



# EUCAST

EUROPEAN COMMITTEE  
ON ANTIMICROBIAL  
SUSCEPTIBILITY TESTING

European Society of Clinical Microbiology and Infectious Diseases

## **Implementing EUCAST breakpoints and methodologies**

### **Chairpersons**

Derek Brown (Cambridge, UK and  
Gunnar Kahlmeter (Växjö, Sweden)

### **Speakers**

G Kahlmeter, Sweden  
P Tulkens, Belgium  
A MacGowan, UK  
J Mouton, NL

# Implementation of EUCAST breakpoints and impact on resistance surveillance

Gunnar Kahlmeter

Växjö, Sweden

[Gunnar.kahlmeter@ltkronoberg.se](mailto:Gunnar.kahlmeter@ltkronoberg.se)



# EUCAST

## European Committee on Antimicrobial Susceptibility Testing

- Convened by ESCMID
- Financed by ECDC, ESCMID and the 6 National Breakpoint Committees in Europe (D, F, N, NL, S, UK)
- Decisions by consensus
- Observers from EMEA and ECDC
- Network of experts and industry for consultation

# EUCAST Tasks

- Determine clinical breakpoints for new and existing antimicrobials for bacteria and fungi.
- Determine epidemiological cut-off values (ECOFFs) for all antimicrobials for bacteria, for fungi.
- Provide European standardised and harmonised methods for AST of bacteria and fungi.
- Education of laboratory staff (national and international workshops; ESCMID, ECCMID, ECDC)
- Liaise with European regulatory authorities and NGOs and with international groups involved in AST breakpoints and methodology.

# **EUCAST defines test systems and determines breakpoints:**

**Clinical breakpoints**

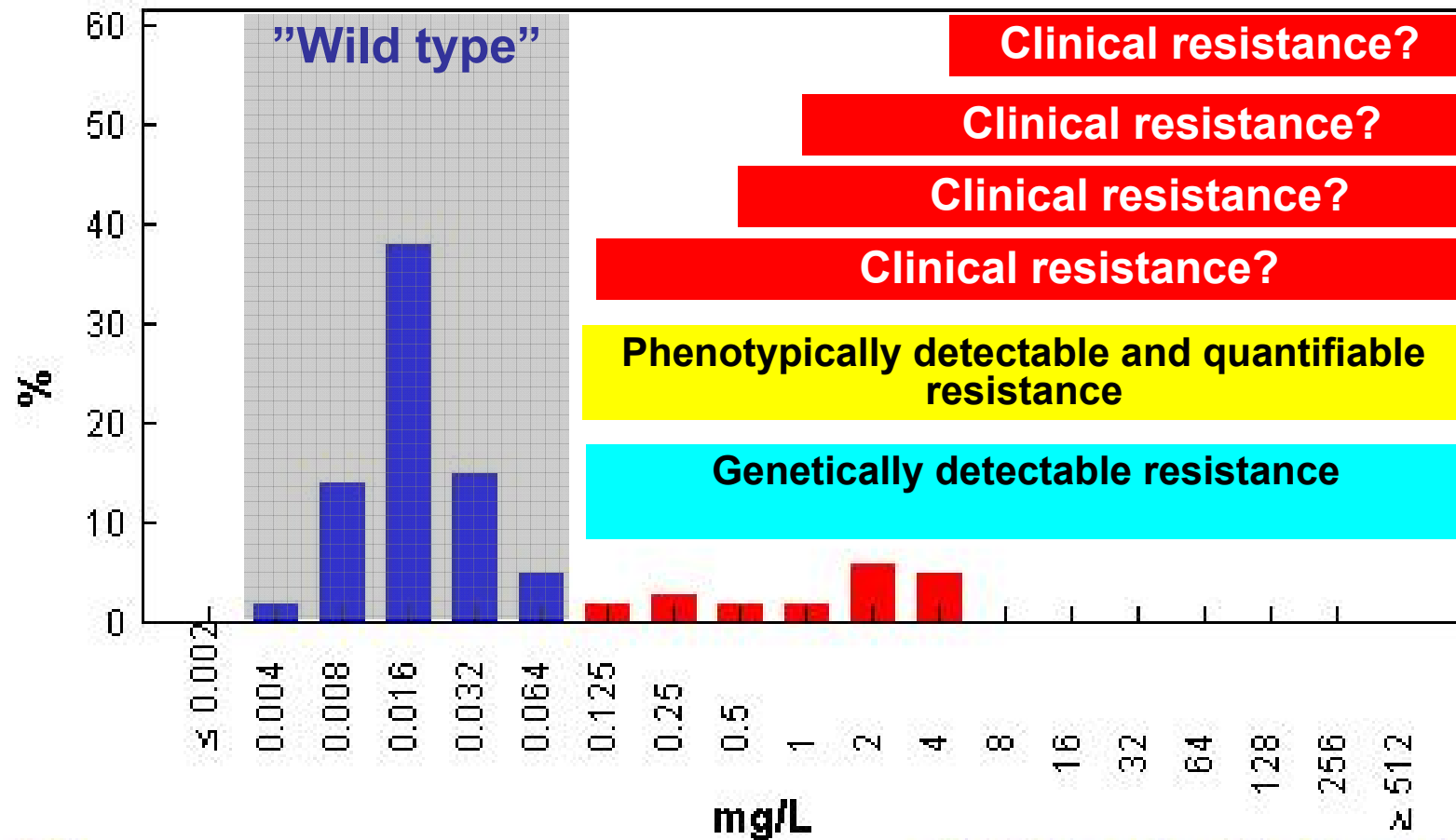
**Epidemiological cut-off values**

- for MIC determination
- for AST automatic devices
- for disk diffusion

# Benzylopenicillin / *Streptococcus pneumoniae*

Antimicrobial wild type distributions of microorganisms - reference database

## EUCAST MIC Distribution



MIC

37642 observations (32 data sources)

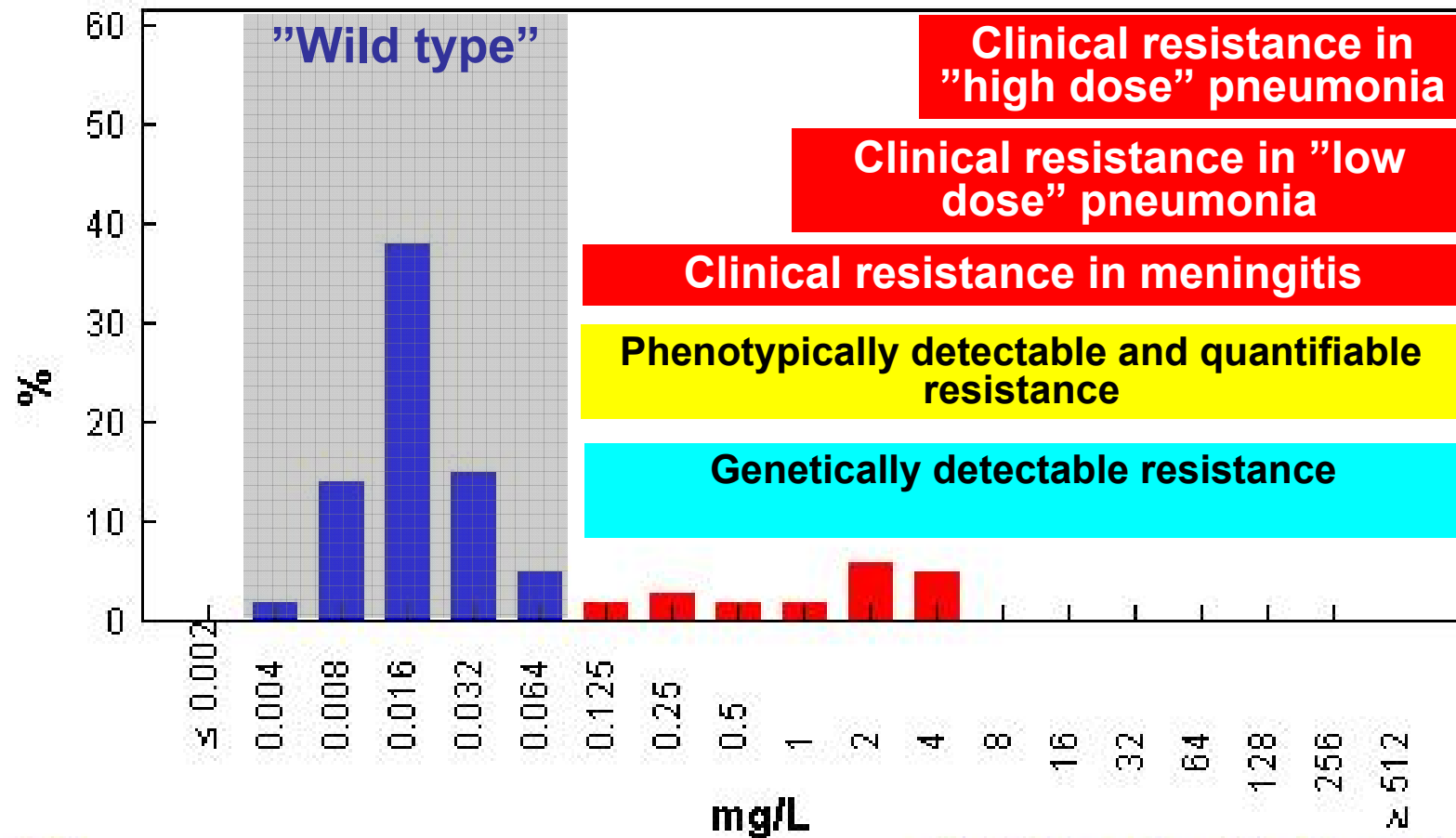
Epidemiological cut-off: WT  $\leq 0.064$  mg/L

