

RELEASE NOTES

It is recommended that you place this document in your Operator's Manual for easy reference.

Appendix D
Ancillary Testing from the SurePath[®] Preservative Fluid Collection Vial

Product(s) Affected:

SurePath[®] Preservative Fluid Collection Vial

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Appendix D

Ancillary Testing from the SurePath[®] Preservative Fluid Collection Vial

An aliquot of the specimen (up to 0.5 mL) may be removed from the SurePath[®] Preservative Fluid Collection Vial for ancillary testing *prior* to the SurePath[®] Pap test process.

In order to perform *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC) testing using BD ProbeTec[™] *Chlamydia trachomatis* (CT) Q^x and *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assays out of the SurePath[®] Preservative Fluid Collection Vial, specific processing steps must be followed as detailed in this section.

Procedure

Note: Sufficient volume is available in the SurePath[®] Preservative Fluid Collection Vial to allow removal of up to 0.5 mL of homogenous mixture of cells and fluid for ancillary testing, while still being able to perform a Pap test using the PrepStain[®] system (requires 8.0 ± 0.5 mL).

Note: A maximum of 0.5 mL aliquot may be removed prior to processing the SurePath[®] Pap test. Only one aliquot may be removed from the SurePath[®] Preservative Fluid Collection Vial prior to performing the Pap test, regardless of the volume of the aliquot.

1. In order to ensure a homogenous mixture, the SurePath[®] Preservative Fluid Collection Vial must be vortexed for 10-20 seconds and the 0.5 mL aliquot must be removed within one minute of vortexing.
2. A polypropylene aerosol barrier pipette tip that is sized appropriately for the volume being withdrawn must be used for aliquot removal. *Note:* Serological pipettes should not be used. Good laboratory practices must be followed to avoid introducing contaminants into the SurePath[®] Preservative Fluid collection vial or the aliquot. Aliquot removal should be performed in an appropriate location outside an area where amplification is performed.
3. Visually check the aliquot material in the pipette for evidence of large gross particulates or semi-solids. Evidence of such material encountered while withdrawing the aliquot material should prompt return of all the material to the specimen vial and disqualify the specimen for ancillary testing prior to performing the Pap test.

4. For instructions on processing the aliquot using the BD ProbeTec™ *Chlamydia trachomatis* (CT) Q^x and *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assays, refer to the Package Inserts provided by the assay manufacturer.

Limitations of Procedure

A volume of 8.0 ± 0.5 mL of the gynecologic specimen collected in the SurePath® Preservative Fluid Collection Vial is required for processing the SurePath® Pap test in the laboratory.

General precautions on ancillary testing from SurePath® Preservative Fluid Collection Vial

While there is no evidence that removal of an aliquot from the SurePath® Preservative Fluid Collection Vial affects the quality of the specimen for cytology testing, rare instances of misallocation of pertinent diagnostic material may occur during this process. Healthcare providers may need to acquire a new specimen if the results do not correlate with the clinical history of the patient. Furthermore, cytology addresses different clinical questions than sexually transmitted disease (STD) testing; therefore, aliquot removal may not be suitable for all clinical situations. If necessary, a separate specimen may be collected for STD testing rather than taking an aliquot from the SurePath® Preservative Fluid Collection Vial.

Aliquot removal from low-cellularity specimens may leave insufficient material in the SurePath® Preservative Fluid Collection Vial for preparation of a satisfactory SurePath® Pap test.