QM-kontrollierte EUCAST Antibiogramme:

Wie geht das in der Routine?

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Überblick

- Was sagen uns die EUCAST-Dokumente bezüglich Qualitätskontrolle für die Empfindlichkeitstestung?
  - Blättchendiffusion
  - Bouillon-Mikrodilution

- Wie geht das QM-kontrollierte Antibiogramm in unserem Labor?
  - Praktische Durchführung
  - Dokumentation der Ergebnisse

- Was sagen uns die Hersteller-Vorgaben?
  - Automatisierte Systeme
  - Kommerzielle BMD-Formate
  - Gradientendiffusion
  - Agardilution

QK – Empfindlichkeitstestung Pilze

EUCAST EUROPEAN COMMITTEE ON ANTIMICROBIAL SUSCEPTIBILITY TESTING
European Society of Clinical Microbiology and Infectious Diseases

European Committee on Antimicrobial Susceptibility Testing

Routine and extended internal quality control for MIC determination and agar dilution for yeasts, moulds and dermatophytes as recommended by EUCAST

Version 7.0, valid from 2023-08-14

This document should be cited as: "The European Committee on Antimicrobial Susceptibility Testing. Routine and extended internal quality control for MIC determination and agar dilution for yeasts, moulds and dermatophytes as recommended by EUCAST. Version 7.0, 2023. http://www.eucast.org."

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Quelle: https://www.eucast.org/astoffungi/qcafsttables, zuletzt geprüft 13.10.2023

QK – Empfindlichkeitstestung Mykobakterien

Mycobacterium tuberculosis EUCAST Clinical Breakpoint Tables v. 13.1, valid from 2023-06-29

Expert Rules and Expected Phenotypes

For abbreviations and explanations of breakpoints, see the Notes sheet

Listed breakpoints have been set in parallel with marketing authorisation by EMA. Breakpoints for other agents have not yet been established. Infections with *M. tuberculosis* are always treated with two or more agents.

MIC determination using broth microdilution according to the EUCAST reference method for the *Mycobacterium tuberculosis* complex
Medium: Middlebrook 7H9 with 10% OADC in polystyrene plates
Inoculum: 1x10$_5$ CFU/mL
Incubation: Plates sealed with a plastic lid, air, 36±1°C, 7-21 days
Reading: At the earliest time point (7, 14 or 21 days) when the 1% growth control shows visible growth, read MICs at the lowest concentration of the agent that completely inhibits visible growth
Quality control: *Mycobacterium tuberculosis* H37Rv ATCC 27294

Quelle: https://www.eucast.org/clinical_breakpoints, zuletzt geprüft 13.10.2023

Definition Qualitätskontrolle

Qualitätskontrolle bezieht sich auf den Prozess, bei dem die Produkte oder Dienstleistungen in einem Unternehmen oder einer Organisation regelmäßig überprüft werden, um sicherzustellen, dass sie den festgelegten Qualitätsstandards entsprechen. Diese Überprüfung kann an verschiedenen Stellen während des Produktions- oder Dienstleistungsprozesses erfolgen und dient dazu, Fehler oder Mängel frühzeitig zu erkennen und zu beheben.

Das Ziel der Qualitätskontrolle besteht darin, sicherzustellen, dass die Endprodukte oder Dienstleistungen den Anforderungen und Erwartungen der Kunden entsprechen. Dazu können verschiedene Messungen, Tests und Inspektionen durchgeführt werden, um sicherzustellen, dass die Produkte oder Dienstleistungen den spezifizierten Standards und Richtlinien entsprechen.

Qualitätskontrolle ist ein entscheidender Bestandteil des Qualitätsmanagements und kann zur kontinuierlichen Verbesserung der Prozesse und Produkte beitragen. Durch die Implementierung eines effektiven Qualitätskontrollsystems können Unternehmen sicherstellen, dass sie konsistente und hochwertige Produkte oder Dienstleistungen liefern, was letztendlich zur Steigerung der Kundenzufriedenheit und zur Stärkung der Wettbewerbsfähigkeit beiträgt.

Quelle: https://chat.openai.com/, zuletzt geprüft 20.10.2023

Methoden – Empfindlichkeitstestung

- **Blättchendiffusion gemäß EUCAST**
  - BD
  - Mast
  - Liofilchem
  - ThermoFisher/Oxoid
- **Bouillon-Mikrodilution, BMD**
  - Gemäß ISO 20776
  - Kommerzielle Systeme (ComASP, Liofilchem; Sensititre, ThermoFisher; UMIC bzw. Micronaut, Bruker)
- **Agardilution für Fosfomycin und Clindamycin**
  - Kommerzielle Systeme (AD Fosfomycin, Blood AD Clindamycin, Liofilchem)
- **Gradientendiffusion**
  - Etest, bioMérieux
  - MTS - MIC Test Strips, Liofilchem
- **Automatisierte Methoden**
  - Phoenix, BD
  - Vitek 2, bioMérieux

Blättchendiffusion nach EUCAST

Ausführliche Dokumentation auf www.eucast.org

AST of bacteria

- IVDR
- Media preparation
- MIC determination
- **Disk diffusion methodology**
- Disk diffusion implementation
- Breakpoint tables
- Quality Control
- Strains with defined susceptibility
- Calibration and validation
- Warnings!
- MIC testing services from EUCAST
- Previous versions of documents

See also **EUCAST instruction videos** with subtitles in many languages.

- **Disk diffusion manual v 11.0** (2 January, 2023)
- **Disk diffusion - Slide show v 11.0** (2 January, 2023)
- **Disk diffusion - Reading guide v 10.0** (2 January, 2023)
- **Anaerobic bacteria - disk diffusion methodology v 2.0** (2 January 2023). QC recommendations are now included in the general **QC document**.
  Disk diffusion breakpoints for anaerobic bacteria are valid for FAA with 5% mechanically defibrinated horse blood as the only additive.
- **Anaerobic bacteria - disk diffusion reading guide v 2.0** (2 January 2023).
  Disk diffusion breakpoints for anaerobic bacteria are valid for FAA with 5% mechanically defibrinated horse blood as the only additive.

For translations to other languages - contact National AST committees (NAC).

Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 13.10.2023

QK-Hinweis in den Breakpoint Tabels

***Enterobacterales* ***

EUCAST Clinical Breakpoint Tables v. 13.1, valid from 2023-06-29

Expert Rules and Expected Phenotypes

For abbreviations and explanations of breakpoints, see the Notes sheet

MIC determination (broth microdilution according to ISO standard 20776-1 except for mecillinam and fosfomycin where agar dilution is used)
Medium: Mueller-Hinton broth (for cefiderocol, see https://www.eucast.org/eucastguidancedocuments/)
Inoculum: 5x10^5 CFU/mL
Incubation: Sealed panels, air, 35±1°C, 18±2h
Reading: Unless otherwise stated, read MICs at the lowest concentration of the agent that completely inhibits visible growth. See "EUCAST Reading Guide for broth microdilution" for further information

Disk diffusion (EUCAST standardised disk diffusion method)
Medium: Mueller-Hinton agar
Inoculum: McFarland 0.5
Incubation: Air, 35±1°C, 18±2h
Reading: Unless otherwise stated, read zone edges as the point showing no growth viewed from the back of the plate against a dark background illuminated with reflected light. See "EUCAST Reading Guide for disk diffusion" for further information.

