29212 (00087*)	50-100	none-poor	<=10%	colourless
Proteus mirabilis ATCC 25933	50-100	fair-good	30-40%	colourless, may have black centre
Shigella flexneri ATCC 12022 (00126*)	50-100	good	40-50%	colourless
Salmonella Typhimurium ATCC 14028 (00031*)	50-100	good-luxuriant	>=50%	colourless with black centre
Salmonella Enteritidis ATCC 13076 (00030*)	50-100	good-luxuriant	>=50%	colourless with black centre

Key : *Corresponding WDCM numbers.
Formerly known as *Enterobacter aerogenes*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (8,9).

Reference

1. Lennette and others (Eds.), 1985, Manual of Clinical Microbiology, 4th ed., ASM, Washington, D.C.
2. Lipps WC, Braun-Howland EB, Baxter TE,eds. Standard methods for the Examination of Water and Wastewater, 24th ed. Washington DC:APHA Press; 2023.
3. Salfinger Y., and Tortorello M.L. Fifth (Ed.), 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
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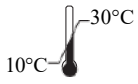

Storage temperature

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Columbia Blood Agar Base

M144

Intended Use:

For preparation of blood agar, chocolate agar and for preparation of various selective and identification media and isolation of organisms from clinical and non clinical samples.

Composition**

Ingredients	Gms / Litre
Peptone, special	23.000
Corn starch	1.000
Sodium chloride	5.000
Agar	15.000
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 44.0 grams of in 1000 ml purified/ distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C before adding heat sensitive compounds.
For Blood Agar: Add 5% v/v sterile defibrinated sheep blood to sterile cool base.
For Chocolate Agar: Add 10% v/v sterile defibrinated sheep blood to sterile cool base. Heat to 80°C for 10 minutes with constant agitation.
The medium can be made selective by adding different antimicrobials to sterile base.
For *Brucella* species: Add rehydrated contents of 1 vial of NPBCVN Selective Supplement (FD005) to 500 ml sterile molten base.
For *Campylobacter* species: Add rehydrated contents of 1 vial of Blaser-Wang Selective Supplement (FD006) or Butzler Selective Supplement (FD007) or Skirrow Selective Supplement (FD008) or VTCA Selective Supplement (FD090) or Butzler VI Selective Supplement (FD106) to 500 ml sterile molten base along with rehydrated contents of 1 vial of Minerals Growth Supplement (FD009) and 5-7% v/v horse or sheep blood.
For *Gardnerella* species: Add rehydrated contents of 1 vial of GNA Selective Supplement (FD056) to 500 ml sterile molten base.
For Cocci: Add rehydrated contents of 1 vial of NC Selective Supplement (FD030) or NNP Selective Supplement (FD031) or CO Selective Supplement (FD119) to 500 ml sterile molten base.

Principle And Interpretation

Columbia Blood Agar Base was devised by Ellner et al (1). This medium contains special peptone which supports rapid and luxuriant growth of fastidious and non-fastidious organisms. Also, this medium promotes typical colonial morphology; better pigment production and more sharply defined haemolytic reactions. Fildes found that Nutrient Agar supplemented with a digest of sheep blood supplied both of these factors and the medium would support the growth of *H. influenzae* (2,3). The inclusion of bacitracin makes the enriched Columbia Agar Medium selective for the isolation of *Haemophilus* species from clinical specimens, especially from upper respiratory tract (4). Columbia Agar Base is used as the base for the media containing blood and for selective media formulations in which different combinations of antimicrobial agents are used as additives.
Corn starch serves as an energy source and also neutralizes toxic metabolites. Sheep blood permits the detection of haemolysis and also provides heme (X factor) which is required for the growth of many bacteria. However it is devoid of V factor (Nicotinamide adenine dinucleotide) and hence *Haemophilus influenzae* which needs both the X and V factors, will not grow on this medium.
Columbia Agar Base with added sterile serum provides an efficient medium for *Corynebacterium diphtheriae* virulence test medium. After following the established technique for *C. diphtheriae,* lines of toxin-antitoxin precipitation are clearly visible in 48 hours. Many pathogens require carbon dioxide; therefore, plates may be incubated in an atmosphere containing approximately 3-10% CO_2.
Precaution: Brucella cultures are highly infective and must be handled carefully; incubate in 5-10% CO_2. Campylobacter species are best grown at 42°C in a micro aerophillic atmosphere. Plates with Gardenerella supplements plates should be incubated at 35°C for 48 hours containing 7% CO_2 (2).

Type of specimen

Clinical samples : throat swabs, pus.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (5,6).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Certain fastidious organisms like *Haemophilus influenzae* may not grow on the medium, blood supplementation may be required.
2. As this medium have a relatively high carbohydrate content, beta-hemolytic *Streptococci* may exhibit a greenish hemolytic reaction which may be mistaken for the alpha haemolysis.
3. Biochemical characterization is required on colonies of pure culture for complete identification.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder.

Gelling

Firm, comparable with 1.5% Agar gel.

Colour and Clarity of prepared medium

Basal medium: Light amber coloured clear to slightly opalescent gel.
After addition of 5%w/v sterile defibrinated blood : Cherry red coloured opaque gel forms in Petri plates.

Reaction

Reaction of 4.4% w/v aqueous solution at 25°C. pH : 7.3±0.2

pH

7.10-7.50

Cultural Response

Cultural characteristics observed with added 5% w/v sterile defibrinatedblood, after an incubation at 35-37°C for 24-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Haemolysis
Neisseria meningitidis ATCC 13090	50-100	luxuriant	>=70%	none
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50-100	luxuriant	>=70%	beta / gamma
Staphylococcus epidermidis ATCC 12228 (00036*)	50-100	luxuriant	>=70%	gamma
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50-100	luxuriant	>=70%	beta / gamma
Streptococcus pneumoniae ATCC 6303	50-100	luxuriant	>=70%	alpha
Streptococcus pyogenes ATCC 19615	50-100	luxuriant	>=70%	beta
Clostridium sporogenes ATCC 19404 (00008*)	50-100	luxuriant	>=50 %	
Clostridium sporogenes ATCC 11437	50-100	luxuriant	>=50 %	
Clostridium perfringens ATCC 13124 (00007*)	50-100	luxuriant	>=50 %	
Clostridium perfringens ATCC 12934	50-100	luxuriant	>=50 %	

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (5,6).

Reference

1. Ellner P. P., Stoessel C. J., Drakeford E. and Vasi F., 1966, Am. J. Clin. Pathol., 45:502.
2. Fildes P., 1920, Br. J. Exp. Pathol., 1:129.
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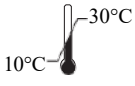

Storage temperature

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Mueller Hinton Agar

M173

Intended Use:

Recommended for determination of susceptibility of microorganisms to antimicrobial agents isolated from clinical samples.

Composition**

Ingredients	Gms / Litre
HM infusion B from #	300.000
Acicase ##	17.500
Starch	1.500
Agar	17.000
Final pH (at 25°C)	7.3±0.1

**Formula adjusted, standardized to suit performance parameters
- Equivalent to Beef infusion from
- Equivalent to Casein acid hydrolysate

Directions

Suspend 38.0 grams in 1000 ml purified/ distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates. Note: The performance of this batch has been tested and standardised as per the current CLSI (formerly, NCCLS) document M6-protocols for Evaluating Dehydrated Mueller Hinton Agar.

Principle And Interpretation

The Mueller Hinton formulation was originally developed as a simple, transparent agar medium for the cultivation of pathogenic *Neisseria* species (1). Other media were subsequently developed that replaced the use of Mueller Hinton Agar for the cultivation of pathogenic *Neisseria* species, but it became widely used in the determination of sulfonamide resistance of gonococci and other organisms. Mueller Hinton Agar is now used as a test medium for antimicrobial susceptibility testing (2). Mueller Hinton Agar is recommended for the diffusion of antimicrobial agents impregnated on paper disc through an agar gel as described in CLSI Approved Standard (3). Mueller Hinton Agar has been selected by the CLSI for several reasons:

i. It demonstrates good batch-to-batch reproducibility for susceptible testing.

ii. It is low in sulfonamide, trimethoprim and tetracycline inhibitors.

iii. It supports the growth of most non-fastidious bacterial pathogens and

iv. Many data and much experience regarding its performance have been recorded (4).

Kirby-Bauer et al recommended this medium for performing antibiotic susceptibility tests using a single disc of high concentration (5). WHO Committee on Standardization of Susceptibility Testing has accepted Mueller Hinton Agar for determining the susceptibility of microorganisms because of its reproducibility (6). Mueller Hinton Agar with 5% sheep blood and Mueller Hinton Agar with Hemoglobin have been recommended for antimicrobial susceptibility testing of *Streptococcus pneumoniae* and *Haemophilus influenzae*.

HM infusion B from and acicase provide nitrogenous compounds, carbon, sulphur and other essential nutrients. Starch acts as a protective colloid against toxic substances present in the medium. Starch hydrolysis yields dextrose, which serves as a source of energy. These ingredients are selected for low thymine and thymidine content as determined by MIC values for

Enterococcus faecalis with sulfamethoxazole trimethoprim (SXT).

The Kirby-Bauer procedure is based on agar diffusion of antimicrobial substances impregnated on paper discs. This method employs disc with a single concentration of antimicrobial agent and the zone diameters observed are correlated with minimum inhibitory concentration (MIC) values (7,1,2). A standardized suspension of the organism is swabbed over the entire surface of the medium.

Paper discs impregnated with specific amounts of antimicrobial agents are then placed on the surface of the medium, incubated and zones of inhibition around each disc are measured. The susceptibility is determined by comparing with CLSI standards (4). The various factors, which influence disc diffusion susceptibility tests, are agar depth, disc potency, inoculum concentration, pH of the medium and beta-lactamase production by test organisms (4,8).

Mueller Hinton Agar is not appropriate for assay by disc diffusion method with slow growing organisms, anaerobes and capnophiles. With slow growing organisms, increased incubation may cause deterioration of diffusing antibiotic and produce unprecise readings (9).

Type of specimen

Clinical samples : Isolated microorganisms from urine , stool etc.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (3,5).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. This medium is recommended for susceptibility testing of pure cultures only.
2. Inoculum density may affect the zone size. Heavy inoculum may result in smaller zones or too less inoculum may result in bigger zones.
3. Fastidious organisms may not grow on this medium and may require supplementation of blood.
4. Fastidious anaerobes may not grow on this medium.
5. As antimicrobial susceptibility is carried with antibiotic disc, proper storage of the disc is desired which may affect the potency of the disc.
6. Under certain circumstances, the in vitro results of antibiotic susceptibility may not show the same in vivo.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder.

Gelling

Firm, comparable with 1.7% agar gel.

Colour and Clarity of prepared medium

Light amber coloured clear to slight opalscent gel froms in Petri plates.

Reaction

Reaction of 3.8% w/v aqueous solution at 25°C. pH : 7.3±0.1

pH

7.20-7.40

Cultural Response

Cultural characteristics observed after incubation at 30-35°C for 18 -24 hours for bacterial cultures.

For testing *S. pneumoniae* : The medium was supplemented with 5% Sheep blood and incubated at 35°C for 16-18 hours at 5% CO_2 .

For testing *H. influenaze* : The medium was supplemented with 5g/l of Yeast extract & 2 vials /l of Haemophilus Growth Supplement (FD117 containing 15 mg/l of Haematin + 15 mg/l of NAD) and incubated at 35°C for 20-24 hours at 5% CO_2.

Antibiotic Sensitivity test

Various discs were tested for standard ATCC strains and zone of inhibition were measured after an incubation 30-35°C for 18 hours. (As per the latest CLSI Protocol M6 & Standards as per the current CLSI M100).

Thymine/Thymidine Content

The zones for these discs are indicative of the Thymine/Thymidine content of the medium.

Divalent Cation Content

$ The zones for these discs are indicative of the Divalent Cation content of the medium

Thymine/Thymidine Content

The zones for these discs are indicative of the Thymine/Thymidine content of the medium.

Divalent Cation Content

$ The zones for these discs are indicative of the Divalent Cation content of the medium

Organism	Growth	Standard Zone	Zone of inhibition Observed
***Escherichia coli* ATCC 25922 (00013*)**	luxuriant		
Cephalothin CEP 30mcg		29-37 mm	29 -37 mm
Chloramphenicol C 30 mcg		21-27 mm	21 -27 mm
Co-Trimoxazole COT 25 mcg #		23-29 mm	23 -29 mm
Cefotaxime CTX 30 mcg		29-35 mm	29 -35 mm
Gentamicin GEN 10 mcg		19-26 mm	19 -26 mm
Sulphafurazole SF 300 mcg		15-23 mm	15 -23 mm
***Staphylococcus aureus* subsp. *aureus* ATCC 25923 (00034*)**	luxuriant		
Co-Trimoxazole COT 25 mcg #		# 20 mm (Clear zone)	>=20 mm
Cefoxitin CX 30 mcg		23-29 mm	23 -29 mm
Erythromycin E 15 mcg		22-30 mm	22 -30 mm
Linezolid LZ 30 mcg		25-32 mm	25 -32 mm
Oxacillin OX 1mcg		18-24 mm	18 -24 mm
Pristinomycin RP 15 mcg		21-28 mm	21 -28 mm
Tetracycline TE 30 mcg $		18-25 mm	18 -25 mm
Ciprofloxacin CIP 5mcg		22-30 mm	22 -30 mm
***Pseudomonas aeruginosa* ATCC 27853 (00025*)**	luxuriant		
Ceftazidime CAZ 30 mcg		22-29 mm	22 -29 mm
Ciprofloxacin CIP 5mcg		30-40 mm	30 -40 mm
Tobramycin TOB 10 mcg $		19-25 mm	19 -25 mm
Amikacin AK 30 mcg $		18-26 mm	18 -26 mm
Aztreonam AT 3mcg		23-29 mm	23 -29 mm
Cephotaxime CTX 30 mcg		18-22 mm	18 -22 mm
Gentamicin GEN 10 mcg $		16-21 mm	16 -21 mm
Imipenem IPM 10 mcg		20-28 mm	20 -28 mm
Piperacillin PI 100 mcg		12-18 mm	25 -33 mm
***Escherichia coli* ATCC 35218**	luxuriant		
Amoxyclav AMC 30 mcg		18-24 mm	18 -24 mm
Piperacillin/Tazobactam PIT 100/10 mcg		24-30 mm	24 -30 mm
Ticarcillin TI 75 mcg		6 mm	6 -6 mm
Ticarcillin/Clavulanic acid TCC 75/10mcg		20-28 mm	20 -28 mm
Ampicillin AMP 10 mcg		16-22 mm	16 -22 mm
Ampicillin/Sulbactam A/S 10/10 mcg		29-37 mm	29 -37 mm
***Enterococcus faecalis* ATCC 29212 (00087*)**	luxuriant		
Trimethoprim TR 5 mcg #		# 20 mm	>=20 mm
Vancomycin VA 30 mcg		17-21 mm	17 -21 mm
***Staphylococcus aureus* subsp. *aureus*ATCC 43300 (MRSA) (00211*)**	luxuriant		
Oxacillin OX 1 mcg		Very Hazy to No Zone	No zone

Key : *Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use.

Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,5).

Reference

1. Murray P. R., Baron J. H., Pfaller M. A., Jorgensen J. H. and Yolken R. H., (Ed.), 2003, Manual of Clinical Microbiology, 8th Ed., American Society for Microbiology, Washington, D.C.
2. National Committee for Clinical Laboratory Standards, 2000, Approved Standard: M7-A5. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that grow aerobically, 5th Ed., NCCLS, Wayne, Pa.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
4. MacFaddin J. F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams and Wilkins, Baltimore
5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
6. Present Status and Future Work, WHO Sponsored collaborative study, Chicago, Oct. 1967.
7. Ericsson H. M. and Sherris J. L., 1971, Acta Pathol. Microbiol., Scand. Sect B Suppl., 217:1.
8. National Committee for Clinical Laboratory Standards, 1986, Proposed Standards, M6-P, NCCLS, Villanova, Pa.
9. Mueller J. H. and Hinton J., 1941, Proc. Soc. Exp. Biol. Med., 48:330.

Revision : 05/2022

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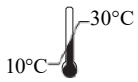
IVD *In vitro* diagnostic medical device



Storage temperature

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CE Marking

Do not use if package is damaged

Disclaimer :

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Anaerobic Agar

M228

Intended Use:

Recommended for the cultivation of anaerobic bacteria, especially *Clostridium* species and other anaerobic organisms from clinical and non-clinical samples.

Composition**

Ingredients	Gms / Litre
Tryptone	20.000
Dextrose (Glucose)	10.000
Sodium chloride	5.000
Sodium thioglycollate	2.000
Sodium formaldehyde Sulfoxylate	1.000
Methylene blue	0.002
Agar	20.000
Final pH (at 25°C)	7.2±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 58.0 grams in 1000 ml purified/ distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Anaerobic Agar was originally designed for surface cultivation of members of the genus *Clostridium* and other anaerobic organisms on plates (1). This medium is suitable for isolation of facultative and obligate anaerobes and for the study of colonial morphology as colonies can be readily seen on the light coloured agar and are easily accessible (2,3). Anaerobic bacteria vary in their sensitivity to oxygen and nutritional requirements (3). Anaerobic bacteria lack cytochromes and thus are unable to use oxygen as a terminal electron acceptor (4).

This medium contains sodium thioglycollate and sodium formaldehyde sulphoxylate that provide adequate anaerobiosis which is indicated by methylene blue present in the medium which yields blue colour to medium in presence of oxygen. Tryptone and dextrose provide essential nutrients while sodium chloride maintains osmotic equilibrium.

Dispense 50-60 ml medium per 95 x 20 mm plate. For best results, use porous tops for the plates during solidification to get the dry surface. Inoculation can be done by streaking or smearing. Cover the inoculated plate with sterile Brewer Anaerobic Petri dish cover. Incubate aerobically, as desired. When standard plates are used, dispense 0.1 to 1.0 ml of inoculum into plates and mix with 20 - 25 ml of sterile medium. After solidification, incubate anaerobically as required by particular organism under study. Methylene blue is inhibitory to some anaerobic microorganisms.

Type of specimen

Clinical- stool, abscess

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (3,5).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1.Ensure that the clinical samples are properly transported under anaerobic conditions.
2.Proper anaerobic conditions must be maintained for optimal recovery of organisms
3.Methylene blue is toxic to certain anaerobes.
4.Further biochemical and serological tests must be performed for confirmation.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Cream to yellow homogeneous free flowing powder

Gelling
Firm, comparable with 2.0% agar gel.

