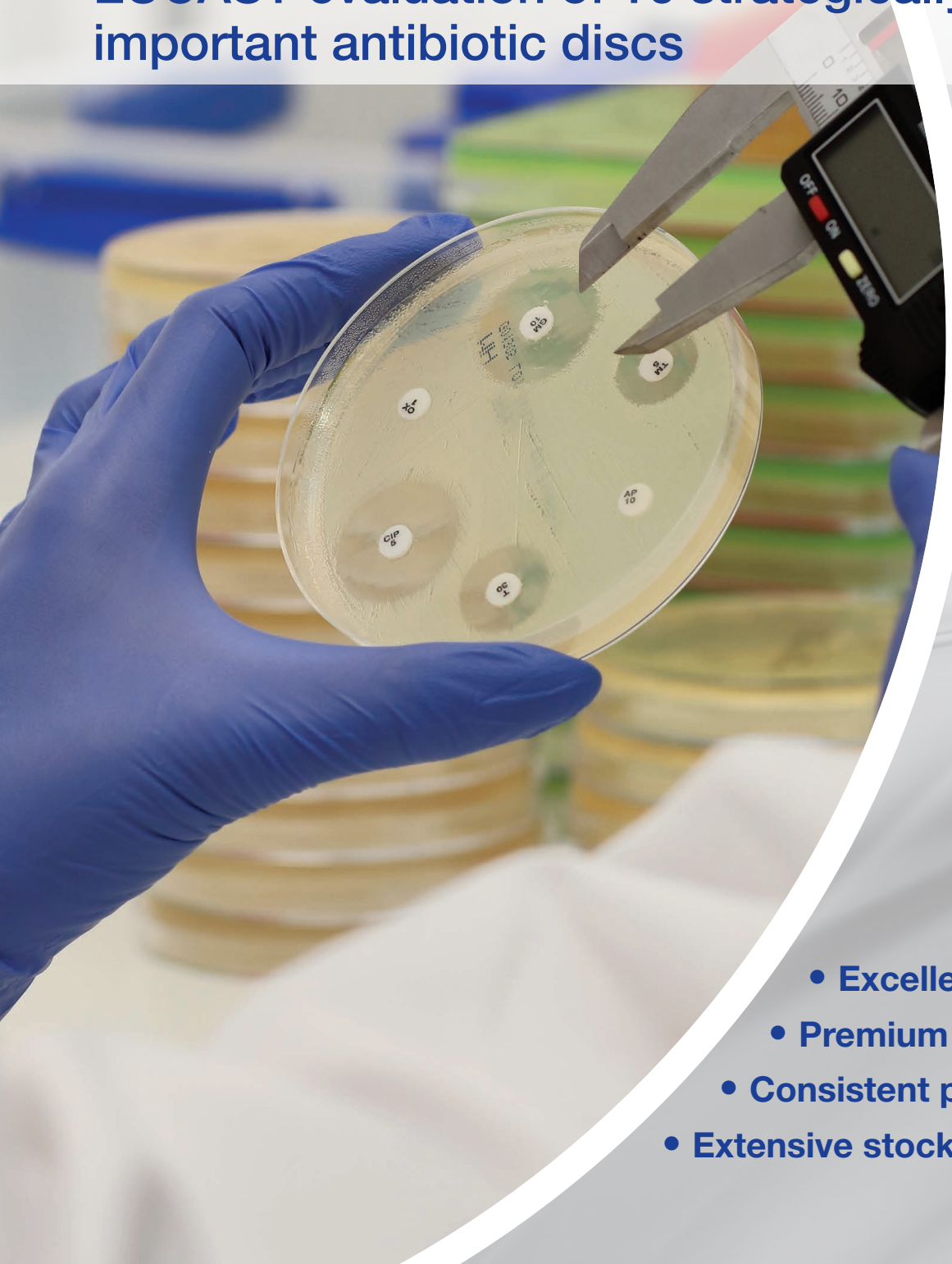
IVD solutions through partnership

Mast Group

MASTDISCS® AST

EUCAST evaluation of 16 strategically important antibiotic discs



- Excellent reproducibility
- Premium quality products
- Consistent performance
- Extensive stock range

MASTS' Performance on EUCAST study 2014-2017: Evaluation of 16 selected discs from nine manufacturers

EUCAST evaluated the disc potency of 16 antimicrobial susceptibility test discs from nine manufacturers against EUCAST targets and ranges for relevant quality control strains. The discs that were chosen for the study were representative of their central role in the EUCAST disc testing system e.g. discs used for screening or important resistance mechanisms, or because of problems detected by the laboratories including the EUCAST Development Laboratory (a copy of the report may be downloaded from www.eucast.org).