EUCAST Clinical Breakpoint Tables v. 13.1, valid from 2023-06-29

Disk diffusion (EUCAST standardised disk diffusion method)
Medium: Mueller-Hinton agar
Inoculum: McFarland 0.5
Incubation: Air, 35±1°C, 18±2h
Reading: Unless otherwise stated, read zone edges as the point showing no growth viewed from the back of the plate against a dark background illuminated with reflected light. See "EUCAST Reading Guide for disk diffusion" for further information.

Quality control: *Escherichia coli* ATCC 25922. For agents not covered by this strain and for control of the inhibitor component of beta-lactam inhibitor-combination disks, see EUCAST QC Tables.

members of this family are now included in other families within the order *Enterobacterales*. Breakpoints in this table apply to all

Quelle: https://www.eucast.org/clinical_breakpoints, zuletzt geprüft 16.10.2023

Blättchendiffusion gemäß EUCAST

EUCAST EUROPEAN COMMITTEE ON ANTIMICROBIAL SUSCEPTIBILITY TESTING

European Society of Clinical Microbiology and Infectious Diseases

Antimicrobial susceptibility testing

EUCAST disk diffusion method

Version 11.0

January 2023

Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 13.10.2023

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Blättchendiffusion gemäß EUCAST

Contents		Page
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„15-15-15-Regel“

Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 13.10.2023

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9 Qualitätskontrolle

- **Auswahl der QK-Stämme**
  - Empfindliche Stämme → Tabelle 4
  - Resistente Stämme → erweiterte QK Tabelle 5
  - Erwerb der Stämme
    - Direkt beim Stammsammlungsanbieter (ATCC, DSMZ, NCTC, CIP, CECT, CCUG)
    - Kommerzielle Anbieter

      Cultiloops, ThermoFisher

      KWIK-STIK, Mikrobiologics

9 Qualitätskontrolle

- **Unsere Auswahl der QK-Stämme für regelmäßige Blättchen-QK**

	ATCC-Stamm	Keimname	Platte
→	ATCC 25922	*E. coli*	MH
→	ATCC 35218	*E. coli*	MH
→	ATCC 700603	*K. pneumoniae*	MH
→	ATCC 27853	*P. aeruginosa*	MH
→	ATCC 29213	*S. aureus*	MH
→	NCTC 12493	*S. aureus*	MH
→	ATCC 29212	*E. faecalis*	MH
→	ATCC 51299	*E. faecalis*	MH
→	ATCC 49619	*S. pneumoniae*	MHF
→	ATCC 49766	*H. influenzae*	MHF
→	ATCC 49247	*H. influenzae*	MHF

→ 7 Stämme für Routine-QK

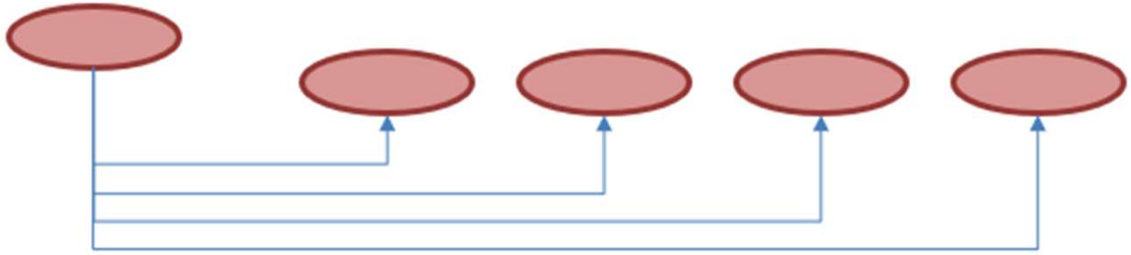
→ 4 Stämme für erweiterte QK

9 Qualitätskontrolle

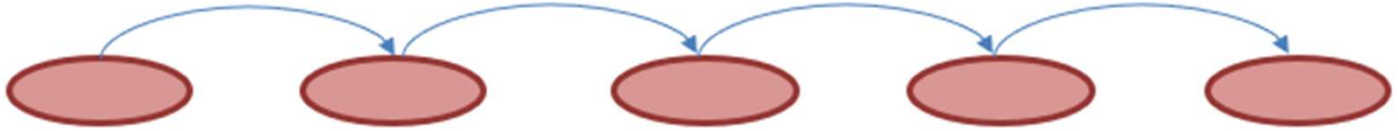
- Auswahl der QK-Stämme
- **System der Stammhaltung mithilfe von Cryobanks**
  - Pro Stamm 2 Cryobanks
    - 1 x „in-use“
    - 1 x als Archiv bei -70°C

Subkultur der QK-Stämme

- **Subkultur der Stämme, praktisches Beispiel**
  - Wöchentlich 1 Glasperle aus „in-use“-Cryobank ausimpfen.
  - Ausgehend von dieser Reinkultur wird täglich eine Subkultur erstellt.



  - Anspruchsvolle Stämme (z.B. *S. pneumoniae*) sollten seriell von Tag zu Tag subkultiviert werden.



9 Qualitätskontrolle

- Auswahl der QK-Stämme
- System der Stammhaltung mithilfe von Cryobanks
- **Testdurchführung bei QK-Stämmen wie bei Routineproben**
  - 15 – 15 – 15 – Regel
  - Inkubationsbedingungen (18 ± 2 h, 35 ± 1°C, ± CO_2, max. 5 Platten stapeln)
- **Ablesen der Hemmhöfe wie bei Routineproben**
  - Beurteilung des konfluierenden Wachstums
  - Hemmhöfe mit Lineal bzw. Schublehre abmessen
- **Ergebnisse für 81 Blättchen in jedem Testansatz**

9 Qualitätskontrolle

- Auswahl der QK-Stämme
- System der Stammhaltung mithilfe von Cryobanks
- Testdurchführung wie bei Routineproben
- Ablesen der Durchmesser wie bei Routineproben
- **Punkt 9.5 im Manual**
  - Beurteilung der QK-Messwerte
  - Frequenz der QK-Tests

  „…should be set up daily, or at least four times a week.....read and evaluate **before** reporting AST results…“

EUCAST EUROPEAN COMMITTEE ON ANTIMICROBIAL SUSCEPTIBILITY TESTING

European Society of Clinical Microbiology and Infectious Diseases

European Committee on Antimicrobial Susceptibility Testing

Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST

Version 13.2, valid from 2023-06-29

Quelle: https://www.eucast.org/ast_of_bacteria/quality_control, zuletzt geprüft 16.10.2023

QK – Ziel- und Grenzwerte

Routine QC

EUCAST QC Tables v. 13.2, valid from 2023-06-29

Escherichia coli ATCC 25922

(NCTC 12241, CIP 76.24, DSM 1103, CCUG 17620, CECT 434)

Test according to EUCAST methodology for non-fastidious organisms (MH broth and agar). See EUCAST Breakpoint Tables for short descriptions of MIC and disk diffusion methodology.