Colour and Clarity of prepared medium
Light amber coloured, clear to slightly opalescent gel forms in Petri plates that becomes greenish due to aeration on standing

Reaction
Reaction of 5.8% w/v aqueous solution at 25°C. pH : 7.2±0.2

pH
7.00-7.40

Cultural Response
Cultural characteristics observed under anaerobic condition after an incubation at 35-37°C for 48-72 hours.

Organism	Inoculum (CFU)	Growth	Recovery
Clostridium perfringens ATCC 12924	50-100	good-luxuriant	>=50%
Clostridium sporogenes ATCC 11437	50-100	good-luxuriant	>=50%
Clostridium butyricum ATCC 13732	50-100	good-luxuriant	>=50%

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,5).

Reference

1. Brewer J. H., 1942, Science, 95:587.
2. Vera J., 1942, J. Bacteriol., 44:497.
3. Isenberg (Ed.), 1992, Clinical Microbiology Procedures Handbook, American Society for Microbiology, Washington, D.C.
4. Baron E. J., Peterson and Finegold S. M., Bailey & Scotts Diagnostic Microbiology, 9th Ed., 1994, Mosby-Year Book, Inc., St. Louis, Mo.
5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology,11th Edition. Vol. 1.

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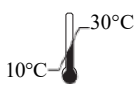
IVD *In vitro* diagnostic medical device



Storage temperature

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Disclaimer :

Tinsdale Agar Base

M314

Tinsdale Agar Base with supplement is used for selective isolation and differentiation of *Corynebacterium diphtheriae* .

Composition**

Ingredients	Gms / Litre
Peptic digest of animal tissue	20.000
Sodium chloride	5.000
L-Cystine	0.240
Sodium thiosulphate	0.430
Agar	15.000
Final pH (at 25°C)	7.4±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 40.67 grams in 1000 ml distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 50°C and aseptically add Diphtheria Virulence Supplement (FD073, Part A and Part B). Mix well and pour into sterile Petri plates.

Principle And Interpretation

The Corynebacteria are gram-positive, non-sporulating, non-motile rods. They are often club-shaped and frequently banded or beaded with irregularly stained granules. These bacteria are generally aerobic or facultative, but microaerophilic species do occur. *Corynebacterium diphtheriae* produces a powerful exotoxin that causes diphtheria in humans. In nature, *C. diphtheriae* occurs in nasopharyngeal area of infected persons or healthy carriers.

The three biotypes of *C. diphtheriae* are *mitis* , *intermedius* and *gravis* (6). The signs and symptoms of diphtheria are sore throat, malaise, headache and nausea (2). Tinsdale Agar Base Medium was developed by Tinsdale (1) for the selective isolation and differentiation of *C. diphtheriae* from diphtheroids. This medium was modified by Billings (2), which improved the recovery and differential qualities of *C. diphtheriae* . The present medium is according to the modified Billings Medium. Moore and Parsons (3) confirmed the halo formation as a characteristic property of *C. diphtheriae* with the exception of *C. ulcerans* , which forms colony with similar features as *C. diphtheriae* .

Peptic digest of animal tissue provides nitrogenous compounds. L-cystine and sodium thiosulphate form the H2S indicator system. Potassium tellurite from the supplement inhibits all gram-negative bacteria and most of the upper respiratory tract normal flora.

C. diphtheriae forms grayish black colonies surrounded by a dark brown halo while diphtheroids commonly found in the upper respiratory tract do not form such colonies. Dark brown halo around the colony is due to H2S production from cystine combining with the tellurite salt. Moore and Parsons (3) found Tinsdale Medium as an ideal medium for the routine cultivation and isolation of *C. diphtheriae* . They also confirmed the stability of halo formation on clear medium and its specificity for *C. diphtheriae* and *C. ulcerans* . *C. ulcerans* found in nasopharynx form colonies same as *C. diphtheriae* and require further biochemical confirmation (4).

Do not incubate the plates in 5-10% CO2 as it retards the development of characteristic halos (5). Tinsdale Agar is not suitable as a primary plating medium, since it may not support the growth of some strains of *C. diphtheriae* (6). *C. ulcerans* , *C. pseudotuberculosis* and (rarely) *Staphylococcus* species may produce a characteristic halo on Tinsdale Agar (6).Several organisms may exhibit slight browning on Tinsdale Agar in 18 hours; therefore the plates should be read after complete incubation period (48 hours) (6).

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling
Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium
Light amber coloured clear to slightly opalescent gel forms in Petri plates

Reaction
Reaction of 4.07% w/v aqueous solution at 25°C. pH : 7.4±0.2

pH
7.20-7.60

Cultural Response
M314: Cultural characteristics observed after an incubation at 35-37°C for 40-48 hours with added Diptheria Virulence Supplement (FD073, Part A and Part B).

Organism	Inoculum (CFU)	Growth	Recovery	Colony characteristics
Corynebacterium diphtheriae type gravis	50-100	good-luxuriant	>=50%	brown-black with halo
Corynebacterium diphtheriae type intermedius	50-100	good-luxuriant	>=50%	brown-black with halo
Corynebacterium diphtheriae type mitis	50-100	good-luxuriant	>=50%	brown-black with halo
Klebsiella pneumoniae ATCC 13883	>=10^3	inhibited	0 %	
Streptococcus pyogenes ATCC 19615	50-100	good	40-50%	black pin point, without halo

Storage and Shelf Life

Store below 30°C in tightly closed container and the prepared medium at 2 - 8°C. Use before expiry date on the label.

Reference

1. Tinsdale G. F. W., 1947, J. Pathol. Bacteriol., 59:461.
2. Billings E., 1956, An investigation of Tinsdale Tellurite Medium: its usefulness and mechanisms of halo-formation, M.S. thesis, University of Michigan, Ann Arbor, Mich.
3. Moore M. S. and Parsons E. I., 1958, J. Infect. Dis., 102:88.
4. MacFaddin J. F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. I, Williams and Wilkins, Baltimore.
5. Murray P. R., Baron E. J., Jorgensen J. H., Pfaller M. A., Yolken R. H., (Eds.), 8th Ed., 2003, Manual of Clinical Microbiology, ASM, Washington, D.C
6. Isenberg, (Eds.), 1992, Clinical Microbiology Procedures Handbook, Vol. 1, American Society for Microbiology, Washington, D.C.

Revision : 1 / 2011

Bile Esculin Azide Agar

M493

Intended Use:

For selective isolation and presumptive identification of faecal Streptococci.

Composition**

Ingredients	Gms / Litre
Tryptone	17.000
HM peptone B #	5.000
Proteose peptone	3.000
Bile ##	10.000
Esculin	1.000
Ferric ammonium citrate	0.500
Sodium chloride	5.000
Sodium azide	0.150
Agar	15.000
Final pH (at 25°C)	7.1±0.2

Equivalent to Beef extract ## - Equivalent to Oxgall

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 56.65 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Caution: *Sodium azide has a tendency to form explosive metal azides with plumbing materials. It is advisable to use enough water to flush off the disposables.*

Principle And Interpretation

Group D Streptococci possess the group D lipoteichoic acid antigen in their cell walls. Former Group D species, which are predominant normal inhabitants of the human gastrointestinal tract, are termed as faecal Streptococci or Enterococci (1). The unique ability of Enterococci to split esculin was reported by Meyer and Schonfeld (2). Enterococci and Group D Streptococci hydrolyse esculin to esculetin and dextrose, which reacts with ferric citrate producing brownish black precipitate (3). The use of esculin hydrolysis in identification of Enterococci was first cited by Rochaix (4). Bile Esculin Agar was originally formulated by Swan (5) for the isolation and identification of Group D Streptococci from food. Facklam and Moody (6) further reported that using Bile Esculin Agar, Group D Streptococci could be differentiated from non Group D Streptococci.

Bile Esculin Agar was also shown to aid differentiation of *Enterobacteriaceae, Klebsiella, Enterobacter, Serratia* from other *Enterobacteriaceae* genera (7) on the basis of esculin hydrolysis. However, other tests such as salt tolerance should be performed for identifying Enterococci (8).

Bile Esculin Azide Agar is a modification of Bile Esculin Agar as per Isenberg (9). In this medium the bile concentration is reduced and additional sodium azide is incorporated.

Tryptone, proteose peptone and HM peptone B serves as sources of carbon, nitrogen, amino acids, vitamins and essential growth nutrients. Bile and sodium azide inhibits most of the other accompyning bacteria. Esculin in the medium is hydrolyzed to esculetin and dextrose. Esculetin reacts with ferric citrate to form a dark brown or black complex, visualized as a zone of black precipitate around the colonies. If the media is dispensed in tubes in the form of slants, a positive reaction is indicated by blackening of more than half of the slant within 24-48 hours. If blackening is totally absent or if less than half of the slant is blackened within 24-48 hours, the test is negative. Viridans Streptococci sometimes exhibit a weak positive reaction. Also, *Leuconostoc, Pediococcus, Lactococcus* species causing human infections give a positive bile esculin test (10). To enhance the growth of Enterococci, Bile Esculin Agar can be supplemented with 50ml/l horse serum (3). Suspected water samples are filtered using membrane filters. These membrane filters are aseptically placed on Slanetz and Bartely Medium (M612I). Red or maroon coloured colonies observed after incubation are further confirmed by aseptically transferring the membrane filter on to Bile Esculin Azide Agar plate preheated to 44°C. Incubation at 44 ± 0.5°C for 2 hours is done following the inoculation.

All typical colonies exhibiting a brown black colouration in the surrounding medium are counted as intestinal Enterococci (10). Alternatively Bile Esculin Azide Agar can also be used for direct isolation of Enterococci (without membrane filter), by incubation at 35-37°C for 18-24 hours.

Type of specimen

Clinical- Faeces, Food samples

Specimen Collection and Handling:

For food samples, follow appropriate techniques for sample collection and processing as per guidelines (4).

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (8,9).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Cream to yellow homogeneous free flowing powder
Gelling
Firm, comparable with 1.5% Agar gel
Colour and Clarity of prepared medium
Amber coloured, clear to slightly opalescent gel with a bluish tinge forms in Petri plates.
Reaction
Reaction of 5.67% w/v aqueous solution at 25°C. pH : 7.1±0.2
pH
6.90-7.30
Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Esculin Hydrolysis
Enterococcus faecalis ATCC 29212 (00087*)	50-100	luxuriant	>=50%	positive reaction, blackening of medium around the colony
Escherichia coli ATCC 25922 (00013*)	>=10^4	inhibited	0%	
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50-100	good	40-50%	negative reaction
Proteus mirabilis ATCC 25933	50-100	good	40-50%	negative reaction
Streptococcus pyogenes ATCC 19615	50-100	none-poor	<=10%	negative reaction

Key : *Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (8,9).

Reference

1. Edberg S. C., Pittman S., and Singer J. M., 1977, J. Clin. Microbiol., 6:111.
2. Murray P. R., Baron E. J., Jorgensen J. H., Pfaller M. A., Yolken R. H.,(Eds.), 8th Ed., 2003, Manual of Clinical Microbiology, ASM, Washington, D.C.
3. Facklam R., 1972, Appl. Microbiol., 23:1131.
4. Salfinger Y., and Tortorello M.L. , 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
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7. Meyer and Schonfeld, 1926, Zentralbl. Bakeriol, Parasitenk. Infectionskr. Hyg. Abt. Orig. 99:402.
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10. Rochaix, 1924, Comt. Rend. Soc. Biol., 90:771.

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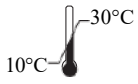

Storage temperature

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Lactobacillus MRS Agar

M641

Intended use

For isolation and cultivation of Lactobacilli.

Composition**

Ingredients	Gms / Litre
Proteose peptone	10.000
HM Peptone B #	10.000
Yeast extract	5.000
Dextrose (Glucose)	20.000
Tween 80 (Polysorbate 80)	1.000
Ammonium citrate	2.000
Sodium acetate	5.000
Magnesium sulphate	0.100
Manganese sulphate	0.050
Dipotassium hydrogen phosphate	2.000
Agar	12.000
Final pH (at 25°C)	6.5±0.2

**Formula adjusted, standardized to suit performance parameters
Equivalent to Beef extract

Directions

Suspend 67.15 grams in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Lactobacilli MRS media are based on the formulation of deMan, Rogosa and Sharpe (1) with slight modification. It supports luxuriant growth of all Lactobacilli from oral cavity (2), dairy products (3), foods (2), faeces (4,5) and other sources (6).

Proteose peptone and HM peptone B supply nitrogenous and carbonaceous compounds. Yeast extract provides vitamin B complex and dextrose is the fermentable carbohydrate and energy source. Polysorbate 80 supplies fatty acids required for the metabolism of Lactobacilli. Sodium acetate and ammonium citrate inhibit Streptococci, moulds and many other microorganisms. Magnesium sulphate and manganese sulphate provide essential ions for multiplication of lactobacilli. Phosphates provide good buffering action in the media.

Lactobacilli are microaerophilic and generally require layer plates for aerobic cultivation on solid media. When the medium is set, another layer of un-inoculated MRS Agar is poured over the surface to produce a layer plate. Lactobacilli isolated on MRS Agar should be further confirmed biochemically.

Type of specimen

Clinical samples - urine, faeces, etc.; Food and dairy samples

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (4,5).

For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (2,7,8).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2. Further Biochemical and serological testing is required for complete identification.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within theexpiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to light yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.2% Agar gel.

Colour and Clarity of prepared medium

Medium to dark amber coloured, clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 6.71% w/v aqueous solution at 25°C. pH : 6.5±0.2

pH

6.30-6.70

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours or longer.(with 5% CO2)

Organism	Inoculum (CFU)	Growth	Recovery
Lactobacillus casei ATCC 9595	50-100	luxuriant	>=50%
Lactobacillus fermentum ATCC 9338	50-100	luxuriant	>=50%
Lactobacillus leichmannii ATCC 7830	50-100	luxuriant	>=50%
Lactobacillus plantarum ATCC 8014	50-100	luxuriant	>=50%
Lactobacillus saki ATCC 15521(00015*)	50-100	luxuriant	>=70%
Lactobacillus lactis ATCC 19435(00016*)	50-100	luxuriant	>=70%
Pediococcus pentosaceas ATCC 33316(00158*)	50-100	luxuriant	>=70%

Key: (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store dehydrated powder and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

References

1. deMan J., Rogosa M. and Sharpe M., 1960, J. Appl. Bacteriol., 23:130.
2. American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.
3. Marshall R.T. (Ed.), 1992, Standard Methods for the Examination of Dairy Products, 16th ed., APHA, Washington,D.C.
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5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
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7. Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
8. Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.

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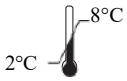

Storage temperature

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Anaerobic Blood Agar Base

M975A

Intended Use:

Recommended for cultivation of anaerobic microorganisms, including very fastidious organisms from clinical specimens.

Composition**

Ingredients	Gms / Litre
Tryptone	15.000
Soya peptone	5.000
Yeast extract	5.000
Sodium chloride	5.000
L-Cysteine	0.500
Hemin	0.005
Agar	13.500
Final pH (at 25°C)	7.4±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 44.0 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Add the rehydrated contents of one vial of Vitamin K1 supplement (FD114). Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C and aseptically add 5% v/v sterile defibrinated sheep blood. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Anaerobic Blood Agar base serves as a nutritious, nonselective medium allowing the cultivation of not only fastidious anaerobes but also of aerobic and microaerophillic microorganisms (1). It promotes both typical pigment formation in *Bacteroides melaningenicus* and displays double haemolytic reaction in *Clostridium perfringens* with added blood to the medium base. The inner zone of haemolysis is due to toxin and the outer zone of incomplete haemolysis to toxin (lecithinase activity). Tryptone, soya peptone and yeast extract in the medium provides carbon and nitrogenous source, long chain amino acids, vitamins and other essential nutrients. Presence of Hemin and Vitamin K1 supports the growth of typical fastidious bacteria like *Bacteroides* species and gram positive spore bearers like *Clostridium* species. Addition of blood provides nutrients and helps to differentiate haemolytic organisms. Sodium chloride helps in maintaining the osmotic equilibrium.

Type of specimen

Clinical samples- stool, abscess

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (2,3).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Due to nutritional variations, certain strains may show poor growth.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within expiry period when stored at the recommended temperature.

Quality Control

Appearance
Yellow to tan coloured homogeneous free flowing powder

Colour and Clarity of prepared medium
Basal medium : Yellow coloured; with addition of 5% v/v sterile, defibrinated sheep blood : cherry red coloured
Basal medium : slightly opalescent; After addition of 5% v/v sterile, defibrinated sheep blood : opaque gel in petri plates

Reaction
Reaction of 4.4% w/v aqueous solution at 25°C. pH : 7.4±0.2

pH
7.20-7.60

Cultural Response
Cultural characteristics observed after 24-48 hours at 35-37°C with 5-10% CO_2

Organism	Growth
Bacteroides fragilis ATCC 25285	luxuriant
Bacteroides melaninogenicus ATCC 25611	luxuriant
Peptostreptococcus anaerobius ATCC 27337	luxuriant

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,3).

Reference

1. Dowell, Jr., V.R., Lombard,G.L, Thompson,F.S, Armfield,A.Y.: Media for isolation, characterization and identification of obligately anaerobic bacteria- US Department of Health and Human services, centers for Disease Control (1977).
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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30°C
10°C
Storage temperature

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Sabouraud Chloramphenicol Agar

M1067

Intended use

For the selective cultivation of yeasts and moulds from clinical and non-clinical samples.

Composition**

Ingredients	Gms / Litre
Tryptone	5.000
Peptone	5.000
Dextrose (Glucose)	40.000
Chloramphenicol	0.050
Agar	15.000
Final pH (at 25°C)	5.6±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 65.05 grams in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Caution: *Some pathogenic fungi may produce infective spores which are easily dispersed in air, so examination should be carried out in safety cabinet.*

Principle And Interpretation

Sabouraud Chloramphenicol Agar is cited as Medium C and recommended for cultivation of yeasts and moulds. This medium was described originally by Sabouraud (1) for the cultivation of fungi, particularly useful for the fungi associated with skin infections. The medium is often used with antibiotics such as Chloramphenicol (2) for the isolation of pathogenic fungi from materials containing large numbers of fungi or bacteria.

Tryptone and peptone provide nitrogenous and carbonaceous compounds, long chain amino acids, and other essential growth nutrients. Dextrose provides an energy source. Chloramphenicol inhibits a wide range of Gram-positive and Gram-negative bacteria which makes the medium selective for fungi (3). The low pH favors fungal growth and inhibits contaminating bacteria from clinical specimens (4).