Results from the first study were released at ECCMID 2014; the antibiotic discs and QC strains used in the studies are seen in Table 1. Manufacturers were offered the opportunity to submit new disc lots for a second study to improve their results (see Table 2 for results).

Antimicrobial discs and QC strains

	QC Strain						
Antimicrobial agent	**Disc Content µg**	***E.coli* ATCC 25922**	***P. aeruginosa* ATCC 27853**	***S. aureus* ATCC 29213**	***E. faecalis* ATCC 29212**	***S. pneunmoniae* ATCC 49619**	***H. influenzae* ATCC 49766**
Benzylpenicillin	1 unit	-	-	×	-	×	×
Amoxicillin-clavulanic acid	20-10	×	-	-	-	-	-
Piperacillin-tazobactam	30-6	×	×	-	-	-	-
Oxacillin	1	-	-	-	-	×	-
Mecillinam	10	×	-	-	-	-	-
Cefotaxime	5	×	-	-	-	×	×
Cefoxitin	30	-	-	×	-	-	-
Ceftazidime	10	×	×	-	-	-	-
Meropenem	10	×	×	-	-	×	-
Ciprofloxacin	5	×	-	×	×	-	-
Norfloxacin	10	×	-	×	×	-	-
Pefloxacin	5	×	-	-	-	-	-
Gentamicin	10	×	-	×	-	-	-
Tobramycin	10	×	-	×	-	-	-
Erthromycin	15	-	-	×	-	×	-
Tetracycline	30	-	-	×	-	×	×

Table 1.

MAST is EUCAST compliant, and was able to supply all of the requested discs, not all manufacturers supplied all discs. MAST is pleased to confirm that all discs we supplied were consistently of a high quality, and was only one of three manufacturers who did not have any discs fall into the 'red' category in the original study in 2014.The red catergory meant that discs were completely out of range and most probably contain either less than half or more than twice the nominal amount of the active agent. Laboratories were warned against the use of the discs and manufacturers were recommended that they should withdraw these discs from the market

MAST had thirteen discs that were within ±1mm of the target value (green category), and two discs, Ciprofloxacin 5ug and Meropenem 10ug were within ± 2mm - of the target value (yellow category). Tetracycline 30ug was >2mm from target but still within the QC range (orange category).

The Ciprofloxacin 5ug and Meropenem 10ug results were consistent with results derived from other manufacturer's discs; therefore the QC ranges are being reviewed by EUCAST. Consequently, no action can be taken until the EUCAST revision is complete. Although Tetracycline 30ug performed within the acceptable ranges, Mast launched an internal investigation to see if any further improvements could be made to the process.

For the second study in 2015 manufacturers had been informed individually of their results and asked to supply new disc lots for all agents with deviating results.

Some manufactuers chose not to supply new disc lots ,whereas others sent new discs for a few agents or all agents included in the first study.

Mast did not re-submit any discs for the second study, as it was not to confirm reproduciblity and primarily aimed at companies displaying poor results and/or significant failings in order to improve their results. In some cases improvements were observed, but in others the performance had deteriorated.

In June 2016 EUCAST re-analysed data 1 (see updated table 2) as result in changes in QC criteria for H influenza ATCC 49766 with Cefotaxime 5 ug (2015) and *E.coli* ATCC 25922 with Meropenem 10ug (2016)

For the 2014-2016 studies **MAST**DISCS® had an acceptable performance across all discs tested, on in-house prepared Mueller Hinton agar plates using MH agar from two manufacturers.

In 2017 EUCAST again invited manufacturers to participate in a repeat of these studies. In November 2017, EUCAST provided the manufacturers participating in this study a review of their latest findings (see Table 3). This demonstrates a dramatic improvement in the majority of manufacturer's performances with fewer discs out of range when compared to the first study. The report highlighted that from **2014 to 2017 MAST has maintained a high level of consistency of well calibrated discs maintaining quality and performance throughout all three studies.**

MASTDISCS® produced results 100% within the ranges set out by EUCAST and Mast's reproducibility continues to be a high standard is for all **MAST**DISCS® QC combinations. EUCAST are continuing to monitor antibiotic discs and companies are expecting a request for another submission in 6 months time.