Antimicrobial agent	MIC (mg/L)		Disk content (µg)	Inhibition zone diameter (mm)	
	Target[1]	Range[2]		Target[1]	Range[2]
Amikacin	1-2	0.5-4	30	22-23	19-26
Amoxicillin	4	***2-8***	-	-	-
Amoxicillin-clavulanic acid[3,4]	4	2-8	20-10	21	18-24[5]
Ampicillin	4	2-8	10	18-19	15-22[5]
Ampicillin-sulbactam[4,6]	***2***	***1-4***	10-10	21-22	19-24[5]
Azithromycin	-	-	15	***17***	***14-20***[7]
Aztreonam	0.125	0.06-0.25	30	32	28-36
Cefadroxil	-	-	30	***17***	***14-20***
Cefalexin	***8***	***4-16***	30	***18***	***15-21***
Cefazolin	2	1-4	30	24	21-27
Cefepime	0.03-0.06	0.016-0.125	30	34	31-37
Cefiderocol[8]	0.125-0.25	0.06-0.5	30	***27***	***24-30***
Cefixime	0.5	0.25-1	5	***23***	***20-26***
Cefotaxime	0.06	0.03-0.125	5	***28***	***25-31***
Cefoxitin	4	2-8	30	26	23-29
Cefpodoxime	0.5	0.25-1	10	25-26	23-28
Ceftaroline	0.06	0.03-0.125	5	***27***	***24-30***

Quelle: https://www.eucast.org/ast_of_bacteria/quality_control, zuletzt geprüft 16.10.2023

QK – Ziel- und Grenzwerte

Control of the inhibitor component of β-lactam-inhibitor combinations

Test according to EUCAST methodology for non-fastidious organisms (MH broth and agar). See EUCAST Breakpoint Tables for short descriptions of MIC and disk diffusion methodology.

Escherichia coli ATCC 35218

(NCTC 11954, CIP 102181, DSM 5923, CCUG 30600, CECT 943)

TEM-1 β-lactamase-producing strain (non-ESBL)

Antimicrobial agent	MIC (mg/L)		Disk content (µg)	Inhibition zone diameter (mm)	
	Target[1]	Range[2]		Target[1]	Range[2]
Amoxicillin-clavulanic acid[3]	***8-16***	***4-32***	20-10	19-20	17-22[4]
Ampicillin-sulbactam[5]	***32-64***	***16-128***	10-10	16	13-19[4]
Ceftolozane-tazobactam[6,7]	0.125	0.06-0.25	30-10	28	25-31
Piperacillin-tazobactam[6,7]	1	0.5-2	30-6	***24***	***21-27***
Ticarcillin-clavulanic acid[3]	16	8-32	75-10	23	21-25

Methicillin resistance in *Staphylococcus aureus*

Staphylococcus aureus NCTC 12493

(CCUG 67181)

Methicillin resistant (MRSA), *mecA* positive

Antimicrobial agent	Disk content (µg)	Target susceptibility[1]	Range[2] (mm)	Comments
Cefoxitin	30	R	***14-20***	

Quelle: https://www.eucast.org/ast_of_bacteria/quality_control, zuletzt geprüft 16.10.2023

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Beurteilung der Messwerte

- **Dokumentation – Sichtbarmachen der QK-Ergebnisse**
  - Beurteilung der QK-Ergebnisse **vor** der Ausgabe von Befunden
  - Sichtbarmachen von Trends und Abweichungen

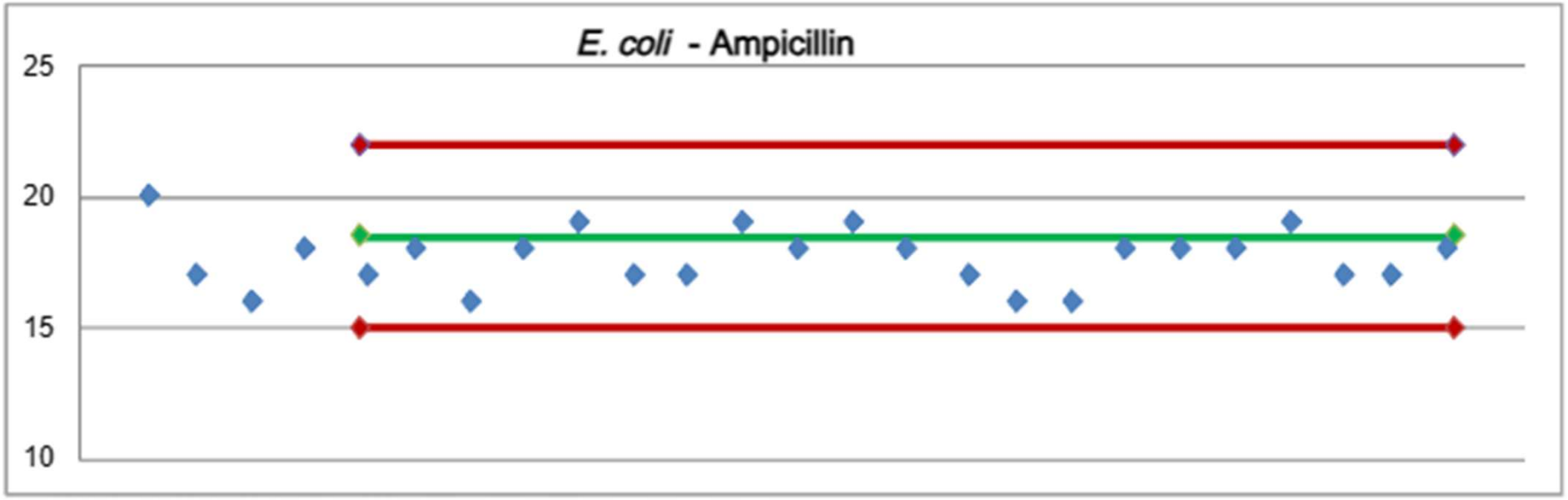
- **Unser Zugang zum Sichtbarmachen von Messwerten**
  - Excel-Datei mit einem Tabellenblatt für jeden QK-Stamm
  - Farbliche Kennzeichnung der Messwerte
  - Diagrammen für die Beurteilung von Trends

Beispiel *E. coli* ATCC 25922

		Target [mm]	18,5	21	18	23	26
		Range [mm]	15	18	15	20	23
			22	24	21	26	29
ange-legt	abge-lesen	Eingabe PC	Ampicillin AMP 10	Augmentin AMC 30	Cefalexin CL 30	Cefuroxim CXM 30	Ceftazidim CAZ 10
CM	CM	IS	17	20	17	22	26
Mwe	MWe	KB	18	20	17	22	26
Sho/KN	SHo	KN	17	20	17	21	25
Abl	Abl	Mwe	17	22	17	21	26
KT	KN	Mwe	18	20	17	21	25
MWe	CM	MWe	18	22	17	22	26
MWe	KN	IS	17	21	18	23	25
KB	MWe	KB	16	20	17	21	24
KB	KB	CM	18	22	17	22	26
KB	CM	MWe	17	20	17	22	26
KB	KB	CM	18	20	17	21	26
IS	Abl	IS	20	20	18	23	28
KB	MWe	KB	17	20	17	22	26
KN, KB	KB	KN	16	22	17	22	25
ABl	KB	KB	18	20	17	21	26
ABl	IS	AL	17	20	17	22	27
AL/KB	CM	KB	18	22	17	22	26
ABl	Abl	Sho	16	22	17	21	26
SR	Abl	SR	18	22	17	22	26

Beispiel *E. coli* ATCC 25922 – Ampicillin

- Zielwert: 18 – 19 mm
- Grenzwerte: 15 – 22 mm



Beurteilung der QK-Ergebnisse

9.5 Use the recommended routine QC strains to monitor test performance. Use an overnight culture of the QC strain and follow the same testing procedure as for clinical isolates.