Type of specimen

Clinical samples - skin scrapings, nail scrapings; Food and dairy samples.

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (5,6). For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (7,8,9). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Certain pathogenic fungi may show poor growth on this medium.
2. Presence of chloramphenicol may inhibit certain pathogenic fungi.
3. Overheating of the medium may result in low productivity and softening of gel.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder.

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light amber coloured clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 6.5% w/v aqueous solution at 25°C. pH : 5.6±0.2

pH

5.40-5.80

Cultural Response

Cultural characteristics observed after an incubation at 20-25°C for 48-72 hours (Incubate for 7 days for Trichophyton species).

Organism	Inoculum (CFU)	Growth	Recovery
Aspergillus brasiliensis ATCC 16404 (00053*)	50-100	good-luxuriant	
Candida albicans ATCC 10231 (00054*)	50-100	good-luxuriant	>=50%
Escherichia coli ATCC 25922 (00013*)	>=10^4	inhibited	0%
Lactobacillus casei ATCC 334	>=10^4	inhibited	0%
Saccharomyces cerevisiae ATCC 9763 (00058*)	50-100	good-luxuriant	>=50%
Trichophyton rubrum ATCC 28191	50-100	good-luxuriant	
Escherichia coli NCTC 9002	>=10^4	inhibited	0%
Escherichia coli ATCC 8739 (00012*)	>=10^4	inhibited	0%

Key : *Corresponding WDCM numbers.

Storage and Shelf Life

Store the dehydrated powder and prepared medium on receipt between 15-25°C in a tightly closed container. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use.

Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (5,6).

Reference

1.Sabouraud K., 1892, Ann. Dermatol. Syphilol, 3:1061.

2.Ajello L., 1957, J. Chron. Dis., 5:545.

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7.American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.
8.Salfinger Y., and Tortorello M.L. Fifth (Ed.), 2015, Compendium of Methods for the Microbiological Examination of Foods, American Public Health Association, Washington, D.C.
9.Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.

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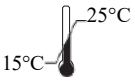

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HiCrome™ Candida Differential Agar

M1297A

Intended Use

HiCrome™ Candida Differential Agar is recommended for rapid isolation and identification of *Candida* species from mixed cultures in clinical and non-clinical samples.

Composition**

Ingredients	Gms / Litre
Peptone, special	15.000
Yeast extract	4.000
Dipotassium hydrogen phosphate	1.000
Chromogenic mixture	7.220
Chloramphenicol	0.500
Agar	15.000
Final pH (at 25°C)	6.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 42.72 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. DO NOT AUTOCLAVE. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Perry and Miller (3) reported that *Candida albicans* produces an enzyme b -N-acetyl- galactosaminidase and according to Rousselle et al (4) incorporation of chromogenic or fluorogenic hexosaminidase substrates into the growth medium helps in identification of *C.albicans* isolates directly on primary isolation. HiCrome™ Candida Differential Agar is a selective and differential medium, which facilitates rapid isolation of yeasts from mixed cultures and allows differentiation of *Candida* species namely *C.albicans, C.krusei, C.tropicalis* and *C.glabrata* on the basis of colouration and colony morphology. On this medium results are obtained within 48 hours and it is useful for the rapid and presumptive identification of common yeasts in Mycology and Clinical Microbiology Laboratory. Peptone special and yeast extract provides nitrogenous, carbonaceous compounds and other essential growth nutrients. Phosphate buffers the medium well. Chloramphenicol suppresses the accompanying bacterial flora. *C.albicans* appear as light green coloured smooth colonies, *C.tropicalis* appear as blue to metallic blue coloured raised colonies. *C.glabrata* colonies appear as cream to white smooth colonies, while *C.krusei* appear as purple fuzzy colonies.

Type of specimen

Clinical samples - skin scrapings, urine.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (3,4).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic Use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Variations in colour intensity may be observed for *Candida* isolates depending on the presence of enzymes.
2. Other *Candida* species may produce light mauve coloured colonies which is also produced by other yeast cells. This must be confirmed by further biochemical tests.
3. Other filamentous fungi also exhibit colour on this medium.

Performance And Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Cream to beige homogeneous free flowing powder

Gelling
Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium
Light amber coloured, clear to slightly opalescent gel forms in Petri plates

Reaction
Reaction of 4.27% w/v aqueous solution at 25°C. pH : 6.3±0.2

pH
6.10-6.50

Cultural Response
Cultural characteristics observed after an incubation at 30-35°C for 40-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of Colony
Candida albicans ATCC 10231 (00054*)	50-100	good-luxuriant	>=50%	light green
Candida glabrata ATCC 15126	50-100	good-luxuriant	>=50%	cream to white
#Teunomyces krusei ATCC 24408	50-100	good-luxuriant	>=50%	purple, fuzzy
Candida tropicalis ATCC 750	50-100	good-luxuriant	>=50%	blue to purple
Candida kefyr ATCC 66058	50-100	good-luxuriant	>=50%	cream to white with slight purple centre
Candida utilis ATCC 9950	50-100	good-luxuriant	>=50%	pale pink to pinkish purple
Candida parapsilosis ATCC 22019	50-100	good-luxuriant	>=50%	white to cream
Candida membranifaciens ATCC 20137	50-100	good-luxuriant	>=50%	white to cream
Candida dubliensis NCPF 3949	50-100	good-luxuriant	>=50%	pale green
Escherichia coli ATCC 25922 (00013*)	>=10^4	inhibited	0%	
Staphylococcus aureus subsp.aureus ATCC 25923 (00034*)	>=10^4	inhibited	0%	

Key : *Corresponding WDCM numbers. # - Formerly known as *Candida krusei*

Storage and Shelf Life

Store between 15-25°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

References

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
3. Perry J. L. and Miller G. R., 1987, J. Clin. Microbiol., 25: 2424 -2425.
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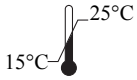

Storage temperature

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HiCrome™ UTI Agar

M1353

Intended use

Recommended for presumptive identification and confirmation of microorganisms mainly causing urinary tract infections, can also be used for testing water, food, environmental and other clinical samples.

Composition**

Ingredients	Gms / Litre
Peptone, special	15.000
Chromogenic mixture	2.450
Agar	15.000
Final pH (at 25°C)	6.8±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 32.45 grams in 1000 ml purified /distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Urinary tract infections are bacterial infections affecting parts of urinary tract. The common symptoms of urinary tract infection are urgency and frequency of micturition, with associated discomfort or pain. The common condition is cystitis, due to infection of the bladder with a uropathogenic bacterium, which most frequently is *Escherichia coli,* but sometimes *Staphylococcus saprophyticus* or especially in hospital-acquired infections, *Klebsiella* species, *Proteus mirabilis*, other coliforms, *Pseudomonas aeruginosa* or *Enterococcus faecalis* (1). HiCrome™ UTI Agar is formulated on basis of work carried out by Pezzlo (2) Wilkie et al (3), Friedman et al (4), Murray et al (5), Soriano and Ponte (6) and Merlino et al (7). These media are recommended for the detection of urinary tract pathogens where HiCrome™ UTI Agar has broader application as a general nutrient agar for isolation of various microorganisms. It facilitates and expedites the identification of some gram-negative bacteria and some gram-positive bacteria on the basis of different contrasted colony colours produced by reactions of genus or species specific enzymes with two chromogenic substrates. The chromogenic substrates are specifically cleaved by enzymes produced by *Enterococcus* species, *E.coli* and coliforms. Presence of amino acids like phenylalanine and tryptophan from peptones helps for detection of tryptophan deaminase activity, indicating the presence of *Proteus* species, *Morganella* species and *Providencia* species.

One of the chromogenic substrate is cleaved by ß-glucosidase possessed by Enterococci resulting in formation of blue colonies. *E.coli* produce pink colonies due to the enzyme ß-D-galactosidase that cleaves the other chromogenic substrate. Further confirmation of *E.coli* can be done by performing the indole test. Coliforms produce purple coloured colonies due to cleavage of both the chromogenic substrate. Colonies of *Proteus, Morganella* and *Providencia* species appear brown because of tryptophan deaminase activity. Peptone special provides nitrogenous, carbonaceous compounds, long chain amino acids, vitamins and other essential growth nutrients. This medium can be made selective by supplementation with antibiotics for detecting microorganisms associated with hospital borne infections.

Type of specimen

Clinical samples : urine, faeces, Food samples, Water samples.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (8,9).

For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (10,11).

For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards (12).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and

culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2.Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.
3.Since it is an enzyme-substrate based reaction, the intensity of colour may vary with isolates.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light amber coloured, clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 3.24% w/v aqueous solution at 25°C. pH : 6.8±0.2

pH

6.60-7.20

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 16-24 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of Colony
Escherichia coli ATCC 25922 (00013*)	50-100	luxuriant	>=70%	Purple to magenta
Enterococcus faecalis ATCC 29212 (00087*)	50-100	luxuriant	>=70%	blue-green, (small)
Klebsiella pneumoniae ATCC 13883 (00097*)	50-100	luxuriant	>=70%	blue to purple, mucoid
Proteus mirabilis ATCC 12453	50-100	luxuriant	>=70%	light brown
Pseudomonas aeruginosa ATCC 27853 (00025*)	50-100	luxuriant	>=70%	colourless (greenish pigment may be observed)
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50-100	luxuriant	>=70%	cream to golden yellow

Key : *Corresponding WDCM numbers.

Storage and Shelf Life

Store between 15-25°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (8,9).

Reference

1. Collee J. G., Fraser A. G., Marmion B. P., Simmons A., (Eds.), Mackie and McCartney, Practical Medical Microbiology, 1996, 14th Edition, Churchill Livingstone.
2. Pezzlo M., 1998, Clin. Microbiol. Rev., 1:268-280.
3. Wilkie M. E., Almond M. K., Marsh F. P., 1992, British Medical Journal 305:1137-1141.
4. Friedman M. P. et al, 1991, J. Clin. Microbiol., 29:2385-2389.
5. Murray P., Traynor P. Hopson D., 1992, J. Clin. Microbiol., 30:1600- 1601.
6. Soriano F., Ponte C., 1992, J. Clin. Microbiol., 30:3033-3034.
7. Merlino et al, 1995, Abstr. Austr. Microbiol. 16(4):17-3.
8. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
9. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
10. Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
11. Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.
12. Lipps WC, Braun-Howland EB, Baxter TE,eds. Standard methods for the Examination of Water and Wastewater, 24th ed. Washington DC:APHA Press; 2023.

Revision : 06/2023

HiMedia Laboratories Pvt. Limited,
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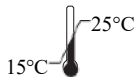
IVD ***In vitro* diagnostic medical device**



Storage temperature

EC REP CEpartner4U, Esdoornlaan 13,
3951DB Maarn, NL
www.cepartner4u.eu

CE Marking

Do not use if package is damaged

Bifidobacterium Broth

M1395

Intended Use:

Recommended for cultivation of *Bifidobacterium infantis.*

Composition**

Ingredients	Gms / Litre
Tryptone	20.000
Peptone	10.000
Yeast extract	10.000
Tomato juice, solids	16.650
Dextrose (Glucose)	20.000
Polysorbate 80 (Tween 80)	2.000
Final pH (at 25°C)	6.8±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 78.65 grams in 1000 ml purified / distilled water . Heat if necessary to dissolve the medium completely. Distribute in tubes or flasks as desired. Sterilize by autoclaving at 15lbs pressure for 15 minutes.

Principle And Interpretation

The genus *Bifidobacterium* is the third most numerous bacterial population found in the human intestine after Bacteroides and *Eubacterium*. It is an anaerobic bacteria that makes up the gut microbial flora, it resides in the colon and have health benefits for their hosts. Bifidobacteria are also associated with lower incidences of allergies (1,2). Bifidobacterium Broth is used for the cultivation and maintenance of *Bifidobacterium* species. The medium is used exclusively for the cultivation of *Bifidobacterium infantis* (3).

Tryptone, Peptone and yeast extract provides essential growth nutrients. Glucose is the energy source and sodium chloride maintains isotonic conditions. Tomato juice helps in maintaining acidic pH while polysorbate 80 provides fatty acids required for metabolic activity of *Bifidobacterium*.

Type of specimen

Clinical samples- faeces; Dairy samples.

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (4,5). For dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (6,7). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic Use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Further biochemical and serological tests must be carried out for complete identification.
2. *Bifidobacterium* species are strict anaerobes, hence condition must be appropriately maintained.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Cream to yellow homogeneous free flowing powder
Colour and Clarity of prepared medium
Amber coloured clear solution in tubes

Reaction
Reaction of 7.86% w/v solution at 25°C. pH : 6.8±0.2
pH
6.60-7.00
Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 24-48 hours.

Organism	Inoculum (CFU)	Growth
Bifidobacterium infantis ATCC 25962	50-100	good-luxuriant
Bifidobacterium bifidum ATCC 15696	50-100	good-luxuriant
Bifidobacterium breve ATCC 15698	50-100	good-luxuriant

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-25°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

Reference

1.Bjorksten B., Sepp E., Julge K., Voor T., and Mikelsaar M., 2001, J. Allergy Clin. Microbiol., Volume 108, Issue 4, 516-520.
2.Guarner F., and Malagelada J. R., 2003, The Lancet, Vol. 361, Issue 9356, 8 February 2003, 512-519
3.Atlas R. M. 2004, 3rd Edi. Handbook of Microbiological Media, Parks, L. C. (Ed.), CRC Press, Boca Raton.4.
4.Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
5.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
6.American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., WashingtonD.C.
7.Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed.,APHA Inc., Washington, D.C.

Revision : 03/2022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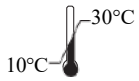
IVD *In vitro* diagnostic medical device



Storage temperature

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Hottinger Broth

M1425

Intended Use:

Recommended for cultivation of less fastidious microorganisms and determination of indole in accordance with USSR State Pharmacopoeia.

Composition**

Ingredients	Gms / Litre
Fish peptone	20.000
Yeast extract	2.000
Tryptophan	1.000
Final pH (at 25°C)	7.4±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 23.0 grams in 1000 ml purified/distilled water. Heat if necessary to dissolve the medium completely. Dispense into tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

Principle And Interpretation

Hottinger Broth is used for cultivation of less fastidious microorganisms and determination of indole as per USSR State Pharmacopeia (1).

Fish peptone and yeast extract provides the nitrogenous source and essential nutrients for growth of organisms. The production of indole from tryptophan is a diagnostic test used for identifying enteric bacteria. After incubation, indole can be identified by a red dye complex reaction with one of several reagents eg. Kovac's Reagent which consists of amyl alcohol, dimethylaminobenzaldehyde and concentrated hydrochloric acid (2).

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling:

For pharmaceutical samples, follow appropriate techniques for sample collection and processing as per guidelines (1). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Light amber coloured clear solution

Reaction

Reaction of 2.3% w/v aqueous solution at 25°C. pH : 7.4±0.2

pH

7.20-7.60

Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 18-48 hours.

Organism	Growth	Indole production
Escherichia coli ATCC 25922 (00013*)	good	Positive reaction,red ring at the interface of the medium
Pseudomonas aeruginosa ATCC 27853 (00025*)	good	Negative reaction,no colour development/ cloudy ring
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	good	Negative reaction,no colour development/ cloudy ring
Streptococcus pyogenes ATCC 19615	good	Negative reaction,no colour development/ cloudy ring

Key : *Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-25°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

Reference

1. State Pharmacopoeia of USSR.
2. Harrigar W.F and McCarran M.E (1966) Laboratory Methods in Microbiology Academic Press 53.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
4. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

Revision : 05/2023

Urea Indole Medium

M1784

To differentiate micro-organisms especially *Enterobacteriaceae* on the basis of their ability to hydrolyze urea and indole production

Composition**

Ingredients	Gms / Litre
L- Tryptophan	3.000
Sodium chloride	5.000
Potassium phosphate, monobasic	1.000
Potassium phosphate, dibasic	1.000
Urea	20.000
Phenol red	0.012
Final pH (at 25°C)	6.8±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 30.01 grams in 1000 ml distilled water. Dissolve the medium completely and sterilize by filtration . DO NOT AUTOCLAVE. Aseptically, dispense into sterile tubes.

Principle And Interpretation

Strains of *Enterobacteria* are associated with abscesses, pneumonia, meningitis, septicemia and infections of wounds, the urinary tract and the intestine. They are a major component of the normal intestinal flora of humans but are relatively uncommon at other body sites. Of clinically significant isolates, *Enterobacteriaceae* may account for 80% of gram-negative bacilli and 50% of all clinically significant isolates in clinical microbiology laboratories (1).

Urea Indole Medium is used for the identification of *Enterobacteria* on the basis of Urease and indole production and the transdeamination of tryptophan. This medium is very useful in the identification of *Proteus* species from *Salmonella* and *Shigella* species. The results for urease production should be noted prior to indole reaction , as addition of Kovacs reagent , decolourizes the medium, due to drop in pH.

L- Trypytophan is an essential amino acid and is converted to skatole and indole, which is detected by the addition of Kovacs Reagent (R008). Sodium chloride maintains the osmotic balance. The phosphates helps in the buffering of the medium. Microorganisms that possess the enzyme urease hydrolyse urea , releasing ammonia, which is detected by the pH indicator phenol red . The alkalinility so developed imparts pink colour to the medium (2).

Quality Control

Appearance
Light yellow to light pink homogeneous free flowing powder

Colour and Clarity of prepared medium
Yellow to light orange coloured clear solution

Reaction
Reaction of 3.00% w/v aqueous solution at 25°C. pH : 6.8±0.2

pH
6.60-7.00

Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours.

Cultural Response

Organism	Inoculum (CFU)	Growth	Urease

Escherichia coli ATCC 25922	50-100	luxuriant	Negative reaction,no change
Proteus mirabilis ATCC 12453	50-100	luxuriant	Positive reaction, Pink colour
Proteus vulgaris ATCC 13315	50-100	luxuriant	Positive reaction, Pink colour
Salmonella Typhimurium ATCC 14028	50-100	luxuriant	Negative reaction,no change

Storage and Shelf Life

Store below 8°C in tightly closed container and prepared medium at 2-8°C. Use before expiry period on the label

Reference

1.Patrick R. Murray et al, Manual of Clinical Microbiology, Sixth Edition, 444 - 445.
2.Roland F. Bourbon D, Sztrum S. Ann. Inst. Pasteur, 73. 914-916.

