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.

It is also essential to follow the manufacturer's instructions for the handling of wastes (eg, used test cartridges) to prevent contamination.

IMM.41930 Safe Specimen Handling/Processing **Phase II**

The laboratory safely handles and processes specimens, including those suspected to contain highly infectious pathogens.

NOTE: Suggested topics to be considered in the development of policies and procedures include the need for tight sealing of containers, avoiding spills of hazardous materials, requirements for wearing gloves, the need for respirator protection, availability and use of vaccinations, and the hazards of sniffing plates.

For specimens suspected of containing highly infectious pathogens, laboratories must review national, federal, state (or provincial), and local guidelines for the handling of specimens from patients suspected to have high risk pathogens, such as Francisella tularensis, avian influenza, Ebola, MERS coronavirus, SARS coronavirus, SARS-CoV-2 coronavirus, or any infectious agent that has a high potential to cause disease in individuals and communities.

Evidence of Compliance:

✓ Records of universal precaution for all personnel handling suspected infectious pathogens

REFERENCES

1) Wooley DP, Byers KB, eds. Biological Safety, Principles and Practices, 5th ed. ASM Press. 2017.
2) Miller JM, Astles R, Baszler T, et al. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories, Recommendations of a CDC-convened, Biosafety Blue Ribbon Panel. MMWR. 2012; 61:1-102.
3) Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, 6th ed. June 2020.

IMM.41940 Final Report **Phase I**

The final report includes a summary of the test method and information regarding clinical interpretation if appropriate.

NOTE: For tests that may be performed by either direct antigen or molecular-based methods (PCR), including the test method in the report is important for interpretation of the results. The report must include a brief description of the method if the methodology is not explicit in the test name.