Clinical breakpoints: S  $\leq 0.064$  mg/L, R  $> 2$  mg/L

## Benzylopicillin / *Streptococcus pneumoniae*

Antimicrobial wild type distributions of microorganisms - reference database

### EUCAST MIC Distribution



MIC

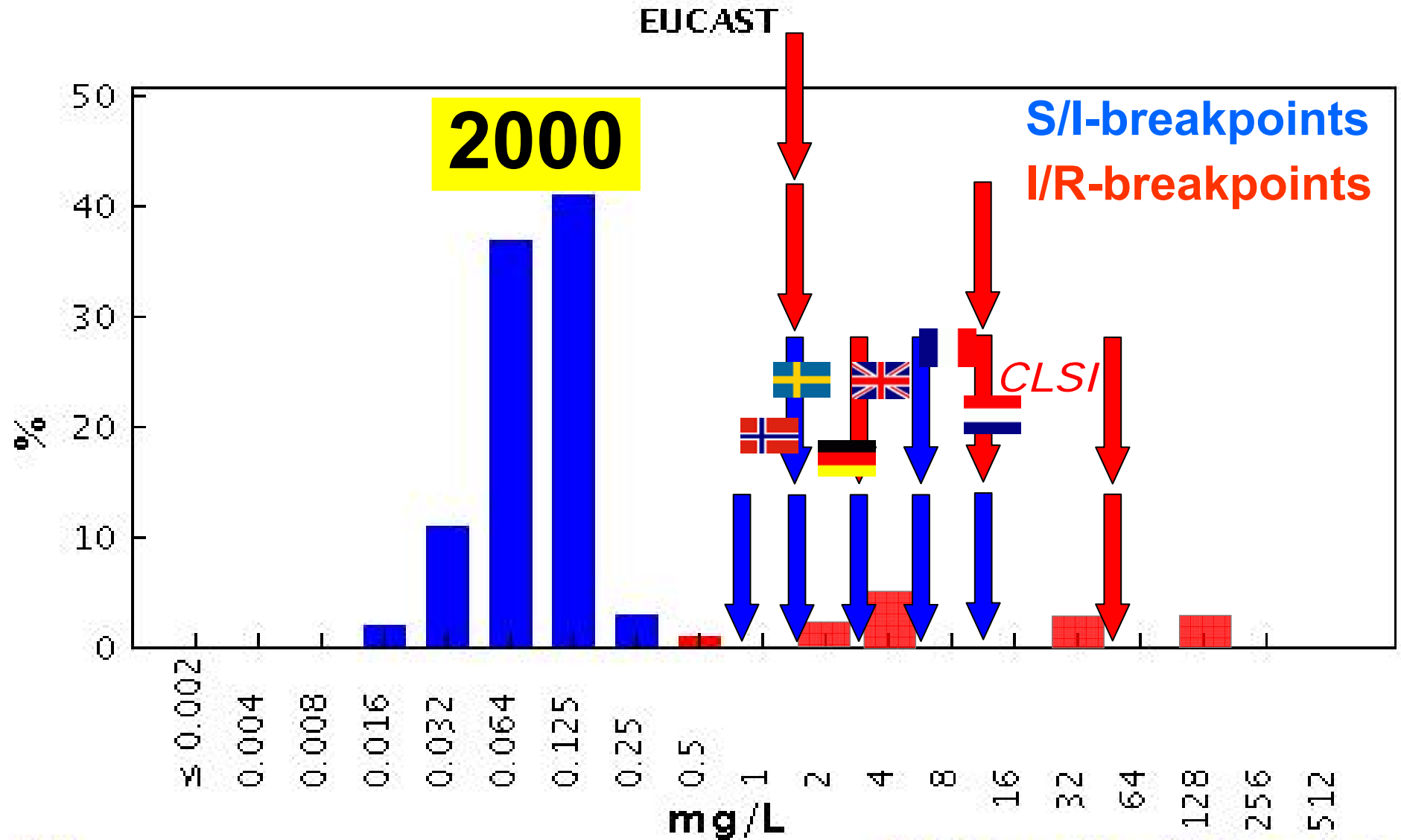
37642 observations (32 data sources)

Epidemiological cut-off: WT ≤ 0.064 mg/L

Clinical breakpoints: S ≤ 0.064 mg/L, R > 2 mg/L

# Cefotaxime / Escherichia coli

Antimicrobial wild type distributions of microorganisms - reference database



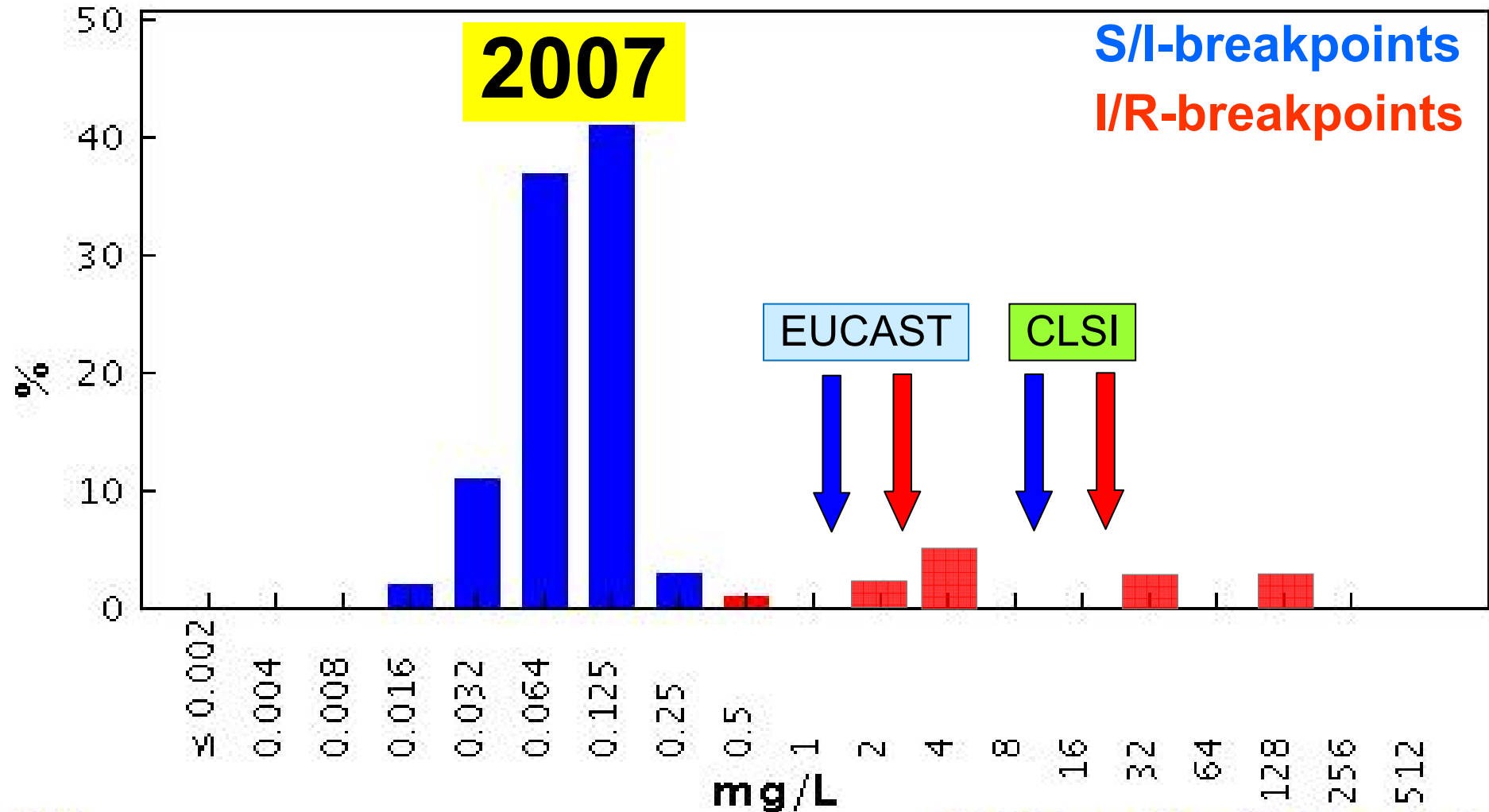
MIC  
Epidemiological cut-off: WT ≤ 0.25 mg/L