Revision : 1 / 2011

Mueller Hinton Agar, 2% Glucose with Methylene blue

M1825

Mueller Hinton Agar, 2% Glucose with Methylene blue is recommended for testing performing Antifungal Disk Diffusion Susceptibility of yeasts.

Composition**

Ingredients	Gms / Litre
Beef infusion from	300.000
Casein Acid Hydrolysate	17.500
Starch	1.500
Glucose	20.000
Methylene blue	0.0005
Agar	17.000
Final pH (at 25°C)	7.3±0.1

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 58 grams in 1000 ml distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15lbs pressure (121°C) for 15 minutes. Mix well before pouring.

The performance of this batch has been tested and standardized as per the current CLSI (formerly NCCLS) document M44-A2 in Method for Antifungal Disk Diffusion susceptibilty Testing of yeasts

Principle And Interpretation

The Mueller Hinton formulation was originally developed as a simple, transparent agar medium for the cultivation of pathogenic species (1). Mueller Hinton Agar, Modified (as per CLSI for antifungal) is recommended for the diffusion of antifungal agents impregnated on paper disc through an agar gel as described in CLSI Approved Standard (2).

When supplemented with glucose to a final concentration of 2%, it provides for suitable fungal growth. The addition of methylene blue to a final concentration of 5µg/ml enhances zone edge definition.

Kirby-Bauer et al recommended Mueller Hinton Agar for performing antibiotic susceptibility tests using a single disc of high concentration (4). WHO Committee on Standardization of Susceptibility Testing has accepted Mueller Hinton Agar for determining the susceptibility of microorganisms because of its reproducibility (3). Mueller Hinton Agar with 5% sheep blood and Mueller Hinton Agar with Haemoglobin have been recommended for antimicrobial susceptibility testing of *Streptococcus pneumoniae* and *Haemophilus influenzae* . Similarly Mueller Hinton Agar, Modified (as per CLSI for antifungal) is recommended for antifungal susceptibity testing of discs.

Beef infusion and casein acid hydrolysate provide nitrogenous compounds, carbon, sulphur and other essential nutrients. Starch acts as a protective colloid against toxic substances present in the medium. Starch hydrolysis yields dextrose, which serves as a source of energy. Glucose serves as an energy source for fungal cultures while Methylene blue enhances zone edge definition.

Technique:

Preparation of Inoculum:

1. Inoculum is prepared by picking five distinct colonies of approximately 1mm from 24 hours old culture grown on Sabouraud Dextrose Agar (M063) and incubated at 35 ± 2°C. Colonies are suspended in 5ml of sterile 0.85% Saline.

2. Vortex the resulting suspension and adjust the turbidity to yield 1 x 106 - 5 x 106 cells /ml (i.e. 0.5 McFarland standard).

Test Procedure:

1. Prepare plates with Mueller Hinton Agar, Modified (as per CLSI for antifungal) for carrying out susceptibility of antifungal discs. The medium in the plates should be sterile and have a depth of about 4 mm.

2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the Petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.

3. Apply the discs using aseptic technique. Deposit the discs with centers at least 24 mm apart. (Not more than 12 discs should be placed on a 150-mm plate or not more than 5 discs on a 100-mm plate

4. Invert the plates and place in an incubator set to 35 ± 2°C within 15 minutes after the discs are applied.

5. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniformly circular and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation.

Quality Control

Appearance
Light yellow to yellow may have slight blue tinge homogeneous free flowing powder

Gelling
Firm, comparable with 1.7% agar gel.

Colour and Clarity of prepared medium
amber coloured clear to slightly opalescent gel froms in Petri plates

Reaction
Reaction of 5.8% w/v aqueous solution at 25°C. pH : 7.3±0.1

pH
7.20-7.40

Cultural response
A luxuriant growth of test organisms was observed on Mueller Hinton Agar, Modified (as per CLSI for antifungal) in 24-48 hours at 33-37°C along with inhibition zones with respective antibiotic concentrations

Cultural Response

Organism	Inoculum (CFU)	Growth	Recovery	Amphotericin-B AP(100units)	Amphotericin-B AP(20 mcg)	Amphotericin-B AP(50 mcg)
Cultural response						
Candida albicans ATCC 90028	50-100	Luxuriant	>=70%	10 -17 mm	10 -15 mm	31 -42 mm
Candida parapsilosis ATCC 22019	50-100	luxuriant	>=70%	11 -20 mm	10 -17 mm	28 -37 mm
Candida tropicalis ATCC 750	50-100	luxuriant	>=70%	8 -12 mm	8 -10 mm	13 -17 mm
Candida krusei ATCC 6258		luxuriant	>=70%	9 -14 mm	8 -12 mm	16 -25 mm
Candida albicans ATCC 10231	50-100	luxuriant	>=70%	10 -18 mm	10 -16 mm	30 -40 mm
Saccharomyces cerevisiae ATCC9763	50-100	luxuriant	>=70%	11 -18 mm	8 -12 mm	29 -38 mm

Storage and Shelf Life

Store dehydrated powder below 30°C and prepared medium at 2-8°C. Use before expiry date on the label.

Reference

1.Mueller J. H. and Hinton J., 1941, Proc. Soc. Exp. Biol. Med., 48:330.
2.Method for Antifungal Disk Diffusion Susceptibilty Testing of yeasts; Approved Guideline Second Edition M44-A2 Vol.24 No.17.
3.Present Status and Future Work, WHO Sponsored collaborative study, Chicago, Oct. 1967.
4.Bauer A. W., Kirby W. M., Sherris J. L. and Turck M., 1966, Am. J. Clin. Pathol., 45:493.

Revision : 1 / 2011

Disclaimer :

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McFarland Standard set **R092**

McFarland standards are used to perform spectrophotometric comparisions of bacterial densities in water, saline or liquid growth medium. It provides laboratory guidance for the standardization of numbers of bacteria for susceptibility testing or other procedure requiring a standardization of the inoculum like growth promotion test (GPT).

Set Contains:

R092A (Standard 0.5)- 1 tube

R092B (Standard 1)-1 tube

R092C (Standard 2)- 1 tube

R092D (Standard 3)- 1 tube

R092E (Standard 4)- 1 tube

Directions

Prepare the inoculum of culture required for testing by using sterile saline. Match the density of the resultant suspension with the density of the desired standard. The standards must be thoroughly mixed on a vortex mixture at the time of use to obtain a uniform suspension. Adjust the density of cell suspension by adding saline if it is more turbid as compared to the desired standard or by adding culture if it is dilute. Check the density of the turbidity by determining the absorbance of 0.5 McFarland standard using a spectrophotometer with a 1 cm light path. The absorbance at 625 nm should be 0.08 to 0.10. The standards should be checked regularly to ensure the density accuracy.

Interpretation

McFarland standards are a set of tubes with increasing concentration of Barium Sulphate suspension. The turbidity of Barium Sulphate's white precipitation is used as a point of comparision of bacterial suspensions to known bacterial turbidity.

McFarland Standard	0.5	1	2	3	4
Approximate Corresponding suspension x 10^8 CFU/ml	1.5	3	6	9	12

Limitation of procedure

1. Coloured media may interfere with result interpretation and give incorrect results.

2. Bacterial suspensions of older cultures may not be comparable with expected bacterial counts.

Storage

Store the standards at 2-8°C, away from light after each use.

Reference

1. McFarland, J.1907. Nephelometer: JAMA 14:1176-1178

2. Murry,PR; Baron,EJ; Jorgensen,JH;Landry,ML;Pfaller,MA; Manual of Clinical Microbiology 9th edition ASM press, Washington DC.

Gram's Iodine

S013

Intended use

Grams's Iodine is used as mordant in Gram's staining method.

Composition**

Ingredients

Iodine	1.0 ml
Potassium iodide	2.0 ml
Distilled water	300.0 ml

**Formula adjusted, standardized to suit performance parameters

Directions

1. Prepare a thin smear on clear, dry glass slide.
2. Allow it to air dry and fix by gentle heat.
3. Flood with Gram's Crystal Violet (S012) for 1 minute. (If over staining results in improper decolourization of known gram-negative organisms, use less crystal violet).
4. Wash with tap water.
5. Flood the smear with Gram’s Iodine (S013). Allow it to remain for 1 minute.
6. Decolourize with Gram's Decolourizer (S032) until the blue dye no longer flows from the smear. (Acetone may be used as a decolourizing agent with caution, since this solvent very rapidly decolourized the smear).
7. Wash with tap water.
8. Counter stain with 0.5% w/v Safranin (S027) for 20 seconds and rinses off with water.
9. Wash with tap water.
10. Allow the slide to air dry or blot dry between sheets of clean bibulous paper and examine under oil immersion objective.

Principle And Interpretation

The Gram stain is a differential staining technique most widely applied in all microbiology disciplines laboratories. It is one of the most important criteria in any identification scheme for all types of bacterial isolates. Different mechanisms have been proposed to explain the gram reaction. There are many physiological differences between gram-positive and gram negative cell walls Ever since Christian Gram has discovered Gram staining, this process has been extensively investigated and redefined In practice, a thin smear of bacterial cells is stained with crystal violet, then treated with an iodine containing mordant to increase the binding of primary stain A decolourizing solution of alcohol or acetone is used to remove the crystal violet from cells which bind it weakly and then the counterstain (like safranin) is used to provide a colour contrast in those cells that are decolourized. Gram-positive bacteria have a thick mesh-like cell wall made of peptidoglycan (50–90% of cell envelope), and as a result are stained purple by crystal violet, whereas gram-negative bacteria have a thinner layer (10% of cell envelope), so do not retain the purple stain and are counter-stained pink by safranin. In a properly stained smear by gram staining procedure, the gram-positive bacteria appear blue to purple and gram negative cells appear pink to red.

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Type of specimen

Any isolated colony on primary or subculture plates can be isolated from following specimens. Clinical specimen: Blood, urine, CSF, pus, wounds, lesions, body tissues, sputum etc. From environment: Air, water, soil, sludge, waste water, food, dairy samples etc.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines
For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines
For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards.
Generally, the smear is made in laboratory; however, when there is a concern that transport will be delayed or that the preservation for culture will alter the specimen, prepare smear and submit slides to the laboratory.

Warning and Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/ eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Use results of Gram stains in conjunction with other clinical and laboratory findings. Use additional procedures (e.g., special stains, inclusion of selective media, etc.) to confirm findings suggested by gram-stained smears.
2. Proper smear preparation is key to obtaining good gram staining results. Avoid excessive material or thick smears which may interfere with the passage of light and lead to distortion of images.
3. Overheating slides during heat fixation can distort the appearance of the organisms.
4. Only fresh cultures and specimens should be gram stained since cell wall integrity of older cells may give improper gram staining characteristics. Gram positive organisms that have lost cell wall integrity because of old age or antibiotic treatment may appear pink.
5. The decolorization step is the most important step in the gram-staining process. Over decolorization results in an abundance of bacteria that appear gram negative, while under decolorization results in too many bacteria that appear to be gram-positive.
6. The procedure given is based on an ideal thin smear of cells. Staining and decolorization times may vary depending on the sample and its thickness.
7. False Gram stain results may be related to inadequately collected specimens or delay in transit.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature

Quality Control

- **Appearance :** Yellow to dark brown coloured solution.
- **Clarity :** Clear without any particles.

- **Microscopic Examination :** Gram staining is carried out where Gram's Iodine is used as one of the stains and staining characteristics of organisms are observed under microscope by using oil immersion lens.
- **Results :** Gram-positive microorganisms : violet
  Gram-negative microorganims : pinkish red

Storage and Shelf Life

Store between 10 - 30 °C in tightly closed container and away from bright light. Use before expiry date on label. On opening, product should be properly stored in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques .

Reference

1. Downes F. P. and Ito K. (Ed.), 2001, Compendium of Methods for the Microbiological Examination of Foods, 4th ed., APHA, Washington, D.C.
2. Rice E.W., Baird, R.B., Eaton A. D., Clesceri L. S. (Eds.), 2012, Standard Methods for the Examination of Water and Wastewater, 22nd ed., APHA, Washington, D.C.
3. Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
5. Jorgensen,J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
6. Shanhooltzer, C. J., P. Schaper ,and L.R. Peterson 1982 .Concentrated Gram stain smear prepared with a cytospin centrifuge. J.clin. Microbiol.16:1052-1056
7. Thorpe, J.E., R.P.Banghman,P.T. Frame,T.A. Wessler,and J.L. Staneck.1987.Bronchoalveolar lavage for diagnosing acute bacterial pneumoniae .J.Infect.Dis.155:855-861
8. Brown,M.S.,and T.C. Wu. 1986. The Gram stain morphology of fungi, mycobacteria, and Pneumocytis carinii. J.Med .Techno l3:495-499
9. Washington, J.A.1986.Rapid diagnosis by microscopy. Clin.Microbiol. Newsl.8:135-137
10. Lamanna and Mallette, 1965, Basic BActeriology,3rd ed.,Williams and Wilkins Co.,Baltimore.
11. Salton,1964,The Bacterial cell Wall, Elsevier, Amsterdam.

Storage temperature

Do not use if package is damaged

IVD

In vitro diagnostic medical device

CE Marking

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Revision: 02/2022

Disclaimer :

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Furazolidone FR 50 mcg SD015

Furazolidone FR 50 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients	Concentration
Furazolidone	50 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland (prepared by mixing 0.5 ml of 1.175% barium chloride and 99.5 ml of 0.36N sulfuric acid). Dilute the inoculum or incubate further as necessary to attain comparative turbidity. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 625 nm)
3. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "FR 50" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
E. coli (25922)	20-25
S.aureus (25923)	18-22

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :
Use following media to carry out susceptibility test
For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)
For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)
For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood
For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

*** Not for Medicinal Use**

IVD — In vitro diagnostic medical device

CE — CE Marking

Storage temperature

Do not use if package is damaged

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Revision : 03 / 2022

Nystatin NS 100 Units SD025

Nystatin NS 100 Units discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients	Concentration
Nystatin	100 Units/disc

Susceptibility Test Procedure:

Preparation of Inoculum:

1. Inoculum is prepared by picking five distinct colonies of approximately 1mm from 24 hours old culture grown on Sabouraud Dextrose Agar (M063) and incubated at 35 ± 2°C. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield 1 x 10^6 - 5 x 10^6 cells /ml (i.e. 0.5 McFarland standard).

Test Procedure:

1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye (M1825) for carrying out susceptibility of antifungal discs. The medium in the plates should be sterile and have a depth of about 4 mm.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
3. Apply the discs using aseptic technique. Deposit the discs with centers at least 24 mm apart.
4. Invert the plates and place in an incubator set to 35 ± 2°C within 15 minutes after the discs are applied.
5. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniformly circular and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation.

Principle:

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "NS 100" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye after 24-48 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
C.albicans (90028)*	19-27
C.parapsilosis (22019)*	16-25
C.tropicalis (750)*	16-21
C.krusei(6528)*	15-20
C.albicans(10231)	15-23
S.cerevisiae(9763)	17-25

* = Q.C. Strains recommended by CLSI

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guidelines-Second edition Vol.29 No.17, August- 2009 CLSI document M44-A2. For more details refer to this volume

Note :
Use following media to carry out susceptibility test
For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)
For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)
For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood
For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

*** Not for Medicinal Use**

IVD — In vitro diagnostic medical device

CE — CE Marking

Storage temperature

Do not use if package is damaged

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Revision : 03 / 2022

Penicillin G P 1 unit SD089

Penicillin G P 1 unit discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby-Bauer Method

Composition

Ingredients*	Concentration
Penicillin G	1 unit/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby-Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for 2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland (prepared by mixing 0.5 ml of 1.175%barium chloride and 99.5 ml of 0.36N sulfuric acid). Dilute the inoculum or incubate further as necessary to attain comparative turbidity. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 625 nm)
3. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Kirby-Bauer Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "P 1" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
S.aureus (29213)	12-18

Storage and Shelf-life:

On receipt discs should always be stored at -20°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

IVD — In vitro diagnostic medical device

CE Marking

Storage temperature

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*** Not for Medicinal Use**

Ceftriaxone CTR 10 mcg SD109

Ceftriaxone CTR 10 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby-Bauer Method

Composition

*Ingredients	Concentration
Ceftriaxone	10 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby-Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland (prepared by mixing 0.5 ml of 1.175% barium chloride and 99.5 ml of 0.36N sulfuric acid). Dilute the inoculum or incubate further as necessary to attain comparative turbidity. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 625 nm)
3. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CTR 10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
E. coli (25922)	29-35
S.aureus (25923)	22-28
P.aeruginosa (27853)	17-23

Storage and Shelf-life:

On receipt discs should always be stored at -20°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :
Use following media to carry out susceptibility test
For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)
For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)
For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood
For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

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Storage temperature

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Revision : 03 / 2022

Amphotericin-B AP 100 units SD111

Amphotericin-B AP 100 units discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients	Concentration
Amphotericin-B	100 units/disc

Susceptibility Test Procedure:

Preparation of Inoculum:

1. Inoculum is prepared by picking five distinct colonies of approximately 1mm from 24 hours old culture grown on Sabouraud Dextrose Agar (M063) and incubated at 35 ± 2°C. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield 1 x 10^6 - 5 x 10^6 cells /ml (i.e. 0.5 McFarland standard).

Test Procedure:

1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye (M1825) for carrying out susceptibility of antifungal discs. The medium in the plates should be sterile and have a depth of about 4 mm.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
3. Apply the discs using aseptic technique. Deposit the discs with centers at least 24 mm apart.
4. Invert the plates and place in an incubator set to 35 ± 2°C within 15 minutes after the discs are applied.
5. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniformly circular and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation.

Principle:

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "AP 100" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye after 24-48 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
C.albicans (90028)*	10-17
C.parapsilosis (22019)*	11-20
C.tropicalis (750)*	8-12
C.krusei (6528)*	9-14
C.albicans(10231)	10-18
S.cerevesiae (9763)	11-18

* = Q.C. Strains recommended by CLSI

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guidelines-Second edition Vol.29 No.17, August- 2009 CLSI document M44-A2. For more details refer to this volume

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Revision : 1 / 2012

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Itraconazole IT 10 mcg SD221

Itraconazole IT 10 mcg discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients	Concentration
Itraconazole	10 mcg/disc

Susceptibility Test Procedure:

Preparation of Inoculum:

1. Inoculum is prepared by picking five distinct colonies of approximately 1mm from 24 hours old culture grown on Sabouraud Dextrose Agar (M063) and incubated at 35 ± 2°C. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield 1 x 10^6 - 5 x 10^6 cells /ml (i.e. 0.5 McFarland standard).

