

Simplexa™ Troubleshooting Guide

PURPOSE:

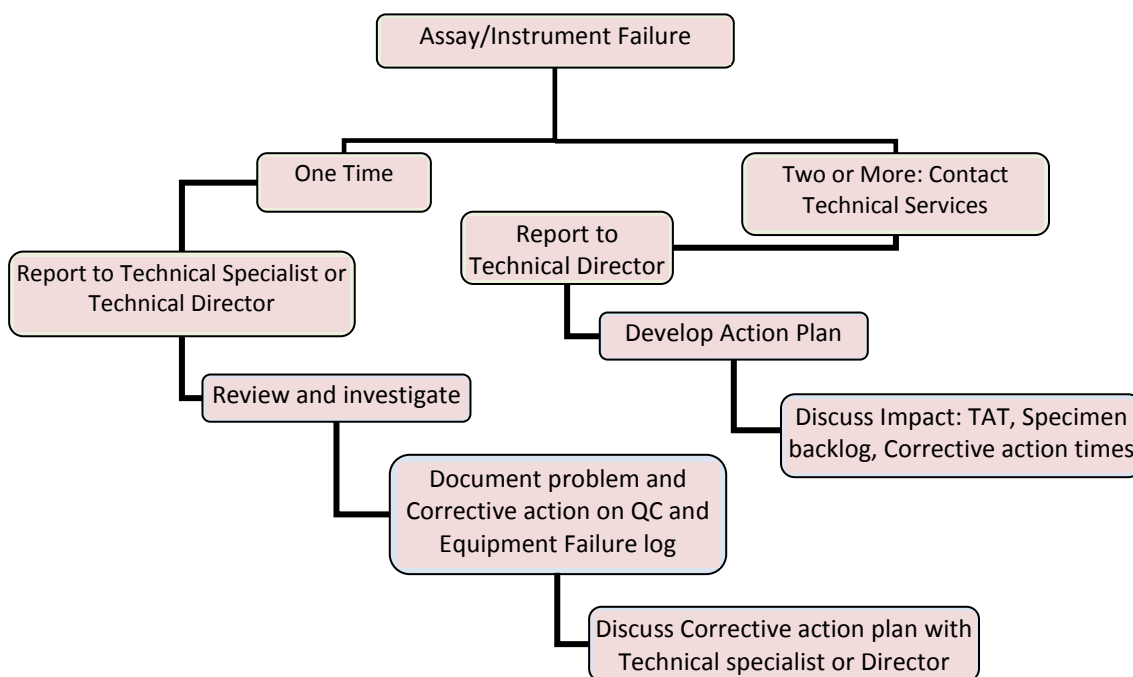
- This procedure provides instructions for troubleshooting problems based on symptoms including a potential cause with recommendations for solutions.

DOCUMENTATION/RECORDS

- BORDP Segment Report
- GASDN Segment Report
- RIP Segment Report
- QC and Equipment Failure Log

PROCEDURE A: Follow the protocol below for troubleshooting assay and/or instrument failures

Assay / Instrument Failure Protocol



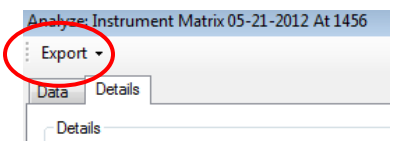
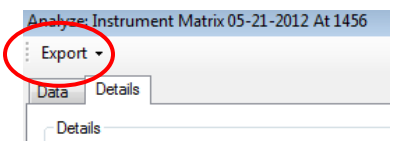
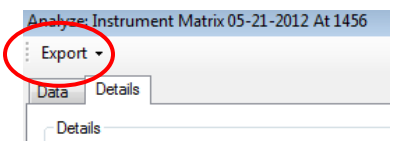
PROCEDURE B: Follow the steps in the table below for troubleshooting invalid results, warnings and error codes

General Information

Activity	Step	Action	Related Doc
Warning messages and error codes	1	<p>Simplexa 3M™ Integrated Cycler errors will display in a dialog box on the screen</p> <ul style="list-style-type: none"> ▪ Text will explain the cause of the problem ▪ The user will be provided information to follow to resolve the error 	<p>Simplexa Operator's Manual IVD</p> <p>Appendix B: Troubleshooting</p>

Activity	Step	Action	Related Doc
	2	Trouble shooting categories for error and dialog messages are as follows: <ul style="list-style-type: none"> Communication errors Data Analysis errors Gantry errors Motor errors Optics errors Temperature errors 	Simplexa Operator's Manual IVD
	3	Refer to <i>Simplexa Operator Manual, Appendix B: Troubleshooting</i> for recommended actions <ul style="list-style-type: none"> Error codes and messages with possible causes and corrective actions Barcode scanner not reading; see procedure D Instrument is not responding Instrument is not displaying Instrument toolbar is not displaying Cannot select an assay during run set-up Run button is grayed out 	DiaSorin/Focus technical service 1-800-838-4548, option 3
Technical support	4	If unable to resolve problem, contact DiaSorin/Focus technical service	
	5	Technical Service may ask you to generate and send a Service Packet file; see Procedure B for downloading a *.icz file	
Instrument return	6	If it is determined that the instrument must be returned for service, <i>decontaminate the Simplexa before shipping</i> ; Refer to procedure MB 4.02	MB 4.02 Simplexa Decontamination
Records	7	Document all problems and actions in the QC and Equipment Failure Log	
	8	File a St. Croix report if repair or preventative maintenance is required	

