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

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. S & C: 16-20-CLIA: Policy Clarification on Acceptable Control Materials Used when Quality Control (QC) is Performed in Laboratories. April 8, 2016.

MOLECULAR-BASED MICROBIOLOGY TESTING - WAIVED TESTS

The requirements in this section apply to molecular-based microbiology tests classified as waived. Microbiology testing performed by nonwaived molecular-based methods must be inspected with the Microbiology Checklist.

Inspector Instructions:

	• Sampling of QC statistics • Sampling of molecular microbiology specimen handling and processing policies and procedures • Sampling test reports (test methodology, clinical interpretation)
	• What is your course of action when monitored statistics increase above the expected positive rate?

IMM.41900 Quality Monitoring Statistics **Phase I**

The laboratory monitors for the presence of false positive results (eg, due to nucleic acid contamination) for all molecular microbiology tests.

NOTE: Examples include review of summary statistics (eg, monitoring percentage of positive results relative to current local and regional rates and increased positive Strep results above historical rate within a run or over multiple runs), performance of wipe (environmental) testing, and review and investigation of physician inquiries. Based on monitoring data, the laboratory may implement additional mitigation strategies to minimize the risk of contamination, such as process controls.

Evidence of Compliance:

✓ Records of data review, wipe testing, statistical data evaluation and corrective action if indicated

REFERENCES
1) Borst A, Box AT, Fluit AC. False-positive results and contamination in nucleic acid amplification assays: suggestions for a prevent and destroy strategy. *Eur J Clin Microbiol Infect Dis*. 2004; 23(4):289-99.
2) Cone RW, Hobson AC, Huang ML, Fairfax MR. Polymerase chain reaction decontamination: the wipe test. *Lancet*.1990; 336:686–687.
3) McCormack JM, Sherman ML, Maurer DH. Quality control for DNA contamination in laboratories using PCR- based class II HLA typing methods. *Hum Immunol*. 1997;54:82–88.
4) Clinical and Laboratory Standards Institute (CLSI). *Establishing Molecular Testing in Clinical Laboratory Environments;* 1st ed. CLSI document MM19-A. Clinical and Laboratory Standards Institute, Wayne, Pennsylvania, 2011.

IMM.41920 Specimen Handling **Phase II**

The laboratory uses appropriate processes to prevent specimen loss, alteration, or contamination during collection, transport, processing and storage.

NOTE: Specimen collection, processing and storage must follow manufacturer's instruction and limit the risk of preanalytical error. For example, there must be a procedure to ensure absence of cross-contamination of samples during processing/testing for respiratory specimens that may be sent for further testing.