# 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. The GenMark eSensor XT-8 and DiaSorin Liaisons will be evaluated for the detection of influenza A, B and RSV four times a year on a monthly rotation.

## DOCUMENTATION/RECORDS

* Instrument specific result reports
* Instrument Comparison Testing Schedule: Maintenance Check-off sheet
* MB 5.07.F1 Instrument Comparison log for eSensor XT-8 and DiaSorin Liaisons
* MB 5.07.F2 Instrument Comparison log for DiaSorin Liaisons: Bordetella
* MB 5.07.F3 Instrument Comparison log for DiaSorin Liaisons: Group A Strep

## 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 eSensor XT-8 and DiaSorin Liaisons

Method/Instrument Comparison

| **Activity** | Step | **Action** | **Related Doc** |
| --- | --- | --- | --- |
| **Select Sample** | 1 | Select the analyte to be compared by both methods/instruments according to the **bimonthly** rotation: Flu A, Flu B or RSV | MB 5.07.F1 Instrument Comparison Log |
|  | 2 | Select a patient sample or QC containing the analyte to be detected | MB 9.05 RIP Assay |
| **Test** | 3 | Run the patient sample or QC on both Liaison platforms (separate computers) and the XT-8 on the same day following assay procedures | MB 11.05 RVP Assay |
| **Record Results** | 4 | Record the results, positive or negative, on the Instrument Comparison Log |  |
| 5 | Acceptable performance criteria: selected analyte is detected by all methods/ instruments |  |
|  | 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: **Bordetella testing**

Method/Instrument Comparison

| **Activity** | Step | **Action** | **Related Doc** |
| --- | --- | --- | --- |
| **Select Sample** | 1 | Select the analyte to be compared by all instruments according to the **quarterly** rotation: B. pertusiss or B. parapertussis | MB 5.07.F2 Instrument Comparison Log |
|  | 2 | Select a patient sample or QC containing the analyte to be detected |  |
| **Test** | 3 | Run the patient sample or QC on both Liaison platforms (separate computers, rotate instruments)  NOTE: QC from a routine patient run can be used as one of the comparators | MB 6.05 BORD Simplexa Bordetella pertussis, parapertussis Assay |
| **Record Results** | 4 | Record the results, positive or negative, on the Instrument Comparison Log |  |
| 5 | Acceptable performance criteria: selected analyte is detected by all methods/ instruments |  |
|  | 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 C:** Follow the activity below for instrument Comparison testing on the DiaSorin Liaisons: **Group A Strep Testing**

Method/Instrument Comparison

| **Activity** | Step | **Action** | **Related Doc** |
| --- | --- | --- | --- |
| **Select Sample** | 1 | A QC or patient sample for Group A Strep testing is to compared by all instruments **Biannually.** | MB 5.07.F3 Instrument Comparison Log |
|  | 2 | Select a patient sample or QC containing the analyte to be detected |  |
| **Test** | 3 | Run the patient sample or QC on both Liaison platforms (separate computers, rotate instruments)  NOTE: QC from a routine patient run can be used as one of the comparators | MB 8.05 GAS Simplexa Group A Strep Assay |
| **Record Results** | 4 | Record the results, positive or negative, on the Instrument Comparison Log |  |
| 5 | Acceptable performance criteria: selected analyte is detected by all methods/ instruments |  |
|  | 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 D:** 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 QC or patient sample for HSV 1 and 2 testing is to compared by all instruments **Quarterly.** | MB 5.07.F3 Instrument Comparison Log |
|  | 2 | Select a patient sample or QC containing the analyte to be detected |  |
| **Test** | 3 | Run the patient sample or QC on both Liaison platforms (separate computers, rotate instruments)  NOTE: QC from a routine patient run can be used as one of the comparators | MB 12.0 Simplexa HSV 1 and 2 Direct Assay |
| **Record Results** | 4 | Record the results, positive or negative, on the Instrument Comparison Log |  |
| 5 | Acceptable performance criteria: selected analyte is detected by all methods/ instruments |  |
|  | 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 |  |

**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 |