# RVP New Lot and/or New Shipment and Monthly Quality Control

PURPOSE

* This procedure provides instructions for verifying RVP reagent performance

#### ABBREVIATIONS

* CLSI: Clinical Laboratory and Standards Institute
* EXC: extraction control
* MM: master mix
* NEGC: negative control
* NFW: nuclease free water
* RT-PCR: reverse transcription polymerase chain reaction
* PCTL: process control
* POSC: positive control
* QC: quality control
* RT: room temperature
* RVP: Respiratory Viral Panel
* VTM: viral transport media

Area/Room 1: Clean room

Area/Room 2: Processing room

Area/Room 3: Amplification room

#### MATERIALS

| **Equipment** | **Reagents** | **Supplies** |
| --- | --- | --- |
| Room 1 * Adjustable pipettes
* Cold block
* Freezer, -20° C
* Laminar air-flow hood
* Refrigerator 2 – 8° C
* Vortex mixer

Room 2* Adjustable pipettes
* BioHit 8 channel pipette
* Bio-Safety Cabinet (BSC)
* Cold Block
* Freezer, -70° C
* Magnetic rack
* Mini-centrifuge
* NucliSens easyMag
* Refrigerator 2 – 8° C
* Tube racks, 1.5 – 2 ml
* Vortex mixer

Room 3* Adjustable pipettes
* Cold Block
* Freezer, -20° C
* GenMark eSensor XT-8 instrument
* Mini-centrifuge
* PCR thermocycler
* PCR workstation
* Vortex mixer
 | eSensor *RVP* kit: Product No. MT005102 | Sterile filtered 10 μl pipette tips |
| easyMAG Lysis buffer, 2 ml | Sterile filtered 30 μl pipette tips |
| easyMAG Buffer 1 | Sterile filtered 100 μl pipette tips |
| easyMAG Buffer 2 | Sterile filtered 200 μl pipette tips |
| easyMAG Buffer 3 | Sterile filtered 1000 μl pipette tips |
| MagSil | Micro tubes 1.5 ml, RNase/DNase free |
| Molecular grade water, nuclease free | Nitrile gloves (powder-free) |
| Viral transport media (VTM) | PCR 8 tube strips with caps |
| Viral isolates: H1, H3, RSV, Flu B | easyMag disposable vessel strips and tips |
| Patient hMPV sample | BioHit pipette tips |
| Sani-Cloth Bleach Wipes (10%) | BioHazard wipes |
| 70% alcohol | Gripper rack |
| Household bleach | Sharps disposal container |
| MMQCI RVP Control Panel  |  |
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**PROCEDURE A:** Follow the instructions for use of the MMQCI RVP control panel

RVP control panel – Monthly QC

| **Activity** | **Step** | **Action** | **Related Doc** |
| --- | --- | --- | --- |
| MMQCI RVP | 1 | The RVP control panel consists of 2 vials M244 and M245, single use only |  |
| Control Panel | 2 | Allow the vials to warm to RT |  |
| 1X use | 3 | Vortex each vial for 5 s prior to use |  |
|  | 4 | Spin for 5 s to pull down the matrix |  |
|  | 5 | Extract both vials on the easyMag, 200 µl supernatant adding 10 µl IC to each; final elution 60 µl |  |
|  | 6 | Vortex the eluate for 5 sec; allow to sit in magnetic rack for 10 min |  |
|  | 7 | Include a POSC/EXC and NEGC with known performance in each test run |  |
|  | 8 | Attach RUO RV reports to worksheet | [MB 11.08.F3](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/QC/212338.pdf)RVP Monthly QC Worksheet |
|  | 9 | Archive result forms in *New Lot Inventory and QC* manual |  |
|  | 10 | Check off RVP monthly QC form, date and initial | MB 11.08.F4RVP Monthly QC Worksheet |

