DIRECT ANTIGEN TESTING

Inspector Instructions:

- Sampling of direct antigen testing policies and procedures
- Sampling of QC records

IMM.41810 Group A Streptococcus Direct Antigen Detection **Phase I**

If group A Streptococcus direct antigen testing is performed on pediatric patients, confirmatory testing is performed on negative samples.

NOTE: Cultures or other confirmatory tests must be performed on pediatric specimens that test negative when using antigen detection methods or if the manufacturer's guidelines include recommendations for culture follow-up. The laboratory policy must take into account the sensitivity of the assay in use, the age and clinical presentation of the patient, and other factors.

REFERENCES
1) Shulman S, Bisno A, Clegg H, et al. Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America. *Clin Infect Dis.* 2012;55(10). doi: 10.1093/cid/cis629.

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IMM.41820 *Clostridioides (formerly Clostridium) difficile* **Phase II**

The laboratory defines criteria for the rejection of specimens for *C. difficile* and/or *C. difficile* toxin testing in stool.

NOTE: The laboratory, in collaboration with institutional stakeholders (eg, infection prevention and control, antimicrobial stewardship, infectious disease physicians), must develop criteria for rejection of inappropriate specimens submitted to the laboratory for C. difficile testing. For example, these criteria may include stool consistency (eg, test only unformed stool), repeat testing (eg, do not perform repeat testing during the same episode of diarrhea), and any exceptions. Reference or commercial laboratories may not have the ability to collaborate with stakeholders, but still need to define rejection criteria.

Evidence of Compliance:

✓ Records of specimen rejection such as rejection log or patient report

REFERENCES
1) Novak-Weekley SM, *et al. Clostridium difficile* testing in the Clinical Laboratory by Use of Multiple Testing Algorithms. *Journal of Clinical Microbiology* 2010; 48:889-893
2) Eastwood K, *et al*. Comparison of Nine Commercially Available *Clostridium difficile* Toxin Detection Assays, a Real-Time PCR Assay for *C. difficile tcdB* and a Glutamate Dehydrogenase Detection Assay to Cytotoxin Testing and Cytotoxigenic Culture Methods. *Journal of Clinical Microbiology* 2009; 47:3211-3217
3) Peterson LR and Robicsek A. Does my Patient have *Clostridium difficile* Infection? *Annals of Internal Medicine* 2009; 151:176-178

IMM.41830 CSF Back-Up Cultures **Phase II**

If bacterial antigen-detection methods are used, back-up cultures are performed on both positive and negative CSF specimens.

NOTE: Total dependence on a bacterial antigen test for the diagnosis of bacterial meningitis does NOT meet accreditation requirements. Meningitis may be caused by bacteria not detected by the antigen tests. In addition, it is important to recover the causative agent for susceptibility

testing. Thus, culture is essential for proper evaluation of bacterial meningitis, and must be performed on the patient specimen - if not performed on site by the laboratory, the inspector must seek evidence that a culture has been performed in a referral laboratory.

Evidence of Compliance:

- ✓ Records of back-up CSF cultures performed on-site **OR** records indicating that cultures are performed at another location **OR** records that order for CSF bacterial antigen was blocked by the computer due to no order for a culture

REFERENCES

1) Forward KR. Prospective evaluation of bacterial antigen detection in cerebral spinal fluid in the diagnosis of bacterial meningitis in a predominantly adult hospital. *Diagn Micro Infect Dis.* 1988;11:61-63
2) Maxson S, *et al.* Clinical usefulness of cerebrospinal fluid bacterial antigen studies. *J Pediat.* 1994; 125:235-238
3) Finlay FO, *et al.* Latex agglutination testing in bacterial meningitis. *Arch Dis Child.* 1995;73:160-161
4) Rathore MH, *et al.* Latex particle agglutination tests on the cerebrospinal fluid. A reappraisal. *J Florida Med Assoc.* 1995;82:21-23
5) Kiska DL, *et al.* Quality assurance study of bacterial antigen testing of cerebrospinal fluid. *J Clin Micro.* 1995;33:1141-1144

IMM.41840 Cryptococcal Antigen — Phase II

If cryptococcal antigen-detection methods are used on CSF, back-up cultures are performed on positive CSF specimens submitted for diagnosis.

NOTE: It is important to recover the causative organism for precise identification (C. neoformans vs. C. gattii) and potential susceptibility testing. Back-up cultures of follow-up specimens used for trending the antigen titer are not required. If culture is not performed on site by the laboratory, the laboratory must show evidence that it has been performed in a referral laboratory.

Evidence of Compliance:

- ✓ Records of back-up CSF cultures performed on-site **OR** records indicating that cultures are performed at another location

IMM.41850 Direct Antigen Test QC - Nonwaived Tests — Phase II

For nonwaived direct antigen tests performed on patient specimens, positive and negative controls are tested and recorded each day of testing, or more frequently if specified in the manufacturer's instructions, laboratory procedure or the CAP Checklist.

NOTE: This requirement pertains to nonwaived tests with a protein, enzyme, or toxin which acts as an antigen. Examples include, but are not limited to: Group A Streptococcus antigen, C. difficile toxin, fecal lactoferrin and immunochemical occult blood tests. For panels or batteries, controls must be employed for each antigen sought in patient specimens.

If an internal quality control process (eg, electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director defining the control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.

For each test system that requires an antigen extraction phase, as defined by the manufacturer, the system must be checked with an appropriate positive control that will detect problems in the extraction process. If an IQCP is implemented for the test, the laboratory's quality control plan must define how the extraction phase will be monitored, as applicable, based on the risk assessment performed by the laboratory and the manufacturer's instructions.

Evidence of Compliance:

- ✓ Records of QC results including external and internal control processes **AND**
- ✓ Manufacturer product insert or manual