

CE Declaration of Conformity

Name and address of Manufacturer	Atlas Medical GmbH Ludwig-Erhard-Ring 3, 15827 Blankenefelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com
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Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.17.003.0300	Atlas Periodic Acid Schiff (PAS) Stain Kit, 3x100ml	43587
8.17.004.0300	Atlas Iron Stain Kit, 3x100ml	43587
8.17.009.1000	Atlas Gram Stain Kit	43733
8.17.010.0750	Atlas ZN (Kinyoun) stain pack , 3x250ml	43587
8.15.144.0250	Atlas ZN Decolouriser, 250 ml /Bottle	43587
8.17.015.0500	Atlas Diff-3 Stain.	43587
8.17.016.1000	Atlas Papanicolau Stain Pack.	43587
8.17.110.0250	Atlas Papanicolau Stain EA35, 250 ml /Bottle.	43587
8.17.111.0250	Atlas Papanicolau Stain EA36, 250 ml /Bottle	43587
8.17.112.0250	Atlas Papanicolau Stain EA65, 250 ml /Bottle.	43587
8.17.114.0250	Atlas Papanicolau Stain EA50, 250 ml /Bottle.	43587
8.17.115.0250	Atlas Papanicolau Stain OG6, 250 ml /Bottle.	43587
8.17.014.1000	Atlas Reticulocytes stain (Methylene Blue) , 1000 ml /Bottle	43587
8.15.037.0250	Atlas Eosin Y (1%) Stain, 250 ml/Bottle	43587
8.15.038.0250	Atlas Eosin Y (5%) Stain, 250 ml/Bottle.	43587
8.15.041.0250	Atlas Field Stain (Solution A), 250ml/Bottle	43587
8.15.042.0250	Atlas Field Stain (Solution B), 250ml/Bottle	43587
8.15.043.0750	Atlas Field Stain Kit 3x250ml (250ml Fixing Reagent , 250ml Eosin Reagent, 250ml Methylene Blue Reagent).	43587
8.15.047.0250	Atlas Giemsa Stain, 250 ml/Bottle.	43587
8.15.059.0250	Atlas Haematoxylin Harris Stain , 250 ml/Bottle	43587
8.15.069.0250	Atlas Leishman Stain , 250 ml/Bottle.	43587
8.15.069.1000	Atlas Leishman Stain , 1000 ml/Bottle.	43587
8.15.074.0250	Atlas Lugol's Iodine, 250 ml/Bottle.	43587
8.15.078.0250	Atlas May Grunwald Stain, 250 ml/Bottle.	43587
8.15.105.0250	Atlas New Methylene Blue for Reticulocytes, 250 ml/Bottle.	43587
8.15.143.0250	Atlas Wright's Stain, 250 ml/Bottle.	43587
8.15.146.0100	Atlas Immersion oil, 100 Bottle/Box	43587

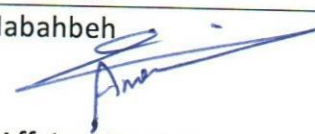
Declaration Ref No: DC21-0249

Date: 15.10.2021

Meets the essential requirements of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And

EN ISO 13485 :2016 , EN 18113-1, -2,;2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

IVD Categorization	Directive 98/79, Other IVDs (Non-annex II, non-self-test).
Conformity Assesment Route	Directive 98/79/EC , Annex III.
Name , Address and Identification number of notified body	N/A

Date of issuance:	15. October.2021
Place	Atlas Medical GmbH
Signed by:	Amani AL-Habahbeh 
Position :	Regulatory Affairs Manager

Atlas Medical GmbH
Ludwig - Erhard Ring 3
15827 Blankenfelde - Mahlow
Tel. (0049) 33708 - 355030

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, 2023 (included)

Valable jusqu'au / Expiry date : October 8th, 2026 (included)

Etabli le / Issued on : October 9th, 2023

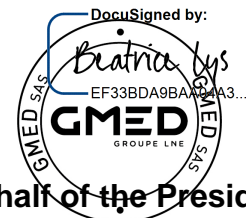


CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 36655-2

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-1



On behalf of the President
Béatrice LYS
Technical Director

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

French version :

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

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

French version:

Siège social, responsable de la mise sur le marché

English version:

Headquarter, legal manufacturer

**Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN**


French version:

Conception, fabrication et contrôle final

English version:

Design, manufacture and final control

2 sites / 2 sites

DocuSigned by:
Beatrice Lys
FF33BDA8...AA04A3...


**On behalf of the President
Béatrice LYS
Technical Director**

GRAM STAIN PACK

IVD For *in-vitro* diagnostic and professional use only

15°C  30°C
Store at Room Temperature

INTENDED USE

Gram Stain used for differentiate between gram positive and gram-negative bacteria.

