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Antimicrobial Susceptibility Test (AST) System Devices – Updating Breakpoints in Device Labeling

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Guidance for Industry and Food and Drug Administration Staff

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This document supersedes Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices (June 2009).

For questions about this document, contact the Division of Microbiology Devices at ASTdevices@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number FDA-2023-D-4045. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Antimicrobial Susceptibility Test (AST) System Devices – Updating Breakpoints in Device Labeling

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance is intended to provide industry and FDA staff with information regarding updating susceptibility test interpretive criteria (STIC)/breakpoints[1] and associated performance data in device labeling for antimicrobial susceptibility test (AST) system devices in response to breakpoint changes posted on the FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria website (STIC Website).[2] This guidance is expected to facilitate the timely adoption of updated breakpoints in AST system devices, which helps to ensure device safety and effectiveness.

This guidance supersedes Sections II.A and V of the FDA guidance "Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices" issued in June 2009 ("June 2009 guidance").[3] As described in the June 2009 guidance, "updating the STIC will significantly affect the safety and effectiveness of the AST system device and, therefore, ordinarily would require submission of a premarket

[1] 'Susceptibility test interpretive criteria' (STIC) is considered synonymous with 'breakpoints,' and these terms are used interchangeably throughout this guidance.

[2] Available at https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria

[3] The STIC Website was established on December 13, 2017, and the guidance entitled "Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria Labeling for NDAs and ANDAs" (December 2017) (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/systemic-antibacterial-and-antifungal-drugs-susceptibility-test-interpretive-criteria-labeling-ndas) superseded Sections I, II.B, III, and IV of the June 2009 guidance. With the issuance of this final guidance, the June 2009 guidance is superseded in its entirety and has been withdrawn.

notification (510(k)) prior to updating device labeling."[4] In the June 2009 guidance, FDA described an enforcement policy where FDA would generally not object to device sponsors updating STIC in their AST system device labeling without a new 510(k) where the updated STIC did not affect acceptable device performance, as described in the "Antimicrobial Susceptibility Test (AST) Systems - Class II Special Controls Guidance,"[5] and the only change to the AST system device labeling was updating STIC. While FDA interpreted this policy to also include breakpoint change protocols, as discussed further below, the June 2009 guidance did not describe the procedures for updating AST system device labeling when using a breakpoint change protocol. This guidance describes approaches for AST system device sponsors to update their STIC in device labeling via predetermined change control plans (PCCPs), and also describes an enforcement policy regarding applying such updates to AST system devices that were cleared without breakpoint change protocols.

This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health and the urgent public health need for sponsors to update breakpoints for legacy AST system devices. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

AST system devices are intended to determine the *in vitro* susceptibility of bacterial or fungal pathogens to different antimicrobial agents. Accurate results are essential for guiding the treatment of infections by clinicians and for monitoring the spread of antimicrobial resistant microorganisms.

Generally, healthcare professionals rely on AST system devices to help choose an appropriate treatment as STIC are the criteria used to interpret AST results. Accumulating clinical and scientific information regarding the use of specific antimicrobials against specific bacteria or fungi may lead to the need to change breakpoint recommendations over time. Changes may occur in response to new information regarding successful treatment of infections, the emergence of new resistance mechanisms, or other factors. Historically, there have been delays in updates of AST system device labeling—following the recommendations of standards development

[4] 21 CFR 807.81(a)(3).

[5] Available at https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/antimicrobial-susceptibility-test-ast-systems-class-ii-special-controls-guidance-industry-and-fda

organizations that breakpoints be changed—until after the relevant antimicrobial drug labeling was revised to include the updated breakpoint.

Antimicrobial resistance (AMR) is a major public health threat to the U.S. According to the Centers for Disease Control and Prevention (CDC), as of 2019, more than 2.8 million antimicrobial-resistant infections occur each year in the U.S., and more than 35,000 people die as a result.[6] The Federal Task Force for Combating Antibiotic-Resistant Bacteria was established to help address the public health threat of AMR.[7] Notably, the Coronavirus Disease 2019 (COVID-19) pandemic had a harmful impact on efforts to combat AMR, resulting in both more resistant infections and more antibiotic use.[8] People of color, pregnant women, older adults, and people with weakened immune systems or certain medical conditions, such as diabetes, are at higher risk.[9] Critical to addressing the urgent public health threat of AMR is its detection. AST system devices with current breakpoints are necessary to detect drug-resistant infections and guide clinicians to the selection of an efficacious antimicrobial. Ensuring current breakpoints in AST system devices supports the National Strategy for Combating Antibiotic-Resistant Bacteria.

