



EU Declaration of Conformity

Name of Device / Product Group	Culture Media (BC, BO, CB, CM, DS, EB, LR, PB, PO, SK)
Group Description	Culture media for the growth, maintenance and/or processing of microorganisms.
Product Code / Product and Trade Name	See attached product schedule
 Legal Manufacturer	Oxoid Limited Wade Road, Basingstoke, Hampshire, RG24 8PW, UK SRN: GB-MF-000016914
 European Authorized Representative	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1 B, 1121 PC Landsmeer, NL SRN: NL-AR-000013157
Risk Class	Class A in accordance with the rules set out in Annex VIII of Regulation (EU) 2017/746 (IVDR)
Conformity Assessment Procedure Performed	Self-declared in accordance with Articles 17 and 48(10) of Regulation (EU) 2017/746 (IVDR)
Certificate(s) Issued	EN ISO 13485:2016 – MD 80930

We, as the legal manufacturer of the device(s) take sole responsibility for and hereby declare that the listed product(s) meet the provisions of the following regulation:

- Regulation (EU) 2017/746 on *in vitro* Diagnostic Medical Devices (IVDR)

Signature:  21st July 2023

Name: Paul Sherlock

Function: Regulatory Affairs

Issued in: United Kingdom

Effective Date: Refer to electronic signature



Product Schedule

The products related to MBD-BT-DOC-0021 Rev 10 - IVDR DOC Oxoid Ltd Class A (Culture Media) are listed below:

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384PeptoneWaterXG	BO0208B	PEPTONE WATER	The Peptone Water (BO0208B, BO0208E, and EB0208B) devices are media for the dilution of microorganisms isolated from clinical samples. The devices can also be supplemented with carbohydrates and indicator for identification purposes. The Peptone Water (BO0208B, BO0208E, and EB0208B) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384018185	58586	0244
	BO0208E			5032384018253		
5032384PurifiedWaterXR	BO0209M	PURIFIED WATER	Thermo Scientific™ Purified Water (BO0209M, BO0209V, BO1336E and EB0209C) devices are media for the dilution of microorganisms isolated from clinical and non-clinical samples. Can also be used as a rinse solution for sterility testing and a reconstitution fluid for freeze dried supplements. The devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384018406	58672	0487
	BO0209V			5032384056736		
5032384NutrientBrothEX	BO0210B	NUTRIENT BROTH	Nutrient Broth (CM0001B, CM0001R) and Nutrient Broth (BO0210B, BO0210E) devices are general-purpose media intended to be used for the cultivation of fastidious and non-fastidious microorganisms from clinical samples (e.g., urine and wounds). Nutrient Broth and Nutrient Broth devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384018468	58586	0197
	BO0210E			5032384018505		
5032384TryptSoyaAgarOL6B	BO0330M	TRYPTONE SOYA AGAR	Thermo Scientific™ Tryptone Soya Agar (CM0131 and BO0330) is a highly nutritious general purpose medium for the growth of fastidious and non-fastidious microorganisms from clinical samples (e.g. urine and wounds). Thermo Scientific™ Tryptone Soya Agar is recommended as a reference medium when testing selective media to measure the degree of inhibition. Tryptone Soya Agar is used in a diagnostic workflow to support the clinicians for the growth of a wide variety of fastidious and non-fastidious microorganisms from clinical samples of patients suspected of having microbial infections.	5032384018772	58685	0171
	BO0330T			5032384018796		
	BO0330V			5032384018819		
50323840.85%SalineOLVZ	BO0334E	0.85% SALINE	The 0.85% Saline Solution (BO0334, BO1176, EB0334, EB1355, EB1364) devices are used as a general purpose 0.85% isotonic saline solution intended to be used for the dilution of microorganisms and as a diluent and for preparing suspensions of microbiological samples. The 0.85% Saline Solution devices are intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various sources where a 0.85% isotonic saline solution is required.	5032384018918	58673	0098
	BO0334M			5032384018956		
	BO0334V			5032384018963		
5032384AlkPeptoneWtrVQ	BO0335E	ALKALINE PEPTONE WATER	Alkaline Peptone Water (CM1028B and BO0335E) devices are enrichment media for the isolation of Vibrio species from faecal samples. Alkaline Peptone Water devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Vibrio species infections.	5032384018987	58684	0174

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384NutrientAgarSlopeKL	BO0336B	NUTRIENT AGAR SLOPE	Nutrient Agar Slope (BO0336B, BO0336E and EB0336B) devices are non-selective media intended to be used for the maintenance of microorganisms isolated from other culture media products previously inoculated using clinical samples (e.g., urine and wound). Nutrient Agar Slope (BO0336B, BO0336E and EB0336B) devices are intended to be used in a diagnostic workflow to support the clinician for the maintenance of bacteria from clinical samples.	5032384019045	58685	0456
	BO0336E			5032384019052		
5032384UreaAgrSlope3W	BO0337B	UREA AGAR SLOPE	Urea Agar Slope (BO0337B and EB0337B) devices are non-selective media intended for use in culture media. Urea Agar Slope (BO0337B and EB0337B) devices are intended to be used to detect rapid urease activity of the Proteae and non-rapid urease activity of some Enterobacteriaceae in faecal and urine samples. The devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Enterobacteriaceae infections.	5032384019069	58585	0234
5032384UreaBrothOLNN	BO0338B	UREA BROTH	Urea Broth Base (Dehydrated) (CM0071B) and Urea Broth (BO0338B, EB0338B) are differential media used to differentiate isolates of Enterobacteriaceae from clinical samples (stool and urine samples) by urease production. Urea Broth Base (Dehydrated) (CM0071B) and Urea Broth (BO0338B, EB0338B) are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having infections caused by urease producing Enterobacteriaceae.	5032384019076	58684	0238
5032384ColChocHrsBldAgrAS	BO0341B	COL. CHOC. HORSE BLOOD AGAR SLOPE	Columbia Agar with Chocolate Horse Blood (PB0124A and BO0341B) is a highly nutritious medium for the growth of fastidious microorganisms from clinical samples (e.g., faecal, urine, genital and throat). Columbia Agar with Chocolate Horse Blood (PB0124A and BO0341B) devices are used in a clinical diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections	5032384019106	58688	0066
5032384SabDexAgarOL5Y	BO0342E	SABOURAUD DEXTROSE AGAR SLOPE	Sabouraud Dextrose Agar (CM0041B, CM0041R, CM0041T, CM0041K, BO0342E, BO0408T, BO0408M, and BO0408V) devices are acidic pH media for the isolation and maintenance of dermatophytes, other fungi and yeasts from skin, hair, nails, genital, respiratory and urine samples from patients. Sabouraud Dextrose Agar (CM0041B, CM0041R, CM0041T, CM0041K, BO0342E, BO0408T, BO0408M, and BO0408V) devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungal infections.	5032384019113	58585	0183
5032384MaxRecDilOL28	BO0348V	MAXIMUM RECOVERY DILUENT	Thermo Scientific™ Maximum Recovery Diluent (CM0733, BO0348 and EB0348) is a protective and isotonic diluent intended to be used for maximal recovery of microorganisms from clinical samples and for preparing suspensions of microbiological samples. Maximum Recovery Diluent devices are intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various samples where an isotonic diluent is required.	5032384019298	58208	0208
	BO0348Z			5032384019304		

Product Schedule

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5032384SabDexAgarOL5Y	BO0408M	SABOURAUD DEXTROSE AGAR	Sabouraud Dextrose Agar (CM0041B, CM0041R, CM0041T, CM0041K, BO0342E, BO0408T, BO0408M, and BO0408V) devices are acidic pH media for the isolation and maintenance of dermatophytes, other fungi and yeasts from skin, hair, nails, genital, respiratory and urine samples from patients. Sabouraud Dextrose Agar (CM0041B, CM0041R, CM0041T, CM0041K, BO0342E, BO0408T, BO0408M, and BO0408V) devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungal infections.	5032384020171	58585	0183
	BO0408T			5032384020218		
	BO0408V			5032384020232		
5032384SabDexChlorOLWS	BO0422F	SAB DEX AGAR + CHLORAMPHENICOL SLOPE	Sabouraud Dextrose Agar and Chloramphenicol Slope (BO0422F) is an acidic pH medium for the detection of fungi and yeasts from clinical samples (respiratory samples, sputum, BAL and tissues/fluid samples). Sabouraud Dextrose Agar and Chloramphenicol Slope (BO0422F) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungal infections.	5032384020652	58585	0167
5032384TSBNovobiocinV9	BO0869S	MODIFIED T.S.B. + NOVOBIOCIN	Tryptone Soya Broth with Novobiocin (BO0869S) is a selective medium intended for use in culture media. Tryptone Soya Broth with Novobiocin (BO0869S) is intended to be used for the selective enrichment of Escherichia coli O157 from faecal samples. Tryptone Soya Broth with Novobiocin (BO0869S) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having E. coli O157 infections.	5032384082513	58684	0192
50323840.85%SalineOLVZ	BO1176B	0.85% SALINE	The 0.85% Saline Solution (BO0334, BO1176, EB0334, EB1355, EB1364) devices are used as a general purpose 0.85% isotonic saline solution intended to be used for the dilution of microorganisms and as a diluent and for preparing suspensions of microbiological samples. The 0.85% Saline Solution devices are intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various sources where a 0.85% isotonic saline solution is required.	5032384178889	58673	0098
5032384BHIBrothOLL3	BO1230D	BRAIN HEART INFUSION	Heart Infusion Broth (CM1032B), Brain Heart Infusion Broth (CM1135B, CM1135R, CM1135T, CM1135K and EB1230E), Brain Heart Infusion (BO1230D and BO1230M) and B.H.I. Broth with Horse Serum (BO1340E) devices are highly nutritious, general purpose media for the growth of fastidious microorganisms from clinical samples (e.g. wounds, genital swabs). Heart Infusion Broth (CM1032B), Brain Heart Infusion Broth (CM1135B, CM1135R, CM1135T, CM1135K and EB1230E), Brain Heart Infusion (BO1230D and BO1230M) and B.H.I. Broth with Horse Serum (BO1340E) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384229895	58684	0181
	BO1230M			5032384229864		

Product Schedule

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5032384NutrientBrothEX	BO1285C	NUTRIENT BROTH + GLASS BEADS	<p>The Thermo Scientific™ Nutrient Broth + Glass Beads (BO1285C) is a bottled, nutritious, general purpose medium intended to be used for the cultivation of fastidious and non-fastidious microorganisms from clinical samples (e.g. urine and wounds). The addition of glass beads allows for the homogenization of the microbiological sample.</p> <p>Nutrient Broth + Glass Beads (BO1285C) and Nutrient Broth No. 2 (CM0067B) are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.</p>	5032384447022	43674	0492
5032384SalineGlassBeadsR3	BO1286B	SALINE + GLASS BEADS	<p>Saline + Glass Beads (BO1286B) is a general purpose isotonic saline solution intended to be used for the dilution of microorganisms and as a diluent and for preparing suspensions of microbiological samples. The addition of glass beads allows for the homogenisation of the microbiological sample. Saline + Glass Beads (BO1286B) is intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various sources where an isotonic saline solution with glass beads is required.</p>	5032384447176	58673	0500
5032384PurifiedWaterXR	BO1336E	PURIFIED WATER	<p>Thermo Scientific™ Purified Water (BO0209M, BO0209V, BO1336E and EB0209C) devices are media for the dilution of microorganisms isolated from clinical and non-clinical samples. Can also be used as a rinse solution for sterility testing and a reconstitution fluid for freeze dried supplements. The devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.</p>	5032384511860	58672	0487
5032384GBSEnrichBrothEJ	BO1338E	GROUP B STREP SELECTIVE ENRICHMENT BROTH	<p>Thermo Scientific™ Group B Strep Selective Enrichment Broth (BO1338E) is a medium for the selective enrichment of β-haemolytic group B-streptococci from vaginal and rectal samples. Group B Strep Selective Enrichment Broth (BO1338E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.</p>	5032384511921	58684	0480
5032384BHIBrothOLL3	BO1340E	B.H.I BROTH + HORSE SERUM	<p>Heart Infusion Broth (CM1032B), Brain Heart Infusion Broth (CM1135B, CM1135R, CM1135T, CM1135K and EB1230E), Brain Heart Infusion (BO1230D and BO1230M) and B.H.I. Broth with Horse Serum (BO1340E) devices are highly nutritious, general purpose media for the growth of fastidious microorganisms from clinical samples (e.g. wounds, genital swabs). Heart Infusion Broth (CM1032B), Brain Heart Infusion Broth (CM1135B, CM1135R, CM1135T, CM1135K and EB1230E), Brain Heart Infusion (BO1230D and BO1230M) and B.H.I. Broth with Horse Serum (BO1340E) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.</p>	5032384511891	58687	0181

