

Abbott

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Field Correction Recall / Urgent Field Safety Notice
Abbott Molecular Inc.

Product: m2000sp Instrument Systems

List Number: 09K14

Serial Numbers: Instruments with System Software Version 6.0 or 7.0 with Specific Application Specification Files

September 23, 2014

Dear Abbott Molecular Customer,

This letter contains important information regarding an issue identified on m2000sp Instruments with software versions 6.0 and 7.0 installed. Please review this information carefully.

Abbott Molecular has identified that some versions of application specifications are incompatible with m2000sp Software. This issue will cause Error Code 9000 ("An unexpected error has occurred: Software error") to be generated when the <Available Reagent Packs> screen is selected. The System Control Center will restart after EC 9000 is acknowledged.

Background

The <Available Reagent Packs> screen displays the available amplification reagent packs for specific assay application specifications (app specs). This feature supports the extended-use of amplification reagents for some RealTime assays.

The incompatible app specs are listed in Appendix 1, Table 1. Application CD-ROMs with compatible app specs are listed in Appendix 1, Table 2.

Potential Impact

If you have an incompatible app spec installed on your m2000sp and the <Available Reagent Packs> is accessed:

- a. between the sample extraction and reagent addition, samples could be lost if the reagent addition run is not initiated within the time period allowed per the assay package inserts.
- b. while a sample extraction run or a reagent addition run is in-process, the run will be lost.
- c. prior to starting a run or after a run has ended, no data or samples will be lost.

If you do not have an incompatible app spec file installed on your m2000sp, as identified in Appendix 1 Table 1, there is no impact.

Necessary Actions

Review the app spec files you have installed on your m2000sp system and delete any incompatible app specs as described in Appendix 1, Table 1. If you have deleted an app spec file and installation of a new app spec file is needed, refer to Appendix 1, Table 2.

Please review this information with laboratory personnel, and retain this communication for future reference. If you have any questions regarding this communication, please contact Technical Support at 1-800-553-7042 Option 2 or your local Abbott Molecular representative. We apologize for any inconvenience this issue may have created for your laboratory.

Sincerely,

Julio Salwen
Quality Assurance
Abbott Molecular, Inc.



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Appendix 1

Table 1. Incompatible Application Specifications

Delete these incompatible app specs from the m2000sp instruments following the **Delete an Application** instructions in Section 5 of the m2000sp Operations Manuals.

| Name | Version(s) | Description |
|---------------------------------|----------------------|---|
| m2000 0.2ml HIV-1 RNA US | 1.10 | Combined m2000sp and m2000rt Application for 0.2ml HIV-1 Assay US |
| m2000 0.2ml HIV-1 RNA | 2.00 3.00 4.00 | Combined m2000sp and m2000rt Application for 0.2ml HIV-1 Assay |
| m2000 0.5ml HIV-1 RNA US | 1.10 | Combined m2000sp and m2000rt Application for 0.5ml HIV-1 Assay US |
| m2000 0.5ml HIV-1 RNA | 2.00 3.00 4.00 | Combined m2000sp and m2000rt Application for 0.5ml HIV-1 Assay |
| m2000 1ml HIV-1 RNA US | 4.10 | Combined m2000sp and m2000rt Application for 1ml HIV-1 Assay US |
| m2000 1ml HIV-1 RNA | 2.00 3.00 4.00 | Combined m2000sp and m2000rt Application for 1ml HIV-1 Assay |
| m2000 0.6ml HIV-1 RNA | 1.00 | Combined m2000sp and m2000rt Application for 0.6ml HIV-1 Assay |
| m2000 0.2ml HCV RNA Application | 2.00 3.00 | Combined m2000sp and m2000rt Application for 0.2ml HCV RNA Assay |
| m2000 0.5ml HCV RNA Application | 2.00 3.00 | Combined m2000sp and m2000rt Application for 0.5ml HCV RNA Assay |
| m2000 0.2ml HBV DNA | 1.00 | m2000 Application for 0.2ml HBV Assay |
| m2000 0.5ml HBV DNA | 1.00 | m2000 Application for 0.5ml HBV Assay |
| m2000 CT DNA protocol | 2.00 3.00 | m2000 CT DNA Application |
| m2000 CTNG DNA protocol | 2.00 3.00 | m2000 CTNG DNA Application |

Table 2. Compatible CD-ROM List Numbers

The CD-ROMs listed below are compatible with m2000sp software v6.0 and 7.0. These app spec files can be installed on the m2000 instruments following the **Install an Application** instructions in Section 5 of the m2000sp Operations Manuals or by contacting your local Abbott Molecular Representative.

| RealTime Assay | Assay List Number | Compatible Assay Application CD-ROM List Number |
|-------------------|-------------------|---|
| CTNG and CT (ROW) | 2G28, 1L31 | 1L70-04 through 1L70-07 and 1L70-40 |
| HBV (ROW) | 2G34 | 8L35-02 through 8L35-04 |
| HCV (ROW) | 4J86 | 1L69-05 through 1L69-07 |
| HIV-1 (ROW) | 2G31 | 1L68-07 through 1L68-11 |
| HIV-1 (US) | 6L18 | 6L83-02 through 6L83-06 |