As part of this effort, section 3044 of the 21st Century Cures Act (Cures Act), signed into law on December 13, 2016, added section 511A (21 U.S.C. 360a-2), "Susceptibility Test Interpretive Criteria for Microorganisms," to the FD&C Act. Section 511A(c) authorizes FDA to recognize, in whole or in part, a consensus standard that provides antimicrobial STIC or establish alternative STIC, and section 511A(b) requires FDA to establish and maintain a dedicated website that contains a list of any appropriate new or updated STIC and standards. Section 511A(e) also clarifies that sponsors of AST system devices may rely on these FDA-recognized or listed STIC to support premarket authorization of their devices, so long as certain conditions are met. This provides for a more streamlined process for incorporating updated antimicrobial susceptibility information into device labeling. In accordance with section 511A(b) of the FD&C Act, FDA established the STIC Website, which serves as the dedicated repository of FDA-recognized STIC. Antimicrobial drug labeling no longer includes breakpoint information, but instead refers to the STIC Website for breakpoint information.

Generally, updating the STIC could significantly affect the safety and effectiveness of the AST system device and, therefore, ordinarily would require submission of a 510(k) prior to updating device labeling.[10] FDA has reviewed and cleared many 510(k) submissions for new AST system devices with "breakpoint change protocols" that allow for changes to breakpoints without a new 510(k) since the establishment of the STIC Website in 2017, as described further below. This has allowed for timely updates to breakpoints in those AST system devices. However, many AST system devices were reviewed and cleared by FDA that did not include a breakpoint change protocol (referred to in this guidance as "legacy AST system devices").

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[6] See CDC's website on COVID-19 & Antimicrobial Resistance, available at https://www.cdc.gov/drugresistance/covid19.html

[7] See the Office of the Assistant Secretary for Planning and Evaluation's National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025, available at https://aspe.hhs.gov/reports/national-action-plan-combating-antibiotic-resistant-bacteria-2020-2025

[8] See CDC's website on COVID-19 & Antimicrobial Resistance.

[9] See CDC's website on CDC's Priority to Address Health Equity Issues Across Antibiotic-Resistant Threats, available at https://www.cdc.gov/drugresistance/solutions-initiative/stories/ar-health-equity.html

[10] 21 CFR 807.81(a)(3).

Additionally, section 3308 of the Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 ("FDORA"), enacted on December 29, 2022, added section 515C "Predetermined Change Control Plans for Devices" to the FD&C Act. Section 515C provides FDA with express authority to approve or clear PCCPs for devices requiring premarket approval or premarket notification. For example, section 515C provides that supplemental applications (section 515C(a)) and new premarket notifications (section 515C(b)) are not required for a change to a device that would otherwise require a premarket approval supplement or new premarket notification if the change is consistent with a PCCP approved or cleared by FDA. Section 515C also provides that FDA may require that a PCCP include labeling for safe and effective use of a device as such device changes pursuant to such plan, notification requirements if the device does not function as intended pursuant to such plan, and performance requirements for changes made under the plan.[11] For purposes of this guidance, consistent with FDORA and section 515C of the FD&C Act, all breakpoint change protocols submitted and cleared in future 510(k) submissions following the publication date of this guidance will be referred to as "PCCPs," and breakpoint change protocols cleared prior to the publication date of this guidance will be referred to as "breakpoint change protocols." In this guidance, we provide recommendations on the marketing submission content for PCCPs for new AST system devices, describe an enforcement policy for legacy AST system devices, and clarify the process for incorporating by reference a cleared PCCP or breakpoint change protocol into a new 510(k) submission for an AST system device.

III. Scope

The scope of this guidance is limited to devices classified under 21 CFR 866.1640, 21 CFR 866.1645, or 21 CFR 866.1650 with the product codes listed below in Table 1 and does not include antimicrobial susceptibility test discs classified under 21 CFR 866.1620.[12] The scope of this guidance is also limited to recommendations and marketing submission content expectations for PCCPs that include planned modifications to update AST system device labeling to include the updated breakpoints. This guidance does not describe recommendations for other planned modifications to AST system devices, including other planned modifications to update AST system device labeling unrelated to updating breakpoints. It is possible that other modifications could significantly affect the safety or effectiveness of the device and may require a new 510(k).[13] FDA recommends consulting the relevant device regulations, including 21 CFR 807.81(a)(3), and the FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device."[14]

Table 1

[11] Sections 515C(a)(3) and (b)(3) of the FD&C Act.