Product Schedule

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5032384ManSaltAgrOLLL	CB0085G	MANNITOL SALT AGAR	Mannitol Salt Agar (CM0085B, CM0085K, CM0085R, CM0085T, CM0085W, CB0085G and PO0151A) devices are selective media for the isolation of pathogenic staphylococci from clinical samples, including wound, faecal and respiratory tract samples. Mannitol Salt Agar devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having staphylococcal infections.	5032384134809	58585	0202

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384NutrientBrothEX	CM0001B	NUTRIENT BROTH	Nutrient Broth (CM0001B, CM0001R) and Nutrient Broth (BO0210B, BO0210E) devices are general-purpose media intended to be used for the cultivation of fastidious and non-fastidious microorganisms from clinical samples (e.g., urine and wounds). Nutrient Broth and Nutrient Broth devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384000975	58585	0197
	CM0001R			5032384282623		
5032384NutrientAgarA7	CM0003B	NUTRIENT AGAR	Thermo Scientific™ Nutrient Agar (CM0003B, CM0003T and CM0003R) devices are a general purpose non-selective medium for the cultivation and maintenance of microorganisms isolated from clinical samples (e.g. urine and wounds), which may be supplemented with blood to facilitate the growth of more fastidious bacteria. Nutrient Agar (CM0003B, CM0003T and CM0003R) devices are intended to be used in a diagnostic workflow to support the clinician for the cultivation and maintenance of bacteria from clinical samples.	5032384001002	58585	0177
	CM0003R			5032384153961		
	CM0003T			5032384001026		
5032384MacConkeyAgrOL3C	CM0007B	MACCONKEY AGAR	MacConkey Agar (CM0007, PO0149A and PB1262E) devices are differential media for the isolation and differentiation of lactose and non-lactose fermenting coliforms and intestinal bacteria pathogens from a wide range of clinical samples direct from the patient, such as urine and faeces, or indirectly from swabs taken from wounds or infections. MacConkey Agar (CM0007, PO0149A and PB1262E) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384001040	58585	0216
	CM0007R			5032384001057		
	CM0007T			5032384001064		
5032384PeptoneWaterXG	CM0009B	PEPTONE WATER	Peptone water (CM0009B) is a medium for the dilution of microorganisms isolated from clinical and non-clinical samples. Can also be supplemented with carbohydrates and indicator for identification purposes. The device is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384001071	58585	0244

Product Schedule

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5032384KingleIronAgrOL7E	CM0033B	KLIGLER IRON AGAR	Thermo Scientific™ Kligler Iron Agar (CM0033B) is differential medium for the identification of Enterobacteriaceae species from clinical samples (e.g. stool and urine) based on dextrose and lactose fermentation as well as hydrogen sulphide production. Thermo Scientific™ Kligler Iron Agar (CM0033B) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384001224	58585	0260
5032384SabDexAgarOL5Y	CM0041B	SABOURAUD DEXTROSE AGAR	Sabouraud Dextrose Agar (CM0041B, CM0041R, CM0041T, CM0041K, BO0342E, BO0408T, BO0408M, and BO0408V) devices are acidic pH media for the isolation and maintenance of dermatophytes, other fungi and yeasts from skin, hair, nails, genital, respiratory and urine samples from patients. Sabouraud Dextrose Agar (CM0041B, CM0041R, CM0041T, CM0041K, BO0342E, BO0408T, BO0408M, and BO0408V) devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungal infections.	5032384001262	58585	0183
	CM0041K			5032384062225		
	CM0041R			5032384001279		
	CM0041T			5032384001286		
5032384UreaAgrSlope3W	CM0053B	UREA AGAR BASE	Urea Agar Base (CM0053B) is a non-selective medium intended for use in culture media. Urea Agar Base (CM0053B), when supplemented with Urea 40% Solution (SR0020K) for the preparation of Christensen's medium, is intended to be used to detect rapid urease activity of the Proteae and non-rapid urease activity of some Enterobacteriaceae in faecal and urine samples. The device is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Enterobacteriaceae infections.	5032384001309	58585	0234
5032384BloodAgrBaseMW	CM0055B	BLOOD AGAR BASE	Thermo Scientific™ Oxoid™ Blood Agar Base (CM0055B and CM0055T) devices are a nonselective, general-purpose medium intended to be used with the addition of blood for the isolation and culture of pathogenic and non-pathogenic microorganisms from clinical samples (e.g., cerebrospinal fluid (CSF), pus and wound swabs, sputum, eye swabs and ear, nose and throat swabs). Blood Agar Base (CM0055B and CM0055T) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having a microbial infection.	5032384001316	58685	0205
	CM0055T			5032384001323		
5032384NutrientBrothEX	CM0067B	NUTRIENT BROTH	Thermo Scientific™ Nutrient Broth No. 2 (CM0067B) is a nutritious, general-purpose medium intended to be used for the cultivation of fastidious and non-fastidious microorganisms from clinical samples (e.g. urine and wounds). Nutrient Broth + Glass Beads (BO1285C) and Nutrient Broth No. 2 (CM0067B) are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384001385	58585	0492

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384EMBAgarOLHX	CM0069B	EOSIN METHYLENE BLUE AGAR	Eosin Methylene Blue Agar (CM0069B) is a versatile medium which is used for the differentiation of Escherichia coli and Enterobacter aerogenes, for the identification of Candida albicans, and for the identification of coagulase-positive staphylococci from faecal samples. Eosin methylene Blue Agar is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having a microbial infection.	5032384001408	58585	0221
5032384UreaBrothOLNN	CM0071B	UREA BROTH BASE	Urea Broth Base (Dehydrated) (CM0071B) and Urea Broth (BO0338B, EB0338B) are differential media used to differentiate isolates of Enterobacteriaceae from clinical samples (stool and urine samples) by urease production. Urea Broth Base (Dehydrated) (CM0071B) and Urea Broth (BO0338B, EB0338B) are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having infections caused by urease producing Enterobacteriaceae.	5032384001422	58684	0238
5032384HoyleAgrFQ	CM0083B	HOYLE MEDIUM BASE	Hoyle Medium Base (Dehydrated) (CM0083B) when supplemented with Laked Horse Blood (SR0048C) and Potassium Tellurite 3.5% solution (SR0030J), is a selective media intended for the isolation and differentiation of Corynebacterium diphtheriae types from wound and upper respiratory samples, including throat and nasal swabs.	5032384001491	58585	0201
5032384ManSaltAgrOLLL	CM0085B	MANNITOL SALT AGAR	Mannitol Salt Agar (CM0085B, CM0085K, CM0085R, CM0085T, CM0085W and PO0151A) devices are selective media for the isolation of pathogenic staphylococci from clinical samples, including wound, faecal and respiratory tract samples. Mannitol Salt Agar devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having staphylococcal infections.	5032384001507	58585	0202
	CM0085K			5032384058419		
	CM0085R			5032384001514		
	CM0085T			5032384001521		
	CM0085W			5032384510641		
5032384S.S.AgarOLN2	CM0099B	S S AGAR	SS Agar (CM0099) devices are a differential selective medium for the isolation of Salmonella and some Shigella species from faecal samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Salmonella and Shigella infections.	5032384001569	58585	0209
	CM0099K			5032384125227		

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384MacConkey3OLAJ	CM0115B	MAC-CONKEY AGAR NO 3	The MacConkey Agar No. 3 (CM0115B, CM0115R, CM0115T, CM0115K, CM0115Q, CM0115V, CM0115W and PO0495A) devices are selective media the differentiation between lactose and non-lactose fermenters with the inhibition of Gram-positive cocci from clinical samples(e.g. faecal, blood, bile, pus, skin, mouth, etc.).The MacConkey Agar No. 3 (CM0115B, CM0115R, CM0115T, CM0115K, CM0115Q, CM0115V, CM0115W and PO0495A) devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384001668	58585	0158
	CM0115K			5032384001675		
	CM0115Q			5032384133369		
	CM0115T			5032384001699		
	CM0115V			5032384305353		
	CM0115W			5032384510658		
5032384CharcoalAgarR7	CM0119B	CHARCOAL AGAR	Charcoal Agar Base (CM0119B) device is non-selective general-purpose dehydrated culture medium for the cultivation and isolation of fastidious organisms especially Bordetella pertussis, Bordetella parapertussis and Haemophilus influenzae from nasopharyngeal/pernasal samples and for subcultures. Charcoal Agar device is used in a diagnostic workflow to aid clinicians in determining potential treatment option for patients suspected of having bacterial infections.	5032384001705	58585	0112
5032384TryptSoyaBrothOL8J	CM0129B	TRYPTONE SOYA BROTH	Tryptone Soya Broth (CM0129B, CM0129K, CM0129R, CM0129T, CM0129V and EB0351W) devices are highly nutritious, general purpose media for the growth of fastidious and non-fastidious microorganisms from a range of clinical samples. The devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having microbial infections.	5032384001729	58687	0155
	CM0129K			5032384001743		
	CM0129R			5032384001750		
	CM0129T			5032384001767		
	CM0129V			5032384305360		
5032384TryptSoyaAgarOL6B	CM0131B	TRYPTONE SOYA AGAR	Thermo Scientific™ Tryptone Soya Agar (CM0131 and BO0330) is a highly nutritious general purpose medium for the growth of fastidious and non-fastidious microorganisms from clinical samples (e.g. urine and wounds). Thermo Scientific™ Tryptone Soya Agar is recommended as a reference medium when testing selective media to measure the degree of inhibition. Tryptone Soya Agar is used in a diagnostic workflow to support the clinicians for the growth of a wide variety of fastidious and non-fastidious microorganisms from clinical samples of patients suspected of having microbial infections.	5032384001774	58685	0171
	CM0131K			5032384058433		
	CM0131Q			5032384133376		
	CM0131R			5032384001781		
	CM0131T			5032384001798		
	CM0131V			5032384305377		
	CM0131W			5032384510665		

