ESfEQA
European Society for External Quality Assessment

Survey for Bacteriology with AST according to EUCAST

EQA Provider: ESfEQA GmbH Heidelberg

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Instructions for Use

Notes:

The Bacteriology scheme is suitable for all medical laboratories that undertake routine bacteriology including the isolation, identification and/or antimicrobial susceptibility testing of bacterial organisms.

The controls are simulated clinical specimens and contain viable bacteria that are categorized as either Risk Group 1 or 2. However, the controls are not of human origin. The controls should only be handled by trained personnel in accordance with local biosafety regulations. After use, all materials should be disposed following biosafety procedures.

Various tasks of the proficiency testing scheme may occasionally be given over to qualified subcontractors. However, ESfEQA is responsible to the participants for the subcontractor's work.

Results from sample analysis may only be disclosed to colleagues from other laboratories after the testing period has been concluded.

By registering for and participating in this EQA participants agree to accept the general terms and conditions of ESfEQA GmbH. These can be retrieved online at www.esfeqa.eu.

1. Intended Use

The samples are intended for use as control material for External Quality Assessment (EQA) in medical laboratories for the following parameters:

(1) **Samples 1 and 2: Identification** of bacterial pathogens**.** Performance requirements include the re-isolation and identification of significant pathogens in the samples.

> Importantly, dispatched samples for identification may be **pathogen-free**. In such a case, please select/submit "**pathogen-free**" as result.
>
> Samples can also be mixed cultures containing more than one significant pathogen or one significant pathogen and normal flora in addition. In the latter case, please submit only the **significant pathogen** as result.

Samples 3 and 4: Antimicrobial Susceptibility Testing (AST) of isolates specified in section 4. Performance requirements include the re-isolation of the corresponding organism and antimicrobial susceptibility testing as described in **section 8** and according to current **EUCAST** guidelines.

The performance criteria for the AST are met if both the participant has reported a result for at least 5 antimicrobial agents per isolate and achieves at least 80% of the possible score for the reported antimicrobial agents per isolate, the AST results being evaluated according to the following scheme:

Target value	Reported result		
	S	I	R
S	2	1	0
I	1	2	1
R	-1	1	2

2. Product Description

The controls are freeze-dried samples of viable microorganisms:

Sample 1: BAC-E_2021_02_a (for Identification only)
Sample 2: BAC-E_2021_02_b (for Identification only)

Sample 3: BAC-E_2021_02_c (for AST only)
Sample 4: BAC-E_2021_02_d (for AST only)

3. Information on samples for use in Identification

Sample 1: Urine sample collected by suprapubic aspiration

Sample 2: CSF sample

4. Information on samples for use in AST

Sample 3: *Acinetobacter baumannii* (isolated from pneumonia)

Sample 4: *Enterococcus faecium* (isolated from uncomplicated urinary tract infection)

5. Storage and Stability

The samples should be stored upright at 2-8 °C. They are stable at least until the deadline for data submission as indicated below. After reconstitution, samples should be processed within 30 minutes.

6. Sample Preparation and Analysis

All specimens should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacterial group studied should be applied throughout sample preparation and analysis. All work including sample preparation should be conducted in a biological safety cabinet.

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For additional handling precautions, refer to the "Technical Rules for Biological Agents - Protective measures for activities involving biological agents in laboratories - TRBA 100" (available at https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/TRBA-100.html), or to "Biosafety in Microbiological and Biomedical Laboratories - CDC/NIH - Latest edition", or to the regulations currently in use in your country.

Rehydrate the pellet in 1.5 ml general purpose broth (e.g. trypticase soy broth) according to your lab procedures. Gently agitate the vial occasionally until the lyophilisate is completely rehydrated and the suspension is homogenous. Inoculate appropriate culture media with a sample from the control according to your lab procedures.

All samples shall be treated the same way as patient samples and analyzed in accordance with the manufacturer instructions for instruments and reagents used.

7. Identification

Methods that can be used for identification include conventional techniques (e.g. Biochemical Bacteria Identification), mass spectrometry (e.g. MALDI-TOF) and nucleic acid testing (NAT).

8. Antimicrobial Susceptibility Testing (AST)

Susceptibility testing can be performed according to current **EUCAST** guidelines using phenotypic methods that include agar dilution, the antibiotic concentration gradient method (Etest), broth microdilution and the disk diffusion method.

For AST of Samples 3 and 4, antibiotics should be selected from the corresponding table displayed below.

Antibiotics for Sample 3	Antibiotics for Sample 4
Amikacin	Amoxicillin
Ciprofloxacin	Amoxicillin-clavulanic acid
Colistin	Ampicillin
Gentamicin	Ampicillin-sulbactam
Imipenem	Ciprofloxacin
Levofloxacin	Gentamicin (High-Level Screen)
Meropenem	Imipenem
Tobramycin	Levofloxacin
Trimethoprim-Sulfamethoxazole	Linezolid
	Nitrofurantoin
	Quinupristin-dalfopristin
	Streptomycin (High-Level Screen)
	Teicoplanin
	Tigecycline
	Vancomycin

AST profiles shall be reported according to current EUCAST guidelines with test results assigned to one of the following AST categories:

S - susceptible, standard dosis regimen

I - susceptible, increased exposure

R - resistant

If an antibiotic agent, which is suitable for AST of a particular organism, is not tested by the participant, it shall be indicated as "not measured" (e.g. if the corresponding antibiotic is not available).

9. Dates and Submission of Test Results

Testing period for Samples 1 - 4: 12/04/21 - 03/05/21

Please submit your results electronically to ESfEQA via the web interface https://teqa.esfeqa.eu. Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance with the registration in TEQA. Alternatively, though not preferred, use the fax form provided on the ESfEQA homepage. In both cases, please indicate the method (and, optionally, the instrument and reagent) used for the analysis of the samples.

When using several methods, instruments or reagents for determining a single parameter (Identification; Anti-microbial Susceptibility Testing), please transmit only the method, instrument and reagent, which ultimately yielded the result for the corresponding parameter.

9.1. For the **Identification** of bacterial isolates, submit one of the following generic methods only:

Biochemical Bacteria Identification (method key code: 100040), MALDI-TOF (code: 100038) or Nucleic Acid Testing (code: 100039).

9.2. For the **AST** of bacterial isolates, submit one of the following generic methods only:

Agar dilution (method key code: 100064), Antibiotic concentration gradient (Etest; code 1000063), Broth Microdilution (code: 286) or Disk diffusion EUCAST (code 100062).

10. Deadline for Data Submission

Deadlines for data submission are (time zone GMT +1):

Samples 1 - 4: 03/05/21

11. Reports and Certificates

The data will be evaluated by ESfEQA. The individual laboratory reports and certificates can be retrieved online at https://teqa.esfeqa.eu. The reports and certificates will be available within 3 weeks after the deadline of data submission.

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