[12] As described in Section IV.B below, the scope of the enforcement policy described in this guidance is limited to legacy AST system devices with product codes listed in Table 1 that have the same intended use and the same technological characteristics, classification regulation, and product code as the AST system device manufactured by the same sponsor for which a PCCP or breakpoint change protocol has been cleared by FDA.

[13] 21 CFR 807.81(a)(3).

[14] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device

Regulation Number[15]	Product Code	Device Type
21 CFR 866.1640	LRG	Instrument For Auto Reader & Interpretation Of Overnight Suscept. Systems
21 CFR 866.1640	JWY	Manual Antimicrobial Susceptibility Test Systems
21 CFR 866.1640	LTT	Panels, Test, Susceptibility, Antimicrobial
21 CFR 866.1640	JTT	Susceptibility Test Powders, Antimicrobial
21 CFR 866.1640	LTW	Susceptibility Test Cards, Antimicrobial
21 CFR 866.1640	NGZ	Susceptibility Test Plate, Antifungal
21 CFR 866.1645	LON	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation
21 CFR 866.1650	PRH	Positive Blood Culture Identification And Ast Kit

FDA encourages manufacturers to contact the Division of Microbiology Devices, Office of Health Technology 7, Office of Product Evaluation and Quality, Center for Devices and Radiological Health (DMD/OHT7/OPEQ/CDRH) with additional questions not addressed in this guidance, including questions regarding whether this guidance is applicable for a specific device. Sponsors may also request feedback through the pre-submission process. In particular, if you are interested in proposing a PCCP in your marketing submission, we encourage you to submit a Pre-Submission to engage in further discussion with CDRH. Please refer to the guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."[16]

IV. Updating Breakpoints in AST System Device Labeling

A. Establishing and Utilizing a PCCP for Breakpoint Updates in a 510(k) Submission for an AST System Device

Generally, updating the STIC of an AST system device could significantly affect the safety and effectiveness of the device, and therefore, such modifications, if not included in a PCCP or breakpoint change protocol, would likely require submission of a 510(k) prior to updating device labeling.[17] In this guidance, FDA describes an approach that would often be least burdensome

[15] Some of these devices are also subject to special controls. FDA recommends that you look at the classification regulation for information on applicable special controls.
[16] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program
[17] 21 CFR 807.81(a)(3).

for manufacturers to incorporate updated breakpoints in AST system device labeling in a timely manner by using a PCCP.

(1) Establishing a PCCP

By proposing a PCCP in a 510(k) submission, AST system device manufacturers can proactively prespecify and seek clearance for breakpoint updates to their device labeling without submitting another 510(k) that would otherwise be required for such a change. FDA recommends that all AST system device 510(k) submissions that do not already have an applicable PCCP include a proposed PCCP in any future 510(k) submission to facilitate the adoption of breakpoint updates in AST system device labeling.

Generally, premarket authorization for an AST system device with a PCCP must be established through the 510(k) pathway, as a PCCP must be reviewed and cleared as part of a 510(k) for the device prior to a sponsor incorporating STIC updates in AST system device labeling under that PCCP.[18] For 510(k) submissions, in making a determination of substantial equivalence where the predicate device was cleared with a PCCP, the subject device must be compared to the version of the predicate device cleared prior to changes made under the PCCP.[19]

The recommended elements for a PCCP to help ensure the AST system devices have the same intended use and technological characteristics are outlined below. The PCCP should contain procedures to help ensure that updates to the breakpoints consistent with those recognized on the STIC Website do not significantly change the performance of the updated AST system device such that the performance of the updated device is maintained when compared to the same most recently cleared AST system device.