6290 observations (12 data sources)  
Clinical breakpoints: S ≤ - mg/L, R > - mg/L

# Cefotaxime / Escherichia coli

Antimicrobial wild type distributions of microorganisms - reference database

EUCAST



MIC

Epidemiological cut-off: WT ≤ 0.25 mg/L

6290 observations (12 data sources)

Clinical breakpoints: S ≤ - mg/L, R > - mg/L

# EUCAST and existing antimicrobials

- Aminoglycosides ✓
- Carbapenems & aztreonam ✓
- Cephalosporins iv ✓
- Cephalosporins oral (finalised May 2009)
- Fluoroquinolones ✓
- Glycopeptides ✓
- Macrolides and lincosamides ✓
- Penicillins ✓
- Tetracyclines ✓
- Miscellaneous antimicrobials ✓
  
- Antifungal drugs (flu- and voriconazole) ✓

# EUCAST

– breakpoint committee for new drugs through European Medicines Agency (EMA)

- Daptomycin ✓
- Tigecycline ✓
- Garenoxacin (✓)
- Doripenem ✓
- New cephalosporin (ongoing)
- Glycopeptides (3 ongoing)
- Fluoroquinolone (1 ongoing)
- Diaminopyrimidine (1 ongoing)
- Extensions of indications

# EUCAST Subcommittee on Anaerobes

Chair Arne Rodloff

- Determined which antimicrobials should have breakpoints for Gram-negative and Gram-positive anaerobes
- Breakpoints for anaerobes
- Investigating methodological aspects on AST of anaerobes

# EUCAST Subcommittee on Expert Rules

Chair Roland Leclercq

- Intrinsic resistance tables
  - Unusual phenotypes tables
  - Interpretive reading of AST tables
- 
- Finalised 2008
  - Revised during 2009
  - "Computerized" in 2009

# Consultation with expert groups

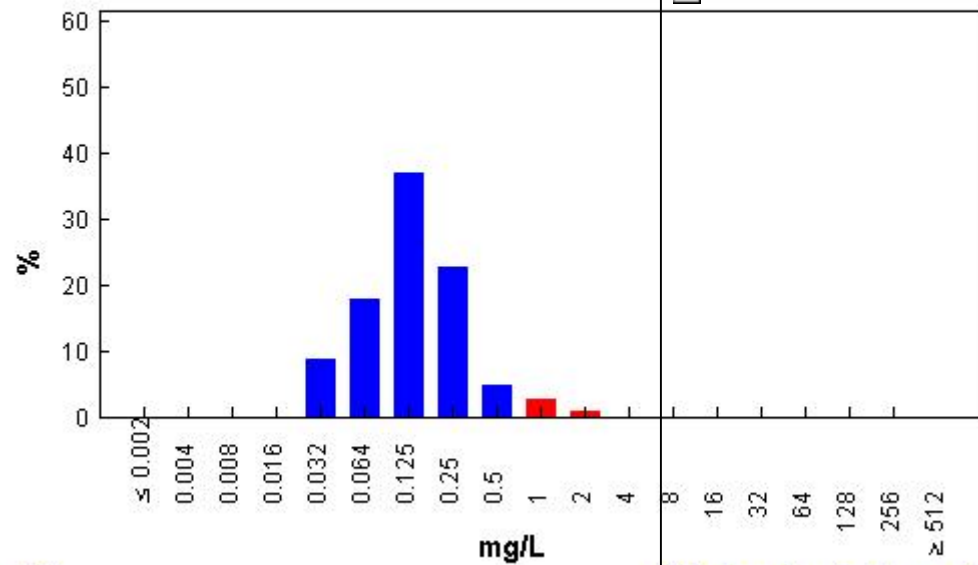
- Neisseria spp (finalised)
- Anaerobes (ESGARAB, ongoing)
- Helicobacter pylori (EHSG, ongoing)
- Clostridium difficile (ESGCD, ongoing)
- Campylobacter (VetCast, ongoing)
- Listeria monocytogenes
- ...

# Anaerobes with ESGARAB

Imipenem / *Bacteroides fragilis*

Antimicrobial wild type distributions of microorganisms - reference database

EUCAST MIC Distribution



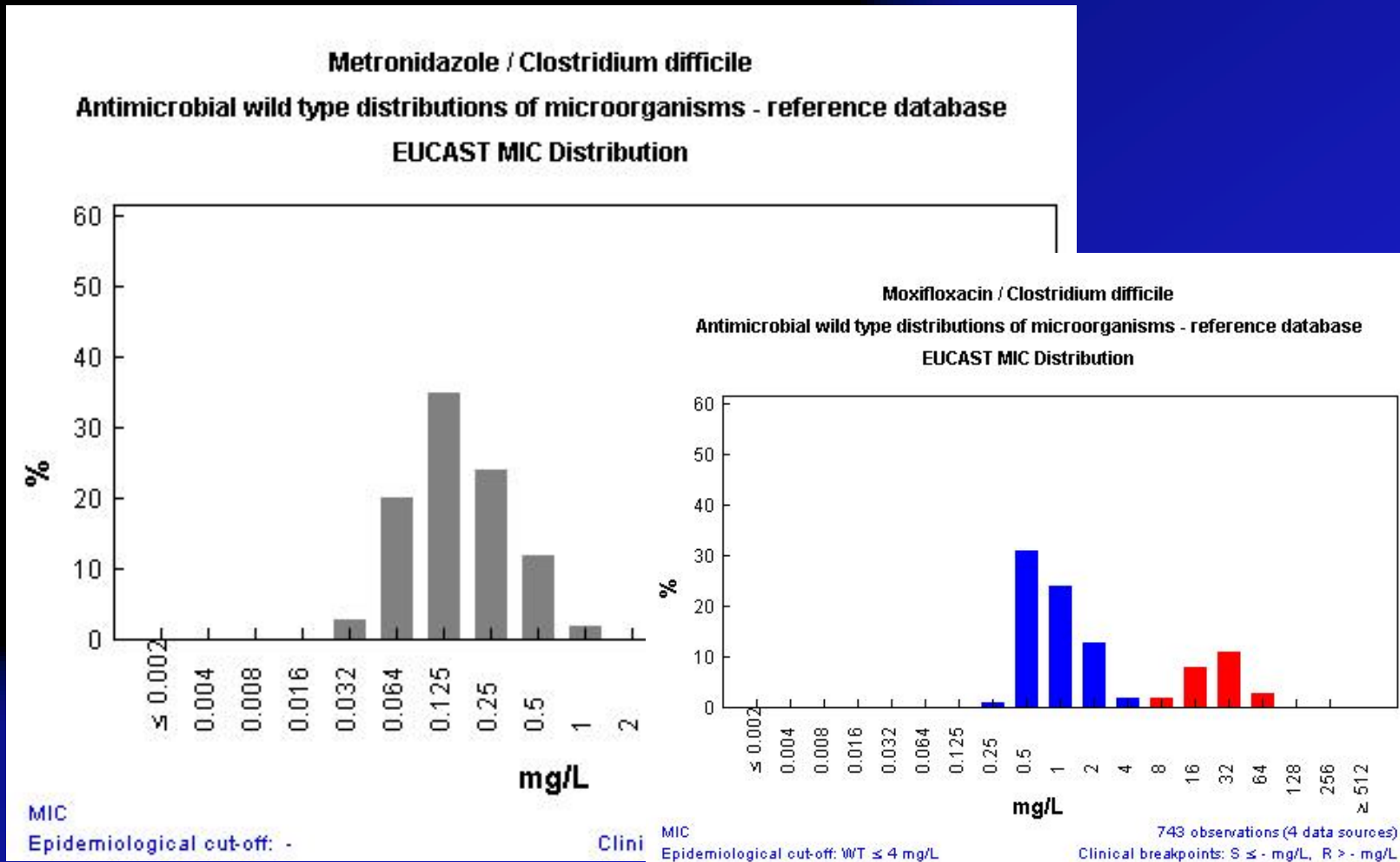
MIC

Epidemiological cut-off: WT  $\leq 0.5$  mg/L

1328 observations (5 data sources)