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384ClostridialAgarF8	CM0149B	REINFORCED CLOSTRIDIAL MEDIUM	Reinforced Clostridial Medium (CM0149B, CM0149T) is a semi-solid medium intended for use in culture media. Reinforced Clostridial Medium (CM0149B, CM0149T) is intended to be used for the cultivation of Clostridium species and other anaerobes from clinical samples (e.g., faeces, blood, and wounds). Reinforced Clostridial Medium (CM0149B, CM0149T) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having anaerobic bacterial infections.	5032384001866	58585	0229
	CM0149T			5032384279999		
5032384ClostridialAgarF8	CM0151B	REINFORCED CLOSTRIDIAL AGAR	Reinforced Clostridial Agar (CM0151B) is a solid medium intended for use in culture media. Reinforced Clostridial Agar (CM0151B) is intended to be used for the cultivation of Clostridium species and other anaerobes from clinical samples (e.g., faeces, blood, and wounds). Reinforced Clostridial Agar (CM0151B) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having anaerobic bacterial infections.	5032384001873	58585	0229
5032384GlucoseBouillon6P	CM0175B	GLUCOSE BROTH	Glucose Broth (CM0175) is a highly nutritious general-purpose medium for the growth of fastidious and non-fastidious microorganisms from clinical samples (e.g., ear, nasal, throat, skin, pus, bile, genital, urine, etc.). Glucose Broth (CM0175) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384001965	58585	0508
5032384ToddHewittBrothM2	CM0189B	TODD-HEWITT BROTH	Thermo Scientific™ Todd-Hewitt Broth (CM0189B) is a medium for the cultivation of streptococci. Todd-Hewitt Broth (CM0189B) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Streptococcal infections.	5032384001972	58585	0243
5032384BismuthSulAgrNK	CM0201B	BISMUTH SULPHITE AGAR (MOD)	Bismuth Sulphite Agar (Modified) (CM0201B) is a selective medium intended to be used for the isolation and preliminary identification of Salmonella Typhi and other salmonellae from faecal samples. Bismuth Sulphite Agar (Modified) (CM0201B) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having salmonellosis.	5032384002016	58585	0256
5032384DCAAgrOLAR	CM0227B	DESOXYCHOLATE CITRATE AGAR	Desoxycholate Citrate Agar (Hynes) (CM0227) is a differential medium for the isolation of Salmonella and Shigella species from faecal samples. Desoxycholate Citrate Agar (Hynes) (PO0126) is a differential medium for the isolation of Salmonella and Shigella species from faecal samples. These devices are intended for in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having enteric infections.	5032384002092	58585	0227

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384TryptBloodAgrCV	CM0233B	TRYPTOSE BLOOD AGAR BASE	Tryptose Blood Agar Base (CM0233B and CM0233T) devices are highly nutritious media which, when supplemented with blood, support the growth of fastidious organisms from clinical samples (e.g. mouth, nasal, and genital swabs). The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384002115	58688	0258
	CM0233T			5032384002122		
5032384BloodAgrBase2BD	CM0271B	BLOOD AGAR BASE NO 2	Blood Agar Base No. 2 (Dehydrated) (CM0271B, CM0271K, CM0271R and CM0271T) devices are nonselective, general-purpose media which may be enriched with blood or supplements for the isolation and cultivation of fastidious pathogens and other microorganisms with clearly visible haemolysis from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). Blood Agar Base No. 2 (Dehydrated) (CM0271B, CM0271K, CM0271R and CM0271T) devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384002214	58685	0172
	CM0271K			5032384002221		
	CM0271R			5032384002238		
	CM0271T			5032384002245		
5032384TripSugIrnOLV6	CM0277B	TRIPLE SUGAR IRON AGAR	Triple Sugar Iron Agar (CM0277B) is a medium used for the differentiation of Enterobacteriaceae from clinical samples such as faecal, pus and exudates, by carbohydrate fermentations and hydrogen sulphide production. The device is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384002290	58585	0241
5032384CLEVOLKP	CM0301B	C L E D MEDIUM	C.L.E.D. Medium (Dehydrated) (CM0301B, CM0301R, CM0301T, CM0301W and CM0301K) is a differential medium for the isolation and enumeration of the common microorganisms causing urinary tract infections from urine samples. C.L.E.D. Medium (Dehydrated) (CM0301B, CM0301R, CM0301T, CM0301W and CM0301K) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having urinary tract infections.	5032384002344	58585	0179
	CM0301K			5032384002351		
	CM0301R			5032384002368		
	CM0301T			5032384002375		
	CM0301V			5032384305384		
	CM0301W			5032384510689		
5032384DNASEAgarAA	CM0321B	DNASE AGAR	DNASE Agar (CM0321B) is a medium used for the differentiation of microorganisms from clinical samples based on deoxyribonuclease activity, particularly Staphylococcus species.	5032384002443	58585	0251

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384BrillGreenAgrOLWG	CM0329B	BRILLIANT GREEN AGAR MODIFIED	Brilliant Green Agar (Modified) (PO0171A, CM0329B, CM0329R, CM0329T and CM0329K) devices are a selective and diagnostic agar for Salmonellae other than Salmonella typhi or Salmonella paratyphi A for clinical samples such as faecal samples. Brilliant Green Agar (Modified) (PO0171A, CM0329B, CM0329R, CM0329T and CM0329K) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Salmonellae infections.	5032384002511	58585	0204
	CM0329R			5032384002528		
	CM0329T			5032384002535		
5032384ColumbiaBldAgrOLNP	CM0331B	COLUMBIA BLOOD AGAR BASE	Columbia Blood Agar Base (CM0331) devices are nonselective, general-purpose medium which may be enriched with blood or supplements intended for the isolation and culture of fastidious microorganisms from clinical samples (e.g., wounds, throat, genital, nose, skin, etc.). Columbia Blood Agar Base devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384002542	58685	0149
	CM0331K			5032384002559		
	CM0331R			5032384002566		
	CM0331T			5032384002573		
	CM0331W			5032384510696		
	CM0331Y			5032384510825		
5032384TCBSCholeraMedVG	CM0333B	T.C.B.S CHOLERA MEDIUM	T.C.B.S. Cholera Medium (CM0333B, CM0333T) devices are selective isolation media for the isolation of Vibrio species from faecal and clinical samples where Vibrio species are suspected to be the cause of infection. T.C.B.S. Cholera Medium (PO0194A) and T.C.B.S. Cholera Medium (CM0333B, CM0333T) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Vibrio species infections.	5032384002580	62706	0222
	CM0333T			5032384002603	62706	
5032384MuellerHintonOL97	CM0337B	MUELLER HINTON AGAR	Mueller Hinton Agar (CM0337) devices are antimicrobial susceptibility testing agars recommended for disc diffusion and also recommended for agar dilution MIC testing. Mueller Hinton Agar (CM0337) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384002610	58639	0477
	CM0337K			5032384002627		
	CM0337R			5032384002634		
	CM0337T			5032384002641		
	CM0337W			5032384510702		

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
8488380MRSAgrOL4V	CM0361B	MRS AGAR	M.R.S. Agar (CM0361B, CM0361R and CM0361T) is a medium for the growth of Lactobacillus species from oral, vaginal and faecal samples. M.R.S. Agar (CM0361B, CM0361R and CM0361T) are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384002733	58585	0189
	CM0361R			5032384068715		
	CM0361T			5032384132157		
5032384SeleniteBrothOLYJ	CM0395B	SELENITE BROTH BASE	Selenite Broth Base (CM0395B) is an enriched medium for the isolation of Salmonella species from faecal and urine samples. Selenite Broth Base is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384002863	58684	0081
5032384MycoplAsAgarOL5S	CM0401B	MYCOPLASMA AGAR BASE	Mycoplasma Broth Base (CM0403B/T) and Mycoplasma Agar Base (CM0401B) are basic media, which when supplemented, supports the growth of Mycoplasma and Ureaplasma species from genital and respiratory samples.	5032384002887	58585	0186
5032384MycoplAsAgarOL5S	CM0403B	MYCOPLASMA BROTH BASE	Mycoplasma Broth Base (CM0403B/T) and Mycoplasma Agar Base (CM0401B) are basic media, which when supplemented, supports the growth of Mycoplasma and Ureaplasma species from genital and respiratory samples.	5032384002894	58684	0186
	CM0403T			5032384155712		
5032384MuellerHintonOL97	CM0405B	MUELLER HINTON BROTH	Mueller Hinton Broth (CM0405) devices are antimicrobial susceptibility testing broths recommended for Minimum Inhibitory Concentration (MIC) testing. Mueller Hinton Broth devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384002900	58641	0477
5032384HektoenEntAgrOLFL	CM0419B	HEKTOEN ENTERIC AGAR	Hektoen Enteric Agar (CM0419) is a differential medium for the isolation of Shigella and Salmonella species from faecal samples.	5032384002955	58585	0200
	CM0419K			5032384039418		
	CM0419R			5032384032730		
	CM0419W			5032384510726		
5032384CLEDrades7T	CM0423B	CLED MEDIUM WITH ANDRADE INDICATOR	CLED Medium with Andrade's Indicator (CM0423, CM1051 and PO0121) devices are differential media for the isolation and enumeration of the common microorganisms causing urinary tract infections from clinical samples such as urine samples. CLED Medium with Andrade's Indicator devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having urinary tract infections.	5032384002986	58585	0176

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384SchaedlerAgarOLYM	CM0437B	SCHAEDLER AGAR	Schaedler Anaerobe Agar (CM0437) is a medium for the growth of aerobic and anaerobic microorganisms from faecal samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384003044	58685	0184
	CM0437V			5032384305438		
5032384XLDMediumOL7Q	CM0469B	XLD MEDIUM	The XLD Agar (CM0469, PO0931 and PO0164) devices are selective media for the isolation of Salmonella and Shigella species from faecal samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Salmonella and Shigella bacterial infections.	5032384003129	58585	0163
	CM0469R			5032384003136		
	CM0469T			5032384003143		
	CM0469W			5032384510733		
5032384SchaedlerBrothOLRS	CM0497B	SCHAEDLER BROTH	Schaedler Anaerobe Broth (CM0497) is a medium for the general growth of anaerobic microorganisms from clinical samples (e.g., wound, and respiratory samples). Schaedler Anaerobe Broth is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384003297	58684	0240
5032384MacConkNoSaltOLXF	CM0507B	MACCONKEY AGAR (WITHOUT SALT)	MacConkey Agar without Salt (CM0507, PO0148A and PO0165E) devices are differential media for the isolation of Gram-negative organisms whilst suppressing the swarming of Proteus species from clinical samples, including urine samples. MacConkey Agar without Salt (CM0507, PO0148A and PO0165E) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections including urinary tract infections (UTIs).	5032384003327	58585	0195
	CM0507K			5032384003334		
	CM0507R			5032384003341		
	CM0507W			5032384510740		
5032384CaryBlairMediumTX	CM0519B	CARY-BLAIR MEDIUM	Cary-Blair Medium (CM0519B) is a transport medium that can be used for clinical samples (e.g. faecal samples and rectal swabs) suspected of containing enteric pathogens. Cary-Blair Medium (CM0519B) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384003402	58564	0261
5032384DrigalskLacAgrOLJJ	CM0531B	DRIGALSKI LACTOSE AGAR	Drigalski Lactose Agar (CM0531B) is a selective differential medium for the isolation and differentiation of lactose and non-lactose fermenting bacteria, as well as isolation of Gram-negative bacteria from urine, faecal samples or wound samples. Drigalski Lactose Agar (CM0531B) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384003426	58585	0245