Test Procedure:

1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye (M1825) for carrying out susceptibility of antifungal discs. The medium in the plates should be sterile and have a depth of about 4 mm.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
3. Apply the discs using aseptic technique. Deposit the discs with centers at least 24 mm apart.
4. Invert the plates and place in an incubator set to 35 ± 2°C within 15 minutes after the discs are applied.
5. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniformly circular and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation.

Principle:

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "IT 10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye after 24-48 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
C.albicans (90028)*	16-20
C.parapsilosis (22019)*	11-18
C.tropicalis (750)*	8-13
C.krusei(6528)*	8-15
C.albicans(10231)	18-22

* = Q.C. Strains recommended by CLSI

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guidelines-Second edition Vol.29 No.17, August- 2009 CLSI document M44-A2. For more details refer to this volume

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Revision : 1 / 2012

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Fluconazole FLC 25 mcg SD232

Fluconazole FLC 25mcg discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients	Concentration
Fluconazole	25mcg/disc

Susceptibility Test Procedure:

Preparation of Inoculum:

1. Inoculum is prepared by picking five distinct colonies of approximately 1mm from 24 hours old culture grown on Sabouraud Dextrose Agar (M063) and incubated at 35 ± 2°C. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield 1 x 10^6 - 5 x 10^6 cells /ml (i.e. 0.5 McFarland standard).

Test Procedure:

1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye (M1825) for carrying out susceptibility of antifungal discs. The medium in the plates should be sterile and have a depth of about 4 mm.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
3. Apply the discs using aseptic technique. Deposit the discs with centers at least 24 mm apart.
4. Invert the plates and place in an incubator set to 35 ± 2°C within 15 minutes after the discs are applied.
5. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniformly circular and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation.

Principle:

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization.

Antimicrobial agent	Interpretative criteria for	Resistant mm or less	S-DD# mm	S mm or more
Fluconazole 25mcg	*Candida* spps	14	15-18	19

S-DD - Susceptible - Dose dependent

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "FLC 25" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye after 24-48 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
C.albicans (90028)*	28-39
C.parapsilosis (22019)*	22-33
C.tropicalis (750)*	26-37
C.albicans(10231)	25-30

* = Q.C. Strains recommended by CLSI

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guidelines-Second edition Vol.29 No.17, August- 2009 CLSI document M44-A2. For more details refer to this volume
2. Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility Testing Of Yeasts, Third International Supplement CLSI document - M44-S3.

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Revision : 1 / 2012

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Cefoperazone/Sulbactam CFS 75/10 mcg SD254

Cefoperazone/Sulbactam CFS 75/10mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients	Concentration
Cefoperazone/Sulbactam	75/10 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland (prepared by mixing 0.5 ml of 1.175% barium chloride and 99.5 ml of 0.36N sulfuric acid). Dilute the inoculum or incubate further as necessary to attain comparative turbidity. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 625 nm)
3. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CFS 75/10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
E. coli (25922)	27-33
S.aureus (25923)	23-30
P.aeruginosa (27853)	20-25

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :
Use following media to carry out susceptibility test
For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)
For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)
For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood
For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

*** Not for Medicinal Use**

Voriconazole VRC 1 mcg SD277

Voriconazole VRC 1 mcg discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients	Concentration
Voriconazole	1mcg/disc

Susceptibility Test Procedure:

Preparation of Inoculum:

1. Inoculum is prepared by picking five distinct colonies of approximately 1mm from 24 hours old culture grown on Sabouraud Dextrose Agar (M063) and incubated at 35 ± 2°C. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield 1 x 10^6 - 5 x 10^6 cells /ml (i.e. 0.5 McFarland standard).

Test Procedure:

1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye (M1825) for carrying out susceptibility of antifungal discs. The medium in the plates should be sterile and have a depth of about 4 mm.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
3. Apply the discs using aseptic technique. Deposit the discs with centers at least 24 mm apart.
4. Invert the plates and place in an incubator set to 35 ± 2°C within 15 minutes after the discs are applied.
5. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniformly circular and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation.

Principle:

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization.

Antimicrobial agent	Interpretative criteria for	Resistant mm or less	S-DD# mm	S mm or more
Voriconazole 1 mcg	*Candida* spps	13	14-16	17

S-DD - Susceptible - Dose dependent

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "VRC 1" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye after 24-48 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
C.albicans (90028)*	31-42
C.parapsilosis (22019)*	28-37
C.krusei (6528)*	16-25
C.albicans(10231)	30-40
S.cerevesiae (9763)	29-38

* = Q.C. Strains recommended by CLSI

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guidelines-Second edition Vol.29 No.17, August- 2009 CLSI document M44-A2. For more details refer to this volume
2. Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility Testing Of Yeasts, Third International Supplement CLSI document - M44-S3.

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Mast Group Ltd., has been a manufacturer of antibiotic susceptibility test products since 1957, and continues to be at the forefront of developments in this field. With an ever-expanding portfolio of antibiotic susceptibility, combination and identification discs, Mast Group Ltd. supplies the most comprehensive range available worldwide. Mast Group Ltd. also offers a range of services including **mast**pharma® development and **mast**pharma® stability for the evaluation of novel antimicrobial compounds for the pharmaceutical industry.

Disc diffusion is still the most popular method for determining bacterial antibiotic susceptibility in the treatment of infectious disease, as highlighted by the variety of international standardised procedures including The European Committee on Antimicrobial Susceptibility Testing (EUCAST) and The Clinical and Laboratory Standards Institute (CLSI).

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STOCKCART	Stock Susceptibility Cartridge Discs of a single type	EUCAST Compliant	1 pack
FUNGCART	Stock Antifungal Cartridge Discs of a single type		1 pack
SPECIALCART	Cartridge Discs made to special order*		Min 18 packs
MASTDISCS®	**(99+/- 2 discs per vial)**		
STOCKDISC	Stock Susceptibility Discs of a single type		1 vial
FUNGDISC	Stock Antifungal Discs of a single type		1 pack
SPECIALDISC	Discs made to special order*		Min 22 packs
TOOL/C	*Set up charge for Special Discs in vials or cartridges A one off charge for customisation of each new specification		per new specification

Disc Diffusion Susceptibility Testing

MASTDISCS® *AST*

ANTIBIOTIC SUSCEPTIBILITY DISCS IN CARTRIDGES - STOCK RANGE

Description **Antibiotic & Content µg per disc** (unless otherwise stated)	**STANDARD**		**Order Code** **Cartridges** **5 × 50 discs**
	EUCAST	**CLSI**	
Amikacin 30	✓	✓	AK30C
Amoxicillin/clavulanic acid 2-1	✓	-	AUG3C
Amoxicillin/clavulanic acid 20-10	✓	✓	AUG30C
Ampicillin 2	✓	-	AP2C
Ampicillin 10	✓	✓	AP10C
Ampicillin/Sulbactam 10-10	✓	✓	SAM20C
Azithromycin 15	-	✓	ATH15C
Aztreonam 30	✓	✓	ATM30C
Bacitracin 10 units	-	-	BA10C
Carbenicillin 100	✓	-	PY100C
Cefaclor 30	✓	✓	CFC30C
Cefadroxil 30	✓	-	CDX30C
Cefalexin 30	✓	-	CFX30C
Cefalothin 30	-	✓	KF30C
Cefazolin 30	-	✓	CZ30C
Cefepime 30	✓	✓	CPM30C
Cefiderocol 30	✓	✓	FDC30C
Cefixime 5	✓	✓	CFM5C
Cefotaxime 5	✓	-	CTX5C
Cefotaxime 30	-	✓	CTX30C
Cefoxitin 30	✓	✓	FOX30C
Cefpodoxime 10	✓	✓	CPD10C
Ceftaroline 5	✓	-	CPT5C
Ceftaroline 30	-	✓	CPT30C
Ceftazidime 10	✓	-	CAZ10C
Ceftazidime 30	-	✓	CAZ30C
Ceftazidime/avibactam 10-4	✓	-	CZA14C
Ceftazidime/avibactam 30-20	-	✓	CZA50C
Ceftibuten 30	✓	✓	CFB30C
Ceftolozane/tazobactam 30-10	✓	✓	C/T40C
Ceftobiprole 5 NEW	✓	-	BPR5C
Ceftriaxone 5	-	✓	CRO5C
Ceftriaxone 30	✓	✓	CRO30C
Cefuroxime 30	✓	✓	CXM30C
Chloramphenicol 30	✓	✓	C30C
Ciprofloxacin 5	✓	✓	CIP5C
Clarithromycin 15	-	✓	CLA15C
Clindamycin 2	✓	✓	CD2C
Delafloxacin 5	-	✓	DLX5C
Doripenem 10	✓	✓	DOR10C
Doxycycline 30	-	✓	DXT30C
Eravacycline 20	✓	✓	ERV20C
Ertapenem 10	✓	✓	ETP10C
Erythromycin 15	✓	✓	E15C
Fosfomycin/Glucose-6-Phosphate 200	✓	✓	FOT200C
Fusidic Acid 10	✓	-	FC10C
Gentamicin 10	✓	✓	GM10C
Gentamicin 30	✓	-	GM30C
Gentamicin 120	-	✓	GM120C
Imipenem 10	✓	✓	IMI10C
Imipenem/relebactam 10-25	-	✓	IMR35C
Kanamycin 30	-	✓	K30C
Lefamulin 20	-	✓	LMU20C
Levofloxacin 5	✓	✓	LEV5C
Linezolid 10	✓	-	LZD10C
Linezolid 30	-	✓	LZD30C
Mecillinam 10	✓	✓	MEC10C
Meropenem 10	✓	✓	MEM10C

Disc Diffusion Susceptibility Testing

MASTDISCS® *AST*

ANTIBIOTIC SUSCEPTIBILITY DISCS IN CARTRIDGES - STOCK RANGE

Description **Antibiotic & Content µg per disc** (unless otherwise stated)	**STANDARD**		**Order Code** **Cartridges** **5 × 50 discs**
	EUCAST	**CLSI**	
Meropenem/Vaborbactam 20-10	✓	✓	MEV30C
Metronidazole 5	✓	-	MZ5C
Minocycline 30	-	✓	MN30C
Moxifloxacin 5	✓	✓	MFX5C
Mupirocin 200	✓	-	MUP200C
Nalidixic Acid 30	✓	✓	NA30C
Neomycin 10	✓	-	NE10C
Netilmicin 10	✓	-	NET10C
Netilmicin 30	✓	-	NET30C
Nitrofurantoin 100	✓	-	NI100C
Nitrofurantoin 300	-	✓	NI300C
Nitroxoline 30	✓	-	NIB30C
Norfloxacin 10	✓	✓	NOR10C
Novobiocin 5	-	-	NO5C
Ofloxacin 5	✓	✓	OFX5C
Oxacillin 1	✓	✓	OX1C
Pefloxacin 5	✓	-	PEF5C
Penicillin G 1 unit	✓	-	PG1C
Penicillin G 10 units	-	✓	PG10C
Piperacillin 30	✓	-	PRL30C
Piperacillin 100	-	✓	PRL100C
Piperacillin/tazobactam 30-6	✓	-	PTZ36C
Piperacillin/tazobactam 100-10	-	✓	PTZ110C
Rifampicin 5	✓	✓	RP5C
Streptomycin 10	-	✓	S10C
Streptomycin 300	✓	✓	S300C
Tedizolid 2	✓	✓	TZD2C
Teicoplanin 30	✓	✓	TEC30C
Temocillin 30	✓	-	TEM30C
Tetracycline 30	✓	✓	T30C
Ticarcillin 75	✓	✓	TC75C
Ticarcillin/clavulanic acid 75-10	✓	✓	TIM85C
Tigecycline 15	✓	✓	TGC15C
Tobramycin 10	✓	✓	TN10C
Trimethoprim 5	✓	✓	TM5C
Trimethoprim/sulfamethoxazole 1.25/23.75	✓	✓	TS25C
Vancomycin 5	✓	-	VA5C
Vancomycin 30	-	✓	VA30C
Blank discs	-	-	BD0680W/C/NCE

Disc Diffusion Susceptibility Testing

MASTDISCS® AST

NON CLINICAL ANTIBIOTIC SUSCEPTIBILITY DISCS IN CARTRIDGES - STOCK RANGE

Description **Antibiotic & Content µg per disc** (unless otherwise stated)	**Order Code** **Cartridges** **5 × 50 discs**
Amoxicillin 25	A25C/NCE
Colistin Sulphate 10	CO10C/NCE
Colistin Sulphate 25	CO25C/NCE
Polymyxin B 300 units	PB300C/NCE

MASTDISCS® AST

SPECIALIST VETERINARY SUSCEPTIBILITY DISCS - STOCK RANGE

Description **Antibiotic & Content µg per disc** (unless otherwise stated)	**Order Code** **Cartridges** **5 × 50 discs**
Cefquinone 30	CEQ30C/NCE
Cefoperazone 30	CPZ30C/NCE
Enrofloxacin 5	ENF5C/NCE
Florfenicol 30	FFC30C/NCE
Gamithromycin 15	GAM15C/NCE
Marbofloxacin 5	MAR5/NCE
Pradofloxacin 5	PRA5/NCE
Tildipirison 60	TIP60/NCE
Tylosin 30	TY30C/NCE

Disc Diffusion Susceptibility Testing

Order No	Product	Mechanism	Packsize (tests)

MASTDISCS AST

ANTIBIOTIC SUSCEPTIBILITY DISCS IN VIALS - STOCK RANGE

Description **Antibiotic & Content µg per disc** (unless otherwise stated)	**STANDARD**		**Order Code** **Vials** **99+/- 2 discs**
	EUCAST	**CLSI**	
Bacitracin 10 units	-	-	BA10
Cefpodoxime 10	✓	✓	CPD10
Gentamicin 10	✓	✓	GM10
Metronidazole 5	✓	-	MZ5
Nalidixic Acid 30	✓	-	NA30
Oxacillin 1	✓	✓	OX1
Penicillin G 1 unit	✓	-	PG1
Vancomycin 5	✓	-	VA5
Blank discs	-	-	BD0638W/NCE

MASTDISCS AST

NON CLINICAL ANTIFUNGAL SUSCEPTIBILITY DISCS IN CARTRIDGES AND VIALS - STOCK RANGE

Description **Antibiotic & Content µg per disc** (unless otherwise stated)	**Order Code** **Cartridges** **5 × 50 discs**
Amphotericin B 20	AMB20C/NCE
Clotrimazole 10	CTM10C/NCE
Econazole 10	ECN10C/NCE
Fluconazole 10	FCN10C/NCE
Fluconazole 25	FCN25C/NCE
Flucytosine 1	FY1C/NCE
Ketoconazole 10	KCA10C/NCE
Miconazole 10	MCL10C/NCE
Nystatin 100	NY100C/NCE

Disc Diffusion Susceptibility Testing

Order No	Product	Mechanism	Packsize (tests)

MASTDISCS® *Combi*

COMBINATION DISC SETS FOR THE DETECTION OF ANTIBIOTIC RESISTANCE

D52C	Extended Spectrum ß Lactamase Set	ESßL	50 tests
D62C	Cefotaxime 30 & Cefotaxime 30/Clavulanic Acid 10	ESßL	150 tests
D63C	Cefepime 30 & Cefepime 30/Clavulanic Acid 10	ESßL	150 tests
D64C	Ceftazidime 30 & Ceftazidime 30/Clavulanic Acid 10	ESßL	150 tests
D66C	Cefpodoxime 10 & Cefpodoxime 10/Clavulanic Acid 1	ESßL	150 tests
D67C	Extended Spectrum ß Lactamase Set (CPD10)	ESßL	50 tests
D68C	AmpC & ESBL Detection Set	AmpC/ESBL	50 tests
D69C	AmpC Detection Set	AmpC	50 tests
D72C	AmpC, ESßL & Carbapenemase Detection Set	AmpC/ESßL/Carbapenemase	50 tests
D73C	MAST® *Carba plus*	MBL/KPC/OXA	50 tests
D76C	ESßL Detection Set (EUCAST)	ESßL	50 tests

Additional carbapenemase screening and identification tests

D71C	MAST® CAT-ID - For presumptive identification of carbapenemase production	250 tests
D74	MAST® ICT - screening test for the detection of carbapenemase production in Enterobacterales, *Pseudomonas* and *Acinetobacter* spp.	25 tests
TEM30C	To aid presumptive identification of OXA-48	5 × 50 discs

RAPID CARBAPENEMASE DETECTION

DNA/LYO5	Rapid molecular carbapenemase detection in Enterobacterales, *Pseudomonas* spp. and *Acinetobacter* spp.	10 tests
PACE-ID	Colorimetric test for the rapid detection of carbapenemase producing *Pseudomonas* spp., *Acinetobacter* spp.and Enterobacterales.	48 tests

MASTDISCS® *AST*

PENICILLIN DISCS

For detecting the emergence of penicillin resistance. (99+/- 2 discs or 5 × 50 discs in cartridges)

PG1	Penicillin G	1 unit (vials)	1 vial
PG1C	Penicillin G	1 unit (cartridges)	1 pack

HIGH CONTENT AMINOGLYCOSIDE DISCS

The following discs are available to special order and subject to 6 weeks lead time.
For detecting high level aminoglycoside resistance. (99+/- 2 discs or 5 × 50 discs in cartridges)

GM500C	500 µg	Min order
K1000C/NCE	1000 µg	18 packs
K1000/NCE	1000 µg	Min order 22 vials

Any code with a suffix of '/NCE' is not CE marked and for veterinary or research use only.

Disc Diffusion Susceptibility Testing

Order No	Product	Packsize

DISCMASTER DISPENSER

Robust and reliable antimicrobial cartridge disc dispensers designed for use with MASTDISCS®
Antimicrobial Susceptibility Test Cartridges.

MDD65	MAST® DISCMASTER Dispenser - 6 place	1
SILICA63	Silica Gel Capsule for MAST® DISCMASTER	4
SHD5	Single Cartridge Hand Dispenser	5
CANISTER	Canister for MDD64 models and below	1
CANISTER65	Canister for MDD65 MAST® DISCMASTER Dispenser	1

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ZT147 V10.0 CEA 01/23

accuracy and quality as a science

tcs biosciences

Selectrol® Technical Guide

Selectrol® : Manufactured under licence from Public Health England Culture Collections

SELECTROL® - FREEZE-DRIED ORGANISMS IN A DISC

Quality control of microbial characterisation tests, culture media and antimicrobial susceptibility determinations is best accomplished by the use of microorganisms with well-documented and stable phenotypic and genotypic characteristics.

