D5471

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1256 Standard: Control procedures

(e) For reagent, media, and supply checks, the laboratory must do the following:

(e)(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in §493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

Interpretive Guidelines §493.1256(e)(1)

Review the laboratory's quality control records and note when lot numbers change.

NOTE: Media checks are defined under §493.1256(e)(4) Guidelines.

The laboratory must demonstrate that each reagent performs within the specifications established by the laboratory for the test procedure. Documentation of concurrent testing of reagents or acceptable quality control results will satisfy this requirement.

Reagents, disks, and test procedures used for identification purposes may include, but are not limited to, catalase, coagulase plasma, oxidase, bacitracin, optochin, Cefinase™, ONPG, X, and V factor strips and disks, germ tube, yeast morphology media, and

commercial identification systems.

A negative reactivity control is not required for the mycology germ tube test.

Test each batch, lot, and shipment for positive and negative reactivity for reagents such as:

- Bacitracin;

- Catalase;

- Cefinase;

- Coagulase plasma;

- ONPG;

- Optochin;

- Oxidase;

- Spot indole; and

- X and V factor strips and disks.

For bacteriology, XV discs or strips need only be checked with an organism that produces a positive reaction.

Probes §493.1256(e)(1)

What records does the laboratory have to demonstrate that controls are tested when shipments of reagents, discs, stains, antisera or identification systems are opened or when the laboratory prepares these materials? Use D5471 for not recording performance and for nonperformance of quality control checks and stain checks.