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384S.S.AgarModifiedVU	CM0533B	S S AGAR (MODIFIED)	SS Agar (Modified) (CM0533) devices are a differential selective medium for the isolation of Salmonella and Shigella species from faecal samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Salmonella and Shigella infections.	5032384003433	58585	0209
5032384DermaselAgrOLUS	CM0539B	DERMASEL AGAR BASE	Dermasel Agar Base (Dehydrated) (CM0539B) when supplemented with Dermasel Selective Supplement (SR0075E) is a selective medium intended to be used for the isolation and identification of dermatophytes and other fungi from samples such as hair, skin scrapings and nails. Dermasel Agar Base (Dehydrated) (CM0539B) when supplemented with Dermasel Selective Supplement (SR0075E) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having infections caused by dermatophytes and other fungi. The device is for professional use only, is not automated and nor is it a companion diagnostic.	5032384003457	58585	0254
5032384PseudoAgarBseDH	CM0559B	PSEUDOMONAS AGAR BASE	Pseudomonas Agar Base (Dehydrated) (CM0559B, CM0559R, CM0559T), when supplemented with C-N Supplement (SR0102E) or C-F-C Supplement (SR0103E), is a selective medium for the isolation of Pseudomonas spp. from a wide range of clinical samples including urine, wound swabs, and sputum. When supplemented with Pseudomonas C-N Supplement (SR0102E) it is recommended for the selective isolation of Pseudomonas aeruginosa and when supplemented with Pseudomonas C-F-C Supplement (SR0103E) it is recommended for the selective isolation of Pseudomonas spp. generally. Pseudomonas Agar Base with C-N Supplement or C-F-C Supplement added, is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Pseudomonas infections.	5032384003549	58585	0175
	CM0559R			5032384085224		
	CM0559T			5032384282647		
5032384PEMBAAgrOLXM	CM0617B	PEMBA AGAR	Thermo Fisher™ Oxoid™ Bacillus cereus Selective Agar Base (PEMBA) (CM0617) is a selective medium intended for use in culture media. Bacillus cereus Selective Agar Base (PEMBA) is intended to be used for the isolation of Bacillus cereus from faecal samples. Bacillus cereus Selective Agar Base (PEMBA) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having infections caused by Bacillus cereus.	5032384003662	58685	0178
	CM0617R			5032384085217		
	CM0617T			5032384116744		
5032384WilkinsChalgAgr5U	CM0619B	WILKINS CHALGREN ANAEROBE AGAR	Wilkins-Chalgren Anaerobe Agar (CM0619) devices are media for the growth of anaerobic microorganisms from clinical samples, such as soft tissue and skin.	5032384003679	62706	0224
	CM0619W			5032384510757		

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384WilkinsChalgBrthS6	CM0643B	WILKINS CHALGREN ANAEROBE BROTH	Wilkins Chalgren Anaerobe Broth (CM0643) is media for the growth of anaerobic microorganisms from clinical samples (including prosthetic joint aspirate, peri-prosthetic biopsy, intra-operative specimens (debridement and retention or revision surgery), prostheses). This device is intended for use in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384003730	58585	0249
5032384YersiniaAgarOLY9	CM0653B	YERSINIA SELECTIVE AGAR BASE	Yersinia Selective Agar Base (Dehydrated) (CM0653), when supplemented with Yersinia Selective Supplement (SR0109), is a selective medium for the isolation of Yersinia enterocolitica from faecal samples. Yersinia Selective Agar Bases (Dehydrated), with Yersinia Selective Supplement added, is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having yersiniosis.	5032384003761	62082	0196
	CM0653T			5032384003778		
5032384CampySelectAgarAW	CM0689B	CAMPYLOBACTER AGAR BASE	Campylobacter Selective Agar (Skirrow) (PB0118A) is a selective medium for the isolation of Campylobacter species from faecal samples. Campylobacter Agar Base (CM0689B) is a selective medium which when supplemented, is used for the isolation of Campylobacter species from faecal samples. These devices are used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	5032384003877	58585	0217
5032384SeleniteBrothOLYJ	CM0699B	SELENITE CYST.BROTH BASE	The Selenite Cystine Broth Base (CM0699B) and Selenite Cystine Broth (EB1322E) devices are a selective enrichment media for the isolation of Salmonella species from clinical faecal and urine samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having salmonellosis.	5032384003914	58684	0236
5032384MaxRecDilOL28	CM0733B	MAXIMUM RECOVERY DILUENT	Thermo Scientific™ Maximum Recovery Diluent (CM0733, B00348 and EB0348) is a protective and isotonic diluent intended to be used for maximal recovery of microorganisms from clinical samples and for preparing suspensions of microbiological samples. Maximum Recovery Diluent devices are intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various samples where an isotonic diluent is required.	5032384003976	58586	0208
	CM0733R			5032384003983		
	CM0733T			5032384058037		
5032384CCDASelMedOLP	CM0739B	BLOOD FREE CAMPY SELECT AGAR	Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated) (CM0739B, CM0739R and CM0739T) when supplemented with CCDA Selective Supplement (SR0155E or SR0155H), is a blood-free selective medium intended for the isolation of Campylobacter species from faecal samples. Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated), with CCDA Selective Supplement added, is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having campylobacteriosis.	5032384003990	58688	0170
	CM0739R			5032384035755		
	CM0739T			5032384004003		
	CM0739V			5032384305506		

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384MLCBAgarOL65	CM0783B	MLCB AGAR	Thermo Scientific™ MLCB Agar (CM0783B) is a selective medium for the isolation of Salmonella species (not Salmonella Typhi or Salmonella Paratyphi A) from faecal samples. MLCB Agar (CM0783B) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Salmonella infections.	5032384004041	58585	0250
5032384SorbMacConkOLSY	CM0813B	SORBITOL MACCONKEY AGAR	Sorbitol MacConkey Agar (PO0232A) and Sorbitol MacConkey Agar (CM0813B, CM0813R) are selective and differential media for the detection of Escherichia coli O157 in faecal and urine samples. These devices are intended for in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having enteric infections.	5032384004072	58585	0193
	CM0813R			5032384067039		
5032384SheepBldAgr2Q5	CM0854B	SHEEP BLOOD AGAR NO 2	Sheep Blood Agar Base (CM0854B) is a nonselective medium for the isolation and cultivation of fastidious pathogens and other microorganisms with clearly visible haemolysis from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). Sheep Blood Agar Base (CM0854B) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384004195	58685	0210
5032384BileAesculinAgrHQ	CM0888B	BILE AESCULIN AGAR	Bile Aesculin Agar (PO0169, CM0888) devices are differential media for the isolation and presumptive identification of enterococci and Group D streptococci from clinical samples. Bile Aesculin Agar devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384004409	58585	0226
	CM0888K			5032384035731		
5032384HaemophTestMedOLVH	CM0898B	HAEMOPHILUS TESTING MEDIUM	Haemophilus Test Medium (HTM) Base (CM0898) is a medium formulated for the susceptibility testing of Haemophilus species isolated from clinical samples. The device is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Haemophilus infections.	5032384004454	58611	0237
5032384KimmigAgarOLZN	CM0911B	FUNGAL (KIMMIG) AGAR	Fungal Agar (Kimmig) (CM0911B) is an acidic pH medium intended to be used with the addition of 5 mL/L of glycerol for the isolation and identification of fungi and yeasts from skin, hair, nails, genital, respiratory and urine samples from patients. Fungal Agar (Kimmig) (CM0911B) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungi and yeast infections.	5032384004492	58585	0259

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384KarmaliAgr8J	CM0935B	KARMALI AGAR BASE	Campylobacter Karmali Agar Base (CM0935B), when supplemented with Karmali Campylobacter Selective Supplement (SR0167E) and Modified Karmali Selective Supplement (SR0205E) devices, is a selective medium for the isolation of Campylobacter species from faecal samples. Campylobacter Karmali Agar Base (CM0935B), with Karmali Campylobacter Selective Supplement (SR0167E) and Modified Karmali Selective Supplement (SR0205E) devices added, is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Campylobacter infections.	5032384004645	58585	0211
5032384BrillianceUTIOLBF	CM0949C	BRILLIANCE UTI AGAR	Brilliance™ UTI Agar (CM0949C and CM0949T) devices are differential media for the isolation and presumptive differentiation of the common microorganisms causing urinary tract infections (UTIs) from clinical samples, including urine samples. Brilliance™ UTI Agar (CM0949C and CM0949T) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having UTIs.	5032384496440	58585	0206
	CM0949T			5032384035618		
5032384AnaeroBasAgrK6	CM0972B	ANAEROBE BASAL AGAR	Anaerobe Basal Agar (CM0972B) is a nutritious medium for the growth of anaerobic microorganisms from clinical samples (faecal samples, oral infections, wounds, urine, ulcers, abscesses, bronchial secretions, vaginal discharges, ovarian and peritoneal abscesses). This device is intended for use in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384042111	58688	0180
5032384SorbMacConBCIGBC	CM0981B	SORBITOL MACCONKEY AGAR WITH BCIG	Sorbitol MacConkey Agar (SMAC) with BCIG (CM0981B) is a selective and differential medium intended for use in culture media. The device is intended to be used for the detection of Escherichia coli O157:H7 in clinical faecal and urine samples. Sorbitol MacConkey Agar (SMAC) with BCIG (CM0981B) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Escherichia coli O157:H7 infections.	5032384050826	58585	0230
5032384ModTryptSoyBroth3T	CM0989B	MODIFIED TRYPTONE SOYA BROTH	Modified Tryptone Soya Broth (CM0989B and CM0989G) is a selective medium intended for use in culture media. Modified Tryptone Soya Broth (CM0989B and CM0989G), when supplemented with Novobiocin Selective Supplement (SR0181E), is intended to be used for the selective enrichment of Escherichia coli O157 from faecal samples. Modified Tryptone Soya Broth (CM0989B and CM0989G), with Novobiocin Selective Supplement (SR0181E) added, is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having E. coli O157 infections.	5032384079827	58687	0192
5032384BurkCepAgarAW	CM0995B	BURKHOLDERIA CEPACIA AGAR BASE	A selective medium for the isolation of Burkholderia cepacia from respiratory samples. Can also be used for testing non-sterile inorganic salt solutions with preservative. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Burkholderia cepacia infections.	5032384068333	58585	0228

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384SalmonelChromAgrM8	CM1007B	SALMONELLA CHROMOGENIC AGAR BASE	Salmonella Chromogenic Agar Base (CM1007) is a selective and differential chromogenic medium for the presumptive identification of Salmonella species from faecal samples.	5032384090716	58585	0219
5032384AlkPeptoneWtrVQ	CM1028B	ALKALINE PEPTONE WATER	Alkaline Peptone Water (CM1028B and BO0335E) devices are enrichment media for the isolation of Vibrio species from faecal samples. Alkaline Peptone Water devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Vibrio species infections.	5032384109913	58684	0174
5032384BHIBrothOLL3	CM1032B	HEART INFUSION BROTH	Heart Infusion Broth (CM1032B), Brain Heart Infusion Broth (CM1135B, CM1135R, CM1135T, CM1135K and EB1230E), Brain Heart Infusion (BO1230D and BO1230M) and B.H.I. Broth with Horse Serum (BO1340E) devices are highly nutritious, general purpose media for the growth of fastidious microorganisms from clinical samples (e.g. wounds, genital swabs). Heart Infusion Broth (CM1032B), Brain Heart Infusion Broth (CM1135B, CM1135R, CM1135T, CM1135K and EB1230E), Brain Heart Infusion (BO1230D and BO1230M) and B.H.I. Broth with Horse Serum (BO1340E) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384123933	58687	0181
5032384CLEDrAndrades7T	CM1051T	CLED WITH ANDRADES	CLED Medium with Andrade's Indicator (CM0423B, CM0423R, CM0423K, CM1051T and PO0121A) devices are differential media for the isolation and enumeration of the common microorganisms causing urinary tract infections from clinical samples such as urine samples. CLED Medium with Andrade's Indicator (CM0423B, CM0423R, CM0423K, CM1051T and PO0121A) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having urinary tract infections.	5032384126262	58585	0176
5032384XLT4AgarAH	CM1061B	XLT-4 AGAR	The formulation of XLT-4 Agar Base (CM1061) includes proteose peptone and yeast extract which provide a source of amino nitrogen, along with essential nutrients and vitamins; this ensures optimal growth of salmonellae. The identification Salmonella species is determined by the fermentation of xylose, lactose and sucrose along with the decarboxylation of L-lysine and the production of hydrogen sulphide. Phenol red is the pH indicator and agar is the solidifying agent. XLT-4 Agar Base is supplemented with XLT-4 Selective Supplement (SR0237). XLT-4 Selective Supplement is a selective agent that contains Tergitol 4 also known as Niaproof 4 or sodium tetradecylsulfate) which is an anionic surfactant when added to XLT-4 Agar Base formulation largely inhibits or reduces the growth of unwanted background flora.	5032384131242	62706	0242
	CM1061T			5032384128143		
5032384SabDexAgarOL5Y	CM1062P	SABOURAUD DEXTROSE AGAR	The Thermo Scientific™ Sabouraud Dextrose Agar (for Prepared Medium (CM1062)) when suspended with distilled water, is an acidic pH selective medium intended to be used for the isolation of dermatophytes, other fungi and yeasts from clinical samples such as skin, hair, nails, genital, respiratory and urine samples from patients.	5032384139248	58585	0166
	CM1062T			5032384132119		
	CM1062W			5032384510771		