Bacterial and fungal strains have been selected and recommended by expert bodies, such as EUCAST, CLSI and the European Pharmacopoeia, on the basis of their suitability for monitoring test performance and ensuring the validity of results for testing used in clinical, food, pharmaceutical, water and veterinary laboratories.

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. See also page 14.

Selectrol strains are manufactured exclusively from Public Health England Culture Collections (NCTC® and NCPF®) and are first generation subcultures, unlike many products on the market which are 2nd, 3rd or 4th generation subcultures. They are preserved by long-term storage as freeze-dried cells in order to minimise any alterations to the phenotype caused by mutations.

Passages

A Selectrol® disc is a first generation subculture from a **master culture** sourced from Public Health England Culture Collections, and is designed to be used to obtain **working stock** cultures for use in testing. It is generally accepted that no more than a total of five passages should be made from the **master culture**, in order to avoid genetic drift and mutant selection. Therefore, no more than four passages (fresh cultures) from the **working stock** should be made.

Shelf life

For most strains, Selectrol® discs are guaranteed to contain at least 10^6 organisms at the time of purchase; this number is sufficient to ensure that when the discs are used and stored as directed there will be viable organisms cultivable up to the stated end of the shelf life, which is usually 9 months from the time the vial is first opened.

Quality Control

Selectrol® batches are tested in our UKAS accredited testing laboratory number 2496. A test report for each batch of Selectrol® can be accessed via our website. The reporting of Selectrol® test results via the website comes under our UKAS accreditation.

Selectrol® cultures are rigorously tested to confirm identity, to confirm the possession of essential phenotypic characteristics and to exclude contamination with other organisms. Photographic evidence of the test results is retained for each batch, along with retained appropriately stored samples.

Glossary

AMRHAI: Antimicrobial Resistance and Healthcare Associated Infections reference unit

ATCC®: American Type Culture Collection. ATCC® strains are listed for reference only. ATCC® is a registered trademark of the American Type Culture Collection.

BSAC: British Society for Antimicrobial Chemotherapy - Now superseded by EUCAST

CLSI: Clinical Laboratory Standards Institute. (USA)

CPE: Carbapenemase Producing Enterobacteriaceae

CRE: Carbapenem Resistant Enterobacteriaceae

Culture collection: Cultures of fully characterised organisms maintained in such a way as to minimise sub-culturing. See page 14.

ESBL: Extended Spectrum Beta-Lactamase-producing organism.

EUCAST: European Committee on Antimicrobial Susceptibility Testing.

First generation derivative: A single passage from a master culture, for example a Selectrol® disc.

Master culture: Culture derived from a reference culture vial.

NCPF®: National Collection of Pathogenic Fungi. NCPF® is a registered trademark of Public Health England.

NCTC®: National Collection of Type Cultures. NCTC® is a registered trademark of Public Health England.

Passage: An equivalent term for a subculture.

PHE: Public Health England.

Reference cultures: Quality control strains selected on the basis of their phenotypic biochemical and antimicrobial susceptibility characteristics to be used as controls in microbiological testing. These are obtained as freeze-dried vials from culture collections.

Stock culture: Cultures derived from a Selectrol® disc, which can be stored for up to a week, usually on agar slants.

Working cultures: Stock cultures further sub-cultured to provide 18-24 hour growth for use in testing.

WDCM: World Data Centre for Microorganisms

WFCC: World Federation for Culture Collections

SIGNIFICANT PROPERTIES AND USES OF SELECTROL® ORGANISMS

Aspergillus brasiliensis (formerly *Aspergillus niger*)**:**

MM94 – NCPF® 2275 / ATCC® 16404 / WDCM 00053 – used in pharmaceutical industry for testing media and preservatives. Colonies are initially white or yellowish and on the reverse greyish or greenish-yellow. Sporing heads on the colony surface are initially pale, becoming dark brown to black. Sporulation may be inhibited in sealed plates.

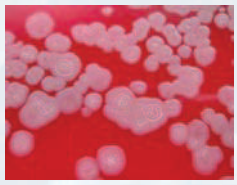
***Bacillus cereus*:**

MM21 – NCTC® 10320 / ATCC® 9634 / WDCM 00001 (recently renamed *Bacillus toyonensis*) – ISO 11133 recommended media and ID test control organism.

MM86 – NCTC® 7464 / ATCC® 10876 – PHE recommended media and ID test control organism.

Bacillus subtilis *(Bacillus subtilis* subsp. *spizizenii)***:**

MM29 – NCTC® 10400 / ATCC® 6633 / WDCM 00003 – used in antibiotic assays (fully sensitive), PHE recommended media and ID test control organism.



***Bacteroides fragilis*:**

MM44 – NCTC® 9343 / ATCC® 25285 – type strain, PHE recommended strain for media and sensitivity test control.

Campylobacter jejuni *(Campylobacter jejuni* subsp. *jejuni)***:**

MM82 – NCTC® 11322 / ATCC® 29428 / WDCM 00156 – PHE recommended strain for media control.

MM36 – NCTC® 11351 / ATCC® 33560 – EUCAST recommended strain for susceptibility testing.

***Candida albicans*:**

MM28 – NCPF® 3255 / ATCC® 2091 / WDCM 00055 – sensitivity control / industrial use.

MM42 – NCPF® 3179 / ATCC® 10231 / WDCM 00054 – pharmaceutical / media testing / PHE recommended strain for media control.

CRE ≡ 'Carbapenem Resistant Enterobacteriaceae' / CPE ≡ 'Carbapenemase Producing Enterobacteriaceae'

There are 5 carbapenemases which are currently a significant problem in the UK – KPC, OXA-48, IMP, NDM and VIM – and PHE recommend that all clinically-significant Gram-negative bacteria should be routinely screened for carbapenemase production, using a recommended carbapenem[2] such as ertapenem or meropenem. Resistant isolates may be investigated further to determine which resistance mechanism is involved using the Modified Hodge Test, MALDI-TOF, PCR or a reference laboratory.

MM55 *Klebsiella pneumoniae* – NCTC® 13440 – produces a Class B VIM-1 Carbapenemase.

MM56 *Klebsiella pneumoniae* – NCTC® 13443 – produces a Class B NDM-1 Carbapenemase.

MM58 *Klebsiella pneumoniae* – NCTC® 13438 – produces a Class A KPC-3 Carbapenemase.

MM59 *Klebsiella pneumoniae* – NCTC® 13442 – produces a Class D OXA-48 Carbapenemase.

MM57 *Escherichia coli* – NCTC® 13476 – produces a Class B IMP Carbapenemase.

MM33 *Escherichia coli* – NCTC® 10418 / ATCC® 10536 – recommended by PHE as a negative control for CRE testing.

***Citrobacter freundii*:**

MM27 – NCTC® 9750 / ATCC® 8090 – type strain.

***Clostridium perfringens*:**

MM45 – NCTC® 8237 / ATCC® 13124 / WDCM 00007 – type strain. PHE recommended strain for food testing (Tryptose Sulphite Cycloserine agar – lactose and gelatin positive) and sensitivity test control. *Clostridium perfringens* is listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001, and should be securely stored in accordance with the guidelines of the Act. However, MM45 is a type A strain, which does not produce the lethal epsilon toxin of potential interest to bioterrorists.

***Clostridium sporogenes*:**

MM31 – NCTC® 532 / ATCC® 19404 / WDCM 00008 – used for media control. PHE recommended strain for media QC (lactose gelatin medium for ID of *C. perfringens* lactose negative and gelatin positive).

***Enterobacter aerogenes*:**

MM26 – NCTC® 10006 / ATCC® 13048 / WDCM 00175 – type strain; used in water, paint and adhesive testing.

***Enterobacter cloacae*:**

MM01 – NCTC® 13380 / ATCC® 23355 / WDCM 00082 – disinfectant control, media testing.

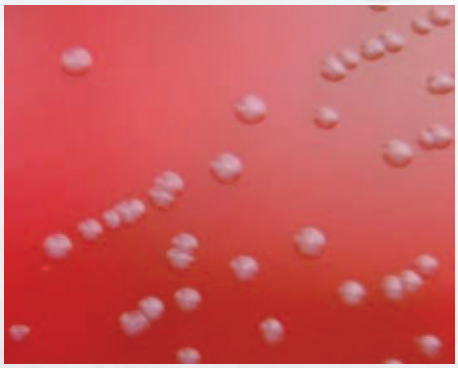
MM51– NCTC® 13406 – PHE recommended strain for QC of AmpC (de-repressed) detection.

***Enterococcus faecalis*:**

MM52 – NCTC® 13379 / ATCC® 51299 / WDCM 00085 – is vancomycin resistant (low-level VanB mediated) and also shows high-level resistance to aminoglycosides. It is used to confirm methodologies used to detect these resistances are working correctly. Lancefield group D.

MM17 – NCTC® 775 / ATCC® 19433 / WDCM 00009 – used in water industry and QC. PHE recommended strain for media control. Fully sensitive. Lancefield group D.

MM18 – NCTC® 12697 / ATCC® 29212 / WDCM 00087 – is fully sensitive to vancomycin and gentamicin. PHE recommended positive control strain for aesculin test. CLSI, EUCAST recommended media control for sulpha / trimethoprim testing and general susceptibility testing control. Lancefield group D.

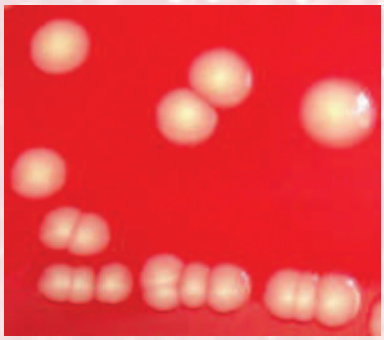


***Enterococcus hirae*:**

MM35 – NCTC® 13383 / ATCC® 10541 / WDCM 00011 – disinfectant control. Used in microbiological assays. Colonies are alpha-haemolytic on sheep blood agar.

***Escherichia coli* strains:**

MM02 – NCTC® 12241 / ATCC® 25922 / WDCM 00013 – EUCAST, CLSI, PHE recommended control strain for susceptibility testing (fully sensitive). Exhibits 2 colony types – the most prevalent type is slightly irregular, smooth and translucent. The secondary type appears more opaque. It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels.



MM57 – NCTC® 13476 – CRE testing control; produces a Class B IMP Carbapenemase.

MM33 – NCTC® 10418 / ATCC® 10536 – (PHE recommended alternative to NCTC 12241) fully sensitive control strain. PHE recommended positive control for indole test, ONPG test, negative control for oxidase test, PHE recommended negative control for CRE and ESBL testing.

MM24 – NCTC® 11954 / ATCC® 35218 – beta-lactamase positive strain. CLSI recommended strain for susceptibility testing ONLY for penicillin / beta-lactamase inhibitor combinations. Sensitive to amoxicillin / clavulanic acid.

MM75 – NCTC® 9001 / ATCC® 11775 / WDCM 00090 – used in water / chemical industry. PHE recommended strain for media QC.

MM93 – NCTC® 12900 / ATCC® 700728 / WDCM 00014 – O157 strain (non-toxigenic). PHE recommended strain for media QC.

MM63 – NCTC® 11560 – beta-lactamase positive strain.

MM38 – NCTC® 12923 / ATCC® 8739 / WDCM 00012 – used in pharmaceutical / water industry. Three colony types: A) Entire, glistening, smooth and translucent. B) Entire, glistening smooth and opaque. C) Irregular, rough and translucent. The rough colonies appear after 48 hours incubation.

MM34 – NCTC® 13846 – Possesses the plasmid-mediated mcr-1 colistin resistance mechanism gene and is recommended by PHE and EUCAST as a control for tests to detect this increasingly prevalent resistance, in conjunction with NCTC® 12241 / ATCC® 25922 (Selectrol strain MM02) as a negative control.

***Haemophilus influenzae* strains:**

MM81 - NCTC® 12699 / ATCC® 49247 – is a 'BLNAR' strain – (beta-lactamase non-producing ampicillin / amoxycillin resistant). These strains are important clinically because the susceptibility results obtained using conventional testing procedures maybe misleading in the case cephalosporins. PHE, CLSI recommended QC strain for susceptibility testing media.

MM98 – NCTC® 11931 – a fully sensitive strain. PHE recommended strain for porphyrin synthesis test, chocolate agar control.

MM100 – NCTC® 8468 / ATCC® 9334 / CCUG 23946 – another fully sensitive strain, which reportedly gives results which are easier to interpret when Mueller-Hinton medium is used in preference to Iso-Sensitest medium. MIC for amoxycillin is 0.5 mg/l.

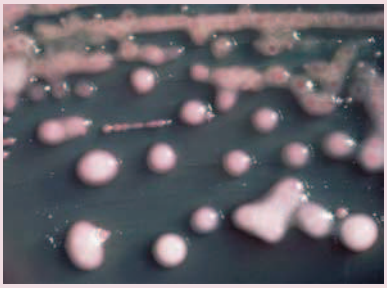
MM37 – NCTC® 12975 / ATCC® 49766 – recommended by EUCAST.

***Klebsiella* strains:**

MM04 *Klebsiella pneumoniae* – NCTC® 9633 / ATCC® 13883 / WDCM 00097 – type strain. Two colony types may be seen. The predominant type is entire and opaque. The secondary type is slightly smaller and translucent.

MM83 *Klebsiella pneumoniae* – NCTC® 13368 / ATCC® 700603 – ESBL-producing strain used as control for ESBL testing. There are two colony types.

MM55 *Klebsiella pneumoniae* – NCTC® 13440 – CRE testing control; produces a Class B VIM-1 Carbapenemase.



MM56 *Klebsiella pneumoniae* – NCTC® 13443 – CRE testing control; produces a Class B NDM-1 Carbapenemase.

MM58 *Klebsiella pneumoniae* – NCTC® 13438 – CRE testing control; produces a Class A KPC-3 Carbapenemase.

MM59 *Klebsiella pneumoniae* – NCTC® 13442 – CRE testing control; produces a Class D OXA-48 Carbapenemase.

MM88 *Klebsiella aerogenes (Raoultella planticola)* – NCTC® 9528 – used in water / pharmaceutical industry. PHE recommended negative control for Tryptone Bile X-Glucuronide agar and Yeast Extract agar.

***Lactobacillus brevis*:**

MM76 – NCTC® 13386 / ATCC® 8287 – used in food industry.

***Legionella pneumophila* serogroup 1:**

MM08 – NCTC® 11192 / ATCC® 33152 / WDCM 00107 – derived from strain isolated from first recognised outbreak of legionellosis in Philadelphia at the Legionnaires' Convention 1976

***Listeria innocua*:**

MM92 – NCTC® 11288 / ATCC® 33090 / WDCM 00017 – type strain. Non-pathogenic.

***Listeria monocytogenes*:**

MM87 – NCTC® 11994 / WDCM 00019 – type strain, PHE recommended positive control strain for Listeria detection in food. Serotype 4b, most common serovar isolated from human infections.

MM48 – NCTC® 7973 / ATCC® 35152 / WDCM 00109 – produces 2 phenotypes, one is beta-haemolytic and virulent, the other non-haemolytic and non-virulent. Serovar 1/2a.

MM77 – NCTC® 13372 / ATCC® 7644 – used in food microbiology Q.C. Colonies exhibit beta-haemolysis on sheep blood agar.

***Neisseria gonorrhoeae*:**

MM96 – NCTC® 12700 / ATCC® 49226 – has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. PHE recommended control for susceptibility testing – methodology assesses the ability of testing to detect resistance rather than sensitivity; this strain has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. Some variation in size and texture of colonies may be observed. Increased CO_2 is helpful in growth.

MM05 – NCTC® 8375 / ATCC® 19424 – is fully sensitive – MIC of penicillin is 0.06 mg/l. PHE recommended strain for media QC.

***Proteus mirabilis*:**

MM43 – NCTC® 13376 / ATCC® 14153 – pharmaceutical / disinfectant / media control.

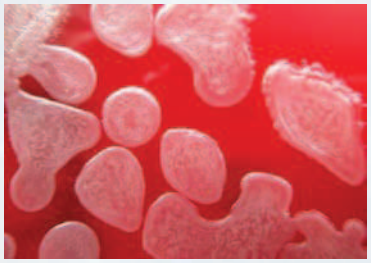
MM68 – NCTC® 10975 – media control. PHE recommended control for motility test.

***Proteus vulgaris*:**

MM09 – NCTC® 4175 / ATCC® 13315 – was the type strain, but is atypical and has been recognised as a separate species – *Proteus hauseri* – it is used for media control. Colonies are glistening with spreading edges.

***Pseudomonas aeruginosa* strains:**

MM10 – NCTC® 12903 / ATCC® 27853 / WDCM 00025 – is fully sensitive to anti-pseudomonal antibiotics (EUCAST susceptibility test control). 2 colony types may be observed: A) predominantly flat, spreading edges and rough surface; B) small and compact. Produces both fluorescein and pyocyanin pigments.



MM65 – NCTC® 10662 / ATCC® 25668 / WDCM 00114 – is fully sensitive. PHE recommended control strain for media control

MM40 – NCTC® 12924 / ATCC® 9027 / WDCM 00026 – used in water industry / disinfectant testing. Colonies on agar plates are entire, glistening and mucoid with a grainy surface. This strain also produces both fluorescein and pyocyanin pigments.

MM41 – NCTC® 13359 / ATCC® 15442 – used in water industry / disinfectant testing. May produce up to 3 different colony types. Pyocyanin is not produced.

***Rhodococcus equi*:**

MM97 – NCTC® 1621 / ATCC® 6939 / WDCM 00028 – type strain.

***Saccharomyces cerevisiae*:**

MM73 – NCPF® 3178 – PHE recommended strain for food testing and enumeration of yeasts and moulds.

MM50 — NCTC® 10716 / WDCM 00058 – used for QC of culture media and for antifungal susceptibility testing.

***Salmonella serotypes*:**

MM11 *Salmonella* Typhimurium – NCTC® 12023 / ATCC® 14028 / WDCM 00031 – (1,4,5,12: i: 1,2) Used for media/test QC. This is a common serotype from animals and from human infections.

The strains listed below are unusual serotypes, used to avoid any chance of confusion with strains commonly found in animals, food, etc, and are used to control media and detection methods in the food industry:

MM89 *Salmonella* Poona – NCTC® 4840 – (13,22: z: 1,6) PHE recommended control strain for food testing.