Control tests should be set up and checked daily, or at least four times per week for antimicrobial agents which are part of routine panels. Control tests should be read and evaluated before reporting susceptibility test results for clinical isolates.

9.5.1 Each day that tests are set up, examine the results of the last 20 consecutive tests. Examine results for trends and for zones falling consistently above or below the target.

9.5.2 If two non-consecutive tests are out of range on the same side of the target, susceptibility test results for clinical isolates may be reported, but investigation is required.

9.5.3 If two consecutive tests are out of range or if multiple disks are out of range on one day, investigate before reporting susceptibility test results for clinical isolates. The tests may have to be repeated.

9.5.4 If resistance in a resistant control strain is not recognised, then suppress susceptibility test results for clinical isolates, investigate and retest.

9.5.5 When investigating for possible sources of errors in disk diffusion, consider problems related to antimicrobial disks, media, test conditions and quality control strains.

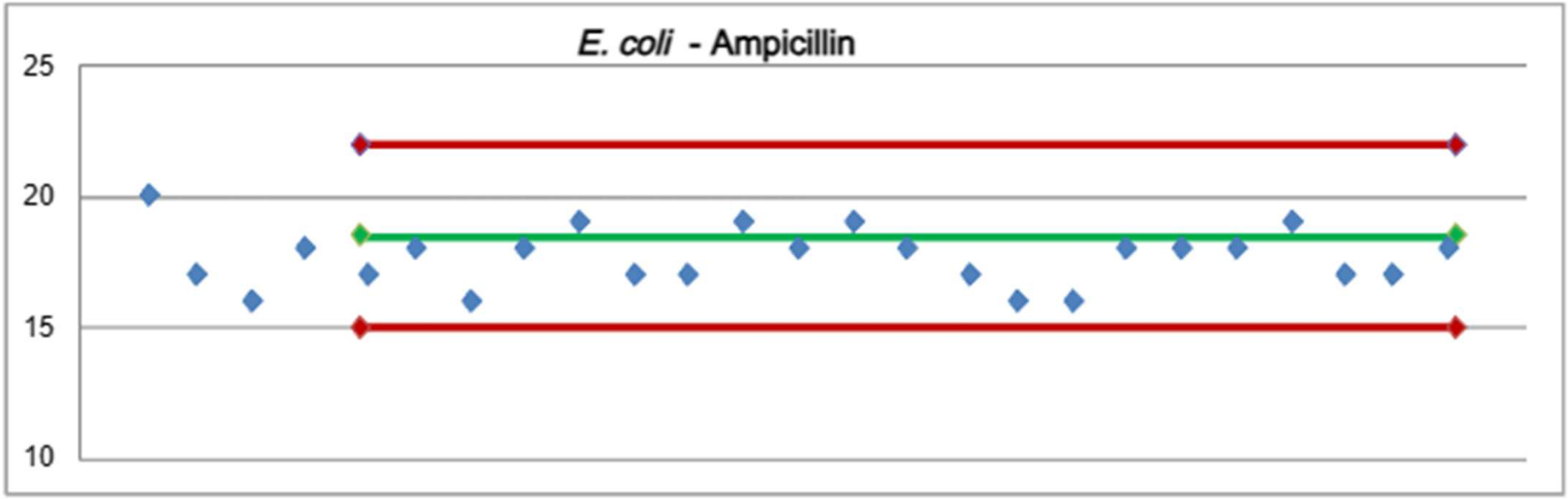
Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 13.10.2023

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Beurteilung der Messwerte

9.5.1 Each day that tests are set up, examine the results of the last 20 consecutive tests. Examine results for trends and for zones falling consistently above or below the target.

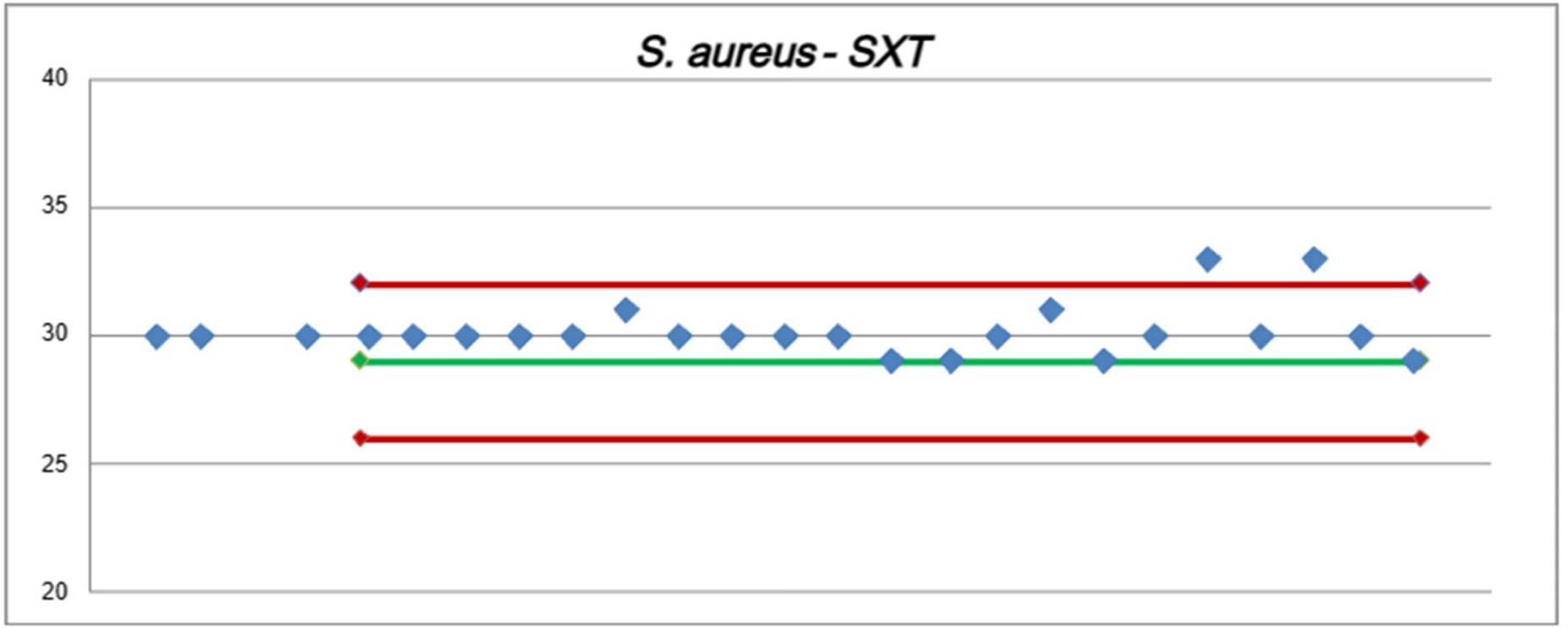
Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 13.10.2023



Beurteilung der Messwerte

9.5.2 If two non-consecutive tests are out of range on the same side of the target, susceptibility test results for clinical isolates may be reported, but investigation is required.

