



Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Product: Alinity m HCV AMP Kit
List Number: 08N50-090

Lot Numbers: 383203, 385720, 381581, 382447

Unique Device Identifiers (UDIs):

(01)00884999047648(10)383203(17)241230(240)08N50-090
(01)00884999047648(10)385720(17)250226(240)08N50-090
(01)00884999047648(10)381581(17)241006(240)08N50-090
(01)00884999047648(10)382447(17)241111(240)08N50-090

October 30, 2023

Dear Abbott Customer,

This letter contains important information regarding Alinity m HCV AMP Kit, List Number 08N50-090 Lot Numbers 383203, 385720, 381581, and 382447 (collectively, "Identified Lots") utilized with the Alinity m System. Please review this information carefully.

Background:

Abbott has identified an increase in potential for reactive negative controls as well as separate instances of false positive results in patient samples when using the Identified Lots of Alinity m HCV AMP Kit. It was discovered that the Identified Lots of Alinity m HCV AMP Kit have lower than the expected range of HCV reference dye fluorescence. Both the false positive results and reactive negative controls manifest as a weak signal with a low MaxRatio (MR) compared to a true positive sample. 95% of the viral load concentrations for the false positive results are between 1.99 and 3.59 Log IU/mL with a mean of 2.79 Log IU/mL and a MR in the range of 0.04 to 0.07.

Potential Impact:

There is a potential of delay in results when using the Identified Lots of Alinity m HCV AMP Kit. If negative control samples are found to be reactive, the run will be invalidated by the Alinity m System.

Separately, there is also a potential of incorrect results due to this issue. Specifically, there is a risk that negative patient samples may be incorrectly identified as positive when using the Identified Lots of Alinity m HCV AMP Kit.

These two issues can occur independently, and false positive results may not always be seen with a reactive negative control.

Necessary Actions:

- Discard all units from Lot Numbers 383203, 385720, 381581, and/or 382447 of List 08N50-090, Alinity m HCV AMP Kit, in your possession. Distribution of these lots by Abbott began on July 3, 2023; June 1, 2023; February 22, 2023; and April 19, 2023, respectively.
- Complete and return the Customer Reply Form. Replacement kits will be provided based on the discarded quantity indicated on the reply form.



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- If you have forwarded any kits from the Identified Lots of Alinity m HCV AMP Kit to other laboratories, please inform them of this Field Advisory Notice, provide a copy of this letter to them and have them take the necessary actions listed here.
- Refer to Appendix A for a representative phenotype. Continue to follow internal laboratory procedures in the case of suspected incorrect results.
- If patient samples were tested with the identified lots, a review of the previously reported results is recommended. If review of the amplification plots shows the false positive, low level amplification phenotype (Appendix A); correlation with the patient's clinical condition and expected outcomes is recommended.
- If you would like additional support in determining if patient samples at your lab exhibited the false positive phenotype, please contact Abbott customer service.

Please review this information with laboratory personnel and retain this communication for future reference. Please continue to follow your laboratory protocols for any suspected incorrect results. If you have any questions regarding this communication, please contact your local Abbott representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,

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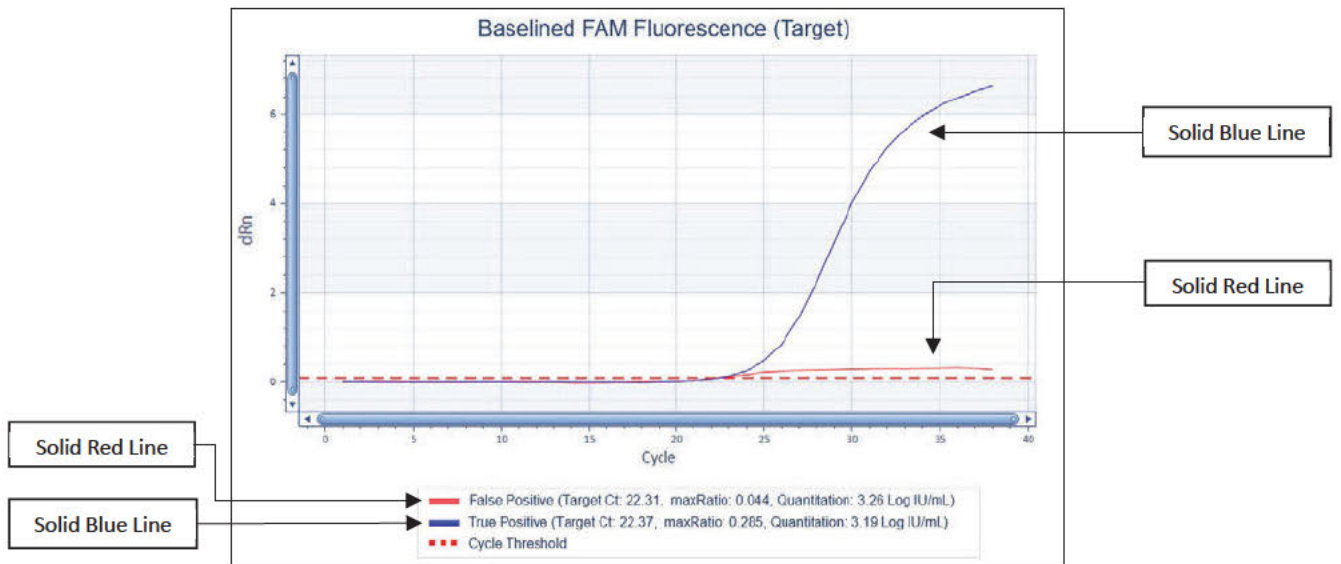
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Appendix A

Figure 1. Baseline Fluorescein Amidites (FAM) Fluorescence:



In the case of a suspected false HCV positive, a curve similar to the solid red line would be expected. In the case of a true positive, a curve similar to the solid blue line would be expected.

For detailed instructions on how to find the graphical representation of the results data, refer to page 425 of the Alinity m System Operations Manual, 09N33-019 (54-605001 / R12) - 2022-03-21 if using Alinity m Software prior to version 1.8.0 and page 425 of 09N33-020 (54-605001 / R13) - 2022-12-16 if using Alinity m Software version 1.8.0.