URGENT FIELD SAFETY NOTICE

March 7, 2016

Re: Potential Vial Barcode Misreads and Importance of Vial Label Quality
Hologic ThinPrep® 5000 Processor with Autoloader

Dear Customer:

An investigation of customer complaints has determined that in rare cases, it is possible, for the ThinPrep® 5000 Processor with Autoloader to misread the value encoded in the vial barcode label. This occurs when the barcode scanner decodes a value that meets all symbology rules and check-digit validation but is not the intended value encoded in the barcode and processes the vial using this identifier. This potential is only present in ThinPrep® 5000 Processor with Autoloader configurations and is not present in the ThinPrep® 5000 Processor Benchtop configuration. In an Autoloader configuration, if a misread occurs, the misread vial ID value is transferred to the slide and a slide is produced with the incorrect identifier. It is difficult to predict how much the misread value will vary from the intended value but our investigation shows that they are usually different enough to be readily identified in batch reports.

Our risk analysis has determined that there is virtually no patient risk and the continued use of the ThinPrep 5000 system with Autoloader is acceptable as this is an extremely rare rate of occurrence. To date, there have only been fifteen reports of a vial barcode misread on the ThinPrep 5000 system. Based on our investigation and what has been reported as complaints, we see this as an extremely low rate of occurrence, 0.0002%. The residual risk would be the potential for misidentification of the resultant patient slide. Internal risk assessment indicates that there are safeguards within standard laboratory practice such as Laboratory Information Management Systems (LIMS) that would help ensure detectability if this issue were to occur.

The investigation has shown that the primary root cause of this rare issue is poor or inconsistent quality and/or out-of-specification (e.g., under-sized) barcode labels. It also indicates that label quality varies greatly from customer to customer and/or supplier to supplier. The ThinPrep 5000 Autoloader Technical Information Reference Guide provides guidance for the vial barcode label format which should be followed. In particular, the height, width, and module width (X dimension) are important specifications. The guide also states that print quality must meet the requirements outlined in the ANSI X3.182 standard.

This statement has been updated to be less ambiguous by adding that labels should be a Grade B or better when verified against this standard. The investigation has determined that thin, semi- transparent labels may cause issues when placed over the existing vial label. In addition, the proper application and positioning of the label on the vial is an important factor in correctly reading the label. We have also

determined that barcode label quality cannot be assessed with the human eye. While the label may look crisp it is impossible to gauge the consistency of module widths across the barcode. A barcode verifier must be used to grade the labels.

The ThinPrep 5000 system will log an error when the vial barcode cannot be read. An occasional error should not cause concern but multiple errors in a short period of time could be an indication of a label quality issue and should not be ignored.

Upon request, Hologic will assist customers in assessing the quality of their labels by grading them against the ANSI X3.182 standard, comparing them to our guidance, and providing recommendations for improvement if needed.

While this is a rare event, Hologic is taking the following steps to ensure vial barcode misreads do not occur:

- Hologic has updated the Technical Information Reference Guide to clarify vial barcode quality and specification requirements.
- A software revision 2.1.1 has been implemented which will include additional safety reads so that the vial will be read multiple times to ensure that all read values are consistent. The additional reading does not impact processing time. This enhanced requirement for multiple successful reads in succession on the AutoLoader may lead to more failure-to-read errors on vials with labels improperly applied, labels of poor quality or labels with inconsistent quality.
- The original 1D barcode scanner will be upgraded to an image-based scanner which internal studies have demonstrated can ensure more reliable barcode scanning as it captures an image of the entire barcode rather than the narrow scanning window of the 1D scanner. This new scanner will support scanning of both 1D and 2D barcodes.

The new labeling, software, and barcode scanners are now available and Hologic will be contacting you soon to schedule these updates.

Please share this notice with those in your organization who may need to be aware of it.

The relevant National Competent Authorities are being advised of this Field Safety Corrective Action.

Please contact International Technical Support by phone (+800-800-29892) or by email at (InternationalTechSupport@Hologic.com) regarding questions or requests for assistance.

Sincerely,

Hologic, Inc.