Results from Studies 2014 to 2016

Antimicrobial agent	Bio-Rad	Lio-filchem	BD	Abtek	SirScan	Oxoid	HiMedia	Bio-analyse	Mast
Benzylpenicillin 1 unit			L		H		NA	H	
Amoxicillin-clavulanic acid 20-10 µg	H			L			H		
Piperacillin-tazobactam 30-6 µg				L	H		NA		
Oxacillin1 µg		L	L		L		H	L	
Mecillinam 10 µg				L	H		H	H	
Cefotaxime 5 µg				NA			NA		
Cefoxitin 30 µg	H*	H		NA			L*		
Ceftazidime 10 µg				L			L		
Meropenem 10 µg	H	H*		L		H	H		
Ciprofloxacin 5 µg			L				H		L
Norfloxacin 10 µg				L	L		H*		
Pefloxacin 5 µg		L	L	NA	NA		H		
Gentamicin 10 µg			H		NA		H		
Tobramycin 10 µg	NA	H					H*		
Erthromycin 15 µg		L	L	L	L		H	L*	
Tetracycline 30 µg		L	L*	L	L*			L	L

Mean value within ± 1 mm of the target value
Mean value > 1 mm but within ± 2 mm of the target value
Mean value > 2 mm from target value but still within the QC Range
Mean value out of the QC target range
Disk included in first study, but not supplied for second study

NA = Not Availablle
H = High, mean value > 1 mm above target
L = Low, mean value > 1 mm below target
***** One or more readings out of QC range

Data from the first study were recalculated to targets and ranges in EUCAST QC Tables v 7.0

Table 2.

Courtesy of EUCAST visit www.eucast.org

Results third study 2017

Antimicrobial agent	Bio-Rad	Lio-filchem	BD	Abtek	SirScan	Oxoid	HiMedia	Bio-analyse	Mast
Benzylpenicillin 1 unit			L		NA				
Amoxicillin-clavulanic acid 20-10 µg	H	L		L			L		
Piperacillin-tazobactam 30-6 µg				L			L	H	H
Oxacillin1 µg	H						H		
Mecillinam 10 µg									
Cefotaxime 5 µg									
Cefoxitin 30 µg			L				L	H	
Ceftazidime 10 µg				L			L*		
Meropenem 10 µg							L*		
Ciprofloxacin 5 µg									
Norfloxacin 10 µg									
Pefloxacin 5 µg		L					H		
Gentamicin 10 µg							H		H
Tobramycin 10 µg							H		
Erthromycin 15 µg									
Tetracycline 30 µg							L		

Mean value within ± 1 mm of the target value
Mean value > 1 mm but within ± 2 mm of the target value
Mean value > 2 mm from target value but still within the QC Range
Mean value out of the QC target range
Disk included in first study, but not supplied for second study

NA = Not Availablle
H = High, mean value > 1 mm above target
L = Low, mean value > 1 mm below target
***** One or more readings out of QC range

Table 3. Courtesy of EUCAST visit www.eucast.org

Readings within range (%)

Manufacturer	First Study	Third Study
Mast	**100**	**100**
Oxoid	**100**	**100**
BD	**99**	**100**
SirScan	**94**	**100**
Bioanalyse	**93**	**100**
Bio-Rad	**93**	**100**
Abtek	**89**	**100**
Liofilchem	**90**	**95**
HiMedia	**67**	**82**
In total (Number of readings)	**92.3**	**97.5**
	(861)	(909)

Table 4. Courtesy of EUCAST visit www.eucast.org

Reproducibility Mast discs 2017

Study design

As a part of the evaluation of 16 antimicrobial discs from nine manufacturers EUCAST looked at the reproducibility within one vial of discs. Three agents were selected: piperacillin-tazobactam 30-6 µg, amoxicillin-clavulanic acid 20-10 µg and tobramycin 10 µg, see lot numbers below. The reproducibility test was performed by testing 20 discs from one vial, using the same inoculum suspension. Disc diffusion was performed according to EUCAST methodology for one susceptible QC strain. For the β-lactam-β-lactamase inhibitor combination discs, a resistant QC strain was added to control the inhibitor component.