Clinical breakpoints: S  $\leq 2$  mg/L, R  $> 8$  mg/L

# C. difficile with ESGCD

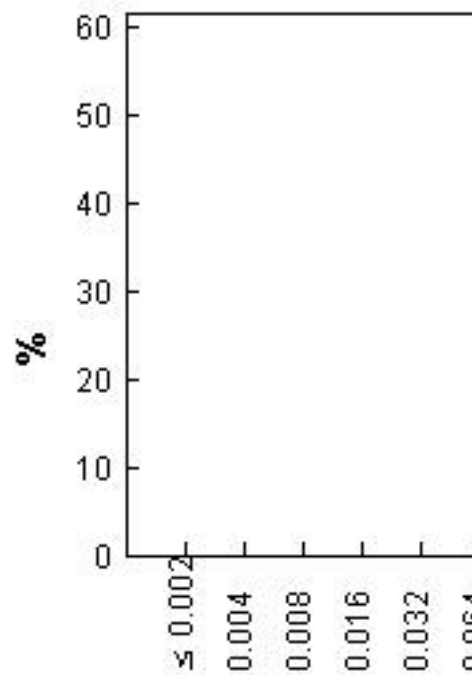


# Campylobacter with Veterinarian microbiology

## Nalidixic acid / *Campylobacter jejuni*

Antimicrobial wild type distributions of microorganisms - reference database

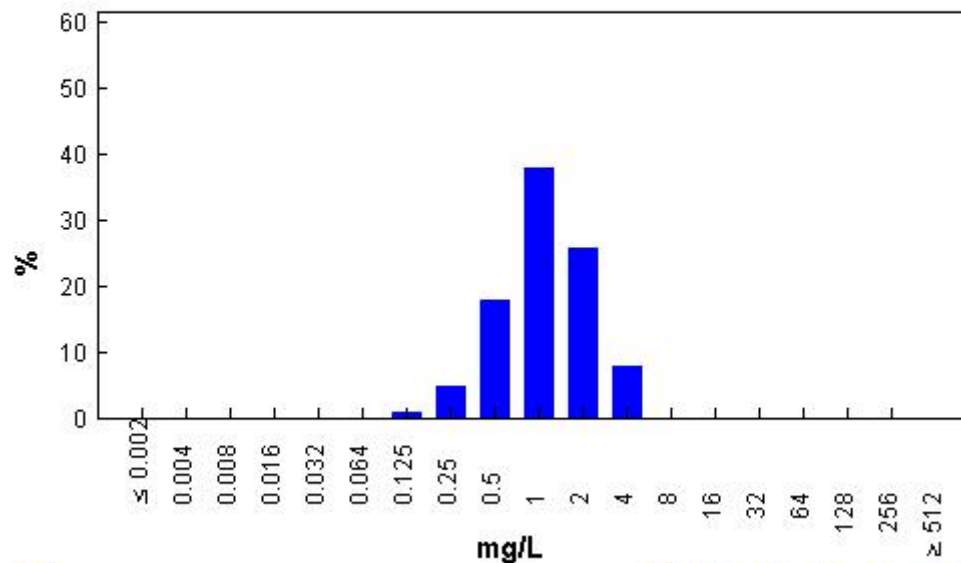
### EUCAST MIC Distribution



## Erythromycin / *Campylobacter jejuni*

Antimicrobial wild type distributions of microorganisms - reference database

### EUCAST MIC Distribution



MIC

Epidemiological cut-off: WT ≤ 16 mg/L

MIC

Epidemiological cut-off: WT ≤ 4 mg/L

1493 observations (18 data sources)

Clinical breakpoints: S ≤ 4 mg/L, R > 4 mg/L

1020 observations (20 data sources)

Clinical breakpoints: S ≤ - mg/L, R > - mg/L

# Participants in UKNEQAS for Microbiology (2008)

Derek Brown, Educational Workshop 5, ECCMID 2009

Austria	43
Belgium	4
Croatia	6
Finland	23
Germany	1
Greece	16
Ireland	45
Italy	124

Netherlands	18
Poland	1
Portugal	52
Romania	2
Sweden	28
Switzerland	24
United Kingdom	278
Other	82

# Breakpoint guidelines used by participants in UKNEQAS 2009

Derek Brown, Educational Workshop 5, ECCMID 2009

<b>Guideline</b>	<b>Number (%) labs</b>
CLSI	368 (53.7)
BSAC (UK)	190 (29.6)
SRGA (Sweden)	36 (4.8)
NWGA (Norway)	6 (0.6)
CRG (Netherlands)	5 (0.7)
<b>EUCAST</b>	<b>4</b>
Other	43
<b>TOTAL</b>	<b>674</b>

# Methods used by participants in UKNEQAS 2008

Derek Brown, Educational Workshop 5, ECCMID 2009

<b>Method</b>	<b>Number (%) labs</b>
Disk diffusion	352 (51)
Automated (CLSI)	240 (31)
MIC	26 (4)
Breakpoint	23 (3)
Other/not stated	81 (11)
Total	672

# EUCAST and CLSI breakpoints are different!

Group of organisms	No. of break-points	Same breakpoint(s) for		
		<b>S</b> and <b>R</b>	<b>S</b>	<b>R</b>
Enterobacteriaceae	36	0	3	3
<i>Pseudomonas</i>	18	1 (IMI)	5	2
<i>Acinetobacter</i>	11	1 (COL)	4	2
Staphylococci	31	4	5	2
Enterococci	14	0	2	3
Streptococci	25	2	5	2
<i>S. pneumoniae</i>	29	3	1	5
<i>H. influenzae</i>	27	0	3	0

## **EUCAST- and CLSI-breakpoints are different**

- The processes for determining breakpoints are now similar but EUCAST has systematically and recently reviewed all breakpoints.
- Structure and organisation of committee.
- The role of industry (consultative vs. part of decision process).
- The number of committee meetings per year (5 vs. 2).
- The relation between committee and regulatory authorities.

# *E.coli, Klebsiella, Proteus*

## EUCAST vs. CLSI

Antimicrobial	EUCAST S≤/R> (mg/L)	CLSI S≤/R> (mg/L)
Ampicillin	8 / 8	8 / 16
Cefotaxime	1 / 2	8 / 32
Ceftazidime	2 / 8	8 / 16
Cefuroxime	8* / 8	4 / 16
Imi-/Meropenem	2 / 8	4 / 8
Ciprofloxacin	0.5 / 1	1 / 2
Gentamicin/Tobra	2 / 4	4 / 8
Amikacin	8 / 16	16 / 32
Trimethoprim	2 / 4	8 / 8
Nitrofurantoin	64 / 64	32 / 64

\*Increased from 4 to 8 mg/L to avoid dividing the wild type MIC distribution

# *Streptococcus pneumoniae*

## EUCAST vs. CLSI

Antimicrobial	EUCAST S≤/R> (mg/L)	CLSI S≤/R> (mg/L)
<b>Benzylpenicillin<sup>Meningitis</sup></b>	<b>0.064 / 0.064</b>	<b>0.064 / 0.064</b>
<b>Benzylpenicillin<sup>Pneumonia</sup></b>	<b>0.064 / 2*</b>	<b>2 / 4**</b>
<b>Penicillin V</b>	<b>PcG 0.064 / 0.064</b>	<b>0.064 / 1</b>
<b>Ampi/Amoxicillin</b>	<b>0.5 / 2</b>	<b>2 / 4</b>
<b>Cefotaxime</b>	<b>0.5 / 2</b>	<b>1 / 2</b>
<b>Moxifloxacin</b>	<b>0.5 / 0.5</b>	<b>1 / 2</b>
<b>Erythromycin</b>	<b>0.25 / 0.5</b>	<b>0.25 / 0.5</b>
<b>Azitromycin</b>	<b>0.25 / 0.5</b>	<b>0.5 / 1</b>

\*MIC-related (0.125 – 2 mg/L) variable dosing for pneumonia

\*\*High dose for pneumonia

# Why European breakpoints in Europe?

- breakpoints for European minimum and maximum dosages
- based on EMEA approved indications and outcome evaluation, Pk/Pd, multiple MIC distributions, and modern principles of determining breakpoints
- accepted by European regulatory authorities (EMA, ECDC) and the only breakpoints in European SPCs
- European (ECDC) "case definitions" for antimicrobial resistance surveillance
- harmonised standards for national and European strategies
- rationale behind decisions transparent and published
- independent of commercial interests
- reviewed at intervals: with every new member of class and on the initiative of a) EMA, b) the profession, c) Company
- in the public domain free of charge

# Implementation

- MIC-testing of any kind ✓
- National systems from France, UK, Sweden ✓
- Phoenix ✓
- Vitek2, MicroScan – ongoing
- Disk diffusion – ongoing

# EUCAST Disk Diffusion Test

# 2009

Methods, QC from autumn 2009  
Breakpoints from late 2009

# EUCAST disk diffusion test

## Non-fastidious organisms

- Mueller-Hinton
- Inoculum 0.5 McFarland
- Incubation 18 +/-2 h
- Disk strengths as CLSI except gentamicin 10µg, tobramycin 10µg, cefotaxime 5µg, ceftazidime 10µg.
- QC strains and reference ranges as ISO and CLSI + three more strains