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384BrillSalmonOG3P	CM1092B	BRILLIANCE SALMONELLA AGAR BASE	Brilliance™ Salmonella Agar Base (CM1092B and CM1092T) devices are selective and differential chromogenic media for the presumptive identification of Salmonella species from faecal samples. Brilliance™ Salmonella Agar Base (CM1092B and CM1092T) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384154692	58585	0159
	CM1092T			5032384276332		
5032384BrillUTIClarOL3Z	CM1106B	BRILLIANCE UTI CLARITY AGAR	Brilliance™ UTI Clarity (CM1106B, CM1106W, CM1106T and PO1110A) devices are differential media for the isolation and presumptive differentiation of the common microorganisms causing urinary tract infections (UTIs) and direct identification of E. coli from clinical samples, including urine samples. Brilliance™ UTI Clarity (CM1106B, CM1106W, CM1106T and PO1110A) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having UTIs.	5032384157433	58585	0160
	CM1106T			5032384168644		
	CM1106W			5032384510795		
5032384ARIAVJ	CM1132T	ANAEROBE RECOVERY AND ISOLATION AGAR (ARIA)	Anaerobe Recovery and Isolation Agar (CM1132T) is a non-selective medium for the growth of fastidious anaerobic microorganisms from clinical samples; the main sample types are pus, fluid and blood. Anaerobe Recovery and Isolation Agar (CM1132T) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections	5032384187416	58585	0215
5032384BHIBrothOLL3	CM1135B	BRAIN HEART INFUSION BROTH	Heart Infusion Broth (CM1032B), Brain Heart Infusion Broth (CM1135B, CM1135R, CM1135T, CM1135K and EB1230E), Brain Heart Infusion (BO1230D and BO1230M) and B.H.I. Broth with Horse Serum (BO1340E) devices are highly nutritious, general purpose media for the growth of fastidious microorganisms from clinical samples (e.g. wounds, genital swabs). Heart Infusion Broth (CM1032B), Brain Heart Infusion Broth (CM1135B, CM1135R, CM1135T, CM1135K and EB1230E), Brain Heart Infusion (BO1230D and BO1230M) and B.H.I. Broth with Horse Serum (BO1340E) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384186068	58687	0181
	CM1135K			5032384186082		
	CM1135R			5032384186075		
	CM1135T			5032384186051		
5032384BrainHeartAgrJE	CM1136B	BRAIN HEART INFUSION AGAR	Brain Heart Infusion Agar (CM1136B and PO1198A) devices are highly nutritious, general purpose media for the growth of fastidious microorganisms from clinical samples (e.g. wounds, genital swabs). Brain Heart Infusion Agar (CM1136B), when used with the addition of Chloramphenicol Selective Supplement (SR0078E and SR0078H), is intended to be used for the isolation of pathogenic fungi from clinical samples. Brain Heart Infusion Agar (CM1136B and PO1198A) devices and Brain Heart Infusion Agar (CM1136B) with the addition of Chloramphenicol Selective Supplement (SR0078E and SR0078H), are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having microbial infections.	5032384185122	58688	0232

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384PurifiedWaterXR	EB0209C	PURIFIED WATER	Thermo Scientific™ Purified Water (BO0209M, BO0209V, BO1336E and EB0209C) devices are media for the dilution of microorganisms isolated from clinical and non-clinical samples. Can also be used as a rinse solution for sterility testing and a reconstitution fluid for freeze dried supplements. The devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384118021	58673	0487
5032384RingersSolutionRS	EB0332D	RINGERS SOLUTION 1/4 STRENGTH	Ringers Solution ¼ Strength (EB0332D) is an isotonic solution intended to be used for the dilution of microorganisms and as a diluent and for preparing suspensions of microbiological samples. Ringers Solution ¼ Strength (EB0332D) is intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various sources where an isotonic solution is required.	5032384027392	43674	0233
50323840.85%SalineOLVZ	EB0334B	SALINE 0.85%	The 0.85% Saline Solution (BO0334, BO1176, EB0334, EB1355, EB1364) devices are used as a general purpose 0.85% isotonic saline solution intended to be used for the dilution of microorganisms and as a diluent and for preparing suspensions of microbiological samples. The 0.85% Saline Solution devices are intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various sources where a 0.85% isotonic saline solution is required.	5032384027408	58673	0098
	EB0334C			5032384140435		
5032384NutrientAgarSlpeKL	EB0336B	NUTRIENT AGAR SLOPE	Nutrient Agar Slope (BO0336B, BO0336E and EB0336B) devices are non-selective media intended to be used for the maintenance of microorganisms isolated from other culture media products previously inoculated using clinical samples (e.g., urine and wound). Nutrient Agar Slope (BO0336B, BO0336E and EB0336B) devices are intended to be used in a diagnostic workflow to support the clinician for the maintenance of bacteria from clinical samples.	5032384027415	58685	0456
5032384UreaAgrSlope3W	EB0337B	UREA AGAR SLOPE	Urea Agar Slope (BO0337B and EB0337B) devices are non-selective media intended for use in culture media. Urea Agar Slope (BO0337B and EB0337B) devices are intended to be used to detect rapid urease activity of the Proteae and non-rapid urease activity of some Enterobacteriaceae in faecal and urine samples. The devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Enterobacteriaceae infections.	5032384027422	58585	0234
5032384UreaBrothOLNN	EB0338B	UREA BROTH	Urea Broth Base (Dehydrated) (CM0071B) and Urea Broth (BO0338B, EB0338B) are differential media used to differentiate isolates of Enterobacteriaceae from clinical samples (stool and urine samples) by urease production. Urea Broth Base (Dehydrated) (CM0071B) and Urea Broth (BO0338B, EB0338B) are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having infections caused by urease producing Enterobacteriaceae.	5032384027439	58684	0234

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384MaxRecDilOL28	EB0348D	MAXIMUM RECOVERY DILUENT	Thermo Scientific™ Maximum Recovery Diluent (CM0733, BO0348 and EB0348) is a protective and isotonic diluent intended to be used for maximal recovery of microorganisms from clinical samples and for preparing suspensions of microbiological samples. Maximum Recovery Diluent devices are intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various samples where an isotonic diluent is required.	5032384027453	58208	0208
5032384TryptSoyaBrothOL8J	EB0351W	TRYPTONE SOYA BROTH	Tryptone Soya Broth (CM0129B, CM0129K, CM0129R, CM0129T, CM0129V and EB0351W) devices are highly nutritious, general-purpose media for the growth of fastidious and non-fastidious microorganisms from a range of clinical samples. The devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having microbial infections.	5032384479061	58586	0155
5032384FstAnrbeBrth28	EB0912H	FASTIDIOUS ANAEROBE BROTH (HPA)	Thermo Scientific™ Oxoid™ Fastidious Anaerobe Broth (HPA) (EB0912H) is a nutritious medium for the isolation of anaerobic microorganisms from clinical samples (e.g., wound and respiratory samples).	5032384138883	58208	0494
5032384SeleniteBrothOLYJ	EB1321E	SELENITE F BROTH	Selenite F Broth (EB1321E) is a selective enrichment medium for the isolation of Salmonella species from faecal and urine samples. Selenite F Broth is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384501755	58684	0081
5032384SeleniteBrothOLYJ	EB1322E	SELENITE CYSTEIN BROTH	The Selenite Cystine Broth Base (CM0699B) and Selenite Cystine Broth (EB1322E) devices are a selective enrichment media for the isolation of Salmonella species from clinical faecal and urine samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having salmonellosis.	5032384501762	58684	0236
5032384MannitolSeleniteXB	EB1323E	MANNITOL SELENITE BROTH	Thermo Scientific™ Oxoid™ Mannitol Selenite Broth (EB1323E) is a selective enrichment medium for the isolation of Salmonella species from faecal and urine samples. Mannitol Selenite Broth (EB1323E) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Salmonella infections.	5032384501779	58684	0495
50323840.85%SalineOLVZ	EB1355B	SALINE 0.85%	The 0.85% Saline Solution (BO0334, BO1176, EB0334, EB1355, EB1364) devices are used as a general purpose 0.85% isotonic saline solution intended to be used for the dilution of microorganisms and as a diluent and for preparing suspensions of microbiological samples. The 0.85% Saline Solution devices are intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various sources where a 0.85% isotonic saline solution is required.	5032384531936	58673	0098

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384InhibiSViralMed2L	EB1359A	THERMO SCIENTIFIC™ INHIBISURE™ VIRAL INACTIVATION MEDIUM	InhibiSURE Viral Inactivation Medium is a liquid medium intended to be used for the collection and inactivation of SARSCoV-2. The product stabilises the viral RNA for transportation and use in subsequent in vitro diagnostic testing procedures. The device is intended to be used with unprocessed nasal swabs, nasopharyngeal swabs and throat swabs.	5032384538522	62392	0056
50323840.85%SalineOLVZ	EB1364B	SALINE 0.85%	The 0.85% Saline Solution (BO0334, BO1176, EB0334, EB1355, EB1364) devices are used as a general purpose 0.85% isotonic saline solution intended to be used for the dilution of microorganisms and as a diluent and for preparing suspensions of microbiological samples. The 0.85% Saline Solution devices are intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various sources where a 0.85% isotonic saline solution is required.	5032384543427	58673	0098
	EB1364Q			5032384543533		
5032384InhibiSViralMed2L	EB1372A	THERMO SCIENTIFIC™ INHIBISURE™ VIRAL INACTIVATION MEDIUM	InhibiSURE Viral Inactivation Medium is a liquid medium intended to be used for the collection and inactivation of RNA enveloped viruses. The product stabilises the viral RNA for transportation and use in subsequent in vitro diagnostic testing procedures. The device is intended to be used with unprocessed nasal swabs, nasopharyngeal swabs and throat swabs.	5032384555925	62392	0502