Antimicrobial agent	Disc lots	Expiry date
Amoxicillin-clavulanic acid 20-10 µg	386313	2018-03
Piperacillin-tazobactam 30-6 µg	386286	2018-10
Tobramycin 10 µg	385212	2020-02

Results

See Table 5. Reproducibility was considered good if the variation for 20 discs from one vial was within the mean value ± 1 mm, and poor if the variation was > 1 mm from the mean value. Also the mean value of testing 20 discs was evaluated against targets and ranges in EUCAST QC Tables v. 7.0 (as in the full evaluation of 16 discs from nine manufacturers).

Conclusions

Reproducibility was good for all disc-QC strain combinations. All results were within quality control ranges and close to the QC target values.

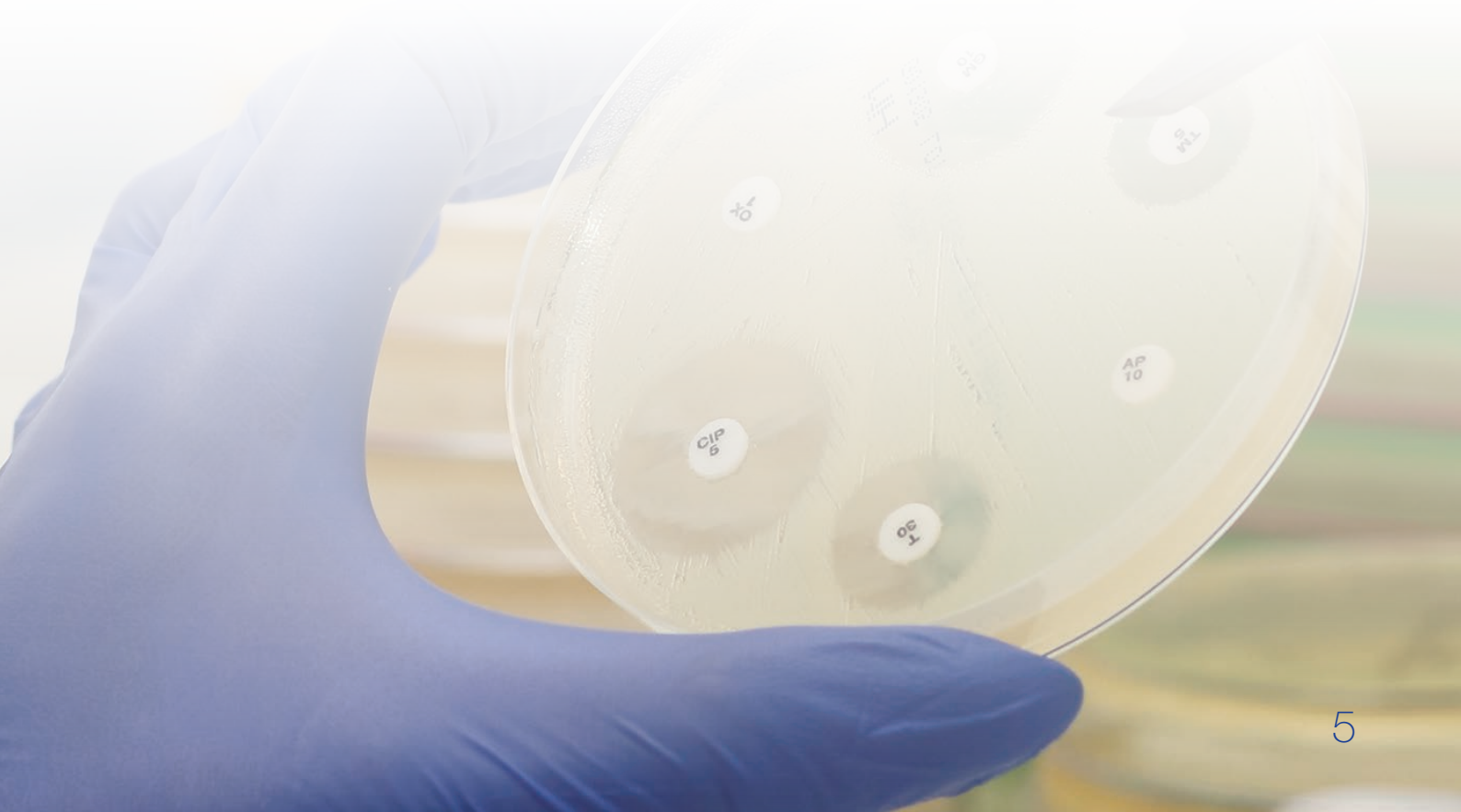


Table 5: Mast Discs Reproducibility Results

	Amoxicillin-clavulanic acid 20-10 µg		Piperacillin-tazobactam 30-6 µg		Tobramycin 10 µg
	E. coli ATCC 25922	*E. coli* ATCC 35218	*E. coli* ATCC 25922	*K. pneu* ATCC 700603	*E. coli* ATCC 25922
	21	19	25	19	23
	21	19	25	19	23
	20	18	25	19	23
	20	19	25	19	23
	21	19	25	19	23
	22	19	25	20	23
	21	19	25	20	23
	20	18	25	20	23
	20	19	25	19	24
	21	19	25	19	23
	21	19	26	19	24
	21	19	25	19	23
	21	19	25	18	23
	22	18	26	19	23
	21	18	26	19	23
	21	19	25	19	24
	20	19	26	19	24
	21	18	26	20	23
	21	18	26	19	23
	21	18	26	20	23
QC Target	**21**	**19-20**	**24**	**17**	**22**
QC Range	**18-24**	**17-22**	**21-27**	**14-20**	**18-26**

Mean	**21**	**19**	**25**	**19**	**23**
Std	***0.6***	***0.5***	***0.5***	***0.5***	***0.4***
Min	**20**	**18**	**25**	**18**	**23**
Max	**22**	**19**	**26**	**20**	**24**

Mean value within ± 1 mm of the target value
Mean value > 1 mm but within ± 2 mm of the target value
Mean value > 2 mm from target value but still within the QC Range
Results out of QC range

Good reproducibility: Variation within mean value ± 1 mm
Poor reproducibility: Variation > 1 mm from mean value

Courtesy of EUCAST visit www.eucast.org

In-use Storage of MASTDISCS® for antibiotic susceptibility testing

Mast Group Limited has undertaken validation studies on representative samples of Mast manufactured antimicrobial susceptibility test discs (**MAST**DISCS®) to establish in-use storage recommendations for the product range.

Based on usage of Mast DiscMaster™ dispensers (MDD63/MDD64) with a correctly maintained and charged desiccant, **MAST**DISCS® in cartridges will maintain their viability for the recommended period of time:
MDD63 - 28 days for standard antibiotics and 17 days for the Carbapenem group.
