EUCAST EUROPEAN COMMITTEE ON ANTIMICROBIAL SUSCEPTIBILITY TESTING

European Society of Clinical Microbiology and Infectious Diseases

Standard Operating Procedure

Format and updating of EUCAST documents

EUCAST SOP 8.2

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Foreword

The European Committee on Antimicrobial Susceptibility Testing (EUCAST) is organised by the European Society for Clinical Microbiology and Infectious Diseases (ESCMID), the European Centre for Disease Prevention and Control (ECDC), and the active national antimicrobial breakpoint committees in Europe. EUCAST was established by ESCMID in 1997, was restructured in 2001-2002 and has been in operation in its current form since 2002.

The current remit of EUCAST is to maintain clinical breakpoints for existing antimicrobial agents in Europe, to determine clinical breakpoints for new agents, to set epidemiological cut-off values, to review and revise breakpoints as required, to develop and refine methodology for antimicrobial susceptibility testing, to maintain a website with MIC and zone diameter distributions of antimicrobial agents for a wide range of organisms and to liaise with European governmental agencies and European networks involved with antimicrobial resistance and resistance surveillance.

Information on EUCAST, EUCAST breakpoints and all documents are freely available on the EUCAST website at http://www.EUCAST.org.

Citation of EUCAST documents

The copyright of all documents and data published on the EUCAST website remains with EUCAST. All are freely available for re-use if reference to the EUCAST website is given and documents and data are not on-sold. Any secondary publication of the data must be referenced with the declaration that "These data have (or this document has) been produced in part under ECDC service contracts and made available at no cost by EUCAST and can be accessed freely on the EUCAST website www.eucast.org. EUCAST recommendations are frequently updated and the latest versions are available at www.eucast.org."

EUCAST documents published on the EUCAST website should be cited in the following way: European Committee on Antimicrobial Susceptibility Testing. Name of document, EUCAST version number, year. Website address.

This SOP should be cited as: “European Committee on Antimicrobial Susceptibility Testing. Format and updating of EUCAST documents, EUCAST SOP 8.2, http://www.eucast.org/sop.

Abbreviations

EUCAST	European Committee on Antimicrobial Susceptibility Testing
ESCMID	European Society for Clinical Microbiology and Infectious Diseases
SOP	Standard Operating Procedure

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1	Scope
1.1	This SOP describes the format of EUCAST documents and procedures for updating the documents.

2	Introduction
2.1	Many EUCAST documents have been produced since the establishment of EUCAST in 1997. The format of the various documents has evolved with experience and this SOP describes the current formats and procedures for update of the documents.
2.2	As the various EUCAST documents have been produced over several years and the frequency of update historically has largely been “as needed”, there is sometimes inconsistency in format and existing documents will be updated to the latest formats as they are reviewed.

3	EUCAST breakpoint tables for antibacterial agents (including antimycobacterial agents)
3.1	**Description** EUCAST breakpoint tables for antibacterial agents include all EUCAST clinical breakpoints and PK/PD breakpoints and the most common dosing strategies for antibacterial agents on which the breakpoints were based (http://www.eucast.org/clinical_breakpoints).
3.2	**Format** The breakpoint tables are presented as Excel spreadsheets with a separate worksheet for each organism group. The Excel worksheets are primarily for screen presentation. A pdf file suitable for printing the complete tables is also available. For common target species/species groups, each worksheet includes the full range of antimicrobial agents grouped according to class, with a final section for miscellaneous agents. For uncommon target species, where data on most antimicrobials are not available, a restricted range of antimicrobials is included, arranged by class. For each agent susceptible and resistant MIC breakpoints are provided in the format S ≤ x, R > y mg/L. Susceptible and resistant zone diameter breakpoints are provided in the format S ≥ x, R < y mm. Breakpoint values for long-established agents are displayed in parentheses when maximum dosing is inadequate to treat wild-type target species causing systemic infections but efficacy is expected when used in conjunction with other active therapy. An additional column, Area of Technical Uncertainty (ATU) is used for both MIC

	and zone diameter breakpoints for circumstances where the value generated in the test is difficult to interpret and requires further consideration and/or testing by the laboratory. A column of notes is included with numbered notes for those related to MIC breakpoints and lettered notes for those relating to zone diameters. Links are included from antimicrobial agent names to rationale documents, from MICs values to MIC distributions and from zone diameter breakpoints to zone diameter distributions. Additional worksheets are as follows: Contents: A list of worksheets is provided with links to individual worksheets for individual organism groups and to additional information on some topics. Notes: Includes explanations of various aspects of the breakpoint tables. Guidance: Provides guidance on reading EUCAST breakpoint tables. Changes: Lists changes to the tables since the previous version. Within the tables all changes since the previous version are highlighted in pale yellow. Dosages: Provides information on the dosing regimens used to set breakpoints.
3.3	**Update frequency** There is one update released each year in January. Additional updates are normally not provided during the year. A major change or addition during the year is published as a separate addendum.
3.4	**Procedure for update** Multiple issues related to breakpoint tables are dealt with by the EUCAST Steering Committee on an ongoing basis. Changes are incorporated into draft update tables which are released for consultation early in December each year. The revised tables are then released early in January each year.