## Streptococci, H.influenzae, etc

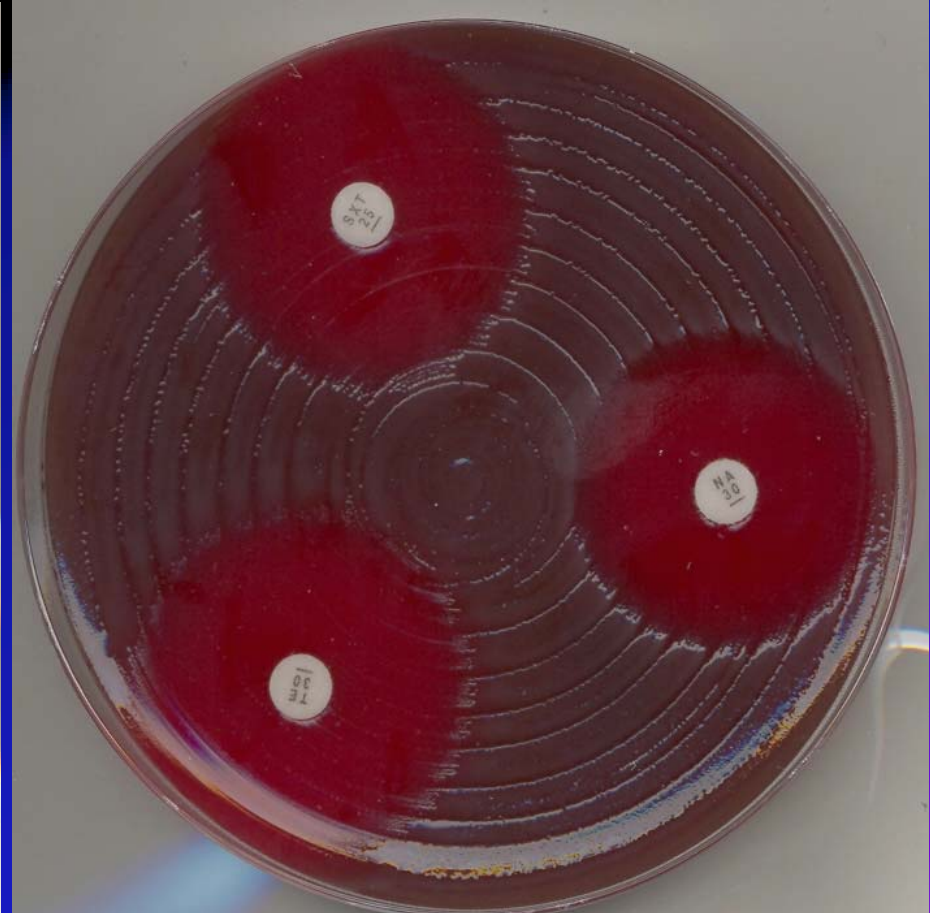
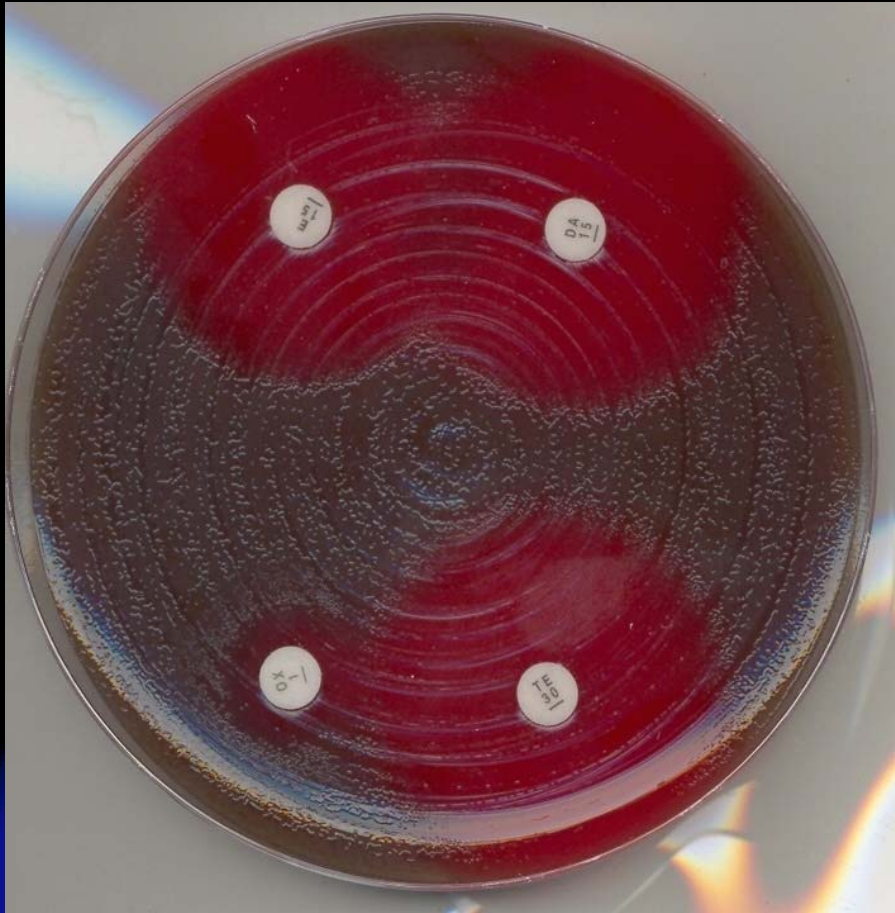
- MH + 5% defibrinated horse blood and 20 mg β-NAD for streptococci, pneumococci and *H. influenzae*
- Inoculum 0.5 McFarland
- Incubation 18 +/-2 h
- Disk strengths as CLSI except gentamicin 10µg, tobramycin 10µg, cefotaxime 5µg, ceftazidime 10µg.
- QC strains and reference ranges as ISO and CLSI + three more strains

# *E. coli* ATCC 25922



***S. pneumoniae* ATCC 49619**

***H. influenzae* NCTC 8468**



MH + 5% defibrinated horse blood and 20 mg/L  $\beta$ -NAD  
Grows streptococci and *H. influenzae*

# EUCAST MIC- and Zone diameter distribution website

>19 000 MIC distributions

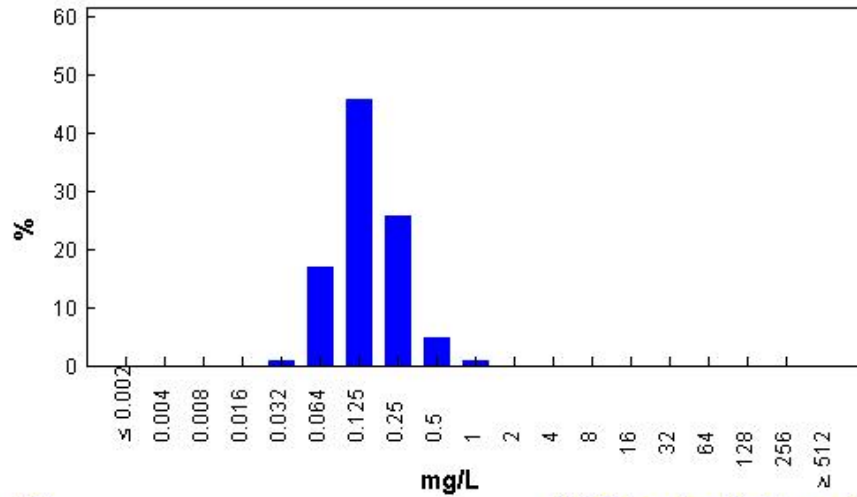
Increasing number of zone diameter distributions

QC ATCC strains (MIC, Zone diameter)

>22 000 hits since ECCMID 2007

### Imipenem / Escherichia coli

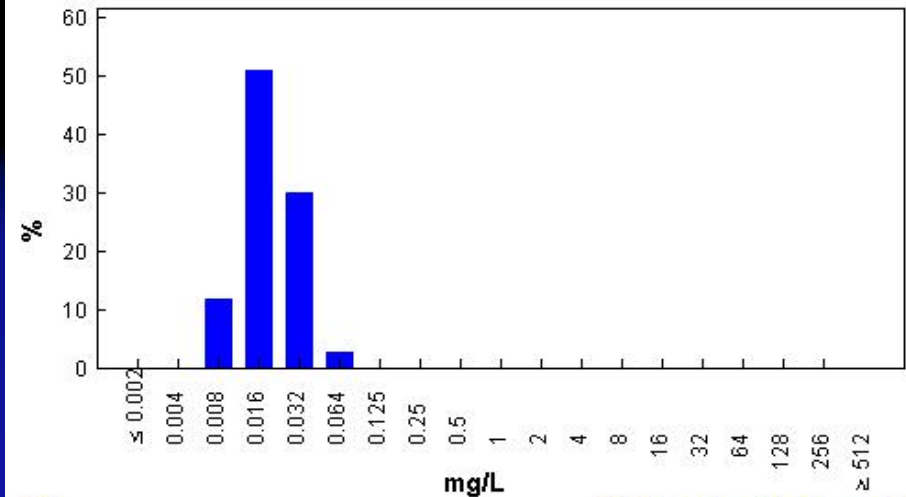
Antimicrobial wild type distributions of microorganisms - reference database  
EUCAST MIC Distribution



MIC 15037 observations (83 data sources)  
Epidemiological cut-off: WT ≤ 1 mg/L Clinical breakpoints: S ≤ 2 mg/L, R > 8 mg/L

