

# Simplexa™ Troubleshooting Guide

## PURPOSE:

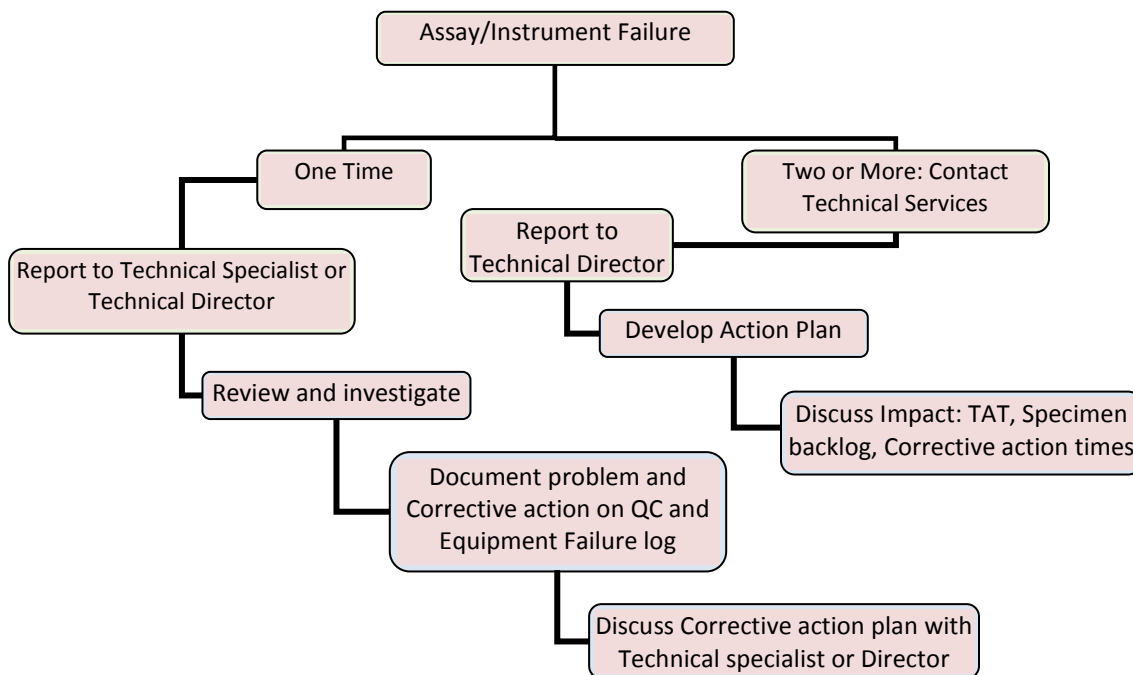
- This procedure provides instructions for troubleshooting problems based on symptoms including a potential cause with recommendations for solutions.

## DOCUMENTATION/RECORDS

- BORD Segment Report
- GASDN 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"> <li>▪ Text will explain the cause of the problem</li> <li>▪ The user will be provided information to follow to resolve the error</li> </ul> | <p>Simplexa Operator Manual<br/> <a href="#">Appendix B: Troubleshooting</a></p> |