INTRODUCTION

Gram staining is used to differentiate bacterial species into two large groups (Gram-positive and Gram-negative) based on the physical properties of their cell walls.

PRINCIPLE

Gram-positive bacteria have a thick mesh-like cell wall made of peptidoglycan (50-90% of cell wall), which stains Blue while gram-negative bacteria have a thinner layer (10% of cell wall), which stains pink. Gram-negative bacteria also have an additional outer membrane which contains lipids, and is separated from the cell wall by the periplasmic space. There are four basic steps of the Gram stain, which include applying a primary stain (crystal violet) to a heat-fixed smear of a bacterial culture, followed by the addition of a trapping agent (Gram's iodine), rapid decolorization with alcohol or acetone, and *counterstaining* with safranin or basic fuchsin.

Crystal violet (CV) dissociates in aqueous solutions into CV⁺ and chloride (Cl⁻) ions. These ions penetrate through the cell wall and cell membrane of both gram-positive and gram-negative cells. The CV⁺ ion interacts with negatively charged components of bacterial cells and stains the cells Blue.

Iodine (I⁻ or I₃⁻) interacts with CV⁺ and forms large complexes of crystal violet and iodine (CV-I) within the inner and outer layers of the cell. Iodine is often referred to as a mordant, but is a trapping agent that prevents the removal of the CV-I complex and therefore color from the cell.

When a decolorizer such as alcohol or acetone is added, it interacts with the lipids of the cell membrane. A gram-negative cell will lose its outer membrane and the lipopolysaccharide layer is left exposed. The

CV-I complexes are washed from the gram-negative cell along with the outer membrane. In contrast, a gram-positive cell becomes dehydrated from an ethanol treatment. The large CV-I complexes become trapped within the gram-positive cell due to the multilayered nature of its peptidoglycan. The decolorization step is critical and must be timed correctly; the crystal violet stain will be removed from both gram-positive and negative cells if the decolorizing agent is left on too long (a matter of seconds).

After decolorization, the gram-positive cell remains Blue. and the gram-negative cell loses its Blue. color. Counterstain, which is usually positively charged safranin or basic fuchsin, is applied last to give decolorized gram-negative bacteria a pink or red color.

MATERIALS

MATERIALS PROVIDED

- Crystal Violet.
- Gram Iodine.
- Gram Decolouriser.
- Counterstain – Safranin O.

Note: This package insert is also used for individually packed reagent.

Packaging Content

REF 8.17.009.0400 (1x100ml Crystal Violet, 1x100ml Iodine Solution, 1x100ml Decolouriser, 1x100ml Safranin O)

REF 8.17.008.1000 (1x250ml Crystal Violet, 1x250ml Iodine Solution, 1x250ml Decolouriser, 1x250ml Safranin O)

REF 8.17.009.1000 (1x250ml Crystal Violet, 1x250ml Iodine Solution, 1x250ml Decolouriser, 1x250ml Safranin O)

REF 8.15.032.0250 (1x250ml Crystal Violet)

REF 8.15.049.0250 (1x250ml Iodine Solution)

REF 8.15.051.0250 (1x250ml Decolouriser)

REF 8.15.125.0250 (1x250ml Safranin O)

STORAGE AND STABILITY

- Store at room temperature.
- Stain Solution is stable up to the printed expiry date.
- Keep the bottles tightly closed to prevent air oxidation.

PRECAUTIONS

- The reagent may cause eye, skin and respiratory tract irritation; so protective clothing should be worn when handling this reagent.
- The reagent is intended for *in vitro* diagnostic use only.
- Do not use this reagent if the label is not available or damaged.
- Test materials and samples should be discarded properly in biohazards container.
- This reagent is considered toxic, so do not drink or eat beside it.
- Wash hands and test table top with water and soap once the testing is done.

PROCEDURE

1. immerse the heat fixed smears with Crystal Violet and allow to stain for up to 1 minute.
2. Wash with tap water.
3. Flood the smear with Gram Iodine for 2 minutes.
4. Wash with tap water.
5. Decolorize the smear for few second only.
6. Wash thoroughly with tap water.
7. Counterstain with Safranin O for up to 2 minutes.
8. Wash and allow to dry.
9. Examine under microscope using oil immersion objective


















RESULTS

- Gram positive organisms (Blue).
- Gram negative organisms (Red).

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Website: www.atlas-medical.com

PPI2112A01

Rev C (27.03.2023)

	Catalogue Number		Temperature limit
	<i>In Vitro</i> diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
	Flammable		