4	**EUCAST breakpoint tables for antifungal agents**
4.1	**Description** EUCAST breakpoint tables for antifungal agents include all EUCAST clinical breakpoints and PK/PD breakpoints for antifungal agents. http://www.eucast.org/clinical_breakpoints
4.2	**Format**

	The breakpoint tables are presented as Excel spreadsheets with a separate worksheet for each organism group. The Excel worksheets are primarily for presentation on screen. A pdf file suitable for printing the complete tables is also available. Each worksheet includes the range of antifungal agents for which breakpoints have been set. For each agent susceptible and resistant MIC breakpoints are provided in the format S ≤ x, R > y mg/L. An additional column, Area of Technical Uncertainty (ATU) is used for both MIC and zone diameter breakpoints for circumstances where the value generated in the test is difficult to interpret and requires further consideration and/or testing by the laboratory. A column of notes relating to the breakpoints is included. Links are included from antimicrobial agent names to rationale documents and from MICs values to MIC distributions. Additional worksheets are as follows: Contents: A list of worksheets is provided. Notes: Includes explanations of various aspects of the breakpoint tables. Changes: Lists changes to the tables since the previous version. Within the tables all changes since the previous version are highlighted in pale yellow. Dosages: Provides information on the dosing regimens a used to set breakpoints.
4.3	**Update frequency** Major updates are released when there are additional breakpoints or changes to existing breakpoints. Additional updates will only be provided to correct inadvertent errors.
4.4	**Procedure for update** Issues related to breakpoint tables are dealt with by the EUCAST Subcommittee on Antifungal Susceptibility Testing. Changes are incorporated into draft update tables which are released for consultation early in December each year. The revised tables are then released early in January each year.

5 EUCAST rationale documents

5.1 Description

EUCAST rationale documents summarise the information on which the EUCAST clinical breakpoints are based.

5.2 Format

The rationale documents are Microsoft Word documents (released as pdf versions) with the following sections:

A title page with the agent name, current version number and a list of previous versions with dates of issue.

A foreword with information about EUCAST and details of how the document should be cited in publications.

A brief introduction covering the chemical grouping, activity against major antimicrobial groups, any resistance mechanisms, licensed clinical use and dosage and, if the breakpoints are being revised, a statement of why the review was undertaken.

Standard and maximum dosing schedules.

MICs distributions and epidemiological cut off values (ECOFFS) for different species.

Previous breakpoints if there were any.

Pharmacokinetic data.

Pharmacodynamic data.

Monte Carlo simulations and PK/PD breakpoints.

Clinical data, particularly data relating MIC to outcome.

A summary of breakpoints and any qualifying notes or comments.

Any exceptions to the breakpoints noted by National Antimicrobial Susceptibility Testing Committees

5.3 Update frequency

Rationale documents will be updated whenever there is a change to MIC breakpoints.

5.4	**Procedure for update** Following discussion in the Steering Committee a revised draft document will be prepared for review by the Steering Committee. If deemed appropriate by the Steering Committee the draft may also be released for wider consultation. When the revised version is agreed by the Steering Committee it will be issued.

6	**EUCAST technical method documents**
6.1	**Description** Technical method documents describe practical procedures, such as MIC and disk diffusion methods.
6.2	**Format** The technical documents are Microsoft Word documents (released as pdf versions) with the following sections: A title page with the agent name, current version number and a list of previous versions with dates of issue. A foreword with information about EUCAST and details of how the document should be cited in publications. Sections covering a description of the method. The number of sections and their content will depend on the particular method.
6.3	**Update frequency** Method documents will be updated whenever there is a change in the method. For the disk diffusion susceptibility testing method, which is subject to continuous development, updates will be restricted to one per year.
6.4	**Procedure for update** Following discussion in the Steering Committee a revised draft document will be prepared for review by the Steering Committee. If deemed appropriate by the Steering Committee the draft may also be released for wider consultation. When the revised version is agreed by the Steering Committee it will be issued.

7	**EUCAST guidance documents**
7.1	**Description** Guidance documents cover particular areas related to antimicrobial susceptibility testing but not covered in detail in the breakpoint tables.

7.2	**Format** The guidance documents are Microsoft Word documents (released as pdf versions). The detailed format will depend on the subject but are usually text with illustrations if necessary.
7.3	**Update frequency** Guidance documents will be updated whenever there are data supporting a change.
7.4	**Procedure for update** Following discussion in the Steering Committee a revised draft document will be prepared for review by the Steering Committee. If deemed appropriate by the Steering Committee the draft may also be released for wider consultation. When the revised version is agreed by the Steering Committee it will be issued.

8	**EUCAST minutes**
8.1	**Description** Minutes are routinely produced for EUCAST Steering Committee meetings and General Committee meetings. Minutes may also be produced for subcommittee meetings. Full details of the preparation of EUCAST minutes are given in EUCAST SOP 7.0, Preparation and Handing of EUCAST Minutes.

9	**EUCAST Standard Operating Procedures**
9.1	**Description** EUCAST SOPs are documents describing agreed EUCAST procedures covering all aspects of the operation of EUCAST
9.2	**Format** The SOPs are Microsoft Word documents (released as pdf versions) with the following sections: A title page with the SOP name, current version number. A list of previous versions with dates of issue.

	A foreword with information about EUCAST and details of how the document should be cited in publications. Sections covering the scope of the SOP, an introduction and sections detailing the procedure depending on the particular procedure.
9.3	**Update frequency** SOPs are reviewed every two years and updated if required.
9.4	**Procedure for update** Following discussion in the Steering Committee, if revision is considered necessary a revised draft document will be prepared for review by the Steering Committee. When the revised version is agreed by the Steering Committee it will be issued.