

**Field Correction Recall /Urgent Field Safety Notice**
Abbott Molecular Inc.**Product:** 5 mL Reaction Vessels**List Number:** 04J71-20**Lot Numbers:** 56944001, 57026001, 57059001, and 57673001

July 3, 2014

Dear Abbott Molecular Customer,

This letter contains important information regarding the 5mL Reaction Vessels **used with the m2000sp Instrument**. Please review this information carefully.

Background

Investigation at Abbott Molecular identified that some of the 5ml Reaction Vessels (RVs) contained in lots 56944001, 57026001, 57059001, and 57673001 (original vendor lot 2198077) may have an insufficient rim. It is estimated that **less than 1%** of RVs within these lots may be defective. These lots have been in distribution since July 2012.

An RV with an insufficient rim may not be held securely in the 1mL Subsystem Carrier. This may cause the RV to be seated incorrectly in the carrier or drop through it.

Potential Impact

If a defective RV drops through the 1mL Subsystem Carrier during loading into the carrier, the RV could not be used.

If a defective RV drops through the 1mL Subsystem Carrier or is not seated correctly during the m2000sp sample extraction run, the most likely outcome is:

- The run would be aborted
- The RV contents would spill onto the worktable.

Although unlikely, incorrect results could be generated if **all** of the following events occurred:

- a defective RV was loaded into the 1mL Subsystem Carrier
- the contents from a dropped RV contaminated another sample **or** the incorrect volume was transferred in/out of the affected sample
- processing of the affected sample(s) on the m2000sp completed without level sense or pipetting error codes
- processing of the affected sample(s) on the m2000rt completed without failure of validity checks

To date, there have been no complaints reported for incorrect results due to this issue.

Necessary Actions

If you have remaining RVs from lots 56944001, 57026001, 57059001, or 57673001 (original vendor lot 2198077), please remove them from use and contact Technical Support at 1-800-553-7042 Option 2 or your local Abbott Molecular representative to coordinate replacement.

Please review this information with laboratory personnel and retain this communication for future reference. If you have any questions regarding this communication, please contact Abbott Molecular. We apologize for any inconvenience this issue may have created for your laboratory.

Sincerely,

A handwritten signature in black ink, appearing to read 'Julio Salwen', with a long horizontal line extending to the right.

Julio Salwen
Quality Assurance
Abbott Molecular Inc.