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Oxoid™ Imipenem Discs 10µg (IPM10)

REF CT0455B

Antimicrobial Susceptibility Test Discs

Note: This IFU should be read in conjunction with the AST generic instructions for use supplied with the product and available online.

Imipenem (10µg) IPM10 Antimicrobial Susceptibility Test Discs (CT0455B) are 6 mm paper discs which contain specific amounts of the antimicrobial agent imipenem. The discs are labelled on both sides with details of the antimicrobial (IPM) and amount present (10µg).

Discs are supplied in cartridges containing 50 discs each. There are 5 cartridges per pack. Each cartridge is individually sealed together with a desiccant tablet in a foil covered transparent blister pack. Imipenem Antimicrobial Susceptibility Test (AST) Discs can be dispensed using a Disc Dispenser (sold separately). Each individual disc should be only used once.

Intended Use

Antimicrobial Susceptibility Test Discs are used in the semi-quantitative agar diffusion test method for in vitro susceptibility testing. Used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having a microbial infection, these discs are intended to determine susceptibility against microorganisms for which Imipenem has been shown to be active both clinically and in vitro. To be used with a pure, agar grown culture.

The device is not automated, is for professional use only and is not a companion diagnostic.

The test provides information to categorise organisms as either resistant, intermediate or susceptible to the antimicrobial agent.

Further requirements for specimen collection, handling and storage of samples can be found in local procedures and guidelines. There is no specified testing population for these discs.

Published clinical breakpoints in the current version of the FDA tables, CLSI M100[1ac], or EUCAST[2] breakpoint tables must be used to interpret the zone size result.

Species with published breakpoints according to current FDA literature:

Gram-Positive
- N/A

Gram-Negative
- Enterobacteriaceae
- Pseudomonas *aeruginosa*
- Acinetobacter *spp.*
- Haemophilus *influenzae* and *parainfluenzae*

Species with published breakpoints according to current CLSI literature:

Gram-Positive
- N/A

Gram-Negative
- Enterobacteriaceae
- *Pseudomonas aeruginosa*
- *Acinetobacter spp.*
- *Haemophilus influenzae* and *parainfluenzae*

Species with published breakpoints according to current EUCAST literature:

Gram-Positive
- *Enterococcus* spp.

Gram-Negative
- Enterobacteriaceae
- *Pseudomonas* spp.

- *Acinetobacter* spp.
- *Haemophilus influenzae*
- *Moraxella catarrhalis*
- *Burkholderia pseudomalle*

Each disc is single use only. The pack contains sufficient test devices for multiple single-use tests.

Principles of Method

Imipenem AST Discs are used in the semi-quantitative agar diffusion test method for in vitro susceptibility testing. For full instructions relating to the generation and interpretation of the results according to CLSI[1bc]/EUCAST[2ab] methodology please refer to the relevant current standards. Tables showing CLSI[1bc]/EUCAST[2] compound/concentrations can be found in their documentation referenced below. Pure cultures of clinical isolates are inoculated onto the test medium and the AST disc placed on the surface. The antibiotic within the disc diffuses through the agar to form a gradient. After incubation, the zones of inhibition around the discs are measured and compared against recognized zone diameter ranges for the specific antimicrobial agent(s)/organism(s) under test.

Metrological Traceability of Calibrator and Control Material Values

Metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of a method for Imipenem AST Discs is based on internationally recognized procedures and standards.

For recommended concentrations, the zone limits are in accordance with the current performance standards for antimicrobial disc susceptibility tests as detailed by CLSI[1bc] and/or EUCAST[2].

Materials Provided

Imipenem AST Discs consist of 6mm diameter paper discs impregnated with a specific amount of antimicrobial agent. The discs are marked on both sides to indicate the agent and amount. Imipenem AST Discs are supplied in cartridges of 50 discs. There are 5 cartridges in each pack. Cartridges are individually packed in a foil-sealed blister pack with a desiccant.

See Table 1 below for a description of components associated with the device. For a description of active reagents that influence the result of the device, please refer to table 2.

Table 1. Materials Provided with CT0455B

Component Description	Material Description
Cartridge with spring, cap and plunger (x5)	Assembly components and plastic cartidge containing 50x AST discs
Desiccant tablet (x5)	Light beige to brown, small lozenge shaped tablets. 1 supplied with each cartridge.
Foil	Foil individually sealing each cartridge with its desiccant.
Susceptibility Test Discs (x250)	Absorbent paper individual discs. 6mm. 50 in each cartridge, 5 cartridges per pack.

