

URGENT MEDICAL DEVICE CORRECTION



June 1st, 2020

To all clients of Longhorn, our distributors, HHS and FEMA who have purchased or been sent tubes of our FDA-cleared PrimeStore® MTM.

Update on PrimeStore® MTM (Molecular Transport Media) and guanidine thiocyanate

We are sending you this letter to notify you that PrimeStore MTM tubes may have been delivered to some users without labels. Users may not be able to identify the tubes as PrimeStore MTM tubes without these labels. If samples stored or transported in PrimeStore MTM tubes are tested on the Hologic Panther or the Hologic Fusion System or come into contact with bleach they can produce cyanide gas. The solution in these tubes contains guanidine thiocyanate and may put laboratory personnel at risk of exposure to cyanide gas when it comes into contact with bleach or reagents containing bleach.

The Hologic Panther and the Hologic Fusion System platforms have a built-in decontamination step post-run analysis. Currently the Hologic decontamination liquid contains bleach that creates a dangerous chemical reaction producing cyanide gas when mixed with guanidine thiocyanate, one of the components of PrimeStore® MTM, lysis buffers and other sample collection devices. The same reaction may occur if the PrimeStore MTM media comes into contact with bleach or other reagents containing bleach. You should evaluate procedures in your laboratory to determine if there is a risk of the PrimeStore® MTM media contacting bleach or reagents containing bleach, such as during routine cleaning or decontamination following a spill.

Please process the inactivated samples in PrimeStore® MTM on molecular diagnostics platforms that do not use or contain bleach, and dispose of all the waste by following your Laboratory's Waste Disposal Protocols for your routine nucleic acid extraction kits (for DNA or RNA) as the guanidine in PrimeStore® MTM aligns with the percentage of guanidine in other lysis buffers.

Should there be any accidental spills of inactivated samples in PrimeStore® MTM tubes, please follow your Laboratory's Safety Guidelines for cleaning up spills from kits that contain guanidine salts. Longhorn recommends using a suitable laboratory detergent and water, followed by a 70% alcohol wipe.

The manufacturer strongly recommends that any sample transport media tubes that cannot be clearly identified as VTM, UTM, or saline should be assumed to be PrimeStore® MTM and therefore should not be processed on the Hologic platforms or decontaminated with bleach.

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If you have received, or do receive, any PrimeStore® MTM tubes that do not have labels applied or included with the shipment, please contact Longhorn Vaccines and Diagnostics immediately and labels will be supplied within 2 business days. If you are able to identify the tubes as PrimeStore MTM and are unable to wait to receive labels, such as when specimens have already been collected, you may test the collected specimens on platforms that do not use bleach. If you receive tubes that have labels with the shipment, but not applied to the tubes, you should apply the labels to each PrimeStore® MTM tube before it is put into use.

Future shipments of PrimeStore® MTM tubes will be individually labeled and the labels will include a warning about the media contacting guanidine thiocyanate. Some tubes already distributed by Longhorn Diagnostics and Vaccines may already be in the supply chain, so you may still receive unlabeled tubes in the near future. Please examine all shipments closely to ensure tubes are appropriately labeled.

Recommended Action

- Do not test samples stored or transported in PrimeStore® MTM tubes on the Hologic Panther or Hologic fusion Systems.
- Do not use bleach or bleach containing reagents for any procedures with the PrimeStore® MTM tubes.
- If tubes are not clearly identified, do not use them with the Hologic Panther or Hologic Fusion System, or with any procedures that will cause the media to come into contact with bleach or reagents containing bleach.
- If you received PrimeStore® MTM tubes with labels included in the shipment, but not on each individual tube, then place the labels on each individual PrimeStore® MTM tube immediately.
- If you received PrimeStore® MTM tubes that are unlabeled, and there were no labels included in the shipment, contact the manufacturer immediately to receive labels.
- If you are able to identify unlabeled tubes as PrimeStore® MTM and are unable to wait to receive labels, such as when specimens have already been collected, you may test the collected specimens on platforms that do not use bleach.
- Transport media which contain guanidine thiocyanate is not universally compatible with all nucleic acid tests, assay verification should be initiated prior to testing patient samples to ensure compatibility.

For questions or to request additional labels, please contact

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