Proposed Microbiology Category Standards – Comments and Responses

Proposed Standards were made available to New York State permitted laboratories and laboratories in application for a permit on March 4th, 2020. The announcement was by e-mail to the facility and laboratory contact person's e-mail address and the Proposed Standards were posted to the CLEP website.

The comment period ended June 15th, 2020. Comments received from any regulated parties and responses are shown here.

Standards will be adopted July 13th, 2020 with an effective date of August 1st, 2020.

Microbiology Categories

Microbiology	
Microbiology Categories	
Proposed Standard	***Proposed Guidance***
Microbiology Standard of Practice 1 (MB S1): Biological Safety Cabinet A class II or higher biological safety cabinet (BSC) must be used when: a) processing specimens submitted for mycobacteriological testing, including slide preparation or handling unsealed mycobacteriology cultures; b) processing patient specimens submitted for isolation of pathogenic fungi or handling cultures of pathogenic fungi; c) inoculating cell cultures with clinical specimens and for all procedures involving the maintenance and processing of inoculated cell cultures and culture-amplified materials; or	Additional required use of the BSC should be established by the laboratory director based on an infectious agent risk assessment (refer to Laboratory Safety Standard of Practice 7 (LS S7): Biohazard Risk Assessment.

d) performing any other procedures that have the potential to create infectious aerosols.	

Microbiology Standard of Practice 1 (MB S1): Biological Safety Cabinet

COMMENT 1:

The phrase “handling cultures of pathogenic fungi” in section “b” of **MB S1** ("processing patient specimens submitted for isolation of pathogenic fungi or handling cultures of pathogenic fungi) is too vague.
Candida albicans and other yeasts are “pathogenic fungi” but I assume the standard is intended for pathogenic molds/dimorphs. There should be a definition of "pathogenic fungi" or a link (eg https://www.asm.org/ASM/media/Policy-and-Advocacy/Biosafety-white-paper-2019.pdf).

RESPONSE 1:

All pathogenic fungi should be handled in the biosafety cabinet. This is an important standard of practice in light of the emergence of drug resistant *Candida* species. There is no change to the standard based on the comment received.

COMMENT 2:

We ask that instead of "laboratory director" it state: laboratory director or assistant director(s) holding an appropriate certificate of qualification.

RESPONSE 2:

According to Laboratory Safety Standard of Practice 7, the director or director designee may perform the Biohazard Risk Assessment. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). There is no change to the standard based on the comment received.

Microbiology Nucleic Acid (MNA) Amplification Assay

Microbiology	
Microbiology Nucleic Acid (MNA) Amplification Assay	
Proposed Standard	***Proposed Guidance***
Microbiology Standard of Practice 4 (MB S4): Microbial Growth Medium Each lot or shipment of commercially prepared or in-house prepared media must be tested: a) on-site for growth, selectivity, and/or inhibition and biochemical responses; or b) by criteria established by the manufacturer or the laboratory in absence of manufacturer instructions. Quality control (QC) checks for sterility, growth, selectivity and/or inhibition and biochemical responses need not be retested by the laboratory provided that: i. for each shipment or lot of media, the laboratory has documentation on the media label, package insert, technical manual, or other document, that the manufacturer's or in-house QC practices conform to specifications; and ii. the laboratory documents receipt and condition of each shipment or lot of media, and notifies the media manufacturer or in-house preparer of: - cracked Petri dishes; - unequal filling of plates; - cracked media in plates; - hemolysis;	Media may be tested concurrent with initial use provided QC results are reviewed prior to release of patient results.

- freezing; - excessive number of bubbles; or - contamination.	

Microbiology Standard of Practice 4 (MB S4): Microbial Growth Medium

COMMENT:

Please clarify: Are Light Cyclers considered a "**closed system**" since the cuvettes or plates are not opened."?

RESPONSE:

A closed system is defined as an instrument in which the patient specimen is directly added to the test unit, device, or cartridge, sealed, and then the testing process is initiated with no additional external manipulation or addition of reagents (either manually or robotically). The Light Cycler does not meet this definition. There is no change to the standard based on the comment received.

Bacteriology

Microbiology	
Bacteriology	
Proposed Standard	***Proposed Guidance***
Laboratories that perform testing for *Chlamydia* culture must follow applicable Virology Culture standards.	

COMMENT:

In the first item under **Bacteriology** (p. 27), "Laboratories that perform testing for Chlamydia must follow applicable Virology Culture standards" should be changed to "Laboratories that perform *Chlamydia* culture must follow applicable Virology Culture standards." The standard does not apply to labs that perform molecular testing for *Chlamydia*.

RESPONSE:

The language has been revised based on the comment received.

Mycology

Microbiology	
Mycology	
Proposed Standard	***Proposed Guidance***
Mycology Standard of Practice 1 (MY S1): Microscopy of Primary Specimens ~~Identification of molds and yeast must utilize direct microscopic examination of the primary specimen using an appropriate mounting medium or stain.~~ If primary specimens are used for the detection of fungal elements by microscopy, it must include appropriate mounting medium or stain.	Based upon clinical history and nature of the clinical specimen, a direct examination may be performed with one of the following reagents or stains: potassium hydroxide; India ink; Cellufluor; Gram stain; Giemsa stain, ethenamine silver stain, or other appropriate method(s). (Note: The listed examples are not all-inclusive).

COMMENT:

Can I get clarification for MY S1. It states “must utilize direct microscopic examination of primary specimen?” Specifically, we process YDS (yeast dermatophyte screens-skin ,hair and nail specimens) and fungal cultures.
KOH smears are difficult to read which would be the method for the skin, hair and nail specimens. I am really not sure what additional information this will give physicians since most of our current PAS slides are negative.
I just think this might be challenging since the current staff members proficient and knowledgeable in the field of mycology is dwindling. Not just for my laboratory but for others as well as our more experienced techs are nearing or about to retire.
Besides, there is a cost involved with doing KOH’s on all specimens. We are at a time where most healthcare facilities are faced with utilizing resources prudently. If there s no added value to this step I have to question why this standard is stated this way.

RESPONSE:

The standard has been changed based on the comment received.

Parasitology

Microbiology	
Parasitology	
Proposed Standard	***Proposed Guidance***
Parasitology Standard of Practice 1 (PS S1): Stool Specimen Preservation for Morphological Examination Stool specimens to be used for parasitological identification based on morphology must be: a) examined within one (1) hour of collection; or b) preserved within one (1) hour of collection using the fixative appropriate for the test being ordered; or c) refrigerated for no more than three (3) hours to preservation.	The laboratory should choose the fixative that is most appropriate for its testing purposes, e.g., PVA for Trichrome, ten (10) percent formalin or SAF for acid-fast staining. When it is anticipated that the time of collection will not be recorded or transport time will be prolonged, laboratories are encouraged to provide stool transport kits containing preservatives. It is recommended that ova and parasite examinations include a concentration step whenever compatible with subsequent testing, as the concentration step significantly increases recovery of parasites.

COMMENT:

Microbiology. PS S1: sections a and b state 1 hour stability, suggest section c also state no more than 1 hour. Extended refrigeration has the potential for lysing amoebas and giardia.

RESPONSE:

There is no change to the timeframes stated in the standard based on the comment received.