

# **Microbiology PT Requirements**

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# Levels of Service

*Have the levels of service or laboratory types listed in subpart I been of assistance to the PT programs when helping laboratories enroll properly or to surveyors in conducting laboratory inspections? If so, should they be retained or revised in any way?*

- Many microbiologists do not understand the levels of service.
- PT programs are required by law to assist laboratories in proper enrollment.
- Accrediting organizations and CMS surveyors use the levels to help guide laboratories in PT enrollment and in monitoring PT performance.
- Smaller laboratories may use the levels to determine what tests require PT.
- PT programs offer modules for all levels of testing, and can assist laboratories in selecting the appropriate module.

## Levels of Service (cont'd)

- ❑ It is difficult to fit some tests performed in physician office laboratories into the current levels of service. Examples include growth/no growth testing, presumptive identification, colony count, and presence/absence of fungus.
- ❑ The levels of service described for mycology prohibit required PT for growth/no growth testing using dermatophyte test media.
- ❑ Laboratories perform different levels of organism identification, such as genus versus species, regardless of their PT level of service. In some cases, the level of identification is based on the culture source.
- ❑ The list of levels needs to be simple and have flexibility that can be linked to what the laboratories perform and report for patient testing.
- ❑ Information regarding changes to the PT requirements will need to be communicated to educate laboratories, surveyors, and PT programs.

# Levels of Service (cont'd)

- ❑ PT programs should provide samples that allow laboratories to perform all testing as they normally would on a patient specimen.
  - Except during laboratory inspections, neither CMS nor PT programs have a system in place to monitor levels of reporting on PT challenges.
  - It is difficult for accrediting organizations to monitor whether PT results are reported at the same level as patient reports due to the roll-up of individual scores on PT components into one overall score.
  - Suggest a mechanism such as including an extra bullet regularly on the PT result form for the laboratory to indicate how they report each organism for patient testing; species level, genus level, gram stain only, etc. This would be similar to how laboratories report their methodology for PT.

# Levels of Service (cont'd)

## WORKGROUP AGREEMENT:

- ❑ Some form of levels or types of service needs to be maintained in the regulations to help laboratories determine what PT they need to perform and assist surveyors in monitoring PT performance and patient testing.
- ❑ Laboratories need to declare their patient reporting practices for organisms included in each PT challenge. However, PT programs may only gather this information as it is the inspecting agency's responsibility to review and take action if necessary.

# Required Categories of Tests

*Should required categories of tests be specified for the microbiology subspecialties; for example, should microbiology PT be regulated based on sample source, complexity of testing, or another method?*

- If PT is required according to specimen source, laboratories may indicate they do not test that source and will not perform PT.
- Source based requirements would present difficulties for PT programs.
- It would be easier for PT programs to grade challenges by using a procedure or category as an analyte.
- When defining categories for regulated PT, need flexibility to allow for inclusion of new technologies.

# Required Categories of Tests (cont'd)

## WORKGROUP AGREEMENT:

- The regulations need to include a clear definition of what microbiology testing requires PT.
- For all microbiology subspecialties, required PT should include, as applicable, stain(s), susceptibility testing, antigen and/or toxin detection, and microbial identification.

# Major Groups of Microorganisms

*Are the major groups of microorganisms listed for each microbiology subspecialty organized appropriately? For example, in bacteriology the major groups include anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, and miscellaneous gram-negative bacteria.*

*If so, how can we ensure the laboratories are adequately challenged over time with each of the major groups for a subspecialty?*

*If not, is there a better way to categorize the microorganisms that should be included in a PT program over time?*

*Should the specific lists of example organisms be retained?*

- Some laboratories misinterpret the regulations and feel that they are responsible for performing PT only on the listed organisms.
- Keep the list of organisms generic to avoid issues with nomenclature changes over time.
- Requirements should assure that PT programs offer a variety of challenges and do not include the same organism multiple times per year in each module or survey.
  - Aerobic and anaerobic organisms should be included in bacteriology.
  - Growth/no growth testing should be included where applicable.

# Major Groups of Microorganisms (cont'd)

## WORKGROUP AGREEMENT:

- ❑ Require PT for a generic list of organisms in each subspecialty. For example, in bacteriology the groups listed should include gram-negative bacilli, gram-positive bacilli , gram-negative cocci, and gram-positive cocci.

# Emerging Pathogens

*Should PT programs be required to offer microorganisms known as common and newly emerging pathogens for a particular sample source?*

- PT content needs to be challenging by including emerging pathogens in the modules.
- Laboratories pass PT more frequently when common organisms are included in challenges.
- Each PT program serves a different population of laboratories; the market dictates the organisms offered either as part of the PT modules or as educational challenges.
- PT programs are hesitant to provide organisms that have the potential to cause laboratorians harm.
- PT programs should provide newly emerging organisms and/or susceptibility patterns as a good practice for the benefit of their customers.