MDD64 - 28 days for all antibiotics including the Carbapenem group.

This is constantly under review and customers will be advised of any changes to this information.

Desiccants should be recharged before first use, thereafter once it has lost its dry state colouration and on at least a weekly basis. (Please refer to the MDD64 dispenser Instructions for Use document (IFU808) at www.mastgrp.com).

Certain methods, including those issued by EUCAST/CLSI specify the maximum period of time that working stocks of **MAST**DISCS® can be used and these must be adhered to in order to maintain compliance to those methods.

Loss of potency of antimicrobial agents is a common source of test error. Laboratories should observe best practice when using and handling susceptibility test discs to ensure correct results are obtained. The following are essential:-

- Stocks of **MAST**DISCS® must be stored between -20°C and +8°C.
- Working stocks of **MAST**DISCS® must be stored between +2°C and +8°C.
- Ensure the dispensers canister has the correct number of desiccant capsules in situ
- Before opening and to prevent condensation, the container and its contents must be allowed to reach room temperature (18-30°C). Moisture and temperature variation will cause the products to degrade. Cartridges containing ß-lactamase inhibitors and carbapenems are particularly susceptible to degradation by moisture.
- After application of **MAST**DISCS®, the in-use cartridges must be returned immediately to sealed dispenser canister with a desiccant at a temperature between +2°C and +8°C.
- Do not use any **MAST**DISCS® left at room temperature for long periods of time without first verifying an acceptable level of performance.
- Discard any **MAST**DISCS® still in primary packaging on the expiry date shown on the container
- Use specified control strains, according to schedules contained within the standardised susceptibility method followed, to monitor the performance of the test.
- Quality Control checks should be carried out on a regular basis to monitor all aspects of antibiotic susceptibility testing to comply with EUCAST/CLSI standards.

We can only guarantee the performance of **MAST**DISCS® in cartridges when they are used in conjunction with **MAST** DiscMaster™ Dispensers (MDD63/MDD64) as they are designed to be used as a composite system.

It is essential these guidelines are adhered to ensure reproducible and accurate results.

To find out more about **MAST**® products
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