**PROCEDURE B:** Follow the activities for testing reagent reactivity in the table below

RVP New reagent lot and/or new shipment verification

| **Activity** | **Step** | **Action** | **Related Doc** |
| --- | --- | --- | --- |
| **Testing requirements** | 1 | Test new reagent lots and/or shipments against old reagent lots before or concurrently with being placed in service. | [MB 5.02](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/Qual/212231.pdf) Standards of Practice |
| **Kit Verification** | 2 | Retest eluates of two known positive patients (different targets) and one known negative patient.  | [MB 11.08.F2](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/QC/212337.pdf)Reagent QC |
|  | 3 | Include a POSC/EXC and NEGC with known performance in each test run |  |
| Results | 4 | Record results on RVP QC worksheet; staple QC worksheet to the eSensor reports |  |
| **Records** | 5 | Archive result forms in *New Lot Inventory and QC* manual |  |
|  | 6 | The patient results must be equivalent to the previous RVP lot/shipment to confirm acceptability of the new RVP lot/shipment |
|  | 7 | Verify that all reagents and materials meet expiration date and QC parameters as per CLSI document MM3-A2. |

**PROCEDURE C:** Follow the activities for troubleshooting verification failures in the table below

Performance Failures

| **Activity** | **Step** | **Action** | **Related doc** |
| --- | --- | --- | --- |
|  | 1 | Verify that the reagent performance is acceptable before implementation of a new lot and/or shipment | [RVP Retest](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/Res/212416.pdf) Recommendations by Report Type[RVP Technical Support](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/Res/212415.pdf) and Troubleshooting |
|  |  | If | Then |
| **Troubleshooting Failures** | Any Control fails | * Document observation/corrective action on QC log
* Do not implement new lot/shipment
* Repeat all testing, extraction, PCR and XT-8 analysis
 |
|  | IC fails | * Poor amplification of sample
* Poor recovery from extracted sample
* System error
* If one or more targets are positive, retest not necessary
* No targets positive, repeat extraction, PCR and XT-8 analysis
 |
|  | POSC/EXC fails | * Amplification failure
* Poor recovery from extracted sample
* Possible reagent or system failure: Review MM preparation and assay set-up
* Repeat run extraction, PCR and XT-8 analysis
 |  |
|  | NEGC failsContamination | * Possible carryover or reagent contamination: Review pipetting technique, glove contamination, possible aerosol creation, and MM preparation
* Repeat run extraction, PCR and XT-8 analysis
 |  |
|  | NEGC failsSystem error | * Report message reads “error” for any target
* Rerun cartridge; call for password, GenMark technical service at 1.800.373.6767
* Retest NEGC only; repeat PCR and XT-8 analysis
 |  |
|  | Problem unresolved | * Call GenMark technical service at 1.800.373.6767
* Notify section technical director or designee
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**REFERENCES**

1. eSensor® Respiratory viral Panel, PI1032 REV:D, December 2013, Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc., 5964 La Place Court, Carlsbad, CA 92008, 1-800-373-6767, ww.genmarkdx.com
2. eSensor XT-8 RVP Control Panel package insert; circular M243 102914.001, Maine Molecular Quality Controls, Inc. [www.mmqci.com](http://www.mmqci.com)
3. CLSI *Molecular Diagnostic Methods for Infectious Diseases;* Approved Guideline – Second Edition, CLSI document MM3-A2, Wayne, PA, Clinical and Laboratory Standards Institute; 2006
4. CLSI *Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*, MM19-A, Vol. 31. No. 21, Wayne, PA, Clinical and Laboratory Standards Institute; 2011
5. CAP All Common Checklist COM.30450 New reagent Lot Confirmation of Acceptability revised 7/29/2013

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| Historical Record |  |
|   | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | P. Ackerman | 07.25.15 | Initial Version |
| 2 | P. Ackerman | 08.28.2016 | Reformatted for CMS upload; changed logo |
|  | 3 | J. Laramie | 11.27.2017 | Changed new lot/shipment QC from MMQCI Control Panel to two previously positive patients (different targets) and one previously negative patient. |