| Activity          | Step | Action   | Related Doc  |
|-------------------|------|--|--|
|                   | 2    | Refer to <i>Simplexa Operator Manual, Appendix B: Troubleshooting</i> for additional recommendations <ul style="list-style-type: none"> <li>▪ Problem scenarios with possible causes and corrective actions</li> <li>▪ Error list with possible causes and corrective actions</li> </ul> |  |
| Technical support | 3    | If unable to resolve problem, contact <b>Focus technical service at 1-800-838-4548 option #3</b>   |  |
|                   | 4    | Technical Service may ask you to generate and send a Service Packet file; see Procedure B for downloading a *.icz file   |  |
| Instrument return | 5    | 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   | <a href="#">MB 4.02</a><br>Simplexa<br>Decontamination |
| Records           | 6    | Document all problems and actions in the QC and Equipment Failure Log  |  |
|                   | 7    | 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   | <a href="#">Simplexa Operator Manual</a> |   |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
|            |  | <table border="1"> <thead> <tr> <th>Step</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Click on run located under <b>Analyze Completed Runs</b>; the 10 most-recent runs are displayed (Fig. 1)</td> </tr> <tr> <td>2</td> <td>If the run is not displayed use <b>Browse Runs</b></td> </tr> <tr> <td>3</td> <td>Click on <b>Export</b> drop down located near the top of the Analyze Screen</td> </tr> <tr> <td>4</td> <td>Select <b>Service Packet</b> from menu</td> </tr> <tr> <td>5</td> <td>Select storage location <b>Removable Disk (E:)</b></td> </tr> <tr> <td>6</td> <td>Click <b>OK</b> after export is successful</td> </tr> <tr> <td>7</td> <td>Email to technical services</td> </tr> </tbody> </table> |  | Step  | Action | 1 | Click on run located under <b>Analyze Completed Runs</b> ; the 10 most-recent runs are displayed (Fig. 1) | 2 | If the run is not displayed use <b>Browse Runs</b> | 3 | Click on <b>Export</b> drop down located near the top of the Analyze Screen | 4 | Select <b>Service Packet</b> from menu | 5 | Select storage location <b>Removable Disk (E:)</b> | 6 | Click <b>OK</b> after export is successful | 7 | Email to technical services |
|            |  | Step   |  | Action  |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
|            |  | 1  |  | Click on run located under <b>Analyze Completed Runs</b> ; the 10 most-recent runs are displayed (Fig. 1) |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
|            |  | 2  |  | If the run is not displayed use <b>Browse Runs</b>  |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
|            |  | 3  |  | Click on <b>Export</b> drop down located near the top of the Analyze Screen                               |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
|            |  | 4  |  | Select <b>Service Packet</b> from menu  |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
| 5          | Select storage location <b>Removable Disk (E:)</b> |  |  |   |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
| 6          | Click <b>OK</b> after export is successful         |  |  |   |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
| 7          | Email to technical services                        |  |  |   |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
|            |  |  |  |   |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
| 4          | Select <b>Service Packet</b> from menu             |  |  |   |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
| 5          | Select storage location <b>Removable Disk (E:)</b> |  |  |   |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
| 6          | Click <b>OK</b> after export is successful         |  |  |   |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |
| 7          | Email to technical services                        |  |  |   |        |   |   |   |  |   |   |   |  |   |  |   |  |   |                             |

| Activity    | Step | Action                         | Related Doc  |
|-------------|------|--------------------------------|--|
| Browse Runs | 4    | Opening a run from Browse Runs |  |
|             |      | Step                           | Action   |
|             |      | 1                              | Select <b>File: Browse runs</b> or <b>Browse Runs</b> from the Quick Pick list |
|             |      | 2                              | Click on <b>My Runs</b> (Fig. 2) if logged into computer or click on user name |
|             |      | 3                              | Click on <b>Completed</b>  |
|             |      | 4                              | Click on the <b>Export</b> button  |
|             |      | 5                              | Select storage location <b>Removable Disk (E:)</b>                             |
|             |      | 6                              | Click <b>OK</b> after export is successful                                     |
|             |      | 7                              | Email to technical services  |

Figure 1: Quick Pick List

File: Browse Runs

Quick Pick: Browse Runs

Quick Pick: Analyze Completed Runs

| Sample ID        | Type    | Destination | Notes |
|------------------|---------|-------------|-------|
| A102312          | Unknown | 13 (D)      |       |
| D7080333         | Unknown | 14 (D)      |       |
| Foley45555       | Unknown | 15 (D)      |       |
| Control Positive | Pos_HCV | 16 (D)      |       |
| Pos_HV1          | Pos_HV1 | 17 (D)      |       |

| Spoke | Sample       | Destination |
|-------|--------------|-------------|
| A     | 100045       | Densen/Toad |
| B     | A02234       | Pos_HCV     |
| C     | 49933        | Pos_HCV     |
| D     | F000045      | Pos_HPV     |
| E     | Pos_HPV      |             |
| F     | Pos_HCV      |             |
| G     | Pos_HV1      |             |
| H     | Robert Today |             |

Figure 2: Browse Runs

Completed Run

| 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             |

Export button

**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 Manual<br><a href="#">Appendix B: Troubleshooting</a> |
|                     | 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 <b>Focus technical service at 1-800-838-4548 option #3</b> if error continues                          |   |

**REFERENCE**

1. Simplexa™ 3M™ Integrated Cyclor Studio 5.0 , 3M™ Integrated Cyclor Operator Manual Reference 34-8710-8382-9, PI.MOL1101.UD\_REV. F for use with user defined assays, Focus Diagnostics 2009-2012, Focus Diagnostics, Inc. Cypress, CA

**Historical Record**

| Version | Written/Revised by: | Effective Date: | Summary of Revisions       |
|---------|---------------------|-----------------|----------------------------|
| 1       | P. Ackerman         | 1.23.16         | Initial Version            |
| 2       | P. Ackerman         | 078.20.16       | Reformatted for CMS upload |