### Meropenem / Escherichia coli

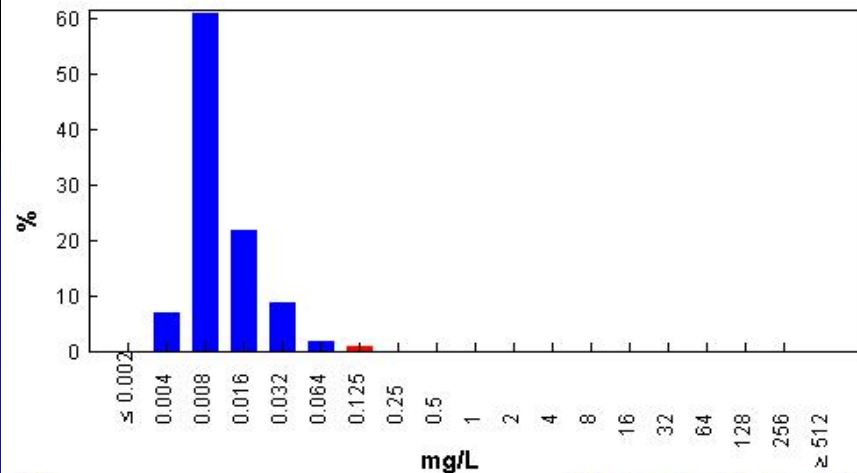
Antimicrobial wild type distributions of microorganisms - reference database  
EUCAST MIC Distribution



MIC 8000 observations (63 data sources)  
Epidemiological cut-off: WT ≤ 0.125 mg/L Clinical breakpoints: S ≤ 2 mg/L, R > 8 mg/L

### Ertapenem / Escherichia coli

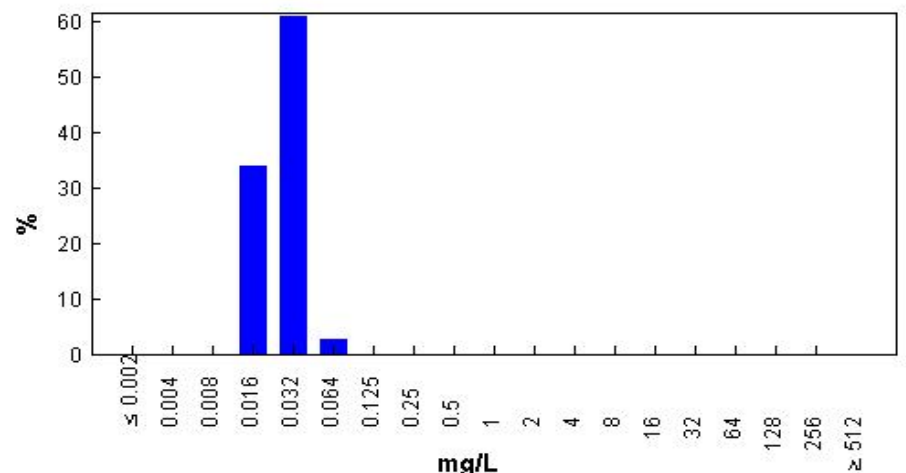
Antimicrobial wild type distributions of microorganisms - reference database  
EUCAST MIC Distribution



MIC 2181 observations (11 data sources)  
Epidemiological cut-off: WT ≤ 0.064 mg/L Clinical breakpoints: S ≤ 0.5 mg/L, R > 1 mg/L

### Doripenem / Escherichia coli

Antimicrobial wild type distributions of microorganisms - reference database  
EUCAST MIC Distribution



MIC 5602 observations (7 data sources)  
Epidemiological cut-off: WT ≤ 0.125 mg/L Clinical breakpoints: S ≤ 1 mg/L, R > 4 mg/L

# Antimicrobial wild type distributions of microorganisms

## Search

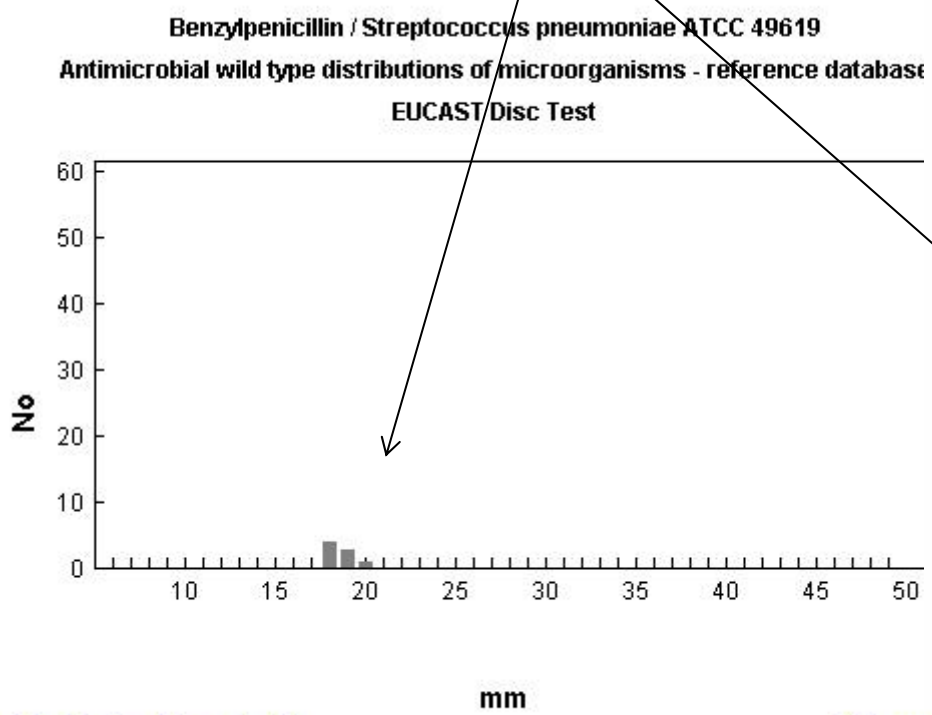
Method:  MIC  Disc diffusion Elements per page: 50  
 Antimicrobial:  Species:  Disc content:

Antimicrobial: Benzylpenicillin (Method: Disc diffusion)

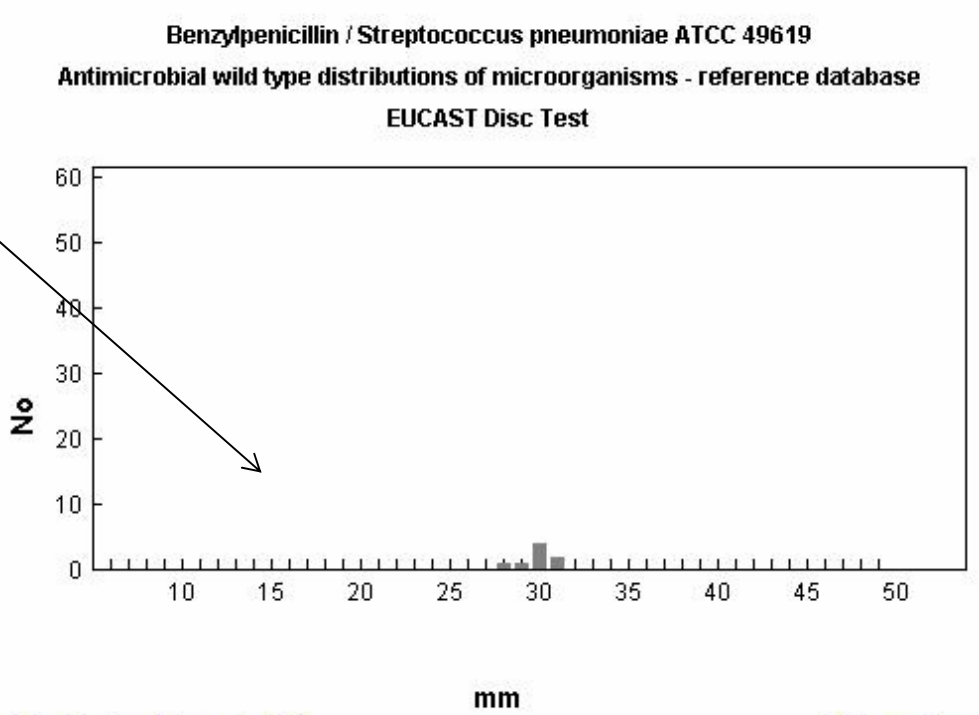
[Show All Graphs](#)

	Disc content	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	S $\geq$	R $<$	ECOFF $\geq$			
<a href="#">Streptococcus pneumoniae ATCC 49619</a>	1	0	0	0	0	0	0	4	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	ND	ND	ND
<a href="#">Streptococcus pneumoniae ATCC 49619</a>	10	0	0	0	0	0	0	0	0	0	0	0	1	5	2	0	0	0	0	0	0	0	0	0	0	0	0	ND	ND	ND