PROCEDURE C: Follow the steps to export a service packet to a USB
Exporting a Service Packet

Activity	Step	Action	Related Doc																
Select run	1	Open a run for analysis from the Quick Pick List or using Browse Runs																	
USB	2	Insert USB device																	
Quick Pick	3	Opening a run from the Quick Pick List	Simplexa Operator's Manual IVD Appendix B: Troubleshooting, B-7																
		<table border="1"> <thead> <tr> <th>Step</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td>a</td> <td>Click on run located under Analyze Completed Runs; the 10 most-recent runs are displayed (Fig. 1)</td> </tr> <tr> <td>b</td> <td>If the run is not displayed use Browse Runs</td> </tr> <tr> <td>c</td> <td>Click on Export drop down located near the top of the Analyze Screen </td> </tr> <tr> <td>d</td> <td>Select Service Packet from menu</td> </tr> <tr> <td>e</td> <td>Select storage location Removable Disk (E:)</td> </tr> <tr> <td>f</td> <td>Click OK after export is successful</td> </tr> <tr> <td>g</td> <td>Email to technical services</td> </tr> </tbody> </table>		Step	Action	a	Click on run located under Analyze Completed Runs ; the 10 most-recent runs are displayed (Fig. 1)	b	If the run is not displayed use Browse Runs	c	Click on Export drop down located near the top of the Analyze Screen 	d	Select Service Packet from menu	e	Select storage location Removable Disk (E:)	f	Click OK after export is successful	g	Email to technical services
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		d		Select Service Packet from menu															
		e		Select storage location Removable Disk (E:)															
f	Click OK after export is successful																		
g	Email to technical services																		

Activity	Step	Action	Related Doc
Browse Runs	4	Opening a run from Browse Runs	
		Step	Action
		a	Select File: Browse runs or Browse Runs from the Quick Pick list
		b	Click on My Runs (Fig. 2) if logged into computer or click on user name
		c	Click on Completed
		d	Click on the Export button
		e	Select storage location Removable Disk (E:)
		f	Click OK after export is successful
		g	Email to technical services

Figure 1: Quick Pick List

File: Browse Runs

Quick Pick: Browse Runs

Quick Pick: Analyze Completed Runs

Figure 2: Browse Runs

Completed Run

Export button

Run Name	Run Date	Segment Count
Expired Quant Prediction Lot 07-28-2010 At 1119	7/28/2010 11:34:21 AM	1
Expired Quant Cal Lots 07-28-2010 At 1048	7/28/2010 11:03:09 AM	1
Expired Qual Lot 07-28-2010 At 0955	7/28/2010 10:08:00 AM	1
Expired IVD Qual Lot 07-28-2010 At 0955	7/28/2010 10:08:00 AM	1
IVD CMV Calibration run	7/14/2010 2:12:17 PM	1
User Defined CMV Calibration run	7/14/2010 1:26:20 PM	1
IVD Run 05-17-2010 At 1450	5/17/2010 3:02:17 PM	1
Run 08-14-2009 At 1115	8/14/2009 12:15:05 PM	3
Run 08-13-2009 At 1302	8/13/2009 1:19:16 PM	3
No Fluorescence Data 08-13-2009 At 1107	8/13/2009 11:23:24 AM	1
Run 08-12-2009 At 1447	8/12/2009 3:02:24 PM	1
Run 08-12-2009 At 1038	8/12/2009 10:53:49 AM	1
Run 08-12-2009 At 1014	8/12/2009 10:29:31 AM	1
Run 08-12-2009 At 0951	8/12/2009 10:06:11 AM	1
Run 08-12-2009 At 0920	8/12/2009 9:35:23 AM	1
Run 08-04-2009 At 1131	8/4/2009 11:46:08 AM	1
RH Beta5.1 08-03-2009 At 1931	8/3/2009 8:49:50 PM	1
12_SegmentTest 07-26-2009 At 1319	7/26/2009 2:38:07 PM	12
Run 07-22-2009 At 1447	7/22/2009 3:57:12 PM	1
Run 07-20-2009 At 0941	7/20/2009 9:49:17 AM	1
070809 HSV1&2 Extraction 07-08-2009 At 1943	7/8/2009 9:00:19 PM	1
BK060909_primer screening 6-9-2009 At 14-1	6/9/2009 3:19:04 PM	1

PROCEDURE D: Follow the steps to reset the barcode scanner

Barcode Scanner

Activity	Step	Action	Related Doc
Scanner not reading	1	The red-laser pattern should surround the outer edge of the barcode when reading the barcode	Simplexa Operator's Manual IVD Appendix B: Troubleshooting B-5
	2	If the barcode reader does not respond, reset by scanning the image located on page B-5, Troubleshooting guide	
	3	4 long beeps indicate that data was not transmitted from the scanner to the computer	
	4	If the scanner continues to beep, disconnect the scanner for 5 sec and then reconnect	
	5	Contact Focus technical service at 1-800-838-4548 option #3 if error continues	

REFERENCE

1. Simplexa™ 3M™ Integrated Cyclor Studio 5.0 , 3M™ Integrated Cyclor Operator Manual Reference 34-8710-8239-1, PI.MOL1101.UD_REV. F for use with IVD assays, Focus Diagnostics 2009-2012, Focus Diagnostics, Inc. Cypress, CA

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1	P. Ackerman	12.08.2016	Initial Version