Table2. Description of Imipenem AST Disc Reagents

Reagent	Description of Function
Imipenem IPM10 - 10µg	Imipenem. $C_{12}H_{17}N_3O_4S$. Antimicrobic agent. White powder.

The concentration of antibiotic on the AST disc is analysed for every batch and is controlled using internal and external specifications (e.g. FDA[3]). The actual concentration is detailed on the Certificate of Analysis.

Imipenem AST Discs can be dispensed using a Disc Dispenser, which is not included with the device.

Shelf-life and Storage Conditions

Unopened cartridges of Imipenem AST discs have a shelf-life of 12 months if stored under the recommended conditions. Unopened cartridges must be stored at -20°C to 8°C until required.

Once opened, cartridges should be stored within the dispenser in the container provided (with an unsaturated (orange) desiccant), or other suitable opaque airtight container with a desiccant to protect the discs from moisture. Dispensers should be stored within the container at 2 - 8°C and be allowed to come to room temperature before opening to prevent the formation of condensation. Once opened from their desiccant-containing packaging, discs should be used within 7 days and only if stored as described in this IFU.

Analytical Performance Characteristics

Table 3. Results summary for tested QC isolates, in accordance with EUCAST methodology

EUCAST Methodology										
Product Batch	**Organism**	**ATCC® number**	**Test Media**	**Lower Limit**	**Upper Limit**	**Calculated reference mid-point value**	**Reading (mm)**			**Mean difference between the experimental values and reference mid-point values (mm) + SD (Coefficient of variance) (%)**
							1	**2**	**3**	
3001661	*Escherichia coli*	25922	MHA	26	32	29	32	32	32	3 ± 0 (CV=0)
	Pseudomonas aeruginosa	27853	MHA	20	28	24	22	22	22	2 ± 0 (CV=0)
	Enterococcus faecalis	29212	MHA	24	30	27	27	27	27	3 ± 0 (CV=0)
	Streptococcus pneumoniae	49619	MHA+5%SB	34	42	38	41	41	41	3 ± 0 (CV=0)
	Hemophilus influenzae	49766	HTM	24	30	27	25	25	25	2 ± 0 (CV=0)
Product Batch	**Organism**	**ATCC® number**	**Test Media**	**Lower Limit**	**Upper Limit**	**Calculated reference mid-point value**	**Reading (mm)**			**Mean difference (mm) + SD (CoV) (%)**
							1	**2**	**3**	
3001662	*Escherichia coli*	25922	MHA	26	32	29	31	31	32	2.33 ± 0.58 (CV=0.25)
	Pseudomonas aeruginosa	27853	MHA	20	28	24	21	21	22	2.67 ± 0.58 (CV=0.22)
	Enterococcus faecalis	29212	MHA	24	30	27	26	26	26	1 ± 0 (CV=0)
	Streptococcus pneumoniae	49619	MHA+5%SB	34	42	38	42	42	42	4 ± 0 (CV=0)
	Hemophilus influenzae	49766	HTM	24	30	27	24	24	24	3 ± 0 (CV=0)
Product Batch	**Organism**	**ATCC® number**	**Test Media**	**Lower Limit**	**Upper Limit**	**Calculated reference mid-point value**	**Reading (mm)**			**Mean difference (mm) + SD (CoV) (%)**
							1	**2**	**3**	
3001695	*Escherichia coli*	25922	MHA	26	32	29	29	29	29	0 ± 0 (CV=0)
	Pseudomonas aeruginosa	27853	MHA	20	28	24	21	21	21	3 ± 0 (CV=0)
	Enterococcus faecalis	29212	MHA	24	30	27	27	27	27	0 ± 0 (CV=0)
	Streptococcus pneumoniae	49619	MHA+5%SB	34	42	38	40	40	40	2 ± 0 (CV=0)
	Hemophilus influenzae	49766	HTM	24	30	27	26	26	26	1 ± 0 (CV=0)

Table 4. Results summary for tested QC isolates, in accordance with CLSI methodology