MM84 *Salmonella* Nottingham – NCTC® 7832 – (16: d: e,n,z15) PHE recommended control for water testing.

***Serratia marcescens*:**

MM12 – NCTC® 13382 / ATCC® 8100 – used for disinfectant testing. PHE recommended negative control for indole test. Colonies are entire, glistening, smooth and translucent. Non-pigmented.

***Staphylococcus aureus*:**

(A) Fully sensitive:

MM85 – NCTC® 6571 / ATCC® 9144 / WDCM 00035 – historically used for susceptibility testing ('Oxford staph'), but largely superseded by MM13 as it has unusually low MIC's and so is unrepresentative of normal range of Staph aureus strains. Sensitive to penicillin and cefoxitin / methicillin / oxacillin. PHE recommended coagulase, DNAse and catalase positive control.

MM13 – NCTC® 12981 / ATCC® 25923 / WDCM 00034 – used in susceptibility and media testing/QC. Fully sensitive to all anti-staphylococcal antibiotics (including penicillin and methicillin / oxacillin). It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels. Colonies are circular white to cream, convex to flat in elevation. After 48 hours incubation a few grey/translucent variants may be noted. Beta-haemolytic on sheep blood agar.

B) Penicillin resistant:

MM14 – NCTC® 12973 / ATCC® 29213 / WDCM 00131 – used for susceptibility testing, especially for automated methodology. EUCAST, CLSI strain. Sensitive to cefoxitin / methicillin / oxacillin. Penicillin resistant – weak beta-lactamase producer. Colonies are beta-haemolytic, and a golden-orange colour.

MM30 – NCTC® 7447 / ATCC® 6538P / WDCM 00033 – used for susceptibility testing/antibiotic assay, disinfectant testing. Cefoxitin / methicillin / oxacillin sensitive. Penicillin resistant. Colonies are weakly beta-haemolytic, coagulase positive and beta-lactamase negative.

(C) MRSA (cefoxitin / methicillin / oxacillin resistant):

MM91 – NCTC® 13373 / ATCC® 43300 / WDCM 00211 (MRSA) – Possesses mecA gene but is hetero-resistant, (so as few as one per thousand cells demonstrate the resistance) and consequently has low-level cefoxitin /oxacillin/methicillin resistance (4.0 mg/l MIC of oxacillin, 8.0 mg/l MIC of cefoxitin – methicillin sensitive strains have MIC of 0.12-0.5 for oxacillin and 1-4 for cefoxitin.); it is used to confirm testing procedures for methicillin resistance are working and provides a more stringent test than testing with an MRSA which shows homogeneous resistance and has a much higher MIC. This organism will have a zone of inhibition reduced in size compared to a fully cefoxitin / oxacillin / methicillin sensitive strain (such as MM13). CLSI recommended strain for MRSA testing. There are two colony types: 1) Beta-haemolytic with a slight yellow tint. 2) Non-haemolytic and white.

MM64 – NCTC® 12493 / WDCM 00212 (MRSA) – possesses mecA gene and shows homogeneous resistance with MIC of >64 for methicillin, which produces high-level cefoxitin / methicillin / oxacillin resistance. EUCAST recommended strain. Instances have been reported where loss of the mecA gene has occurred during storage.

D) Other:

MM46 – NCTC® 10788 / ATCC® 6538 / WDCM 00032 – used in pharmaceutical industry for testing disinfectants etc. Usually yellow pigmented colonies, or can produce a white colonial variant. Beta-haemolytic.

***Staphylococcus epidermidis*:**

MM15 – NCTC® 13360 / ATCC® 12228 / WDCM 00036 – used for media control / antibiotic assay. Colonies are small and beta-haemolytic.

***Streptococcus agalactiae*:** (Beta-haemolytic Streptococcus group B)

MM16 – NCTC® 8181 / ATCC® 13813 – type strain, used for QC. PHE recommended negative control for aesculin test.

Streptococcus pneumoniae strains:

MM95 – NCTC® 12977 / ATCC® 49619 – has low-level, but clinically relevant, resistance to penicillin – this organism is used to assess detection of resistance rather than sensitivity. PHE recommended positive control for bile solubility test. CLSI, EUCAST recommended control strain for susceptibility testing. Serotype 19F.

MM19 – NCTC® 12695 / ATCC® 6303 – is fully sensitive. Colonies are mucoid and alpha-haemolytic. A few colonies may have an irregular edge. Serotype 3.

***Streptococcus pyogenes*:**

MM20 – NCTC® 12696 / ATCC® 19615 – used for QC and media testing. Lancefield group A, beta-haemolytic.
PHE recommended blood agar control.

***Vibrio parahaemolyticus*:**

MM06 – NCTC® 10885 / WDCM 00185 – used for QC of media and ID testing. PHE recommended strain used mainly in the food industry.

***Yersinia enterocolitica*:**

MM80 – NCTC® 12982 / ATCC® 9610 / WDCM 00038 – type strain, used for media control. Serotype O:8, which is a pathogenic serotype, commonest in USA.

References:

1 European Committee on Antimicrobial Susceptibility Testing (EUCAST). Routine and Extended Internal Quality Control for MIC Determination and Disc Diffusion. Version 7.0 - 01.01.2017.

2 UK Standards for Microbiology Investigations. Example Reference Strains for Microbiology Investigations Test Procedures: Bacteriology—Test Procedures | TP 1 | Issue No. 2 | 05.01.2015. Public Health England (PHE).

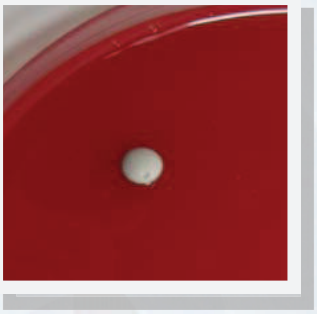
3 Performance Standards for Antimicrobial Disc Susceptibility Tests: Approved Standard—11th Edition. Clinical and Laboratory Standards Institute (CLSI).

How to use Selectrol®

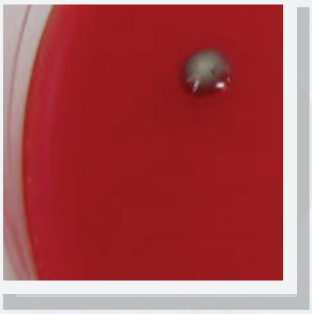
Always warm the vial to ambient temperature before opening.

Be sure to use non-selective culture media to revive the organisms.

For the more fastidious organisms, such as anaerobes, it is generally better to use agar rather than broth for revival.

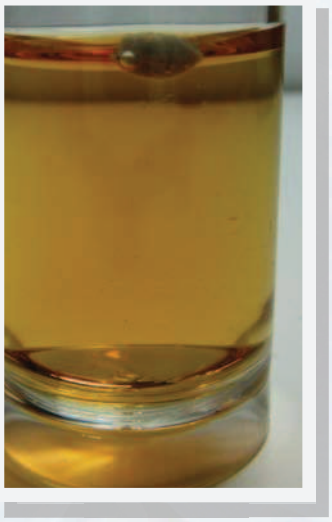


Place disc on suitable growth medium such as blood agar



Leave disc for a few minutes to liquefy, then spread plate and incubate to produce isolated colonies

Obtain a stock culture which can be used to prepare an inoculum for biochemical and antibiotic susceptibility tests



Place disc in a small volume of a suitable broth medium such as brain-heart infusion

Allow disc a few minutes to dissolve, then spread aliquot onto a plate of suitable growth medium

Out-of-specification results

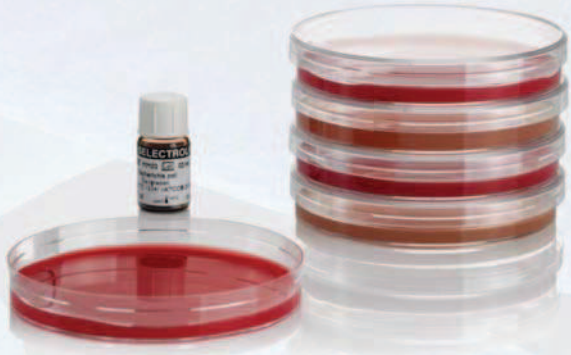
Laboratories use Selectrol® for Quality Control of culture media, biochemical identification tests and antimicrobial susceptibility testing. When a laboratory test result, an MIC or biochemical reaction, is unexpected or out-of-specification, the test should first be repeated to confirm it; an out-of-specification result is an indication that the testing procedure should be reviewed; it is not, in the first instance, a sign of a problem with the control organism.

If incorrect results are obtained on retesting, the explanation could be:

- The test procedure was not followed correctly – check standard operating procedures
- There is an instrumentation error – check calibration, mechanical functioning, etc
- There is a problem with the consumables – out of date, incorrect storage, etc
- The culture of the control organism has become contaminated

Technical Support

If no explanation for out-of-spec results can be found, but repeated tests still give unacceptable results, please contact TCS and / or your relevant reference laboratory or instrument manufacturer for advice. For example, contact AMRHAI at Colindale, London if MIC results are consistently outside the acceptable range. Please retain any remaining discs of organisms about which you have concerns so they can be returned to TCS and investigated alongside retained samples.



Preparing QC and Validation Spikes from Selectrol®

Preparing the spike

- Place a Selectrol® disc in Brain Heart Infusion (BHI) broth* or equivalent, and culture (typically for 18 hours) at the appropriate temperature for the organism (typically 37°C)
- Assume the count in the broth to be 10^8 organisms per ml ---------- (A)
- Mix and transfer 100 µl of (A) to 100 ml of saline or ¼ strength Ringer's solution -- (B)
- Mix and transfer 100 µl of (B) to 10 ml of saline or ¼ strength Ringer's solution --- (C)
- Mix and transfer 100 µl of (C) to your homogenised food sample.

Verifying the inoculum

- Pipette 5 x 10 µl drops from (C) onto each of two agar plates for Miles and Misra counts.

Using the assumptions and dilutions above:

- (A) contains 10^8 organisms per ml
- (B) contains 10^5 organisms per ml
- (C) contains 10^3 organisms per ml

If the Miles and Misra counts indicate that the required count was not achieved:

- If the count was too high by a factor of 10, reduce the volume transferred from (A) to (B) from 100 µl to 10 µl
- If the count was too low by a factor of 10, increase the volume transferred from (A) to (B) from 100 µl to 1 ml.

Keep a record of the correct dilutions for each organism type for future use. You will find that this method is very repeatable.

*Note: BHI broth will work for most of the Selectrol® organisms; however, for fastidious organisms an appropriate culture broth must be selected, e.g. Fastidious Anaerobe Broth for strictly anaerobic organisms.

Culture Collections

Cultures of microorganisms have been deposited and subsequently maintained in 589 collections in 68 countries, and many of the cultures are derived from the same original isolate; the history of each organism, its properties and names of the culture collections which hold it are detailed in the relevant catalogues and websites.

Some of the organisms have been selected and recommended by expert organisations to be supplied as controls for microbiological tests, and when the identical cultures are present in more than one collection they will have a specific designation for each, incorporating the abbreviation for the collection and a reference number.

For example:- *Staphylococcus aureus* NCTC 7447, widely recommended as a control for antimicrobial susceptibility testing, is held in 30 collections, and consequently the phenotypically and genotypically identical organism has 30 different references, such as ATCC 6538P, CIP 53.156, DSM 346 and so on.

In an effort to minimise potential confusion and help users find local sources of reference strains, the WFCC and the WDCM initiated a system that ascribes each recommended QC strain a reference number (WDCM 00001 onwards), cites all collections that contain it and provides contact details and each collection's unique reference. For example, the strain of *Staphylococcus aureus* NCTC 7447 (Selectrol® strain MM33) mentioned above is designated WDCM 00033.

Staphylococcus aureus WDCM 00033

AHU 1142; ATCC™ 6538P; BCRC 10451 ; BTCC 209P; BU 395; CCM 2022; CCTM 596; CCUG 1828; CECT 240; CIP 53.156; CN 3784; CNCTC Mau 28/58; DSM 346; FIRDI 451; IAM 1011; IAM 12082; IEM Mau 28/58; IFO 12732; IFO 3061; IID 671; IMET 10904; JCM 2151; LMG 8195; NCIMB 8625; NCTC 7447; NRRL B-313; OUT 8232; PCI 1209; PZH 8/54; RIMD 3109007; VNIIA 209P;

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. Ideally, as in the case of **Selectrol®**, a single sub-culture only is used, so the **Selectrol®** product is a 'first generation derivative' of a culture supplied by NCTC, and will be identical with regard to its properties and suitability for use in QC applications to a culture of the particular organism obtained from any of the other WDCM listed culture collections.

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
Aspergillus brasiliensis	NCPF® 2275 / ATCC® 16404	MM94	00053
Bacillus cereus	NCTC® 10320 / ATCC® 9634	MM21	00001
Bacillus cereus	NCTC® 7464 / ATCC® 10876	MM86	
Bacillus subtilis	NCTC® 10400 / ATCC® 6633	MM29	00003
Bacteroides fragilis	NCTC® 9343 / ATCC® 25285	MM44	
Campylobacter jejuni	NCTC® 11351 / ATCC® 33560	MM36	
Campylobacter jejuni	NCTC® 11322 / ATCC® 29428	MM82	00156
Candida albicans	NCPF® 3255 / ATCC® 2091	MM28	00055
Candida albicans	NCPF® 3179 / ATCC® 10231	MM42	00054
Citrobacter freundii	NCTC® 9750 / ATCC® 8090	MM27	
Clostridium perfringens	NCTC® 8237 / ATCC® 13124	MM45	00007
Clostridium sporogenes	NCTC® 532 / ATCC® 19404	MM31	00008
Enterobacter aerogenes	NCTC® 10006 / ATCC® 13048	MM26	00175
Enterobacter cloacae	NCTC® 13380 / ATCC® 23355	MM01	00082
Enterobacter cloacae	NCTC® 13406	MM51	
Enterococcus faecalis	NCTC® 775 / ATCC® 19433	MM17	00009
Enterococcus faecalis	NCTC® 12697 / ATCC® 29212	MM18	00087
Enterococcus faecalis	NCTC® 13379 / ATCC® 51299	MM52	00085
Enterococcus hirae	NCTC® 13383 /ATCC® 10541	MM35	00011
Escherichia coli	NCTC® 12241 / ATCC® 25922	MM02	00013
Escherichia coli	NCTC® 11954 / ATCC® 35218	MM24	
Escherichia coli	NCTC® 10418 / ATCC® 10536	MM33	
Escherichia coli	NCTC® 12923 / ATCC® 8739	MM38	00012
Escherichia coli	NCTC® 11560	MM63	
Escherichia coli	NCTC® 9001 / ATCC® 11775	MM75	00090
Escherichia coli CRE	NCTC® 13476	MM57	
Escherichia coli (mcr-1)	NCTC® 13846	MM34	
Escherichia coli O157 (non-toxigenic)	NCTC® 12900 / ATCC® 700728	MM93	00014
Haemophilus influenzae	NCTC® 8468 / ATCC® 9334	MM100	
Haemophilus influenzae	NCTC® 12975 / ATCC® 49766	MM37	
Haemophilus influenzae	NCTC® 12699 / ATCC® 49247	MM81	
Haemophilus influenzae	NCTC® 11931	MM98	
Klebsiella aerogenes	NCTC® 9528	MM88	
Klebsiella pneumoniae	NCTC® 9633 / ATCC® 13883	MM04	00097
Klebsiella pneumoniae	NCTC® 13368 / ATCC® 700603	MM83	
Klebsiella pneumoniae CRE	NCTC® 13440	MM55	
Klebsiella pneumoniae CRE	NCTC® 13443	MM56	
Klebsiella pneumoniae CRE	NCTC® 13438	MM58	

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
Klebsiella pneumoniae CRE	NCTC® 13442	MM59	
Lactobacillus brevis	NCTC® 13386 / ATCC® 8287	MM76	
Legionella pneumophila serogroup 1	NCTC® 11192 / ATCC® 33152	MM08	00107
Listeria innocua	NCTC® 11288 / ATCC® 33090	MM92	00017
Listeria monocytogenes	NCTC® 7973 / ATCC® 35152	MM48	00109
Listeria monocytogenes	NCTC® 13372 ATCC® 7644	MM77	
Listeria monocytogenes	NCTC® 11994	MM87	00019
Neisseria gonorrhoeae	NCTC® 8375 / ATCC® 19424	MM05	
Neisseria gonorrhoeae	NCTC® 12700 / ATCC® 49226	MM96	
Proteus mirabilis	NCTC® 13376 / ATCC® 14153	MM43	
Proteus mirabilis	NCTC® 10975	MM68	
Proteus vulgaris	NCTC® 4175 / ATCC® 13315	MM09	
Pseudomonas aeruginosa	NCTC® 12903 / ATCC® 27853	MM10	00025
Pseudomonas aeruginosa	NCTC® 12924 / ATCC® 9027	MM40	00026
Pseudomonas aeruginosa	NCTC® 13359 / ATCC® 15442	MM41	
Pseudomonas aeruginosa	NCTC® 10662 / ATCC® 25668	MM65	00114
Rhodococcus equi	NCTC® 1621 / ATCC® 6939	MM97	00028
Saccharomyces cerevisiae	NCTC® 10716/ ATCC® 9763	MM50	00058
Saccharomyces cerevisiae	NCPF® 3178	MM73	
Salmonella Nottingham	NCTC® 7832	MM84	
Salmonella Poona	NCTC® 4840	MM89	
Salmonella Typhimurium	NCTC® 12023/ ATCC® 14028	MM11	00031
Serratia marcescens	NCTC® 13382 / ATCC® 8100	MM12	
Staphylococcus aureus	NCTC®12981 / ATCC® 25923	MM13	00034
Staphylococcus aureus	NCTC® 12973 / ATCC® 29213	MM14	00131
Staphylococcus aureus	NCTC® 7447 / ATCC® 6538P	MM30	00033
Staphylococcus aureus	NCTC® 10788 / ATCC® 6538	MM46	00032
Staphylococcus aureus	NCTC® 6571 / ATCC® 9144	MM85	00035
Staphylococcus aureus (MRSA)	NCTC® 12493	MM64	00212
Staphylococcus aureus (MRSA)	NCTC® 13373 / ATCC® 43300	MM91	00211
Staphylococcus epidermidis	NCTC® 13360 / ATCC® 12228	MM15	00036
Streptococcus agalactiae	NCTC® 8181 / ATCC® 13813	MM16	
Streptococcus pneumoniae	NCTC® 12695 /ATCC® 6303	MM19	
Streptococcus pneumoniae	NCTC® 12977 /ATCC® 49619	MM95	
Streptococcus pyogenes	NCTC® 12696 /ATCC® 19615	MM20	
Vibrio parahaemolyticus	NCTC® 10885	MM06	00185
Yersinia enterocolitica	NCTC® 12982 / ATCC® 9610	MM80	00038

