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Title **Contamination Monitoring Procedure Using Wipe Testing for Cobas LIAT PCR System**

Introduction Monitoring for contamination is regularly performed for the Cobas LIAT PCR System for each test method to ensure surfaces and instruments used in molecular testing are free from contamination that could adversely affect the accuracy of results reported on patient specimens. Monthly monitoring is accomplished by performing Wipe Testing on the analyzer and work area. Additional monitoring may be performed when contamination is suspected. This procedure is to be performed for preventive maintenance once a month or when contamination of a molecular assay is suspected.

Scope This procedure is intended for Medical Center Laboratories, Urgent Care Laboratories, and Ambulatory departments where the Cobas LIAT PCR System is deployed for POCT molecular testing.

Purpose The purpose of this procedure is to provide instructions on how to perform a wipe test for assays performed on the Cobas LIAT PCR System. Sampling from each location (analyzer, work surface, etc.) can be tested individually or PCR can be performed on a pool of the samples.

- Materials and supplies**
- Sterile cotton tipped applicators
 - Sterile screw cap conical tube
 - Nuclease Free water
 - Refer to assay procedure for required reagents and supplies
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- Safety Precautions**
- Proper PPE must be worn when performing this procedure
 - Refer to the laboratory safety manual for general safety requirements.
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Procedure This procedure is to be performed monthly for monitoring or when contamination of a molecular assay is suspected.

Step	Action
1	<ul style="list-style-type: none">• Put on proper PPE• Gather required materials and supplies• Testing for contamination is performed once a month or more frequently in the event of a contamination problem.

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Title Contamination Monitoring Procedure Using Wipe Testing for Cobas LIAT PCR System, Continued

2	<ul style="list-style-type: none"> Label two conical tubes as “Clean” and “Sample pool” Add approximately 2 mL nuclease free water to the “Sample pool” tube and about 5 mL nuclease free water to the “clean” tube.
3	<ul style="list-style-type: none"> Sample each location indicated on the Contamination Monitoring Log by dipping the sterile applicator into the nuclease free water “Clean” tube first and then swab designated area or instrument. Sample each instrument and work area individually using separate swabs. After swabbing an area or instrument, perform the following within a Biological safety cabinet (BSC). Place the swab applicator into the 2 mL “Sample pool” tube and swirl and ring out excess material from the swab to release material. Repeat for the next area/instrument using a new, clean swab. Replace cap on the “Sample pool” conical tube. Alternately, each area/instrument can be sampled and tested on the Liat using individual swab and test cartridge.
4	Test collected samples following COBAS® LIAT SYSTEM – CLIA WAVED INFLUENZA A/B and Cobas Liat SARS-CoV-2 & Influenza A/B Procedure
5	Record test results on Contamination Monitoring Log along with performing CLS initials and date/time test performed.

Expected Values

Assay	Expected Result
Influenza A/B	Not Detected for All Targets
SARS-CoV-2 & Influenza A/B	Not Detected for All Targets

If the result is different from the Expected Result:

- Notify manager
- If a pool test as positive, then each individual instrument/work area must be resampled and tested individually.**
- Designate area or instrument as “Contaminated”
- Perform Cleaning and Decontamination procedure.
- Recollect new individual samples from contaminated instrument/location
- Retest for affected assay
- Document all corrective action in the Contamination Monitoring Log
- Monitor area for recurrence of contamination.

Attachments

Contamination Monitoring Log

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Title **Contamination Monitoring Procedure Using Wipe Testing for Cobas LIAT PCR System, Continued**

**Non-
Controlled
Documents**

The following non-controlled documents support this procedure.

- College of American Pathologists Point of Care Checklist
 - Cobas LIAT System Operators Manual
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**Controlled
Documents**

The following controlled documents support this procedure.

Reference
COBAS® LIAT SYSTEM – CLIA WAVED INFLUENZA A/B Procedure
Cobas Liat SARS-CoV-2 & Influenza A/B Procedure
Cleaning and Decontamination Procedure for Cobas LIAT PCR System

Signature Manifest

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Operations Director Approval

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