(2) Utilizing a PCCP

Once a PCCP has been reviewed and cleared in a 510(k) for an AST system device, the PCCP is considered part of the 510(k) clearance. In general, a PCCP should be evaluated within the existing risk management framework of the device and implemented in accordance with the manufacturer's quality system. If the STIC update is consistent with the cleared PCCP, i.e., the STIC update is specified and implemented in accordance with the cleared PCCP, then the sponsor can update the STIC in the labeling of their AST system device without a new 510(k) submission to FDA. The manufacturer must document the change in accordance with the manufacturer's quality system.[20] If the STIC update is not consistent with the cleared PCCP – including if the STIC update is not included in the cleared PCCP or if the STIC update is included in the cleared PCCP but is not implemented in accordance with the cleared PCCP – the sponsor should then proceed to evaluate the modification in accordance with applicable FDA authorities and the FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device,"[21] and proceed accordingly. If, after review of applicable FDA authorities, a

[18] See section 515C(b) of the FD&C Act.
[19] See section 515C(c) of the FD&C Act.
[20] See 21 CFR Part 820.
[21] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device

new 510(k) is required, then the sponsor must submit a 510(k) before the modified device is marketed.[22]

Deviations from a cleared PCCP for breakpoint updates could significantly affect the safety or effectiveness of the device. For example, when updating breakpoints in a manner that is a deviation from the PCCP, the device's clinical functionality or performance specifications could be compromised. Deviations from the PCCP include instances where the PCCP is not followed or cannot be followed. Accordingly, breakpoint updates for an AST system device that are not specified in, or implemented in accordance with, the cleared PCCP generally require submission of a 510(k) prior to updating the AST system device labeling (see Section IV.B of this guidance for discussion on when FDA does not intend to object to certain breakpoint updates applied to cleared AST device systems).[23] In such a circumstance, the modified AST system device would generally be adulterated and misbranded under sections 501(f)(1) and 502(o) of the FD&C Act, respectively.

As mentioned, in accordance with section 515C of the FD&C Act, when using a cleared PCCP, sponsors may implement breakpoint update changes in AST system device labeling without submission of a new 510(k). Updated labeling should be sent to the electronic inbox FDA has designated for receipt, ASTDevices@fda.hhs.gov. FDA believes that this approach will facilitate timely updates to breakpoints in AST system device labeling.

(3) Content of a PCCP

The PCCP should describe: (1) how updated breakpoints will be evaluated by the sponsor; and (2) the procedures the sponsor will use to demonstrate that the use of updated breakpoints, when applied to existing data that support, or have supported, clearance of the device, (a) demonstrates device performance that is maintained when compared to the most recently cleared device, and (b) supports that application of updated breakpoints do not reveal new risks or significantly modify existing risks such that prior submission of a 510(k) would otherwise be required.[24]

If an AST system device manufacturer is interested in establishing a PCCP for breakpoint updates in a 510(k) submission, FDA recommends that their proposed PCCP include the following:

1. A Description of Modifications that includes:
    a. A description of the general applicability of the PCCP to AST system devices with the same technological characteristics; and
    b. The updated breakpoint(s) being adopted, which should be identical to the relevant breakpoint(s) recognized by FDA on the STIC Website and fall within the drug concentration range reviewed and cleared by FDA.
2. A Modification Protocol that includes:
    a. The specific procedures that will be followed to reevaluate previously collected clinical data submitted to and reviewed by FDA in the most recently

[22] 21 CFR 807.81(a)(3).
[23] 21 CFR 807.81(a)(3).
[24] 21 CFR 807.81(a)(3).

cleared 510(k) submission for the AST system device demonstrating that device performance with the updated breakpoint(s) for the drug/organism combination is unchanged or continues to meet prespecified performance criteria for category agreement (CA), essential agreement (EA), and error rates, as applicable;

b. A sufficient number of resistant isolates, based on the microbiology activity spectrum and minimum inhibitory concentration (MIC) distribution data, if applicable, for the drug/organism combination since the most recently cleared 510(k) submission for that AST system device in which the drug/organism combination was evaluated, as determined by the updated breakpoint(s);
c. The planned updates to device labeling as a result of breakpoint updates on the STIC Website; and
d. The planned updates to device labeling to incorporate the new breakpoint information and update the device's performance characteristics or limitations, as determined by the sponsor's evaluation.