Selectrol Strains Listed by WDCM Number

WDCM	Strain Name	Designation	Code
00001	*Bacillus cereus*	NCTC® 10320 / ATCC® 9634	MM21
00003	*Bacillus subtilis*	NCTC® 10400 / ATCC® 6633	MM29
00007	*Clostridium perfringens*	NCTC® 8237 / ATCC® 13124	MM45
00008	*Clostridium sporogenes*	NCTC® 532 / ATCC® 19404	MM31
00009	*Enterococcus faecalis*	NCTC® 775 / ATCC® 19433	MM17
00011	*Enterococcus hirae*	NCTC® 13383 /ATCC® 10541	MM35
00012	*Escherichia coli*	NCTC® 12923 / ATCC® 8739	MM38
00013	*Escherichia coli*	NCTC® 12241 / ATCC® 25922	MM02
00014	*Escherichia coli* O157 (non-toxigenic)	NCTC® 12900 / ATCC® 700728	MM93
00017	*Listeria innocua*	NCTC® 11288 / ATCC® 33090	MM92
00019	*Listeria monocytogenes*	NCTC® 11994	MM87
00025	*Pseudomonas aeruginosa*	NCTC® 12903 / ATCC® 27853	MM10
00026	*Pseudomonas aeruginosa*	NCTC® 12924 / ATCC® 9027	MM40
00028	*Rhodococcus equi*	NCTC® 1621 / ATCC® 6939	MM97
00031	*Salmonella* Typhimurium	NCTC® 12023/ ATCC® 14028	MM11
00032	*Staphylococcus aureus*	NCTC® 10788 / ATCC® 6538	MM46
00033	*Staphylococcus aureus*	NCTC® 7447 / ATCC® 6538P	MM30
00034	*Staphylococcus aureus*	NCTC® 12981 / ATCC® 25923	MM13
00035	*Staphylococcus aureus*	NCTC® 6571 / ATCC® 9144	MM85
00036	*Staphylococcus epidermidis*	NCTC® 13360 / ATCC® 12228	MM15
00038	*Yersinia enterocolitica*	NCTC® 12982 / ATCC® 9610	MM80
00053	*Aspergillus brasiliensis*	NCPF® 2275 / ATCC® 16404	MM94
00054	*Candida albicans*	NCPF® 3179 / ATCC® 10231	MM42
00055	*Candida albicans*	NCPF® 3255 / ATCC® 2091	MM28
00058	*Saccharomyces cerevisiae*	NCTC® 10716/ ATCC® 9763	MM50
00082	*Enterobacter cloacae*	NCTC® 13380 / ATCC® 23355	MM01
00085	*Enterococcus faecalis*	NCTC® 13379 / ATCC® 51299	MM52
00087	*Enterococcus faecalis*	NCTC® 12697 / ATCC® 29212	MM18
00090	*Escherichia coli*	NCTC® 9001 / ATCC® 11775	MM75
00097	*Klebsiella pneumoniae*	NCTC® 9633 / ATCC® 13883	MM04
00107	*Legionella pneumophila* serogroup 1	NCTC® 11192 / ATCC® 33152	MM08
00109	*Listeria monocytogenes*	NCTC® 7973 / ATCC® 35152	MM48
00114	*Pseudomonas aeruginosa*	NCTC® 10662 / ATCC® 25668	MM65
00131	*Staphylococcus aureus*	NCTC® 12973 / ATCC® 29213	MM14
00156	*Campylobacter jejuni*	NCTC® 11322 / ATCC® 29428	MM82
00175	*Enterobacter aerogenes*	NCTC® 10006 / ATCC® 13048	MM26
00185	*Vibrio parahaemolyticus*	NCTC® 10885	MM06
00211	*Staphylococcus aureus* (MRSA)	NCTC® 13373 / ATCC® 43300	MM91
00212	*Staphylococcus aureus* (MRSA)	NCTC® 12493	MM64

Notes

tcs biosciences

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accuracy and quality as a science

tcs biosciences

Selectrol® Technical Guide

Selectrol® : Manufactured under licence from Public Health England Culture Collections

SELECTROL® - FREEZE-DRIED ORGANISMS IN A DISC

Quality control of microbial characterisation tests, culture media and antimicrobial susceptibility determinations is best accomplished by the use of microorganisms with well-documented and stable phenotypic and genotypic characteristics.

Bacterial and fungal strains have been selected and recommended by expert bodies, such as EUCAST, CLSI and the European Pharmacopoeia, on the basis of their suitability for monitoring test performance and ensuring the validity of results for testing used in clinical, food, pharmaceutical, water and veterinary laboratories.

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. See also page 14.

Selectrol strains are manufactured exclusively from Public Health England Culture Collections (NCTC® and NCPF®) and are first generation subcultures, unlike many products on the market which are 2nd, 3rd or 4th generation subcultures. They are preserved by long-term storage as freeze-dried cells in order to minimise any alterations to the phenotype caused by mutations.

Passages

A Selectrol® disc is a first generation subculture from a **master culture** sourced from Public Health England Culture Collections, and is designed to be used to obtain **working stock** cultures for use in testing. It is generally accepted that no more than a total of five passages should be made from the **master culture**, in order to avoid genetic drift and mutant selection. Therefore, no more than four passages (fresh cultures) from the **working stock** should be made.

Shelf life

For most strains, Selectrol® discs are guaranteed to contain at least 10^6 organisms at the time of purchase; this number is sufficient to ensure that when the discs are used and stored as directed there will be viable organisms cultivable up to the stated end of the shelf life, which is usually 9 months from the time the vial is first opened.

Quality Control

Selectrol® batches are tested in our UKAS accredited testing laboratory number 2496. A test report for each batch of Selectrol® can be accessed via our website. The reporting of Selectrol® test results via the website comes under our UKAS accreditation.

Selectrol® cultures are rigorously tested to confirm identity, to confirm the possession of essential phenotypic characteristics and to exclude contamination with other organisms. Photographic evidence of the test results is retained for each batch, along with retained appropriately stored samples.

Glossary

AMRHAI: Antimicrobial Resistance and Healthcare Associated Infections reference unit

ATCC®: American Type Culture Collection. ATCC® strains are listed for reference only. ATCC® is a registered trademark of the American Type Culture Collection.

BSAC: British Society for Antimicrobial Chemotherapy - Now superseded by EUCAST

CLSI: Clinical Laboratory Standards Institute. (USA)

CPE: Carbapenemase Producing Enterobacteriaceae

CRE: Carbapenem Resistant Enterobacteriaceae

Culture collection: Cultures of fully characterised organisms maintained in such a way as to minimise sub-culturing. See page 14.

ESBL: Extended Spectrum Beta-Lactamase-producing organism.

EUCAST: European Committee on Antimicrobial Susceptibility Testing.

First generation derivative: A single passage from a master culture, for example a Selectrol® disc.

Master culture: Culture derived from a reference culture vial.

NCPF®: National Collection of Pathogenic Fungi. NCPF® is a registered trademark of Public Health England.

NCTC®: National Collection of Type Cultures. NCTC® is a registered trademark of Public Health England.

Passage: An equivalent term for a subculture.

PHE: Public Health England.

Reference cultures: Quality control strains selected on the basis of their phenotypic biochemical and antimicrobial susceptibility characteristics to be used as controls in microbiological testing. These are obtained as freeze-dried vials from culture collections.

Stock culture: Cultures derived from a Selectrol® disc, which can be stored for up to a week, usually on agar slants.

Working cultures: Stock cultures further sub-cultured to provide 18-24 hour growth for use in testing.

WDCM: World Data Centre for Microorganisms

WFCC: World Federation for Culture Collections

Culture Collections

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Staphylococcus aureus WDCM 00033

AHU 1142; ATCC™ 6538P; BCRC 10451 ; BTCC 209P; BU 395; CCM 2022; CCTM 596; CCUG 1828; CECT 240; CIP 53.156; CN 3784; CNCTC Mau 28/58; DSM 346; FIRDI 451; IAM 1011; IAM 12082; IEM Mau 28/58; IFO 12732; IFO 3061; IID 671; IMET 10904; JCM 2151; LMG 8195; NCIMB 8625; NCTC 7447; NRRL B-313; OUT 8232; PCI 1209; PZH 8/54; RIMD 3109007; VNIIA 209P;

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Bacillus cereus	NCTC® 7464 / ATCC® 10876	MM86	
Bacillus subtilis	NCTC® 10400 / ATCC® 6633	MM29	00003
Bacteroides fragilis	NCTC® 9343 / ATCC® 25285	MM44	
Campylobacter jejuni	NCTC® 11351 / ATCC® 33560	MM36	
Campylobacter jejuni	NCTC® 11322 / ATCC® 29428	MM82	00156
Candida albicans	NCPF® 3255 / ATCC® 2091	MM28	00055
Candida albicans	NCPF® 3179 / ATCC® 10231	MM42	00054
Citrobacter freundii	NCTC® 9750 / ATCC® 8090	MM27	
Clostridium perfringens	NCTC® 8237 / ATCC® 13124	MM45	00007
Clostridium sporogenes	NCTC® 532 / ATCC® 19404	MM31	00008
Enterobacter aerogenes	NCTC® 10006 / ATCC® 13048	MM26	00175
Enterobacter cloacae	NCTC® 13380 / ATCC® 23355	MM01	00082
Enterobacter cloacae	NCTC® 13406	MM51	
Enterococcus faecalis	NCTC® 775 / ATCC® 19433	MM17	00009
Enterococcus faecalis	NCTC® 12697 / ATCC® 29212	MM18	00087
Enterococcus faecalis	NCTC® 13379 / ATCC® 51299	MM52	00085
Enterococcus hirae	NCTC® 13383 /ATCC® 10541	MM35	00011
Escherichia coli	NCTC® 12241 / ATCC® 25922	MM02	00013
Escherichia coli	NCTC® 11954 / ATCC® 35218	MM24	
Escherichia coli	NCTC® 10418 / ATCC® 10536	MM33	
Escherichia coli	NCTC® 12923 / ATCC® 8739	MM38	00012
Escherichia coli	NCTC® 11560	MM63	
Escherichia coli	NCTC® 9001 / ATCC® 11775	MM75	00090
Escherichia coli CRE	NCTC® 13476	MM57	
Escherichia coli (mcr-1)	NCTC® 13846	MM34	
Escherichia coli O157 (non-toxigenic)	NCTC® 12900 / ATCC® 700728	MM93	00014
Haemophilus influenzae	NCTC® 8468 / ATCC® 9334	MM100	
Haemophilus influenzae	NCTC® 12975 / ATCC® 49766	MM37	
Haemophilus influenzae	NCTC® 12699 / ATCC® 49247	MM81	
Haemophilus influenzae	NCTC® 11931	MM98	
Klebsiella aerogenes	NCTC® 9528	MM88	
Klebsiella pneumoniae	NCTC® 9633 / ATCC® 13883	MM04	00097
Klebsiella pneumoniae	NCTC® 13368 / ATCC® 700603	MM83	
Klebsiella pneumoniae CRE	NCTC® 13440	MM55	
Klebsiella pneumoniae CRE	NCTC® 13443	MM56	
Klebsiella pneumoniae CRE	NCTC® 13438	MM58	

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
Klebsiella pneumoniae CRE	NCTC® 13442	MM59	
Lactobacillus brevis	NCTC® 13386 / ATCC® 8287	MM76	
Legionella pneumophila serogroup 1	NCTC® 11192 / ATCC® 33152	MM08	00107
Listeria innocua	NCTC® 11288 / ATCC® 33090	MM92	00017
Listeria monocytogenes	NCTC® 7973 / ATCC® 35152	MM48	00109
Listeria monocytogenes	NCTC® 13372 ATCC® 7644	MM77	
Listeria monocytogenes	NCTC® 11994	MM87	00019
Neisseria gonorrhoeae	NCTC® 8375 / ATCC® 19424	MM05	
Neisseria gonorrhoeae	NCTC® 12700 / ATCC® 49226	MM96	
Proteus mirabilis	NCTC® 13376 / ATCC® 14153	MM43	
Proteus mirabilis	NCTC® 10975	MM68	
Proteus vulgaris	NCTC® 4175 / ATCC® 13315	MM09	
Pseudomonas aeruginosa	NCTC® 12903 / ATCC® 27853	MM10	00025
Pseudomonas aeruginosa	NCTC® 12924 / ATCC® 9027	MM40	00026
Pseudomonas aeruginosa	NCTC® 13359 / ATCC® 15442	MM41	
Pseudomonas aeruginosa	NCTC® 10662 / ATCC® 25668	MM65	00114
Rhodococcus equi	NCTC® 1621 / ATCC® 6939	MM97	00028
Saccharomyces cerevisiae	NCTC® 10716/ ATCC® 9763	MM50	00058
Saccharomyces cerevisiae	NCPF® 3178	MM73	
Salmonella Nottingham	NCTC® 7832	MM84	
Salmonella Poona	NCTC® 4840	MM89	
Salmonella Typhimurium	NCTC® 12023/ ATCC® 14028	MM11	00031
Serratia marcescens	NCTC® 13382 / ATCC® 8100	MM12	
Staphylococcus aureus	NCTC®12981 / ATCC® 25923	MM13	00034
Staphylococcus aureus	NCTC® 12973 / ATCC® 29213	MM14	00131
Staphylococcus aureus	NCTC® 7447 / ATCC® 6538P	MM30	00033
Staphylococcus aureus	NCTC® 10788 / ATCC® 6538	MM46	00032
Staphylococcus aureus	NCTC® 6571 / ATCC® 9144	MM85	00035
Staphylococcus aureus (MRSA)	NCTC® 12493	MM64	00212
Staphylococcus aureus (MRSA)	NCTC® 13373 / ATCC® 43300	MM91	00211
Staphylococcus epidermidis	NCTC® 13360 / ATCC® 12228	MM15	00036
Streptococcus agalactiae	NCTC® 8181 / ATCC® 13813	MM16	
Streptococcus pneumoniae	NCTC® 12695 /ATCC® 6303	MM19	
Streptococcus pneumoniae	NCTC® 12977 /ATCC® 49619	MM95	
Streptococcus pyogenes	NCTC® 12696 /ATCC® 19615	MM20	
Vibrio parahaemolyticus	NCTC® 10885	MM06	00185
Yersinia enterocolitica	NCTC® 12982 / ATCC® 9610	MM80	00038

Selectrol Strains Listed by WDCM Number

WDCM	Strain Name	Designation	Code
00001	*Bacillus cereus*	NCTC® 10320 / ATCC® 9634	MM21
00003	*Bacillus subtilis*	NCTC® 10400 / ATCC® 6633	MM29
00007	*Clostridium perfringens*	NCTC® 8237 / ATCC® 13124	MM45
00008	*Clostridium sporogenes*	NCTC® 532 / ATCC® 19404	MM31
00009	*Enterococcus faecalis*	NCTC® 775 / ATCC® 19433	MM17
00011	*Enterococcus hirae*	NCTC® 13383 /ATCC® 10541	MM35
00012	*Escherichia coli*	NCTC® 12923 / ATCC® 8739	MM38
00013	*Escherichia coli*	NCTC® 12241 / ATCC® 25922	MM02
00014	*Escherichia coli* O157 (non-toxigenic)	NCTC® 12900 / ATCC® 700728	MM93
00017	*Listeria innocua*	NCTC® 11288 / ATCC® 33090	MM92
00019	*Listeria monocytogenes*	NCTC® 11994	MM87
00025	*Pseudomonas aeruginosa*	NCTC® 12903 / ATCC® 27853	MM10
00026	*Pseudomonas aeruginosa*	NCTC® 12924 / ATCC® 9027	MM40
00028	*Rhodococcus equi*	NCTC® 1621 / ATCC® 6939	MM97
00031	*Salmonella* Typhimurium	NCTC® 12023/ ATCC® 14028	MM11
00032	*Staphylococcus aureus*	NCTC® 10788 / ATCC® 6538	MM46
00033	*Staphylococcus aureus*	NCTC® 7447 / ATCC® 6538P	MM30
00034	*Staphylococcus aureus*	NCTC® 12981 / ATCC® 25923	MM13
00035	*Staphylococcus aureus*	NCTC® 6571 / ATCC® 9144	MM85
00036	*Staphylococcus epidermidis*	NCTC® 13360 / ATCC® 12228	MM15
00038	*Yersinia enterocolitica*	NCTC® 12982 / ATCC® 9610	MM80
00053	*Aspergillus brasiliensis*	NCPF® 2275 / ATCC® 16404	MM94
00054	*Candida albicans*	NCPF® 3179 / ATCC® 10231	MM42
00055	*Candida albicans*	NCPF® 3255 / ATCC® 2091	MM28
00058	*Saccharomyces cerevisiae*	NCTC® 10716/ ATCC® 9763	MM50
00082	*Enterobacter cloacae*	NCTC® 13380 / ATCC® 23355	MM01
00085	*Enterococcus faecalis*	NCTC® 13379 / ATCC® 51299	MM52
00087	*Enterococcus faecalis*	NCTC® 12697 / ATCC® 29212	MM18
00090	*Escherichia coli*	NCTC® 9001 / ATCC® 11775	MM75
00097	*Klebsiella pneumoniae*	NCTC® 9633 / ATCC® 13883	MM04
00107	*Legionella pneumophila* serogroup 1	NCTC® 11192 / ATCC® 33152	MM08
00109	*Listeria monocytogenes*	NCTC® 7973 / ATCC® 35152	MM48
00114	*Pseudomonas aeruginosa*	NCTC® 10662 / ATCC® 25668	MM65
00131	*Staphylococcus aureus*	NCTC® 12973 / ATCC® 29213	MM14
00156	*Campylobacter jejuni*	NCTC® 11322 / ATCC® 29428	MM82
00175	*Enterobacter aerogenes*	NCTC® 10006 / ATCC® 13048	MM26
00185	*Vibrio parahaemolyticus*	NCTC® 10885	MM06
00211	*Staphylococcus aureus* (MRSA)	NCTC® 13373 / ATCC® 43300	MM91
00212	*Staphylococcus aureus* (MRSA)	NCTC® 12493	MM64

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