# Method/Instrument Comparison for Testing the Same Analyte

PURPOSE/PRINCIPLE

The purpose is to evaluate the relationship between test results when two different methods/instruments are used for testing the same analyte. To meet acceptable performance, both methods must detect the analyte.

#### POLICY STATEMENT

Nonwaived instruments used for testing the same analyte are checked against each other at least twice a year (CAP COM.04250)1.

## DOCUMENTATION/RECORDS

* Instrument specific result reports
* Instrument Comparison Testing Schedule: Maintenance Check-off sheet
* MB 5.07.F1 Method Comparison Log, BioFire, GeneXpert, Liaison MDX, Adena MassArray

MB 5.07.F4 Method Comparison Log, Liaisons - HSV 1 and 2

## MATERIALS REQUIRED

* Refer to assay specific procedures for required equipment and reagents

## SAFETY CONSIDERATIONS

* Standard precautions
* Use of engineering controls: Refer to MB 3.01 Engineering Controls to Prevent Nucleic Acid Contamination

**PROCEDURE A:** Follow the activity below for instrument Comparison testing on the BioFire, GeneXpert, DiaSorin Liaison MDX, and the Agena MassArray: **Influenza A, Influenza B, RSV, SARS-CoV-2 and** **Bordetella testing**

Method/Instrument Comparison

| **Activity** | Step | **Action** | **Related Doc** |
| --- | --- | --- | --- |
| **Select Sample** | 1 | A QC sample is to be utilized for a comparison of Influenza A, Influenza B, RSV, SARS-CoV-2, and Bordetella results on the BioFire FilmArray, Cepheid GeneXpert, DiaSorin Liaison MDX instruments, and the Agena MassArray **biannually**  **Sample:** Microbiologics Respiratory Control, Cat No. 8247 | MB 5.07.F1 Instrument Comparison Log |
| **Test** | 2 | Hydrate the pellet with 1,800 uL VTM, vortex 10 seconds, and briefly spin. Change gloves. |  |
| 3 | Run the sample as a patient specimen test would be performed on each platform:  BioFire FilmArray: RP2.1 Assay  Cepheid GeneXpert: Xpress Flu/RSV/SARS-CoV-2 Assay  DiaSorin Liaison MDX: Simplexa COVID-19 Direct Assay **x2**  DiaSorin Liaison MDX: Simplexa Bordetella Direct Assay **x2**  Agena MassArray: SC2 Assay  **NOTE:** The QC must be tested on both Liaison platforms (separate computers, rotate instruments) | MC 10.3 FilmArray Respiratory Panel 2.1  MC 9.90 SARS-CoV-2, Flu and RSV Assay  MB 14.0 Simplexa COVID-19 Direct Assay  MB 13.0 Simplexa Bordetella Direct Assay |
| **Record Results** | 4 | Record the results, on the Instrument Comparison Log |  |
| 5 | Acceptable performance criteria: analytes are detected by all methods/ instruments (when applicable) |  |
|  | 6 | If results are unacceptable, identify the problem and document action on reverse side of the Instrument Comparison Log |  |
|  | 7 | Notify technical director and/or designee if resolution cannot be determined |  |
|  | 8 | Results and actions are reviewed by technical director or designee, as appropriate |  |

**PROCEDURE B:** Follow the activity below for instrument Comparison testing on the DiaSorin Liaisons: **HSV 1 and 2 Testing**

Method/Instrument Comparison

| **Activity** | Step | **Action** | **Related Doc** |
| --- | --- | --- | --- |
| **Select Sample** | 1 | A historical sample positive for HSV 1 or 2 is tested and results are compared by all instruments **biannually.**  **Sample:** Rotate HSV 1 and HSV 2 positive  In the event that a positive samples is not available, QC material will be utilized. | MB 5.07.F4 Instrument Comparison Log |
| **Test** | 2 | Run the QC on both Liaison platforms (separate computers, rotate instruments) | MB 12.0 Simplexa HSV 1 and 2 Direct Assay |
| **Record Results** | 3 | Record the results, positive or negative, on the Instrument Comparison Log |  |
| 4 | Acceptable performance criteria: HSV 1 and 2 are detected by all methods/ instruments |  |
|  | 5 | If results are unacceptable, identify the problem and document action on reverse side of the Instrument Comparison Log |  |
|  | 6 | Notify technical director and/or designee if resolution cannot be determined |  |
|  | 7 | Results and actions are reviewed by technical director or designee, as appropriate |  |

**REFERENCES**

1. Microbiology Checklist requirement : CAP COM.04250, College of American Pathologists Accreditation Program [www.cap.org](http://www.cap.org)

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| Historical Record | | | |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | 1 | P. Ackerman | 05/13/2017 | Initial Version |
|  | 1 | J. Laramie | 05.02.2018 | Biennial review: 05.02.2018 JL |
|  | 2 | J. Laramie | 09.17.2018 | Updated to include comparison testing on newly acquired Liaison instrument with a separate computer |
|  | 3 | J. Laramie | 10.22.2018 | -Added Bordetella and Group A Strep comparison testing (acquired new instrument/computer)  -Changed Liaison/XT-8 comparison testing to a bimonthly rotation |
|  | 4 | Susan DeMeyere | 4.23.19 | Added HSV testing |
|  | 5 | J. Laramie | 10.28.2019 | -Changed from DiaSorin Liaisons to GeneXpert for Flu/RSV  -Removed Group A Strep |
|  | 6 | J. Laramie | 01.27.2020 | -Changed HSV frequency to Biannual using QC material  -Added RP2, Gene Xpert Flu/RSV, and Bordetella comparison |
|  | 7 | J. Laramie | 02.15.2021 | -Added SARS-CoV-2 Testing |
|  | 8 | J. Laramie | 3.29.2021 | -Added sample testing to HSV comparison |