

eSensor® Respiratory Viral Panel (RVP) Assay: Troubleshooting Guide

PURPOSE:

 This procedure provides instructions for troubleshooting problems based on symptoms including a potential cause with recommendations for solutions.

DOCUMENTATION/RECORDS

- RVP Currents RUO Results Report
- RVP Detection Report, RUORV
- QC and Equipment Failure Log

PROCEDURE A: Follow the steps in the table below for troubleshooting invalid results, warnings and errors **General Information**

Activity	Step	Action	Related Doc	
Warning messages and error observations	1	The eSensor XT-8 reports errors and warning messages on the RVP Detection Report and Currents Report		
	2	 Refer to the following documents for troubleshooting: <u>RVP Retest</u> Recommendations by Report Type <u>RVP Technical Support</u> and Troubleshooting <u>RVP Common Issues</u> and Solutions 	eSensor [®] RVP package insert	
Records	3	Document all problems and actions in the QC and Equipment Failure Log		
Technical support	5	If problem cannot be resolved, call GenMark Technical Support @ 1-800-373-6767, option 2.		
	6	To retest a cartridge, tech support must be contacted for special access and password		
	7	Tech support may request files to be sent; see Procedure B, Package Assay Run; Email: <u>TechnicalSupport@genmanrkdx.com</u>		

PROCEDURE B: Follow the steps in the table below to package runs to be sent to technical support **Package Assay Run**

Activity	Step	Action	Related Doc
Log on Username:	1	Log onto the eSensor XT-8 using the password provided by technical support Password of the Day Username IUO Instrument ID L100628	
IUO Instrument ID: L100628		Password Level © Service OSupervisor Generate XT-8 passwords are sensitive and confidential information. Please shred this sheet after use.	
		Service Level Passwords: Thursday 7/16/2015 Px9L5xG4457P7HSP	



Activity	Step	Action	Related Doc
Download data	2	Insert USB	
	3	Select "Reporting" tab	GenMark Customer Training Manual Chapter: Resources
	4	Enter the date for the problem run in the Date From and Date To fields	
	5	Touch the search button located on the bottom right side of the screen	
	6	Touch the Select All button located on the bottom of the screen to select all the samples	
	7	Touch the "Pkg" button; a prompt screen will appear that reads D:\	
	8	Touch the D:\ field	
	9	Touch This Directory field	
	10	When the data download is complete, a message will appear indicating the number of samples successfully packaged	
	11	Remove USB	
Email	12	Email information to TechnicalSupport@genmanrkdx.com	
	13	The files will have the naming convention: TS_Instrument Serial Number_Sample ID_Today's DateXXXX.zip. There will be one file for each sample.	

REFERENCE

1. GenMark Customer Training Manual "Resources". GenMark Diagnostics, 5964 La Place Court, Suite 100, Carlsbad, CA 92008

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1	P. Ackerman	08.12.15	Initial Version
2	P. Ackerman	08.27.2016	Reformatted for CMS upload; changed logo