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384AnaerobeBldAgrGT	PB0112A	ANAEROBE BLOOD AGAR (WC) WITH NEOMYCIN	Anaerobe Blood Agar (WC) with Neomycin (PB0112A) and Anaerobe Blood Agar (W-C) with Nalidixic Acid + Vancomycin (PB0515A) are selective media for the growth of anaerobic microorganisms from clinical samples, such as soft tissue and skin.	5032384017119	58585	0224
5032384AnaerobeBldAgrGT	PB0113A	ANAEROBE BLOOD (WC) NALIDIXIC ACID+TWEEN	Anaerobe Blood Agar (WC) Nalidixic Acid + Tween (PB0113A) is a selective medium for the growth of non-sporing anaerobic microorganisms from clinical samples, such as soft tissue and skin.	5032384017126	58585	0224
5032384BloodAgrBase2BD	PB0114A	BLOOD AGAR + HORSE BLOOD (BLOOD NO 2)	Blood Agar Base No.2 with Horse Blood (PB0114A) is a nutritious nonselective medium for the isolation and cultivation of fastidious pathogens and other microorganisms with clearly visible haemolysis from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). Blood Agar Base No.2 with Horse Blood (PB0114A) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384017133	58688	0172

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384BloodAgrBase2BD	PB0115A	BLOOD NO.2 SHEEP BLOOD	Blood Agar Base No.2 with Sheep Blood (PB0115A) is a nutritious nonselective medium for the isolation and cultivation of fastidious pathogens and other microorganisms with clearly visible haemolysis from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). Blood Agar Base No.2 with Sheep Blood (PB0115A) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384017140	58688	0172
5032384CampySelectAgarAW	PB0118A	CAMPYLOBACTER SELECT AGAR (SKIRROW)	Campylobacter Selective Agar (Skirrow) (PB0118A) is a selective medium for the isolation of Campylobacter species from faecal samples. Campylobacter Agar Base (CM0689B) is a selective medium which when supplemented, is used for the isolation of Campylobacter species from faecal samples. These devices are used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	5032384017171	58585	0217
5032384ColumbiaBldAgarA8	PB0122A	COLUMBIA AGAR WITH HORSE BLOOD	The Columbia Agar with Horse Blood (PB0122A, PB0742E and PO0165E) devices are non-selective media for the isolation of fastidious microorganisms with clearly visible haemolysis from clinical samples taken from the patient (e.g., faecal, urine, genital, and throat). Can also be used for testing non-clinical samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections	5032384030514	58688	0448
5032384ColumbiaBldAgrOLNP	PB0123A	COLUMBIA AGAR WITH SHEEP BLOOD PLUS	Columbia Agar with Sheep Blood (PB0123A) is a nutritious nonselective medium for the growth of fastidious microorganisms with clearly visible haemolysis from clinical samples. Columbia Agar with Sheep Blood (PB0123A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections. The device can also be used for testing non-clinical samples.	5032384017188	58688	0134
5032384ColumChocbiplOLDG	PB0124A	COLUMBIA AGAR + CHOC. HORSE BLOOD	Columbia Agar with Chocolate Horse Blood (PB0124A and BO0341B) is a highly nutritious medium for the growth of fastidious microorganisms from clinical samples (e.g., faecal, urine, genital and throat). Columbia Agar with Chocolate Horse Blood (PB0124A and BO0341B) devices are used in a clinical diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections	5032384489428	58688	0066
5032384ColBldNeomycin7U	PB0219A	COLUMBIA BLOOD AGAR + NEOMYCIN	Columbia Blood Agar with Neomycin (PB0219A) is a selective medium for the growth of anaerobic organisms from clinical samples (e.g., wounds, tissues, throat, blood, genital, bile, pus etc.). Columbia Blood Agar with Neomycin (PB0219A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384017324	58585	0449
5032384ColChocBacit8Y	PB0220A	COLUMBIA CHOCOLATE AGAR +BACITRACIN	Columbia Agar with Chocolate Horse Blood and Bacitracin (PB0220) is intended to be used for the isolation of Haemophilus influenzae from respiratory samples, including sputum, nasal and sinus samples.	5032384017331	58585	0231

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384FAAhrseBldDG	PB0225A	F.A.A. WITH HORSE BLOOD	F.A.A. with Horse Blood (PB0225A) is a non-selective medium for the growth fastidious anaerobic microorganisms from clinical samples (e.g., canalicular pus, cerebrospinal fluid, and blood). F.A.A. with Horse Blood (PB0225A) is used in a diagnostic workflow to aid clinicians determining potential treatment options for patients suspected of having bacterial infections	5032384017362	58585	0213
5032384StrepSelAgr6W	PB0298A	STREPTOCOCCAL SELECT AGAR C.O.B.A.	Streptococcal Selective Agar C.O.B.A. (PB0298A) is a selective medium for the isolation of Streptococcus species with clearly visible haemolysis from clinical samples, including those from the upper respiratory tract, wounds, burns or other sites where there may be an abundance of competing organisms. Streptococcal Selective Agar C.O.B.A. (PB0298A) is used in a diagnostic workflow to aid clinicians determining potential treatment options for patients suspected of having Streptococcus infections.	5032384094059	58585	0458
5032384StaphStrepMedOL76	PB0308A	CNA STAPH/STREP SELECTIVE AGAR	Columbia Horse Blood CNA Agar (PB0308A) is intended for use as a media for the selective isolation of Staphylococcus and Streptococcus species from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). Columbia Horse Blood CNA Agar (PB0308A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384094035	58585	0161
5032384M.HintSBloodOLYH	PB0431A	MUELLER-HINTON AGAR WITH 5% SHEEP BLOOD	Thermo Scientific™ Mueller Hinton Agar with 5% Sheep Blood (PB0431A) device is an antimicrobial susceptibility agar recommended for disc diffusion testing against fastidious microorganisms isolated from clinical samples. The medium device has been developed according to Clinical Laboratory and Standards Institute (CLSI) recommendations. The device is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of bacterial infections.	5032384090419	58639	0476
5032384AnaerobeBldAgrGT	PB0515A	ANAEROBE BLOOD (W-C) NALIDIXIC ACID + VANCOMYCIN	Anaerobe Blood Agar (WC) with Neomycin (PB0112A) and Anaerobe Blood Agar (W-C) with Nalidixic Acid + Vancomycin (PB0515A) are selective media for the growth of anaerobic microorganisms from clinical samples, such as soft tissue and skin.	5032384101818	58688	0224
5032384ColChocBacit8Y	PB0742E	COL. BLD AGAR/CHOC. BACITRACIN BIPLATE	The Columbia Agar with Horse Blood (PB0122A, PB0742E and PO0165E) devices are non-selective media for the isolation of fastidious microorganisms with clearly visible haemolysis from clinical samples taken from the patient (e.g., faecal, urine, genital, and throat). Can also be used for testing non-clinical samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections	5032384017546	62106	0448
5032384ColumbiaBldAgarA8	PB0835A	COLUMBIA BLOOD WITH 8MG/L AZTREONAM	Columbia Blood Agar with 8mg/L Aztreonam (PB0835A) is a nutritious selective medium for the growth of Gram-positive microorganisms with clearly visible haemolysis from clinical samples (e.g., wounds, throat, genital, nose etc.). Columbia Blood Agar with 8mg/L Aztreonam (PB0835A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Gram-positive bacterial infections.	5032384045327	58688	0152

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384StaphStrepMedOL76	PB0935A	STAPH/STREP SELECTIVE AGAR (HPA)	Staph / Strep Selective Agar (HPA (PB0935A)) is a selective medium for the isolation of Staphylococcus and Streptococcus species from clinical samples, including ear, throat, skin and pus from patients. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having staphylococcal/streptococcal infections.	5032384135813	58585	0253
5032384ColumbiaBldAgrOLNP	PB1099A	COLUMBIA AGAR WITH HORSE BLOOD (ORIGINAL)	Columbia Agar with Horse Blood (Original) (PB1099A) is a nutritious nonselective medium for the growth of microorganisms with clearly visible haemolysis from clinical samples. Can also be used for testing non-clinical samples.	5032384154425	58688	0182
5032384UTISTaphStrep2J 5032384BrillIUTIClarOL3Z	PB1155E	CLARITY™ UTI / STAPH-STREP CNA (MODIFIED) BI-PLATE	Brilliance™ Clarity UTI/Staph-Strep CNA (MOD) (PB1155E) is a bi-plate for the isolation and presumptive differentiation of the common microorganisms causing urinary tract infections on the Clarity UTI side from clinical urine samples. The isolation of Staphylococcus and Streptococcus species on the Staph-Strep CNA side from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). Brilliance™ Clarity UTI/Staph-Strep CNA (MOD) (PB1155E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384170371	62106	0160 0161
5032384ColumbiaCAPAgrM8	PB1161A	COLUMBIA CAP SELECTIVE AGAR WITH HORSE BLOOD	Columbia Cap Selective Agar with Horse Blood (PB1161A) is intended for use as a selective medium for the isolation of Staphylococcus and Streptococcus species from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). Columbia Cap Selective Agar with Horse Blood (PB1161A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections	5032384173303	58688	0161
5032384StphStrpSabChlorZF 5032384StaphStrepSabVX	PB1219E	STAPH STREP/SAB+CHLOR BI-PLATE	Staphylococci Streptococci Selective Medium/Sabouraud Glucose Selective Agar with Chloramphenicol (PB1219E) is a biplate for the isolation of Staphylococcus and Streptococcus species on the Staph-Strep side from clinical samples (e.g. wounds, throat, genital, nose, groins etc.). For the isolation of dermatophytes, other fungi and yeasts on the Sabouraud with Chloramphenicol side from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). Staphylococci Streptococci Selective Medium/Sabouraud Glucose Selective Agar with Chloramphenicol (PB1219E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384277001	62106	0161 0167
5032384ActinomycesAgrNF	PB1220A	ACTINOMYCETES SELECTIVE AGAR (FAA + DEEP FILL)	Actinomyces Supplement Agar FAA + Deep Fill (PB1220A) is a selective medium for the isolation of Actinomycetes from clinical samples (e.g., tissues, wounds, abscesses, bronchoalveolar lavage and expectorated sputum samples and bronchial aspirate).	5032384277100	58585	0078

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384CBAStaphStrepEQ	PB1223E	CBA + STAPH STREP (CAP) BIPLATE	Columbia Blood Agar with Horse Blood/Columbia CAP Agar (PB1223E) is intended for use as media for the isolation of microorganisms with clearly visible haemolysis on the CBA side and for the selective isolation of Staphylococcus and Streptococcus species on the Staph-Strep (CAP) side from clinical samples(e.g. wounds, throat, genital, nose, groin etc.).Columbia Blood Agar with Horse Blood/Columbia CAP Agar (PB1223E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384280216	62106	0161 0448
5032384CBAStaphStrepEQ	PB1224E	CBA + CHOC HORSE BLOOD BIPLATE	Columbia Blood Agar/Columbia Agar with Chocolate Horse Blood (PB1224E) is a biplate for the isolation of microorganisms with clearly visible haemolysis on the Columbia side from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). For the isolation of fastidious microorganisms on the Columbia with chocolate blood side from clinical samples (e.g., faecal, urine, genital and throat) Columbia Blood Agar/Columbia Agar with Chocolate Horse Blood (PB1224E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384280230	62106	0161
5032384CLEDLKP	PB1228E	C.L.E.D / STAPH-STREP BIPLATE	C.L.E.D. Medium / Staphylococci-Streptococci Selective Medium (PB1228E) is a bi-plate for the isolation and enumeration of the common microorganisms causing urinary tract infections on the C.L.E.D. side and for the isolation of Staphylococcus and Streptococcus species on the Staph-Strep side from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). C.L.E.D. Medium / Staphylococci-Streptococci Selective Medium (PB1228E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384279746	62106	0179
5032384M.HintHBloodOLRY	PB1229A	MUELLER HINTON AGAR WITH HORSE BLOOD AND 20MG/L NAD	Mueller-Hinton Agar with Horse Blood and NAD (PB1229A) is an antimicrobial susceptibility agar recommended for disc diffusion testing of fastidious microorganisms isolated from clinical samples. Mueller-Hinton Agar with Horse Blood and NAD (PB1229A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384282524	58639	0154
5032384ARIAVJ	PB1243A	ANAEROBE RECOVERY AND ISOLATION AGAR (A.R.I.A.TM)	A.R.I.A. Medium with 5% Horse Blood (PB1243A) is a non-selective medium for the growth of fastidious anaerobic microorganisms from clinical samples; the main sample types are pus, fluid and blood. A.R.I.A. Medium with 5% Horse Blood (PB1243A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384446223	58688	0215
5032384ARIANeoRS	PB1244A	ANAEROBE RECOVERY AND ISOLATION AGAR (A.R.I.A.TM) WITH NEOMYCIN	A.R.I.A. Medium with 5% Horse Blood and Neomycin (PB1244A) is a selective medium for the isolation of fastidious anaerobic microorganisms from clinical samples; the main sample types are pus, fluid and blood. A.R.I.A. Medium with 5% Horse Blood and Neomycin (PB1244A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384445578	58688	0215

