



CPAL

Central Pennsylvania Alliance Laboratory

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PreservCyt® Solution as an Alternative Transport Medium for the Roche Diagnostics Corporation COBAS AMPLICOR™ CT/NG Test

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Effective Date:

July 1, 2009 (Sample volume revision effective February 25, 2010)

Performed:

Tuesday through Saturday (days)

Specimen:

4mL aliquot of PreservCyt media from Patient ThinPrep vial specimen. Order test as **CHLAM CER** (CPAL test number 3010010) (since the specimen source is cervical).

Summary:

CPAL is now accepting cervical specimens collected in ThinPrep vial (PreservCyt media) for Chlamydia and Neisseria Gonorrhoeae PCR testing. This testing is performed using the Roche Amplicor CT/GC test. This specimen type is approved by the FDA for CT/GC testing by this method.

Critical Specimen Processing Prior to Sending to CPAL:

*An aliquot of the PreservCyt media must be removed from the ThinPrep vial **prior** to processing/preparation of the ThinPrep Slide. This is critical in order to avoid contamination of the specimen and potentially leading to erroneous results for GC/CT testing!! Because of the nature of this testing method, no requests for GC/CT testing after ThinPrep slide preparation can be accepted.*

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For questions about this and other information, call Central Pennsylvania Alliance Laboratory at 1-888-480-1422.

Instructions for Removing an Aliquot from the PreservCyt Sample Vial Prior To Performing the ThinPrep Pap Test.

Note: Only one aliquot may be removed from the PreservCyt sample vial prior to performing the ThinPrep Test, regardless of the volume of the aliquot (maximum aliquot volume = 4 mLs)

Note: Good laboratory practice should be followed to avoid introducing contaminants into either the PreservCyt sample vial or the aliquot. It is strongly recommended to use powder free gloves and a pipetting device with an aerosol barrier tip that is sized appropriately for the volume of the aliquot being withdrawn and dispensed. You should not use serological pipets.

Procedure for Removing Aliquot

1. Vortex the vial at high speed for 8 to 12 seconds
(Caution: The desired aliquot must be removed immediately after vortexing the vial to ensure homogeneity of the sample).
2. Carefully remove the vial cap.
3. Using a pipetting device, withdraw an aliquot of **4.0 mL** from the vial. Take care to avoid contaminating gloves with solution. If gloves should become contaminated, replace with a clean pair before proceeding to the next specimen.
4. Dispense the aliquot into a suitably sized and labeled polypropylene tube and close tightly to prevent leakage/evaporation.
5. Using a new pipet tip, withdraw a quantity of unused PreservCyt solution from its container that is equal in volume to that of the aliquot removed from the vial in step 3. (ie if you removed 4.0 mL of specimen for testing, return 4.0 mL of unused PreservCyt to the specimen vial).
6. Transfer the volume of unused PreservCyt solution to the vial from which the aliquot was removed in step 3.
7. Secure the vial cap (The line on the cap and the line on the vial should meet or slightly overlap).

Limitations:

PreservCyt solution used as an alternative collection and transport medium for the Roche Diagnostics COBAS AMPLICOR CT/NG Test is for use only with cervical specimens.

Specimens are stable for the time points indicated on the PreservCyt solution vial. However, testing of all specimens at the earliest interval following collection will help ensure the most accurate test results. Effects of extended storage time and variations associated with specimen shipment have not been assessed.

Samples processed using the **ThinPrep 3000** Processor **may not** be tested for Chlamydia trachomatis and Neisseria gonorrhoeae using the Roche Diagnostics COBAS AMPLICOR CT/NG Test.

Verification Studies

Verification studies were performed in which patient specimens were compared for those patients in which both traditional swab collection and ThinPrep Vials were available for analysis.

Neisseria gonorrhoeae (GC)

55/56 specimens that were identified as negative for GC by traditional swab collection and AMPLICOR screening were negative when ThinPrep specimens were examined. 4/5 specimens that were identified as positive for GC by tradition swab collection and AMPLICOR screening were positive when ThinPrep specimens were examined. This represents a 96.7% agreement between the two collection/testing methods. This result is similar to previous studies¹.

Chlamydia trachomatis (CT)

54/54 specimens that were identified as negative for CT by traditional swab collection and AMPLICOR screening were negative when ThinPrep specimens were examined. 8/8 specimens that were identified as positive for CT by tradition swab collection and AMPLICOR screening were positive when ThinPrep specimens were examined. This represents a 100% agreement between the two collection/testing methods. This result is similar to previous studies¹.

1. Cytoc Corporation PreserveCyt® Solution as an Alternative Transport Medium for the Roche Diagnostics Corporation COBAS AMPLICOR™ CT.NG Test. 86013-001 Rev. D. 2005 Cytoc Corporation.