Pathway for Updating Breakpoints

Breakpoint Assessment

1. Review and record breakpoints that are currently used in the lab.
2. Review and compare the laboratory’s breakpoints to the current (updated) breakpoints.
3. If further action needed: The laboratory is using updated breakpoints.
   - Yes: Design validation studies to update out of date breakpoints.
   - No: Design verification studies to update out of date breakpoints.

Breakpoint Validation/Verification

1. Obtain comparator results using a method previously validated or verified for the updated breakpoints.
2. If appropriate perform discrepancy testing.
3. Perform testing to assess accuracy and precision.
4. Analyze the data.
5. Summarize the study results and submit them for review.
6. If appropriate perform an approved validation or verification study.
7. Implement the updated breakpoints.
8. Notify clinical teams and antimicrobial stewardship teams about the implementation of the updated breakpoints.

Abbreviation: AR, antibiotic resistance; AST, antimicrobial susceptibility testing.

References
1. 2023 BIT Part A. CLSI Breakpoints in Use Template
2. 2023 BIT Part B. CLSI vs. FDA Breakpoints
3. Additional guidance in CLSI M52, Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems
4. 2023 BIT Part C. Breakpoint Implementation Summary
5. Additional guidance in CLSI M52, Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems, Appendix B

This is Figure 1 of the 2023 Breakpoint Implementation Toolkit. To access the entire BIT Toolkit, visit https://clsi.org/bit-toolkit/.