St-



Disc diffusion - Disc content: 1  
Epidemiological out-off: -

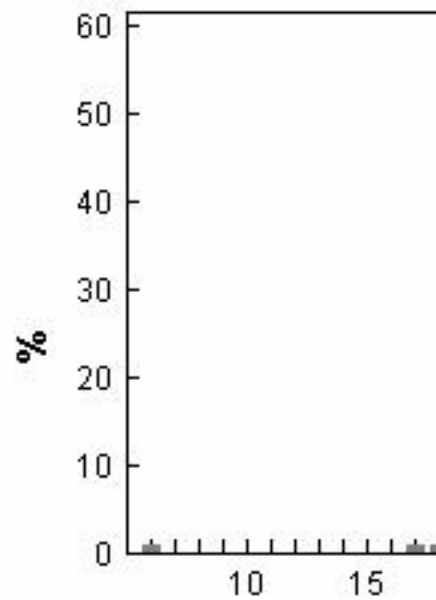


8 observ. Disc diffusion - Disc content: 10  
Epidemiological out-off: -  
Clinical breakpoints: S  $\geq$  mm, R  $<$  mm  
8 observations  
Clinical breakpoints: S  $\geq$  mm, R  $<$  mm

## Antimicrobial wild type distributions of microorganisms

Search

Antimicrobial wild type distributions of microorganisms

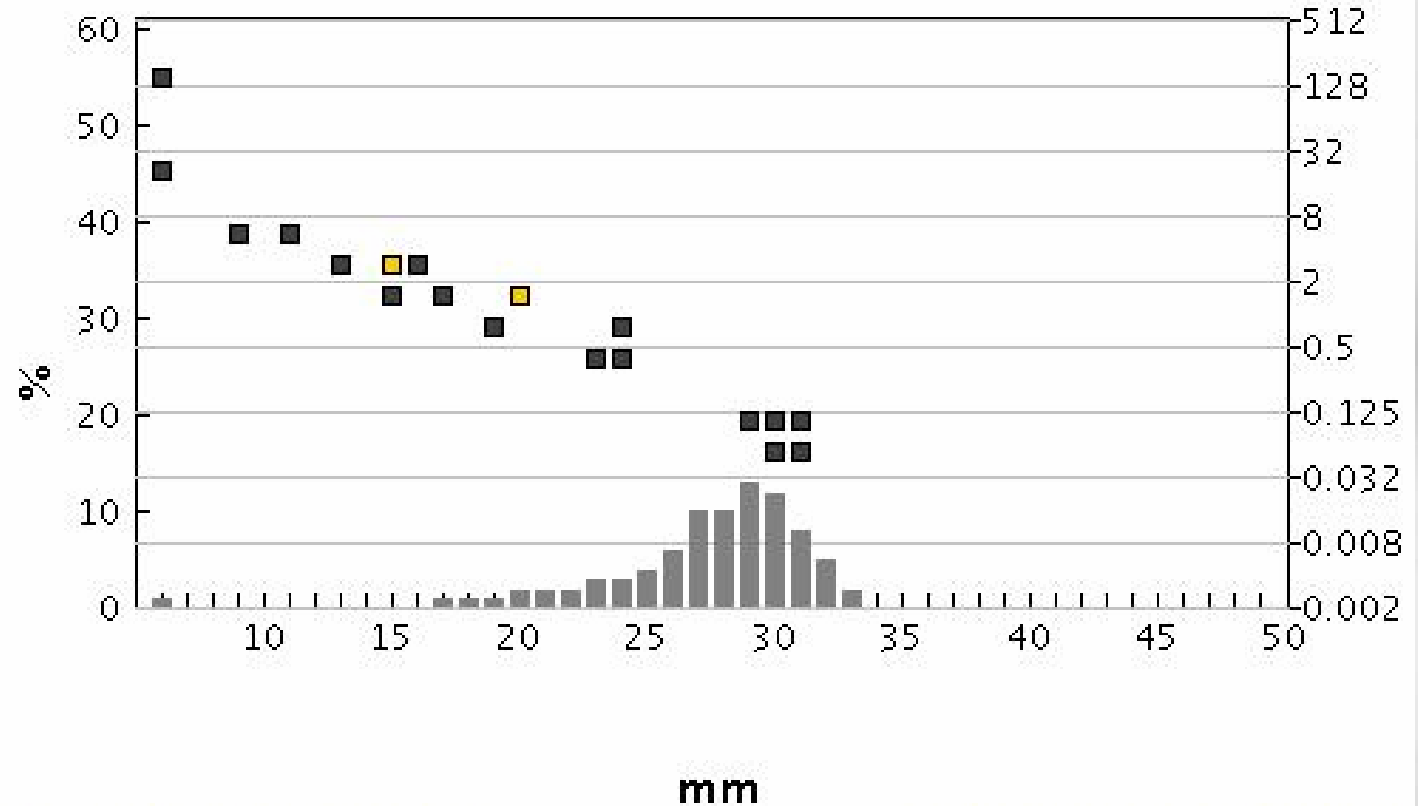


Disc diffusion - Disc content: 10  
Epidemiological cut-off: -

Save image as..

Antimicrobial wild type distributions of microorganisms - reference database

Mecillinam / Escherichia coli  
EUCAST Disc Test

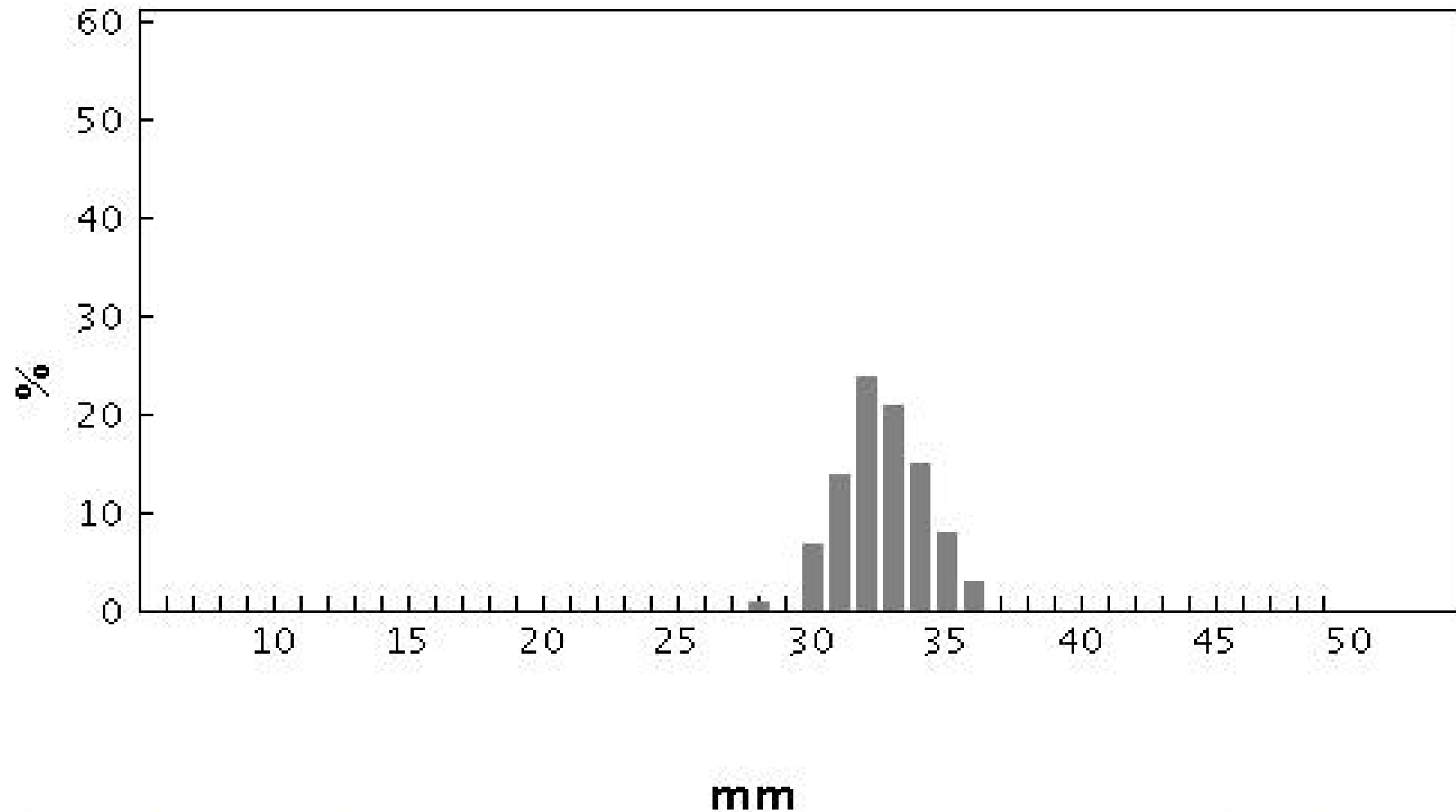


Disc diffusion - Disc content: 10  
Epidemiological cut-off: -

1527 observations (2 data sources)  
Clinical breakpoints: S  $\geq$  - mm, R  $\leq$  - mm

## Meropenem / Escherichia coli

Antimicrobial wild type distributions of microorganisms - reference database  
EUCAST Disc Test