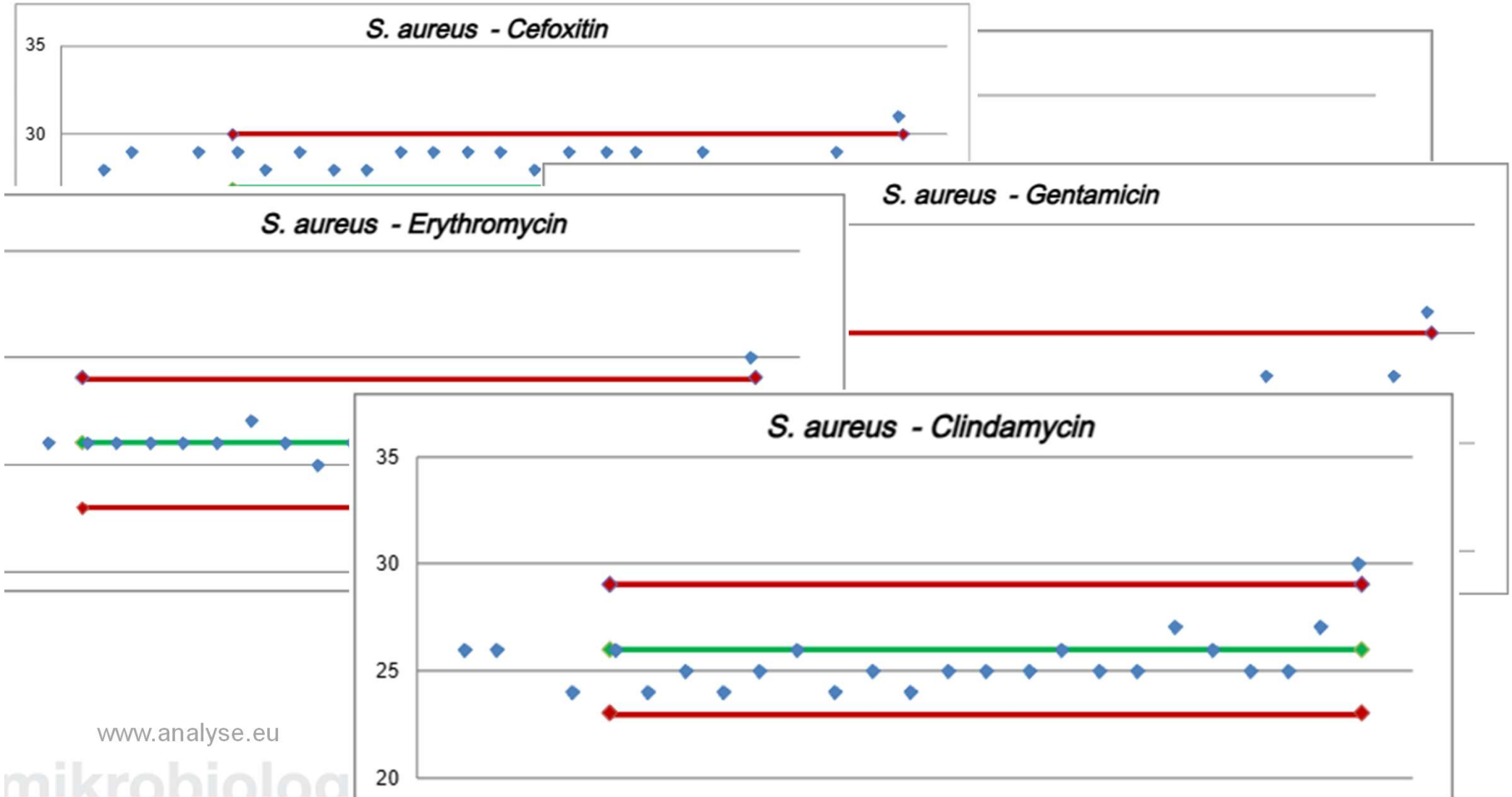
Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 13.10.2023



Beurteilung der Messwerte

9.5.3 If two consecutive tests are out of range or if multiple disks are out of range on one day, investigate before reporting susceptibility test results for clinical isolates. The tests may have to be repeated.

Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 13.10.2023

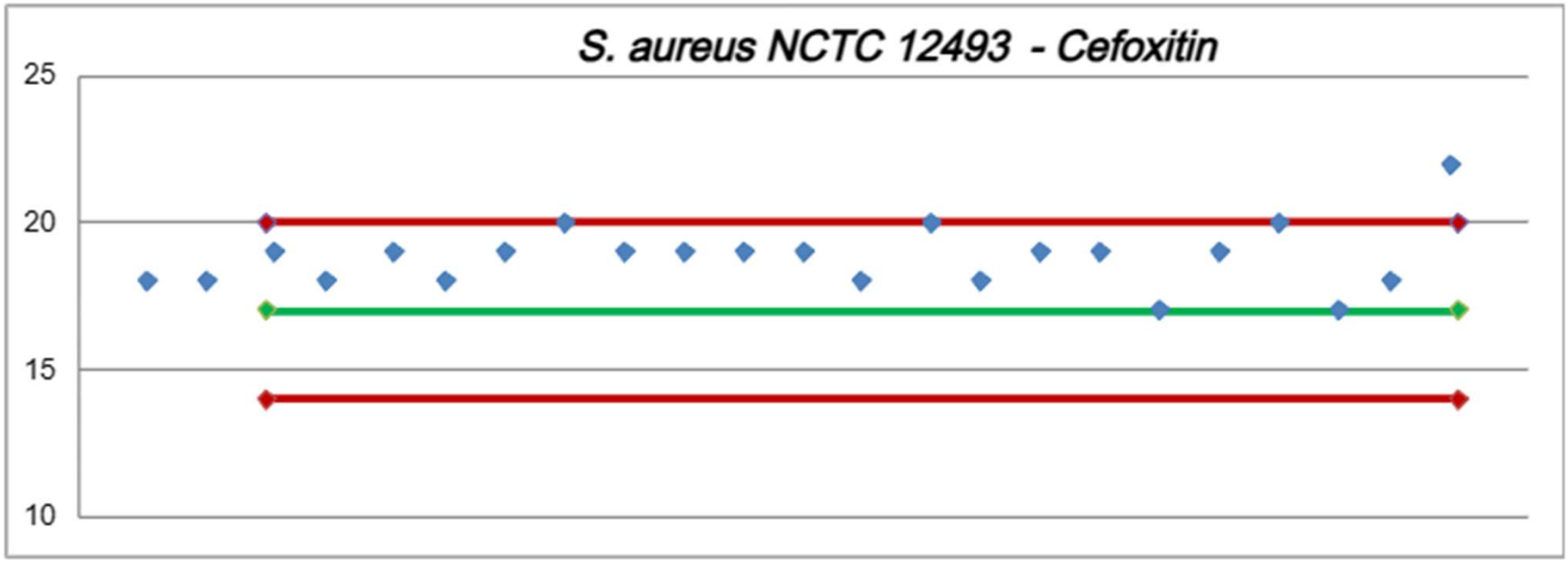


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Beurteilung der Messwerte

9.5.4 If resistance in a resistant control strain is not recognised, then suppress susceptibility test results for clinical isolates, investigate and retest.

Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 13.10.2023



Beurteilung der Messwerte

9.5.5 When investigating for possible sources of errors in disk diffusion, consider problems related to antimicrobial disks, media, test conditions and quality control strains.

Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 13.10.2023

- Troubleshooting
  - Blättchen: Lagerung? Anbruch der Phiole?
  - Nährmedien: Lagerung? Eingangskontrolle?
  - Inkubationstemperatur, Dauer der Inkubation?
  - QK-Stämme?

QK – Blättchendiffusion Anaerobier

EUCAST EUROPEAN COMMITTEE ON ANTIMICROBIAL SUSCEPTIBILITY TESTING
European Society of Clinical Microbiology and Infectious Diseases

Disk diffusion anaerobic bacteria
Version 2.0, January 2023

EUCAST disk diffusion methodology for selected rapidly growing anaerobic bacteria* on Fastidious Anaerobe Agar with defibrinated horse blood (FAA-HB)

Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 16.10.2023

QK – Blättchendiffusion Anaerobier

Disk diffusion anaerobic bacteria
Version 2.0, January 2023

Quality control

1. Perform quality control (QC) at each test occasion. Use an overnight culture of the QC strain and follow the same testing procedure as for clinical isolates.
    a. Use *Bacteroides fragilis* ATCC 25285 and *Clostridium perfringens* ATCC 13124 to monitor the test performance. For QC ranges and targets, see EUCAST QC Tables.
    b. Use *Clostridium perfringens* DSM 25589 with a metronidazole 5 µg disk to monitor the anaerobic atmosphere. This combination has been shown to be a sensitive indicator of the anaerobic atmosphere. Insufficient anaerobicity may affect growth and susceptibility test results for anaerobic bacteria. For interpretive criteria, see EUCAST QC Tables.
        i. The anaerobic atmosphere of workstations requires special attention. Regular service and technical control are necessary.

Quelle: https://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology, zuletzt geprüft 16.10.2023

QK – Rapid AST aus positiven Blutkulturen

EUCAST EUROPEAN COMMITTEE ON ANTIMICROBIAL SUSCEPTIBILITY TESTING

European Society of Clinical Microbiology and Infectious Diseases

European Committee on Antimicrobial Susceptibility Testing

Quality control criteria for the implementation of the RAST method

To be performed when implementing the method, when training new staff or following a change in blood culture system or any other substantial change in the system

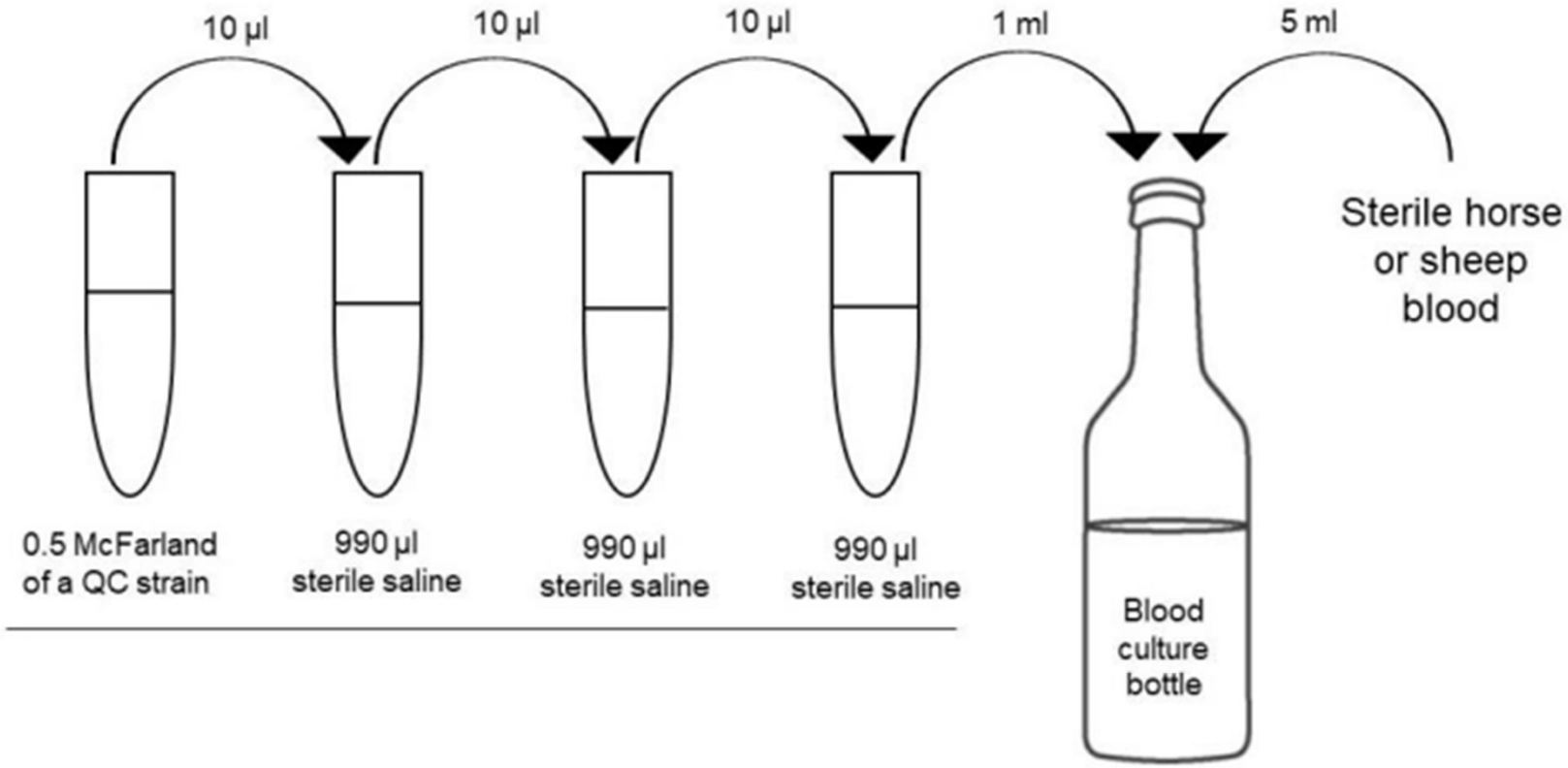
Version 6.1, valid from 2023-06-07

Quelle: https://www.eucast.org/rapid_ast_in_blood_cultures/qualitycontrol, zuletzt geprüft 16.10.2023

QK – Rapid AST aus positiven Blutkulturen

- **Empfehlung seitens EUCAST**
  → Durchführung der QK für die Standardmethode
- **QK, wie im Dokument beschrieben, wenn...**
  - … Einführung der Methode im Labor
  - … Änderung von Reagenzien im Testsystem z.B. Änderung der Blutkulturflaschen
  - … Einschulung von neuem Personal
- **Testung von 5 Stämmen**
  - *E. coli* ATCC 25922
  - *P. aeruginosa* ATCC 27853
  - *S. aureus* ATCC 29213
  - *E. faecalis* ATCC 29212
  - *S. pneumoniae* ATCC 49619

QK – Rapid AST aus positiven Blutkulturen



a) Make a 0.5 McFarland dilution of a QC strain.
b) Dilute according to dilution series above and add horse or sheep blood to the blood culture bottle.
c) Incubate bottle in the blood culture instrument.
d) Process the bottles according to the described RAST methodology when the instrument signals positive.
e) Use the RAST QC criteria available in the RAST QC document to assess the results.