# Emerging Pathogens (cont'd)

*How can we maintain flexibility and keep the program relevant with respect to including new and emerging pathogens and technologies, keeping up with reclassifications and name changes, and describing the appropriate organisms to be included in PT over time?*

- ❑ PT programs have access to groups to review or assist in compiling the list of organisms to include in the modules.
- ❑ PT programs provide CMS the organism list and specifications for microbiology each year.
- ❑ One program provides their proposed list of organisms to CDC for subject matter expert feedback to determine their acceptability for shipping and testing in clinical laboratories.
- ❑ Advisory groups or boards may be used to assist in organism selection.

# Patient Histories

*Should PT programs be required to provide specific elements of a patient history, or sample information needed for laboratories to process and handle PT samples appropriately (as patient samples would be handled)?*

- This information is essential because it will dictate which media to use and/or which test to perform.
- Listing the sample source may lessen the chance of scoring that challenge because laboratories may indicate they do not test that particular source and may not test the challenge.
- Samples should be source neutral for the smaller laboratories that perform limited testing; comprehensive modules should provide challenging sources and organisms.

## WORKGROUP AGREEMENT:

- Patient histories should be provided, but context may be source neutral.

# Gram Stain PT

*Should required PT for Gram stains include organism morphology?*

## WORKGROUP AGREEMENT:

- PT for Gram stains should include both stain reaction and morphology.

# Gram Stain PT (cont'd)

*Should direct specimen Gram stains include additional host elements (e.g. cells, mucus)?*

- ❑ Some laboratories do not perform Gram stains on primary swabs.
- ❑ Vendors have problems supplying slides with additional host elements.
- ❑ Some laboratories enroll in the Gram stain module because they do not perform additional testing on the primary specimen.
- ❑ PT programs provide two different types of gram stain modules.
  - Fixed slides for laboratorians to stain.
  - Culture challenges for laboratorians to culture and perform Gram stain on the growth.

# Mixed Culture Requirements

*Is the current 50% mixed culture requirement appropriate?*

- ❑ Currently, the 50% mixed culture requirement applies to two types of mixed cultures.
  - Samples that require laboratories to report only the principal pathogen.
  - Samples that require laboratories to report all organisms present.
- ❑ Anaerobe challenges tend to be ungraded if sent as part of a mixed culture.
- ❑ There is a need for mixed cultures in PT to simulate real world specimens.
- ❑ Lowering the mixed culture requirement would allow challenges from normally sterile source sites to include only the pathogen.
- ❑ Lowering the mixed culture requirement would allow more negative challenges in modules that screen for a specific organism.

# Mixed Culture Requirements (cont'd)

- ❑ Requiring 50% mixed cultures can create an issue with laboratories performing AST on the correct organism.
  - If PT programs indicate on the challenge to perform AST on the primary pathogen, the laboratories might know that the sample is mixed.
  - Laboratories may have problems determining which organism is considered the primary pathogen in a mixed culture challenge.

## WORKGROUP AGREEMENT:

- ❑ Lower the mixed culture requirement from 50% to 25% for PT challenges of both sample types.

# Antimicrobial Susceptibility Testing

*Should the required PT for bacteriology antimicrobial susceptibility testing (AST) be revised in any way?*

- ❑ Currently, laboratories may only get one challenge per year on AST for some organisms such as gram-positive cocci.
  - Increase AST requirement to six versus three a year.
- ❑ Providing a higher number of AST challenges would have a relatively low impact on laboratories.
- ❑ PT programs do not foresee an issue with adding another AST challenge per event.

# Antimicrobial Susceptibility Testing (cont'd)

## WORKGROUP AGREEMENT:

- ❑ Required PT for AST should be increased to two challenges per event for a total of six challenges per year in bacteriology and should include one gram-positive and one gram-negative organism in each event.

# Antimicrobial Susceptibility Testing (cont'd)

*Should PT be required for susceptibility testing in mycology, virology, or mycobacteriology for organisms other than M. tuberculosis? If so, what should it include?*

- All subspecialties have drug resistant organisms, so there should be a requirement for PT for susceptibility testing in those areas.
- Different methodologies exist for susceptibility testing that need to be monitored by PT.
- Many programs already offer susceptibility testing for other subspecialties.

# Antimicrobial Susceptibility Testing (cont'd)

## WORKGROUP AGREEMENT:

- ❑ PT should be required for laboratories that perform susceptibility testing in all microbiology subspecialties. It should include two challenges per event for a total of six challenges per year and should include resistant organisms.

# Direct Antigen Testing

*Direct antigen testing is only included in bacteriology and virology. Should it be included in other microbiology subspecialties to require PT in those areas as well?*

- Antigen testing may be the only testing performed in a physician office laboratory.
- Consider leaving methodologies out of the regulations. For example, PT should be required if a parasite is identified by any method.
- Since PT programs may provide non-viable organisms for antigen challenges, these samples may not be usable for other methods of testing.

