

ThinPrep® CytoLyt® Solution Quarts Precipitate**Worldwide Distribution****Purpose**

Hologic has identified artifacts in some quart bottles of ThinPrep CytoLyt Solution. Since Hologic is committed to offering quality products and with you and your patients in mind, an in-depth investigation was initiated.

Results from the investigation found that part of the raw material used to make ThinPrep CytoLyt Quart Bottles may precipitate out into solution and appear on prepared samples. The artifact has only been found within a small number of quart bottles of ThinPrep CytoLyt Solution. The precipitate is aluminum acetate, a non-biological material. It may appear as clumped or individual spherical bodies (See Figures 1 and 2).

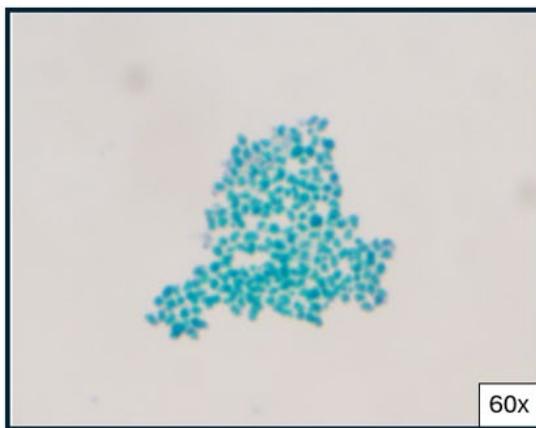


Figure 1: Morphology of precipitate at 60x.

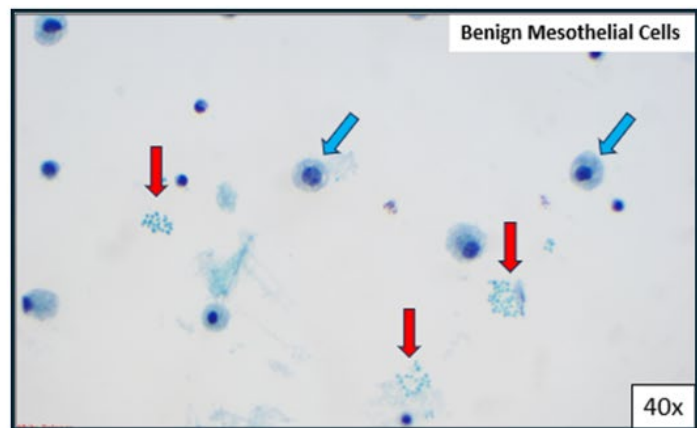


Figure 2: Comparison of precipitate (red arrows) and benign mesothelial cells (blue arrows) at 40x.

After review by two independent physicians, it was determined that there is no risk to patient health. In the process of identifying the artifact as aluminum acetate, routine cytologic special stains and cultures were performed to confirm that it is not fungal or bacterial in origin.

This notification is to inform you of the possibility that you may encounter this artifact on occasion. Laboratories should continue to use this product since there is no risk to patient health.

Scope

CytoLyt Solution is packaged in 3 types of containers: Cups, Tubes and Quart bottles. This notification does not apply to ThinPrep CytoLyt Solution packaged Cups or Tubes.

This notification is intended for Laboratory Managers, Site Administrators and Operators who have received the CytoLyt quart bottles and is effective immediately upon receipt. If you have questions regarding this notification, please contact Hologic Technical Support or your Hologic Representative.

What is Affected

ThinPrep CytoLyt Solution is a methanol-based, buffered cell wash solution designed to lyse red blood cells, prevent protein precipitation, dissolve mucus, and preserve morphology of general cytology cellular samples prior to slide preparation with the ThinPrep processor. It is designed for use with the ThinPrep processor, a cytologic preparation device that produces slides for microscopic examination. ThinPrep CytoLyt Solution enables the transport and preservation of cells for up to eight days at 15°C–30°C.

Table 1 –ThinPrep® CytoLyt® Solution Quart Part Numbers

Product Name	Catalog Number
CYTOLYT, 32 OZ. 4 PACK	0236004
CYTOLYT 32OZ 4PACK INTERNATIONAL	70408-002
CYTOLYT QUARTS (4/CASE), ASIA PACIFIC	70408-003
CYTOLYT QUARTS (4/CASE), CHINA	70408-004

Risk to Health

Hologic has evaluated the risk of using CytoLyt Quarts that contain the precipitate. The resulting artifacts may be present in the same focal plane as the cells when it is presented for cytological evaluation. This may be interpreted as laboratory contamination. As the artifact is not biologic, it was determined there is no risk to patient health.

If you require any technical support, please contact Hologic Technical Support. Country-specific telephone and email contact information for Technical Support can be found at www.hologic.com/support

Revision History:

Revision Date	Revision	Summary of Changes
05/20/2024	001	Initial Release

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