Quelle: https://www.eucast.org/rapid_ast_in_blood_cultures/qualitycontrol, zuletzt geprüft 16.10.2023

QK kommerziell verfügbarer Testsysteme

- Aussage EUCAST: Anwender ist für die Qualitätskontrolle verantwortlich….gemäß Herstellervorgaben.

There are a number of commercially available surrogate MIC determination methods, such as commercial broth microdilution methods, gradient tests, semi-automated devices, etc. It is the responsibility of the manufacturer to guarantee the accuracy of their systems but it is the responsibility of the user to quality control the results obtained with these systems. We also refer the users to the **EUCAST Warnings page** where some of these products listed.

Quelle: https://www.eucast.org/ast_of_bacteria/mic_determination, zuletzt geprüft 09.10.2023

QK – Beispiele automatisierte Systeme

- **BD Phoenix – MIC-Panels**
- **bioMérieux Vitek 2 – AST-Panels**

→ QK-Stämme in den IFUs der Panels

→ eigene Funktion in der Software zu Dokumentation der Ergebnisse im Verlauf und der verwendeten Chargennummern von allen Komponenten

→ Frequenz der QK-Tests

BD Phoenix – Empfehlung für Qualitätskontrolle bei jeder Charge

bioMérieux Vitek 2 – Verweis auf CLSI und/oder lokale Richtlinien

Kommerzielle BMD, z.B. UMIC Colistin, Bruker

9 Quality control

Strips and reagents are subjected to several quality inspections, systematically executed during various production stages. Bacteriological quality control can be performed using the following strains:

Strains	ATCC[1] No.	DSMZ[2] No.	NCTC[3] No.
Escherichia coli	ATCC 25922	DSM 1103	NCTC 12241
Pseudomonas aeruginosa	ATCC 27853	DSM 1117	NCTC 12903
Escherichia coli (mcr-1)	N/A [4]	DSM 105182	NCTC 13846

In the evaluation of the control strains, the MIC values of the control strains used should fall within the quality control ranges of the respective drug tested as specified in the relevant standard.

[1] *ATCC=American Type Culture Collection*

[2] *DSMZ=Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (German Collection of Microorganisms and Cell Cultures Ltd.)*

[3] *NCTC=National Collection of Type Cultures*

[4] *N/A =not applicable*

Quelle: https://www.bruker.com/en/products-and-solutions/microbiology-and-diagnostics/antimicrobial-susceptibility-testing/umic.html, zuletzt geprüft 16.10.2023

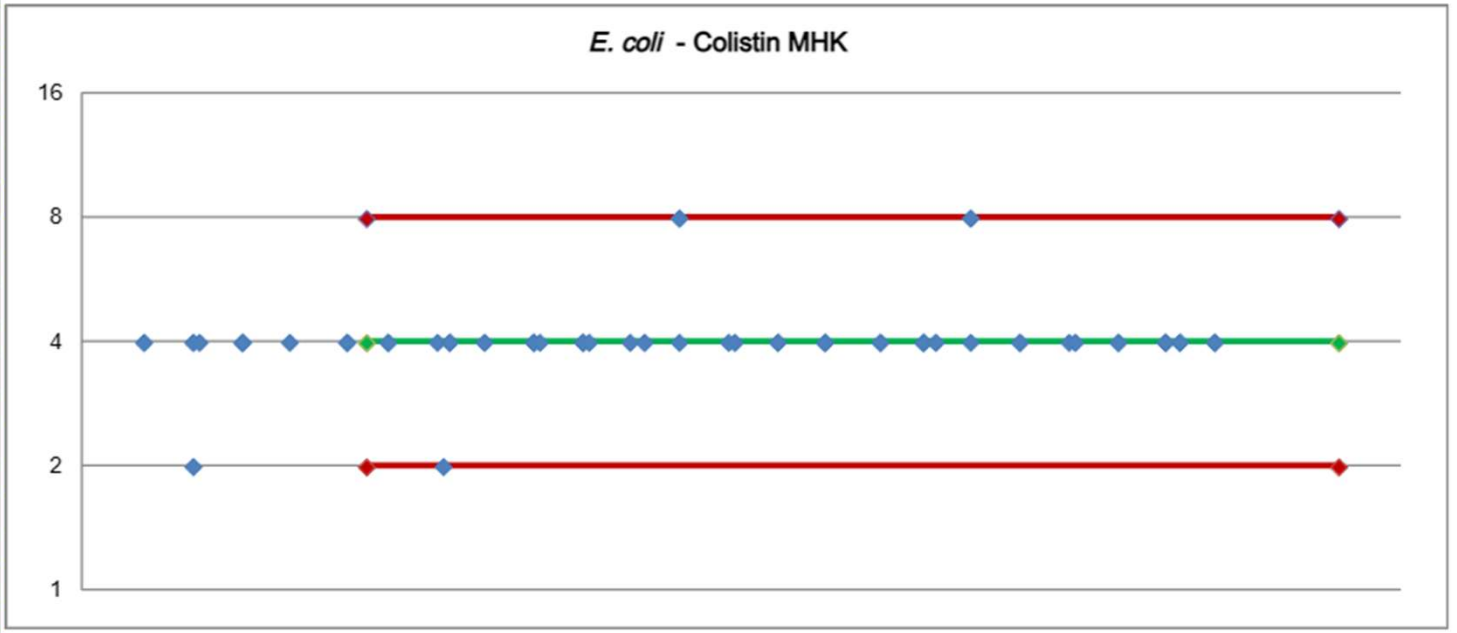
QK – Bouillon-Mikrodilution

- **Dokumentation und Beurteilung der MHK-Werte der QK-Stämme**

E. coli NCTC 13846

Target [mg/L]	4
Range [mg/L]	2 8

abge-lesen	Eingabe PC	Datum der Eingabe am PC	Colistin MHK
ES	ES	17.08.23	4
ES	ES	17.08.23	4
ES	ES	23.08.23	4
ES	ES	23.08.23	4
ES	ES	25.08.23	4
JWP	LB	30.08.23	4
JWP	LB	30.08.23	8
IS	IS	06.09.23	4
IS	IS	06.09.23	4
JWP	ES	13.09.23	4
JWP	ES	14.09.23	4
ES	JWP	20.09.23	4
ES	JWP	20.09.23	4
ES	JWP	27.09.23	4
ES	JWP	27.09.23	4
ES	ES	29.09.23	4
ES	ES	29.09.23	4
JWP	JWP	04.10.23	4
JWP	JWP	04.10.23	4



QK – Gradientendiffusion

The MIC is the basis for any assessment. In the absence of a breakpoint, an assessment can only be made when a trustworthy MIC value can be obtained. Determine the MIC using reference methods or validated surrogate methods.