## WORKGROUP AGREEMENT:

- PT for direct antigen testing should be required for all subspecialties.

# Microbiology PT Grading

*How can the microbiology grading requirements be clarified so that grading is more standardized and applied fairly?*

- Laboratories should not be permitted to report PT results at a lower level than for patient reporting.
- Consider a requirement that a laboratory's current identification scheme for individual organisms matches 95% of the PT reporting results.
- Inspectors are responsible for assuring the laboratory is enrolled and reporting PT to the same extent it reports patient specimens.

# Microbiology PT Grading (cont'd)

- ❑ PT programs can grade based on the separation of responses into different reporting levels. However, PT programs are not responsible for the level of testing a laboratory performs.
- ❑ For smaller PT programs, response separation may create more non-consensus challenges by not having enough participation for grading.
- ❑ Use caution when considering grouping different technologies together for grading purposes, because problems with particular methods could be masked.

# Microbiology PT Grading (cont'd)

## ❑ Are five challenges per event appropriate?

- PT programs agree that five challenges per test event is acceptable.
- Do not increase number of challenges due to cost issues.
- Many laboratories enroll in more than five challenges per event by enrollment in multiple modules.
- It would be difficult to increase the number of challenges using the current grading system.

## ❑ Is the required 80% consensus for grading appropriate?

- PT programs agree that 80% consensus seems to be working.
- Laboratories would object if there was a drop to below 80% consensus for grading.

# Microbiology PT Grading (cont'd)

## WORKGROUP AGREEMENT:

- Retain the five required challenges per event and 80% required consensus for grading.

# Monitoring Performance Over Time

*Since microbiology does not have analytes, should changes be made to microbiology PT grading to allow for monitoring performance over time on a particular test or examination – i.e. Gram stain, culture, or susceptibility testing?*

- Because the bacteriology score that includes identification, susceptibility testing, antigen tests, and Gram stain is rolled up into an overall combined subspecialty score, failures or problems with certain tests may not be readily noticed.
  - Accrediting organizations and surveyors only see the combined score and not the individual component scores.
  - PT programs send reports to subscribers that include all the information on the challenges and how they performed on each, not just the overall rolled-up score.
  - It is not the normal approach for PT programs to separate scores to distinguish category performance as this is not required in the current regulation.

# Monitoring Performance Over Time (cont'd)

- Need some alternative monitoring individual tests or procedures in microbiology instead of the rolled-up score method used now.
  - Would like to retain specialty scores, but provide additional information on the individual scores for monitoring at a procedural level to address problems.
  - Although not done now, PT programs stated it would be possible to transmit scores through the OSCAR system for the individual PT components, although new codes would need to be developed.
  - It was proposed that there be a single score for each subspecialty, but a line item underneath with the score for the individual tests or procedures that are part of the subspecialty score.
  - Regulatory agencies will need to monitor each line item and take actions against poor performing laboratories if scores for individual tests are identified.

# Monitoring Performance Over Time (cont'd)

## WORKGROUP AGREEMENT:

- ❑ All PT programs should be required to provide CMS with the overall score for each subspecialty, with a line item underneath that includes a score on the individual PT tests or procedures that comprised the subspecialty score - such as stain(s), susceptibility testing, antigen and/or toxin detection, and microbial identification.

# Ungraded Challenges

*Should challenges be ungraded when laboratories fail to identify the target(s) if PT programs can demonstrate they provided quality samples?*

- ❑ The current requirement for 80% consensus was designed, in part, to ensure that the PT materials shipped to labs nationwide were received in a viable condition.
- ❑ PT programs require vendors to demonstrate viability on ungraded challenges.

# Ungraded Challenges (cont'd)

*What are the major reasons for ungraded challenges?*

- ❑ Lack of consensus
  - Problems may be compounded when having to incorporate mixed specimens.
- ❑ Small peer groups sometimes do not fit into an all methods category.
- ❑ Provide education, introduction of new organisms, or new susceptibility patterns to subscribers.

# Ungraded Challenges (cont'd)

*Should PT programs resend ungraded challenges and monitor performance over time?*

- Ungraded challenges may be offered as “educational only” challenges, sometimes leading to a higher cost for PT.
- Providing educational critiques on ungraded challenges is helpful.
- Some programs keep track of challenges to ensure low predictability.
- Some programs rotate organisms and include the same organism as part of a challenge once every two years.
- Resending ungraded challenges in a later event for monitoring performance is appropriate.

# Microbiology PT Workgroup Concluding Statement

All laboratories must be enrolled in and have acceptable performance on PT for testing procedures performed for patient samples in their laboratory. Answers provided for PT must reflect the level of reporting the laboratory performs on patient samples. If a PT survey is not available for a test, then an alternative assessment must be performed.