# Clinical and Laboratory Standards Institute (CLSI) Interpretive Category Definitions

## Susceptible

A category defined by a breakpoint that implies that isolates with an MIC at or below or a zone diameter at or above the susceptible breakpoint are inhibited by the usually achievable concentrations of antimicrobial agent when the dosage recommended to treat the site of infection is used, resulting in likely clinical efficacy.

### **Susceptible-Dose Dependent**

A category defined by a breakpoint that implies that susceptibility of an isolate depends on the dosing regimen that is used in the patient. To achieve levels that are likely to be clinically effective against isolates for which the susceptibility testing results (either MICs or zone diameters) are in the susceptible-dose dependent (SDD) category, it is necessary to use a dosing regimen (ie, higher doses, more frequent doses, or both, or extended infusion) that results in higher drug exposure than that achieved with the dose that was used to establish the susceptible breakpoint. Consideration should be given to the maximum literature-supported dosage regimens, because higher exposure gives the highest probability of adequate coverage of a SDD isolate. The drug label should be consulted for recommended doses and adjustment for organ function.

#### Intermediate

A category defined by a breakpoint that includes isolates with MICs or zone diameters within the intermediate range that approach usually attainable blood and tissue levels and/or for which response rates may be lower than for susceptible isolates.

**Note:** The intermediate category implies clinical efficacy in body sites where the drugs are physiologically concentrated or when a higher than normal dosage of a drug can be used. This category also includes a buffer zone, which should prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations, especially for drugs with narrow pharmacotoxicity margins.

### Resistant

A category defined by a breakpoint that implies that isolates with an MIC at or above or a zone diameter at or below the resistant breakpoint are not inhibited by the usually achievable concentrations of the agent with normal dosage schedules and/or that demonstrate MICs or zone diameters that fall in the range in which specific microbial resistance mechanisms are likely, and clinical efficacy of the agent against the isolate has not been reliably shown in treatment studies.

### Nonsusceptible

A category used for isolates for which only a susceptible breakpoint is designated because of the absence or rare occurrence of resistant strains. Isolates for which the antimicrobial agent MICs are above or the zone diameters are below the value indicated for the susceptible breakpoint should be reported as nonsusceptible.

**Note:** An isolate that is interpreted as nonsusceptible does not necessarily mean that the isolate has a resistance mechanism. It is possible that isolates with MICs above the susceptible breakpoint that lack resistance mechanisms may be encountered within the wild-type distribution after the time the susceptible-only breakpoint was set.

### **Epidemiological Cutoff Value**

The MIC or zone diameter that separates microbial populations into those with and without phenotypically detectable resistance (non-wild-type or wild-type, respectively). The epidemiological cutoff value (ECV) defines the highest MIC or smallest zone diameter for the wild type population of isolates. ECVs are based on in vitro data only, using MIC or zone diameter distributions. ECVs are not clinical breakpoints, and the clinical relevance of ECVs for a particular patient has not yet been identified or approved by CLSI or any regulatory agency.

When an ECV is reported, an interpretive category is not assigned, and the following comment will be included: The MIC is in the range observed in isolates (WITH/WITHOUT) acquired resistance; however, correlation with treatment outcome is unknown. Infectious Disease consult is suggested."

# Susceptibility Interpretative Category Definitions (continued)

# Wild-type (WT)

An interpretive category defined by an ECV that describes the microbial population with no phenotypically detectable mechanisms of resistance or reduced susceptibility for an antimicrobial agent being evaluated.

### Non-wild-type (NWT)

An interpretive category defined by an ECV that describes the microbial population with phenotypically detectable mechanisms of resistance or reduced susceptibility for the antimicrobial agent being evaluated.

**Note:** MIC values for which ECVs are defined are not to be interpreted or reported as susceptible, intermediate or resistant but rather as WT or NWT. The ECVs should not be used as clinical breakpoints.

Reprinted with permission from Clinical and Laboratory Standards Institute from: CLSI. Performance Standards for Antimicrobial Susceptibility Testing. 35th ed. CLSI supplement M100. Clinical and Laboratory Standards Institute; 2025.

# **European Committee on Antimicrobial Susceptibility Testing (EUCAST) Interpretive Category Definitions**

### S-Susceptible, standard dosing regimen

A microorganism is categorized as "Susceptible, standard dosing regimen," when there is a high likelihood of therapeutic success using a standard dosing regimen of the agent.

### I-Susceptible, increased exposure\*

A microorganism is categorized as "Susceptible, Increased exposure\*" when there is a high likelihood of therapeutic success because exposure to the agent is increased by adjusting the dosing regimen or by its concentration at the site of infection.

### R-Resistant

A microorganism is categorized as "Resistant" when there is a high likelihood of therapeutic failure even when there is increased exposure.

\* Exposure is a function of how the mode of administration, dose, dosing interval, infusion time, as well as distribution and excretion of the antimicrobial agent will influence the infecting organism at the site of infection.

The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 15.0, 2025. <a href="https://www.eucast.org">www.eucast.org</a>

Page 2 of 2 MC4091-337rev0525