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384CLEdOLKP 5032384CoICAPCLEdNA	PB1248E	COLUMBIA CAP / CLED BI-PLATE	Columbia CAP Agar / C.L.E.D. Medium (PB1248E) is a biplate for the isolation of Staphylococcus and Streptococcus species on the Columbia CAP side and the isolation and enumeration of the common microorganisms causing urinary tract infections on the C.L.E.D. side. Columbia CAP Agar / C.L.E.D. Medium (PB1248E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384448418	62106	0161 0179
5032384ARIAARIANeo99	PB1260E	ANAEROBE RECOVERY AND ISOLATION AGAR (A.R.I.A.™) / ANAEROBE RECOVERY AND ISOLATION AGAR (A.R.I.A.™) WITH HORSE BLOOD AND NEOMYCIN	A.R.I.A. Medium with 5% Horse Blood/A.R.I.A. Medium with 5% Horse Blood and Neomycin (PB1260E) is a biplate for the growth of fastidious anaerobic microorganisms from clinical samples; the main sample types are pus, fluid and blood, on the A.R.I.A. Medium with 5% Horse Blood side and the selective isolation of fastidious anaerobic microorganisms from clinical samples; the main sample types are pus, fluid and blood, on the A.R.I.A. Medium with 5% Horse Blood and Neomycin side. A.R.I.A. Medium with 5% Horse Blood/A.R.I.A. Medium with 5% Horse Blood and Neomycin (PB1260E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections	5032384485260	62106	0215
5032384ColMacConkeyOLYP	PB1262E	COLUMBIA AGAR WITH CHOCOLATED HORSE BLOOD / MACCONKEY AGAR WITH SALT	The Columbia Agar with Chocolate Horse Blood (PB1262E) is a nonselective medium for the isolation of fastidious microorganisms from clinical samples taken from the patient (e.g. faecal, urine, genital and throat). Can also be used for testing non-clinical samples. The device is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections	5032384485857	62106	0066 0216

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384CCDASelMedOLP9	PO0119A	CAMP.BLOOD FREE SELECT AGAR (CCDA)	CCDA Selective Medium (PO0119A) is a selective medium intended for the isolation of Campylobacter species from faecal samples. CCDA Selective Medium (PO0119A) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having campylobacteriosis.	5032384017577	58585	0170
5032384CLEdOLKP	PO0120A	CLED AGAR	C.L.E.D. Agar (PO0120A) is a differential medium for the isolation and enumeration of the common microorganisms causing urinary tract infections from urine samples. C.L.E.D. Agar (PO0120A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having urinary tract infections.	5032384017584	58585	0179

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384CLEDrades7T	PO0121A	CLED AGAR + ANDRADES INDICATOR	CLED Medium with Andrade's Indicator (CM0423B, CM0423R, CM0423K, CM1051T and PO0121A) devices are differential media for the isolation and enumeration of the common microorganisms causing urinary tract infections from clinical samples such as urine samples. CLED Medium with Andrade's Indicator (CM0423B, CM0423R, CM0423K, CM1051T and PO0121A) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having urinary tract infections.	5032384017591	58585	0176
5032384DCAAgarOLAR	PO0126A	DESOXYCHOLATE CITRATE AGAR (HYNES)	Desoxycholate Citrate Agar (Hynes) (CM0227B, CM0227R, CM0227T) is a differential medium for the isolation of Salmonella and Shigella species from faecal samples. Desoxycholate Citrate Agar (Hynes) (PO0126A) is a differential medium for the isolation of Salmonella and Shigella species from faecal samples. These devices are intended for in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having enteric infections.	5032384017614	58585	0227
5032384DNASEAgarAA	PO0128A	DNASE AGAR	DNASE Agar (PO0128A) is a medium used for the differentiation of microorganisms from clinical samples based on deoxyribonuclease activity, particularly Staphylococcus species.	5032384017638	58585	0251
5032384HoylesAgrFQ	PO0143A	HOYLES MEDIUM	Hoyles Medium (PO0143A) is a selective medium for the isolation and differentiation of Corynebacterium diphtheriae from wound and upper respiratory samples, including throat and nasal swabs.	5032384017751	58585	0201
5032384MacConkNoSaltOLXF	PO0148A	MACCONKEY AGAR WITHOUTSALT	MacConkey Agar without Salt (CM0507, PO0148A and PO0165E) devices are differential media for the isolation of Gram-negative organisms whilst suppressing the swarming of Proteus species from clinical samples, including urine samples. MacConkey Agar without Salt (CM0507, PO0148A and PO0165E) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections including urinary tract infections (UTIs).	5032384017799	58585	0195
5032384MacConkeyAgrOL3C	PO0149A	MACCONKEY AGAR WITH SALT	MacConkey Agar (CM0007, PO0149A and PB1262E) devices are differential media for the isolation and differentiation of lactose and non-lactose fermenting coliforms and intestinal bacteria pathogens from a wide range of clinical samples direct from the patient, such as urine and faeces, or indirectly from swabs taken from wounds or infections. MacConkey Agar (CM0007, PO0149A and PB1262E) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384017812	58585	0216
5032384ManSaltAgrOLLL	PO0151A	MANNITOL SALT	Mannitol Salt Agar (CM0085B, CM0085K, CM0085R, CM0085T, CM0085W and PO0151A) devices are selective media for the isolation of pathogenic staphylococci from clinical samples, including wound, faecal and respiratory tract samples. Mannitol Salt Agar devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having staphylococcal infections.	5032384017850	58585	0202

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384MuellerHintonOL97	PO0152A	MUELLER-HINTON AGAR	Mueller Hinton Agar (PO1191S and PO0152A) devices are antimicrobial susceptibility testing agars recommended for disc diffusion. Mueller Hinton Agar devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384017874	58639	0477
5032384SabDexAgarOL5Y	PO0160A	SABOURAUD DEXTROSE AGAR	The Thermo Scientific™ Sabouraud Dextrose Agar is an acidic pH selective medium intended to be used for the isolation of dermatophytes, other fungi and yeasts from skin, hair, nails, genital, respiratory and urine samples from patients.	5032384018000	58685	0166
5032384SabDexChlorOLWS	PO0161A	SABOURAUD DEXTROSE AGAR WITH CHLORAMPHENICOL	Sabouraud Dextrose Agar with Chloramphenicol (PO0161A) is an acidic pH selective medium for the isolation of dermatophytes, other fungi, and yeasts from skin, hair, nails, genital, respiratory and urine samples. Sabouraud Dextrose Agar with Chloramphenicol (PO0161A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungal infections.	5032384018024	58585	0167
5032384SabDexChlorOLWS	PO0162A	SAB.DEXTROSE + CHLOR. + ACTIDIONE	Sabouraud Dextrose Agar with Chloramphenicol and Actidione (PO0162A) and Sabouraud Dextrose Agar with Chloramphenicol and Actidione (DEEP FILL PO0829A) are acidic pH selective media used for the isolation of dermatophytes, other fungi, and yeasts from clinical samples (e.g., throat, ear, hair, nails, genital, respiratory, urine etc.). Sabouraud Dextrose Agar with Chloramphenicol and Actidione devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having dermatophytes, other fungi, and yeast infections including Candida albicans and Trichophyton rubrum.	5032384018055	58585	0168
5032384XLDMediumOL7Q	PO0164A	XLD MEDIUM	The XLD Agar (CM0469B, CM0469R, CM0469T, CM0469W, PO0931A and PO0164A) devices are selective media for the isolation of Salmonella and Shigella species from faecal samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Salmonella and Shigella bacterial infections.	5032384018093	58585	0163

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384ColBldMacConkeyKD 5032384ColAgrMacConkeyS3	PO0165E	COL. BLOOD/MACCONKEY BIPLATE	<p>MacConkey Agar without Salt (CM0507, PO0148A and PO0165E) devices are differential media for the isolation of Gram-negative organisms whilst suppressing the swarming of Proteus species from clinical samples, including urine samples. MacConkey Agar without Salt (CM0507, PO0148A and PO0165E) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections including urinary tract infections (UTIs).</p> <p>The Columbia Agar with Horse Blood (PB0122A, PB0742E and PO0165E) devices are non-selective media for the isolation of fastidious microorganisms with clearly visible haemolysis from clinical samples taken from the patient (e.g., faecal, urine, genital, and throat). Can also be used for testing non-clinical samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.</p>	5032384018116	62106	0195/ 0448
5032384DermaseI AgrOLUS	PO0166A	DERMATOPHYTE MEDIUM + PHENOL RED	<p>Dermatophyte Medium with Phenol Red (PO0166A) is a selective medium used for the isolation of dermatophyte fungi from samples such as hair, skin scrapings and nails. Dermatophyte Medium with Phenol Red (PO0166A) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having infections caused by dermatophyte fungi.</p>	5032384018130	58585	0254
5032384BileAesculinAgrHQ	PO0169A	BILE AESCULIN AGAR	<p>Bile Aesculin Agar (PO0169A, CM0888B and CM0888K) devices are differential media for the isolation and presumptive identification of enterococci and Group D streptococci from clinical samples. Bile Aesculin Agar (PO0169A, CM0888B and CM0888K) devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.</p>	5032384018192	58585	0226
5032384BrillGreenAgrOLWG	PO0171A	BRILLIANT GREEN AGAR (MODIFIED)	<p>Brilliant Green Agar (Modified) (PO0171A, CM0329B, CM0329R, CM0329T and CM0329K) devices are a selective and diagnostic agar for Salmonellae other than Salmonella typhi or Salmonella paratyphi A for clinical samples such as faecal samples. Brilliant Green Agar (Modified) (PO0171A, CM0329B, CM0329R, CM0329T and CM0329K) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Salmonellae infections.</p>	5032384018215	58585	0204
5032384MaltExtractAgrAE	PO0182A	MALT EXTRACT AGAR	<p>Malt Extract Agar (PO0182A) is a non-selective medium for the isolation of yeasts and moulds from clinical samples (e.g., skin, hair, and nails). Malt Extract Agar (PO0182A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungal infections.</p>	5032384018376	58585	0109

