RVP New Lot and/or New Shipment 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	

PROCEDURE A: Follow the instructions for use of the MMQCI RVP control panel

RVP control panel

Activity	Step	Action	Related Doc
MMQCI RVP Control Panel 1X use	1	The RVP control panel consists of 2 vials M244 and M245, single use only	MB 11.08.F2 Reagent QC; MB 11.08.F3 MMQCI Inventory Record
	2	Allow the vials to warm to RT	
	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	Analyze extracted controls; proceed to Procedure B for testing	

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 Standards of Practice
MMQCI Control Panel	2	Each analyte detected in the RVP assay must be challenged with the MMQCI RVP panel to verify that the reagents are working properly	MB 11.08.F2 Reagent QC; MB 11.08.F1 RVP Inventory Record
	3	The MMQCI panel must have been tested on the previous RVP lot prior to testing the new lot/shipment	
	4	Include a POSC/EXC and NEGC with known performance in each test run	
Results	5	Record results on RVP QC worksheet; staple QC worksheet to the eSensor reports	
Records	6	Check off RVP inventory form, date and initial	
	7	Archive result forms in *New Lot Inventory and QC* manual	
	8	The MMQCI results must be equivalent to the previous RVP lot/shipment to confirm acceptability of the new RVP lot/shipment	
	9	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
Troubleshooting Failures	1	Verify that the reagent performance is acceptable before implementation of a new lot and/or shipment		RVP Retest Recommendations by Report Type RVP Technical Support and Troubleshooting
		If	Then	
		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 fails Contamination	▪ 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 fails System 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	

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
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

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