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