Disc diffusion - Disc content: 10  
Epidemiological cut-off: -

582 observations  
Clinical breakpoints: S  $\geq$  - mm, R  $\leq$  - mm

# EUCAST breakpoint tables under development (MIC and Zone diameter)

1 <i>Pseudomonas</i> spp.							
2							
3	Penicillins	MIC breakpoint (mg/L)		Disk content (µg)	Zone diameter breakpoint		Notes (numbers for comments on MIC breakpoints, letters for comments on disk diffusion)
		S ≤	R >		S ≥	R <	
6	Benzylpenicillin	-	-	-	-	-	
7	Ampicillin	-	-	-	-	-	
8	Ampicillin-sulbactam	-	-	-	-	-	
9	Amoxicillin	-	-	-	-	-	
10	Amoxicillin-clavulanate	-	-	-	-	-	
11	Piperacillin <sup>1</sup>	16	16	30	18	18	1. Breakpoints are based on high dose therapy (with or without tazobactam 4 g x 4). The susceptible breakpoints were increased to avoid dividing wild type MIC distributions.
12	Piperacillin-tazobactam <sup>1,2</sup>	16	16	30+6	18	18	See note 1.
13							2. For susceptibility testing purposes, the concentration of clavulanate is fixed at 4 mg/L.
14	Ticarcillin <sup>3</sup>	16	16	75	Pending	Pending	3. Breakpoints are based on high dose therapy (with or without clavulanate 3 g x 4). The susceptible breakpoints were increased to avoid dividing wild type MIC distributions.
15	Ticarcillin-clavulanate <sup>2,3</sup>	16	16	75+10	Pending	Pending	See notes 2 and 3.
25							
26	Cephalosporins	MIC breakpoint (mg/L)		Disk content (µg)	Zone diameter breakpoint		Notes (numbers for comments on MIC breakpoints, letters for comments on disk diffusion)
		S ≤	R >		S ≥	R <	
27							
28							
38	Ceftazidime <sup>1</sup>	8	8	30	17	17	See note 1.
39	Ceftibuten	-	-	-	-	-	
40	Ceftriaxone	-	-	-	-	-	
41	Cefuroxime	-	-	-	-	-	
42	Cefuroxime axetil	-	-	-	-	-	
44							
45	Carbapenems	MIC breakpoint (mg/L)		Disk content (µg)	Zone diameter breakpoint		Notes (numbers for comments on MIC breakpoints, letters for comments on disk diffusion)
		S ≤	R >		S ≥	R <	
46							
47	Doripenem	1	4	10	23	18	
48	Ertapenem	-	-	-	-	-	
49	Imipenem	4 <sup>1</sup>	8	10	19	16	1. The S/I breakpoint was increased from 2 to 4 mg/L to avoid dividing the wild type MIC distribution. The breakpoints relate to high dose frequent therapy.
50	Meropenem	2	8	10	26	21	
52							

# EUCAST QC tables

	A	B	C	D	E	F	G	H
1	<b>MIC and Zone Diameter Limits for Quality Control Strains</b>							
2								
3	<b><i>Escherichia coli</i> ATCC 25922</b>			Mueller-Hinton agar, McFarland 0.5, air, 35±1°C, 18±2 h. Read complete inhibition from the back of the plates against a black background illuminated with reflected light.				
4								
5		<b>MIC</b>		<b>Disk content</b>	<b>Inhibition zone size</b>		<b>Comments</b>	
6	<b>Antimicrobial agent</b>	<b>(mg/L)</b>		<b>(µg)</b>	<b>(mm)</b>			
7		<b>Target</b>	<b>Range<sup>1</sup></b>		<b>Target</b>	<b>Range<sup>2</sup></b>		
8	Amikacin	1-2	0.5-4	30	23	19-26		
9	Amoxicillin-clavulanic acid	4/2	2/1-8/4	20/10	21	18-24		
10	Ampicillin	4	2-8	10	19	16-22	Ignore faint growth that appears as inner zone.	
11	Aztreonam	0.12	0.06-0.25	30	32	28-36		
12	Cefadroxil	-	-	30	<b>18</b>	<b>15-21</b>	EUCAST	
13	Cefepime	0.03-0.06	0.015-0.12	30	34	31-37		
14	Cefotaxime	0.06	0.03-0.12	5	<b>28</b>	<b>25-31</b>		
15	Cefotaxime	0.06	0.03-0.12	30	32	29-35		
16	Cefoxitin	4	2-8	30	26	23-29		
17	Cefpodoxime	0.5	0.25-1	10	26	23-28		
18	Ceftazidime	0.12-0.25	0.06-0.5	10	<b>26</b>	<b>23-29</b>	EUCAST	
19	Ceftazidime	0.12-0.25	0.06-0.5	30	29	25-32		
20	Ceftibuten	0.25	0.12-0.5	30	31	27-35		
21	Cefuroxime	4	2-8	30	23	20-26		
22	Chloramphenicol	4	2-8	30	24	21-27		
23	Ciprofloxacin	0.008	0.004-0.015	5	35	30-40		
24	Ertapenem	0.008	0.004-0.015	10	33	29-36		
25	Gentamicin	0.5	0.25-1	10	23	19-26		
26	Gentamicin	0.5	0.25-1	30	<b>24</b>	<b>21-27</b>	EUCAST	
27	Imipenem	0.12	0.06-0.25	10	29	26-32		
28	Mecillinam	0.06-0.12	0.03-0.25	10	27	24-30		
29	Meropenem	0.015-0.03	0.008-0.06	10	31	28-34		
30	Moxifloxacin	0.015-0.03	0.008-0.06	5	32	28-35		
31	Nalidixic acid	2	1-4	30	25	22-28		
32	Nitrofurantoin	8	4-16	100	<b>21</b>	<b>18-24</b>	EUCAST	
33	Nitrofurantoin	8	4-16	300	23	20-25		
34	Norfloxacin	0.06	0.03-0.12	10	32	28-35		
35	Piperacillin-tazobactam	2/4	1/4-4/4	30/6	<b>24</b>	<b>21-27</b>	EUCAST	
36	Piperacillin-tazobactam	2/4	1/4-4/4	100/10	27	24-30		
37	Rifampicin	8	4-16	5	9	8-10		
38	Tetracycline	1	0.5-2	30	22	18-25		

Targets NOT in italics are from ISO and/or CLSI recommendations

**National strategies and joint  
decisions on AST are needed!**

**Countries are encouraged to form**

**NAC**

**National Antimicrobial Committee**

# National Antimicrobial Committees tasks

- **Antimicrobial susceptibility testing**
  - Strategy at national level
  - Implementation of breakpoints and methods
  - Education through regular national workshops
  - Liaison and consultation with EUCAST
  - Liaison with groups involved in AMR-surveillance (ECDC, EARSS, ....).
  - QA
- Antimicrobial Policies
- Antimicrobial Resistance Surveillance
- Antimicrobial Consumption and Policies

**NAC = existing breakpoint committees**

NAC = existing antibiotic/AST committees



# ENAC

European Network of Antimicrobial  
Committees

=

The future EUCAST General Committee.

# **EUCAST breakpoints**

**available for routine testing  
1st of January 2010:**

**MIC determination – broth, agar dilution or gradient  
methods**

**Automated AST (2009 – 2010)  
EUCAST disk diffusion test**

[Organization](#)

[Clinical breakpoints](#)

[Expert rules](#)

[Distributions of EUCAST MIC values  
of wild type microorganisms](#)

[Distributions of EUCAST disk diffusion  
susceptibility test inhibition  
zone diameters](#)

[EUCAST disk diffusion test](#)

[Meetings](#)

[Documents](#)

[Information for industry](#)

[Links](#)



## The European Committee on Antimicrobial Susceptibility Testing - EUCAST

EUCAST is a standing committee jointly organized by ESCMID, ECDC and European national breakpoint committees. The Steering Committee is the decision making body. It is supported by a General Committee with representatives from European countries, FESCI and ISC. The Steering Committee also consults experts within the fields of Infectious Diseases and Microbiology, pharmaceutical companies and susceptibility testing device manufacturers on EUCAST proposals.

EUCAST has subcommittees on antifungal susceptibility testing, expert rules for antimicrobial susceptibility testing, and antimicrobial susceptibility testing of anaerobes.

EUCAST has harmonized most antimicrobial MIC breakpoints in Europe. Breakpoints for new agents are set as part of the licensing process for new agents through EMEA. EUCAST breakpoints will be available in devices for automated susceptibility testing during 2009. A disk diffusion test calibrated to EUCAST MIC breakpoints is being developed for launch around the end of 2009.

EUCAST invites anyone with an interest in antimicrobial agents in general and antimicrobial breakpoints in particular to contact EUCAST, ESCMID or one of the National Breakpoint Committees.

### News

#### EUCAST at ECCMID

At the 19th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2009) EUCAST will present several sessions

[➔ more](#)

### EUCAST Presentation



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# Thank you!

[gunnar.kahlmeter@ltkronoberg.se](mailto:gunnar.kahlmeter@ltkronoberg.se)

[www.eucast.org](http://www.eucast.org)



**EUCAST**

EUROPEAN COMMITTEE  
ON ANTIMICROBIAL  
SUSCEPTIBILITY TESTING