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384PseudoSelAgrNZ	PO0185A	PSEUDOMONAS SELECTIVE AGAR C-N	Pseudomonas C-N Selective Agar (PO0185A) is a selective medium for the isolation of Pseudomonas spp. from a wide range of clinical samples including urine, wound swabs, and sputum. Pseudomonas C-N Selective Agar (PO0185A) is recommended for the selective isolation of Pseudomonas aeruginosa. Pseudomonas C-N Selective Agar (PO0185A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Pseudomonas infections.	5032384018413	58585	0175
5032384TCBSCholeraMedVG	PO0194A	T.C.B.S. CHOLERA MEDIUM	T.C.B.S. Cholera Medium (PO0194A) is a selective isolation medium for the isolation of Vibrio species from faecal and clinical samples where Vibrio species are suspected to be the cause of infection. T.C.B.S. Cholera Medium (PO0194A) and T.C.B.S. Cholera Medium (CM0333B, CM0333T) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Vibrio species infections.	5032384018574	58585	0222
8488380MRSAgrOL4V	PO0231A	M.R.S. AGAR	M.R.S. Agar (PO0231A) is a general-purpose medium for the growth of Lactobacillus species from oral, vaginal and faecal samples. M.R.S. Agar (PO0231A) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384019786	58585	0189
5032384SorbMacConkOLSY	PO0232A	SORBITOL MACCONKEY	Sorbitol MacConkey Agar (PO0232A) and Sorbitol MacConkey Agar (CM0813B, CM0813R) are selective and differential media for the detection of Escherichia coli O157 in faecal and urine samples. These devices are intended for in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having enteric infections.	5032384019816	58585	0193
5032384YersiniaAgarOLY9	PO0287A	YERSINIA AGAR (CIN MED)	Yersinia Selective Agar (CIN) (PO0287A) is a selective medium for the isolation of Yersinia enterocolitica from faecal samples. Yersinia Selective Agar (CIN) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having yersiniosis.	5032384020362	58585	0196
5032384PseudSelCFCAgrOLUG	PO0291A	PSEUDOMONAS C.F.C. SELECTIVE AGAR	Pseudomonas CFC Selective Agar (PO0291A) is a selective medium for the isolation of Pseudomonas spp. from a wide range of clinical samples including urine, wound swabs, and sputum. Pseudomonas C-F-C Selective Agar (PO0291A) is recommended for the selective isolation of Pseudomonas spp. generally. Pseudomonas C-F-C Selective Agar (PO0291A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Pseudomonas infections. The device is for professional use only, is not automated, nor is it a companion diagnostic.	5032384020447	58585	0175

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384SabDexChlorOLWS	PO0358A	SABOURAUD DEXTROSE & CHLOR.	Sabouraud Dextrose Agar with Chloramphenicol (deep fill) (PO0358A) is an acidic pH selective medium for the isolation of dermatophytes, other fungi, and yeasts from skin, hair, nails, genital, respiratory and urine samples. Sabouraud Dextrose Agar with Chloramphenicol (deep fill) (PO0358A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungal infections.	5032384021086	58585	0167
5032384FAANeoMA	PO0416A	FASTIDIOUS ANAEROBE AGAR WITH NEOMYCIN	The F.A.A. with Neomycin (PO0416A) is a medium for the selective growth of fastidious anaerobic bacteria from clinical samples, such as tissue, stool samples and blood cultures. It is specifically intended to be used to isolate microorganisms from clinical samples for a diagnostic purpose. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections	5032384021529	58585	0094
5032384MacConkey3OLAJ	PO0495A	MACCONKEY AGAR NO 3	The MacConkey Agar No. 3 (CM0115B, CM0115R, CM0115T, CM0115K, CM0115Q, CM0115V, CM0115W and PO0495A) devices are selective media the differentiation between lactose and non-lactose fermenters with the inhibition of Gram-positive cocci from clinical samples (e.g. faecal, blood, bile, pus, skin, mouth, etc.). The MacConkey Agar No. 3 (CM0115B, CM0115R, CM0115T, CM0115K, CM0115Q, CM0115V, CM0115W and PO0495A) devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384022175	58585	0158
5032384BurkCepAgarAW	PO0696A	BURKHOLDERIA CEPACIA MED (MAST)	A selective medium for the isolation of Burkholderia cepacia from respiratory samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Burkholderia cepacia infections.	5032384023943	58585	0228
5032384SorbMacConCefTelYG	PO0702A	SORB. MACCONKEY + CEFIXIME TELLURITE	Sorbitol MacConkey Agar with Cefixime Tellurite (PO0702A) is a selective and differential medium for the detection of Escherichia coli O157:H7 in faecal and urine samples.	5032384024025	62106	0194
5032384DermaselAgrOLUS	PO0737A	DERMASEL AGAR	Dermasel Agar (PO0737A) is a selective medium intended to be used for the isolation and identification of dermatophytes and other fungi from samples such as hair, skin scrapings and nails. Dermasel Agar (PO0737A) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having infections caused by dermatophytes and other fungi.	5032384024506	58585	0254

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384SabDexChlorOLWS	PO0829A	SAB DEX WITH ACTIDIONE AND CHLOR	Sabouraud Dextrose Agar with Chloramphenicol and Actidione (PO0162A) and Sabouraud Dextrose Agar with Chloramphenicol and Actidione (DEEP FILL PO0829A) are acidic pH selective media used for the isolation of dermatophytes, other fungi, and yeasts from clinical samples (e.g., throat, ear, hair, nails, genital, respiratory, urine etc.). Sabouraud Dextrose Agar with Chloramphenicol and Actidione devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having dermatophytes, other fungi, and yeast infections including <i>Candida albicans</i> and <i>Trichophyton rubrum</i> .	5032384043033	58585	0168
5032384XLDMediumOL7Q	PO0931A	XLD AGAR (SPECIAL)	The XLD Agar (CM0469B, CM0469R, CM0469T, CM0469W, PO0931A and PO0164A) devices are selective media for the isolation of <i>Salmonella</i> and <i>Shigella</i> species from faecal samples. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having <i>Salmonella</i> and <i>Shigella</i> bacterial infections.	5032384078318	58585	0163
5032384BurkCepAgarAW	PO0938A	BURKHOLDERIA CEPACIA MEDIUM	A selective medium for the isolation of <i>Burkholderia cepacia</i> from respiratory samples. Can also be used for testing non-sterile inorganic salt solutions with preservative. The devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having <i>Burkholderia cepacia</i> infections.	5032384086115	58585	0228
5032384SalmonelChromAgrM8	PO0958A	SALMONELLA CHROMOGENIC MEDIUM	Salmonella Chromogenic Medium (PO0958) is a selective and differential chromogenic medium for the presumptive identification of <i>Salmonella</i> species from faecal samples.	5032384091911	58585	0219
5032384SabDexChlorOLWS	PO1001A	SAB DEX WITH CHLOR	Sabouraud Dextrose Agar with Chloramphenicol (deep fill) (PO1001A) is an acidic pH selective medium for the isolation of dermatophytes, other fungi, and yeasts from skin, hair, nails, genital, respiratory and urine samples. Sabouraud Dextrose Agar with Chloramphenicol (deep fill) (PO1001A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungal infections.	5032384112821	58585	0167
5032384SabDexChlorOLWS	PO1002A	SABOURAUD DEXTROSE AGAR WITH CHLORAMPHENICOL AND ACTIDIONE (EXTRA DEEP FILL)	Sabouraud Dextrose Agar and Chloramphenicol and Actidione (extra deep fill) (PO1002A) is an acidic pH selective medium for the isolation of dermatophytes, other fungi, and yeasts from skin, hair, nails, genital, respiratory and urine samples. Sabouraud Dextrose Agar and Chloramphenicol and Actidione (extra deep fill) (PO1002A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungal infections.	5032384112838	58585	0167
5032384BrillUTIClarOL3Z	PO1110A	BRILLIANCE UTI CLARITY	Brilliance™ UTI Clarity (CM1106B, CM1106W, CM1106T and PO1110A) devices are differential media for the isolation and presumptive differentiation of the common microorganisms causing urinary tract infections (UTIs) and direct identification of <i>E. coli</i> from clinical samples, including urine samples. Brilliance™ UTI Clarity (CM1106B, CM1106W, CM1106T and PO1110A) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having UTIs.	5032384164028	58585	0160

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384XLT4AgarAH	PO1158A	XLT-4 AGAR	XLT-4 Agar (PO1158A) device contains proteose peptones which act as the nutritional source within the media, whilst yeast extract provides growth promoting B vitamins. The identification Salmonella species is determined by the fermentation of xylose, lactose and sucrose along with the decarboxylation of L- lysine and the production of hydrogen sulphide. An additive anionic surfactant known as Tergitol™/ sodium tetradecyl sulfate acts as an effective selective agent which is active against Gram-positive and many Gram-negative organisms, including Proteus spp. Ammonium Iron (III) citrate helps determine H2S production. Sodium chloride maintains the osmotic equilibrium. Phenol red is the pH indicator and agar is the solidifying agent.	5032384171538	58585	0242
5032384BrillianceStaphPP	PO1186A	BRILLIANCE STAPH 24 AGAR	Brilliance Staph 24 Agar is a chromogenic screening medium for the detection of coagulase-positive staphylococci (CPS) direct from clinical samples, including wound swabs. Brilliance Staph 24 Agar is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having staphylococcal infections.	5032384228850	58585	0148
5032384MuellerHintonOL97	PO1191S	MUELLER-HINTON-AGAR 140 MM (4MM SCH-D.)	Mueller Hinton Agar (PO1191S and PO0152A) devices are antimicrobial susceptibility testing agars recommended for disc diffusion. Mueller Hinton Agar devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384188543	58639	0477
5032384BrainHeartAgrJE	PO1198A	BRAIN HEART INFUSION AGAR (DEEP FILL)	Brain Heart Infusion Agar (CM1136B and PO1198A) devices are highly nutritious, general purpose media for the growth of fastidious microorganisms from clinical samples (e.g. wounds, genital swabs). Brain Heart Infusion Agar (CM1136B), when used with the addition of Chloramphenicol Selective Supplement (SR0078E and SR0078H), is intended to be used for the isolation of pathogenic fungi from clinical samples. Brain Heart Infusion Agar (CM1136B and PO1198A) devices and Brain Heart Infusion Agar (CM1136B) with the addition of Chloramphenicol Selective Supplement (SR0078E and SR0078H), are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having microbial infections.	5032384229918	58585	0232
5032384CTSMACXLDDP	PO1222E	CT SMAC + XLD BI PLATE	Sorbitol MacConkey with Cefixime Tellurite Agar/X.L.D. Agar Biplate (PO1222E) is a selective and differential medium for the detection of Escherichia coli O157:H7 in faecal samples on the Sorbitol MacConkey with Cefixime Tellurite Agar side.	5032384280223	62106	0194

Product Schedule

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384InhibiSViralMed2L	SK01368	THERMO SCIENTIFIC™ INHIBISURE™ VIRAL INACTIVATION NPG SWAB KIT	The InhibiSURE Viral Inactivation Medium is a liquid medium intended to be used for the collection and inactivation of SARSCoV-2. The product stabilises the viral RNA for transportation and use in subsequent in vitro diagnostic testing procedures. The device is intended to be used with unprocessed nasal swabs, nasopharyngeal swabs and throat swabs.	5032384017577	62773	0056
	SK01372	THERMO SCIENTIFIC™ INHIBISURE™ VIRAL INACTIVATION NPG SWAB KIT	InhibiSURE Viral Inactivation Medium is a liquid medium intended to be used for the collection and inactivation of RNA enveloped viruses. The product stabilises the viral RNA for transportation and use in subsequent in vitro diagnostic testing procedures. The device is intended to be used with unprocessed nasal swabs, nasopharyngeal swabs and throat swabs.	5032384555918		0502

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