CLSI Methodology										
Product Batch	**Organism**	**ATCC® number**	**Test Media**	**Lower Limit**	**Upper Limit**	**Calculated reference mid-point value**	**Reading (mm)**			**Mean difference between the experimental values and reference mid-point values (mm) + SD (Coefficient of variance) (%)**
							1	**2**	**3**	
3001661	*Escherichia coli*	25922	MHA	26	32	29	32	32	32	3 ± 0 (CV=0)
	Pseudomonas aeruginosa	27853	MHA	20	28	24	22	22	22	2 ± 0 (CV=0)
	Hemophilus influenzae	49247	HTM	21	29	25	28	28	28	3 ± 0 (CV=0)
Product Batch	**Organism**	**ATCC® number**	**Test Media**	**Lower Limit**	**Upper Limit**	**Calculated reference mid-point value**	**Reading (mm)**			**Mean difference (mm) + SD (CoV) (%)**
							1	**2**	**3**	
3001662	*Escherichia coli*	25922	MHA	26	32	29	31	31	32	2.33 ± 0.58 (CV=0.25)
	Pseudomonas aeruginosa	27853	MHA	20	28	24	21	21	22	2.7 ± 0.58 (CV=0.22)
	Hemophilus influenzae	49247	HTM	21	29	25	26	26	26	1 ± 0 (CV=0)
Product Batch	**Organism**	**ATCC® number**	**Test Media**	**Lower Limit**	**Upper Limit**	**Calculated reference mid-point value**	**Reading (mm)**			**Mean difference (mm) + SD (CoV) (%)**
							1	**2**	**3**	
3001695	*Escherichia coli*	25922	MHA	26	32	29	29	29	29	0 ± 0 (CV=0)
	Pseudomonas aeruginosa	27853	MHA	20	28	24	21	21	21	3 ± 0 (CV=0)
	Hemophilus influenzae	49247	HTM	21	29	25	25	25	25	0 ± 0 (CV=0)

Clinical Performances Characteristics

According to the CLSI disk diffusion breakpoints, 18 isolates were susceptible to imipenem, in contrast, when EUCAST disk diffusion breakpoints were used, four isolates were categorized as susceptible to imipenem. Imipenem showed higher efficacy against Klebsiella pneumoniae carbapenemase (KPC) producing Klebsiella pneumoniae strains than Verona Intergron Encoded Metallo-Beta-Lactamase (VIM) producing strains[4].

Another study[5], aimed to investigate the status of drug resistance and the ampC gene expression of *Enterobacter cloacae*. During the study period, a total of 144 strains of Enterobacter cloacae were isolates from six hospitals. Each isolate was tested for sensitivity against a range of antibiotic discs, results showed sensitivity to imipenem was 98.61%, the highest of all the antimicrobials used.

Serious Incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established. In the event of malfunction do not use device.

References

1. Clinical Laboratory Standards Institute (CLSI).
   a. Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard – M02 - Latest Edition.
   b. Performance Standards for Antimicrobial Susceptibility Testing – M100 – Latest Edition.
   c. Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline – M45 – Latest Edition.
2. European Committee on Antimicrobial Susceptibility Testing (EUCAST).
   a. Antimicrobial Susceptibility Testing, EUCAST disk diffusion method – Latest version.
   b. Reading guide, EUCAST disk diffusion method for antimicrobial susceptibility testing – Latest version.
3. Food and Drug Administration (FDA). CFR Title 21, Volume 5, Part 460 (2005).
4. Zhou, Zhihui, Lanjuan Li, Yunsong Yu, and Yilin Ma. 2003. "The Status of Drug Resistance and AmpC Gene Expression in *Enterobacter Cloacae*." *Chinese Medical Journal* 116 (8): 1244–47
5. Vading, M., Samuelsen, B. Haldorsen, A. S. Sundsfjord, and C. G. Giske. 2011. "Comparison of Disk Diffusion, Etest and VITEK2 for Detection of Carbapenemase-Producing *Klebsiella Pneumoniae* with the EUCAST and CLSI Breakpoint Systems." *Clinical Microbiology and Infection* 17 (5): 668–74. https://doi.org/10.1111/j.1469-0691.2010.03299.x.

Glossary of Symbols

Symbol/Label	Meaning
	Manufacturer
	In Vitro Diagnostic Medical Device
	Temperature limit
	Batch Code
	Catalog Number
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Contains sufficient for <n> tests
	Use-by date
	Do not use if package is damaged and Consult instructions for use
	Authorized representative in the European Community/ European Union
	Unique device identifier
	USA: Caution: Federal law restricts this device to sale by or on order of a Physician


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CE	European Conformity Mark
UKCA	UK Conformity Mark

Revision Information

Version	Date of issue and modifications introduced
1.0	2023-01-25

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