- Broth microdilution is the reference method for aerobic bacteria using MH or MH-F broth depending on species.
- Agar dilution is the reference method for anaerobic bacteria using FAA-HB medium.
- Gradient tests are used in accordance with the manufacturer's recommendation. The test can only be relied on when validated for the species and agent, either by the manufacturer or by the user, and with simultaneous quality control. A gradient test developed and validated for one species cannot automatically be trusted with another species.

Quelle: https://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Guidance_documents/When_there_are_no_breakpoints_20230630_Final.pdf, zuletzt geprüft 16.10.2023

QK – Gradientendiffusion

BIOMÉRIEUX

Etest®

IVD

15211L - 2018/12

TABLE 1: Summary of ETEST® Performance, Interpretive Criteria and Quality Control Ranges

ANTIBIOTIC (1) MIC µg/mL	CODE (2)	PERFORMANCE (3)	N	% EA (4)	INTERPRETIVE CRITERIA (5) MIC µg/mL		S≤	S-DD (8)	I	R≥	QUALITY CONTROL (6)		MIC µg/mL
Amikacin 0.016 - 256	AK	Aerobes	553	95	*Enterobacteriaceae*		16	-	32	64	*S. aureus*	ATCC® 29213™	1 - 4
					P. aeruginosa		16	-	32	64	*E. coli*	ATCC® 25922™	0.5 - 4
					Acinetobacter		16	-	32	64	*P. aeruginosa*	ATCC® 27853™	1 - 4
					Staphylococci		16	-	32	64			
Amoxicillin 0.016 - 256	AC	*S. pneumoniae*	200	98	*S. pneumoniae*	Non meningitis	2	-	4	8	*S. pneumoniae*	ATCC® 49619™	0.032 - 0.125

© Liofilchem® - **Table no.1 MTS™ Interpretative Criteria and Quality Control** - Rev.34 / 20.07.2023

- The present **MTS™ Interpretative Criteria and Quality Control** table might be out of date. Check on-line for the latest update: https://www.liofilchem.com/images/brochure/mic_test_strip_patent/tabella_interpretazione.pdf
- The present **MTS™ Interpretative Criteria and Quality Control** table does not replace the official documents by CLSI, EUCAST and FDA.
- The present **MTS™ Interpretative Criteria and Quality Control** table has been produced in part under ECDC service contracts and made available by EUCAST at no cost to the user and can be accessed on the EUCAST website www.eucast.org. EUCAST recommendations are frequently updated and the latest versions are available at www.eucast.org.

Clinical

Antibiotic	CODE	CLSI INTERPRETATIVE CRITERIA [1]	S≤	SDD MIC µg/mL	I	R≥	EUCAST INTERPRETATIVE CRITERIA [2]	S≤ MIC µg/mL	R> MIC µg/mL	QUALITY CONTROL		MIC µg/mL
AMIKACIN 0.016 - 256 µg/mL	AK	*Enterobacterales*	4		8	16	*Enterobacterales* (systemic infections)	(8)	(8)	*S. aureus*	ATCC® 29213	1-4
		P. aeruginosa	16		32	64	*Enterobacterales* (infections originating	8	8	*E. faecalis*	ATCC® 29212	64-256
		Acinetobacter spp.	16		32	64	from the urinary tract)			*E. coli*	ATCC® 25922	0.5-4
		Other Non-Enterobacterales	16		32	64	*Pseudomonas* spp.	16	16	*P. aeruginosa*	ATCC® 27853	1-4
		EDA [4]					*Acinetobacter* spp.	8	8			
		Enterobacterales	16		32	64	*S. aureus*	(16)	(16)			
		S. aureus	16		32	64	Coagulase-negative staphylococci	(16)	(16)			
							PK/PD (Non-species related) breakpoints	1	1			
AMOXICILLIN 0.016 - 256 µg/mL	AML	*S. pneumoniae* (nonmeningitis)	2		4	8	*Enterobacterales* (iv)	8	8	*K. pneumoniae*	ATCC® 700603	> 128
							Enterobacterales (oral infections	0.001	8	*E. coli*	ATCC® 25922	2-8

Quelle: https://www.liofilchem.com/images/brochure/mic_test_strip_patent/tabella_interpretazione.pdf, zuletzt geprüft 16.10.2023

Agardilution – Enterobakterien

Miscellaneous agents	MIC breakpoints (mg/L)			Disk content (µg)	Zone diameter breakpoints (mm)		
	S ≤	R >	ATU		S ≥	R <	ATU
Chloramphenicol	Note[1]	Note[1]			Note[A]	Note[A]	
Colistin[2]	(2)[3]	(2)[3]			Note[B]	Note[B]	
Daptomycin	-	-			-	-	
Fosfomycin iv[4]	32[5]	32[5]		200[C]	21[D,E]	21[D,E]	
Fosfomycin oral (uncomplicated UTI only), *E. coli*	8[5]	8[5]		200[C]	24[E]	24[E]	

4. Breakpoints for fosfomycin iv are currently under review.

5. Agar dilution is the reference method for fosfomycin. MICs must be determined in the presence of glucose-6-phosphate (25 mg/L in the medium). Follow the manufacturers' instructions for commercial systems.

Quelle: https://www.eucast.org/clinical_breakpoints, zuletzt geprüft 16.10.2023

QK – Agardilution Fosfomycin, Liofilchem

© Liofilchem® - AD Fosfomycin 0.25-256 µg/mL - Rev.1 / 28.04.2020

ENGLISH

AD Fosfomycin 0.25-256

Device for fosfomycin susceptibility testing with the agar dilution method.

USER QUALITY CONTROL

Quality control of AD Fosfomycin 0.25-256 is performed using the following reference strains:

Strain		MIC range (µg/mL)
Escherichia coli	ATCC® 25922	0.5-2
Staphylococcus aureus	ATCC® 29213	0.5-4
Pseudomonas aeruginosa	ATCC® 27853	2-8
Enterococcus faecalis	ATCC® 29212	32-128

IT Patent pending No. 102019000007007, US Patent pending No. 62/850063

Quelle: https://www.liofilchem.com/products/liofilchem-products/category.html?classe=028, zuletzt geprüft 16.10.2023

Fazit

- QK ist substantieller Bestandteil einer Empfindlichkeitstestung gemäß EUCAST und stellt korrekte und reproduzierbare Ergebnisse sicher.
  - Optimum: Check der täglichen QK vor Ausgabe von Befunden
- Einbindung in Routine-Workflow möglich
- Zahlreiche Vorgaben und Dokumente
  - Aktualisierungen auf der EUCAST-Homepage beachten, auch als RSS-Feed verfügbar
- Einsatz kommerzieller Testsysteme:
  - Zugelassene Erreger berücksichtigen
  - Herstellervorgaben einhalten
- QK hilft uns dabei, sicher zu stellen, dass unsere Testmethoden innerhalb der festgelegten Qualitätsstandards fehlerfrei funktionieren.

Danke für Ihre

Aufmerksamkeit!

