

**Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Alinity m System**

Product: Integrated Reaction Unit (IRU)
List Numbers: 08N53-002 and 09N26-010
Not Serial Specific for 08N53-002
Lot Numbers: 766233, 770433, 771200, 771201, and 773642
Unique Device Identifiers (UDIs):
00884999048034
(01)20884999047864(10)766233(11)210614(240)09N26-010
(01)20884999047864(10)770433(11)210621(240)09N26-010
(01)20884999047864(10)771200(11)210712(240)09N26-010
(01)20884999047864(10)771201(11)210719(240)09N26-010
(01)20884999047864(10)773642(11)210723(240)09N26-010

February 11, 2022

Dear Abbott Molecular Customer,

This letter contains important information regarding the Integrated Reaction Unit (IRU) List Number 09N26-010 Lot Numbers 766233, 770433, 771200, 771201, and 773642 used with the Alinity m System. Please review this information carefully.

Background

Abbott has received complaints associated with the Alinity m Reaction Vessels (RVs) detaching from the RV Cap during transport by the pipettor robot. Customers reported finding RVs on the instrument deck, and Abbott has determined that an increase in the frequency of 1998 errors ("Fluorescence signal evaluation did not meet expected criteria. Excessive noise was detected in the reference signal.") is associated with this issue.

RV dropping was observed either after the pipettor robot attempts to snap on the RV Cap, or during transport by the pipettor robot from the Integrated Extraction Unit to the Amp-Detect. Refer to Figure 1 below for images of the RV, RV Cap and Capped RV.

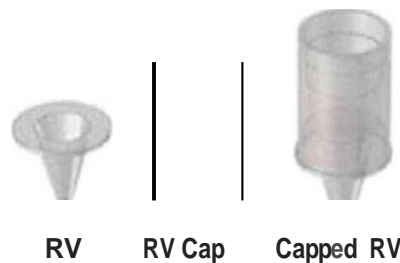


Figure 1. Excerpt from Alinity m Operations Manual, 54-605001/R10, depicts the RV, RV Cap, RV and RV Cap (RV assembly).

Potential Impact

A RV may be left behind in the IRU or detach from the RV Cap during system transport. If this occurs, the system will generate an error code resulting in the sample being sent to exception.

Additionally, if the RV detaches from the RV Cap during system transport to the Amp-Detect within a run, unamplified material extracted from a patient sample may escape the RV to the surrounding area inside the Alinity m System. The RV is sealed with a thin layer of Vapor



Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Alinity m System

Product: Integrated Reaction Unit (IRU)
List Numbers: 08N53-002 and 09N26-010
Not Serial Specific for 08N53-002
Lot Numbers: 766233, 770433, 771200, 771201, and 773642
Unique Device Identifiers (UDIs):

00884999048034

(01)20884999047864(10)766233(11)210614(240)09N26-010
(01)20884999047864(10)770433(11)210621(240)09N26-010
(01)20884999047864(10)771200(11)210712(240)09N26-010
(01)20884999047864(10)771201(11)210719(240)09N26-010
(01)20884999047864(10)773642(11)210723(240)09N26-010

Barrier Solution which should prevent the liquid from escaping the RV. Although improbable, there is a potential for liquid to escape the RV which may lead to an incorrect result (false positive or misquantitation high) if the liquid contaminates another sample.

Abbott has received zero (0) reports of an incorrect result related to this issue. While there is potential impact to results in all Alinity m assays (SARS-CoV-2, Resp-4-Plex, HBV, HCV, HIV-1, EBV, CMV, HPV or STI), there is no impact or change to the assay reagents.

Necessary Actions

Discontinue use of and discard all remaining inventory of IRU Lots 766233, 770433, 771200, 771201, and 773642. To coordinate replacement, contact your local Molecular Diagnostics at Abbott representative.

If RVs are found inside the instrument with no cap and there are associated 1998 errors, please contact an Abbott representative to inspect the instrument. Results generated between the onset of the associated 1998 errors and the identification of the RV with no cap inside the instrument should be considered presumptive. Retesting of samples that yielded positive results during this timeframe should be considered.

Please complete and return the Customer Reply Form.

This field action is to be carried out at the user/customer level. If this product has been further distributed by your facility, please notify any additional impacted customers.

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

Sincerely,

...

FA-AM-FEB2022-267B

Page 2 of 2