B. Applying a PCCP or Breakpoint Change Protocol for Breakpoint Updates to a Cleared AST System Device (Legacy AST System Devices)

FDA intends to help facilitate sponsor updates to their AST system device labeling based on FDA-recognized breakpoint updates for their cleared AST system devices where a PCCP or breakpoint change protocol was not previously submitted as part of a 510(k) submission for that device. As previously stated, generally, updating the STIC of an AST system device could significantly affect the safety and effectiveness of the device, and therefore, such modifications, if not included in a PCCP or breakpoint change protocol, would likely require submission of a 510(k) prior to updating device labeling.[25] For additional information on device modifications that may require a new 510(k), please see FDA's guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device."[26]

At this time, FDA does not intend to object if a sponsor chooses to utilize a PCCP or breakpoint change protocol that has been cleared as part of a sponsor's separate 510(k) to implement breakpoint updates for the sponsor's legacy AST system device that is under the same classification regulation and product code and has the same intended use and the same technological characteristics (e.g., same instrument(s) or device design) as the device for which the protocol was cleared by FDA without submitting a 510(k) prior to making STIC labeling updates.

Use of a cleared PCCP or breakpoint change protocol for updating breakpoints in another AST system device may facilitate timely and efficient updates to these devices, while helping to ensure device safety and effectiveness. In addition, the cleared PCCP or breakpoint change protocol includes procedures to help ensure that updates to the breakpoints consistent with those

[25] 21 CFR 807.81(a)(3).
[26] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device

recognized on the STIC Website do not significantly change the performance of the newly updated (legacy) AST system device such that performance of the updated device is maintained when compared to the same most recently cleared AST system device. In the circumstances described above, even though AST system devices may have different indications for use based on the drug/organism combinations for which they are intended to be used, these devices have the same technological characteristics, fall within the same classification regulation and product code, and have the same intended uses. In these situations, the procedures for implementing breakpoint updates are the same. As such, the risk of raising new issues of safety and effectiveness is mitigated when: (1) a sponsor utilizes a cleared PCCP or breakpoint change protocol from the sponsor's separate 510(k) for an AST system device; (2) that cleared PCCP or breakpoint change protocol is applied to the sponsor's legacy AST system device; and (3) both AST system devices are under the same classification regulation and product code, and have the same intended use and the same technological characteristics.

When a sponsor utilizes a PCCP or breakpoint change protocol that has been cleared as part of that sponsor's separate 510(k) for an AST system device in the circumstances described above, that same sponsor should utilize and reference that protocol to test and evaluate whether FDA-recognized breakpoint updates specified on the STIC Website affect device performance for their legacy AST system device. When the breakpoint updates fall within the prespecified performance criteria in the cleared PCCP or breakpoint change protocol, at this time, FDA generally does not intend to object to distribution and use of the AST system device with the updated STIC labeling without submission of a new 510(k), consistent with the policy described in this guidance.

As previously described, deviations from the cleared PCCP or breakpoint change protocol could significantly affect the safety or effectiveness of the device. Accordingly, this enforcement policy does not apply to other labeling updates to an AST system device that are not specified in, or implemented in accordance with, a cleared PCCP or breakpoint change protocol as described above.

The manufacturer must document the change and use of the cleared PCCP or breakpoint change protocol in accordance with the manufacturer's quality system.[27] The internal documentation supporting the breakpoint updates should include the 510(k) submission number that contained the referenced cleared PCCP or breakpoint change protocol that was followed, a summary of the evaluation in which it was determined that the protocol was appropriately followed, and the determination that this falls within the enforcement policy outlined in this guidance. The sponsor should reference use of the cleared PCCP or breakpoint change protocol, including the 510(k) submission number in which that protocol was reviewed and cleared by FDA, when submitting the updated labeling to FDA via the designated electronic inbox, ASTDevices@fda.hhs.gov.

C. Incorporating By Reference an Authorized PCCP or Breakpoint Change Protocol in a New 510(k) Submission for an AST System Device

[27] See 21 CFR Part 820.

For sponsors who are submitting a new 510(k) and want to rely on a cleared PCCP or breakpoint change protocol that the sponsor previously submitted in a 510(k) submission, the sponsor should incorporate by reference the cleared PCCP or breakpoint change protocol into the new 510(k) submission for their AST system device as described above in Section IV.A. In addition, the sponsor of such a protocol should include in their 510(k) submission a reference to the prior submission (i.e., 510(k) submission number).

FDA believes that this approach would often be least burdensome for device sponsors to provide timely breakpoint updates for their AST system devices to keep appropriate pace with the STIC Website, which may help ensure device safety and effectiveness to support patient care and public health.