

Laboratory Collection Supply Change Notification Impacting Amplified
Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (NG) Testing

May 2018

As a result of Customer Feedback, the collection kits for the **cobas**[®] CT/NG v2.0 Test, a PCR-based method for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, have been updated.

The following kit is being discontinued:

cobas[®] PCR Media Female Swab Sample Kit

The **cobas**[®] PCR Media Female Swab Sample kit used for the collection of specimens for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing with the **cobas**[®] CT/NG v2.0 Test will no longer be available, effective immediately.

The following kit is an appropriate replacement and the specific swab to be used for collection is based on the source of the sample:

cobas[®] PCR Media Dual Swab Sample Kit

The **cobas**[®] PCR Media Dual Swab sample collection kit contains:

- One **larger** polyester, woven swab
 - One **smaller**, flocked swab
 - One tube of **cobas**[®] PCR Media to stabilize the specimen
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- The **cobas**[®] PCR Media Dual Swab Sample kit may be used for collection of the following sample types for the **cobas**[®] CT/NG v2.0 Test:
 - **Using the large, woven swab:**
 - Vaginal Specimens: Clinician-collected and Self-collected
 - Oropharyngeal (Throat) Specimens
 - Rectal Specimens
 - **Using the small, flocked swab:**
 - Endocervical Specimens

See collection and sample handling on reverse side.

- **IMPORTANT NOTES FOR COLLECTION AND SAMPLE HANDLING:**

1. For Endocervical collections, the large, woven swab is used as a “cleaning swab” and should be used to remove mucus from the cervical os and surrounding mucosa. The smaller flocked swab, designed to maximize sample collection and minimize patient discomfort, is used to collect the endocervical specimen to be tested.
2. Conversely, the larger, woven swab in the **cobas**® PCR Media Dual Swab Sample kit is used to collect Vaginal (Clinician-collected and Self-Collected), Oropharyngeal and Rectal samples. For these collections from these sources, submit **only** the larger, woven swab. The smaller, flocked swab is not used for any purpose and may be discarded.
3. Samples that arrive in the laboratory with the woven cleaning swab **and** the smaller flocked swab *will be rejected*.
 - **The rejection policy for improperly collected specimens has not changed. Swab specimens will be rejected by the laboratory:**
 - If they do not contain a swab
 - If they contain 2 swabs
4. The following tests will be affected by this change:

Test Name	Test Code
Neisseria gonorrhoeae & Chlamydia trachomatis STD Panel by Amplification PCR	06842
Chlamydia trachomatis by Amplification PCR	06841

5. Please note that the following collection options are not impacted by this change:
 - **cobas**® PCR Urine sample kit
 - Only if used by your location, otherwise, continue to submit Urine samples in a Urine collection cup and submit promptly to the laboratory.
 - **PreservCyt** Pap Collections for CT/NG
6. New laminated specimen collection guides for vaginal specimen collection and endocervical specimen collection are available for use with the new sample collection kits. Copies may be requested by emailing: tdepalma@acmlab.com
7. You may continue to use the **cobas**® PCR Media Female Swab Sample Kit until your supply is depleted or until the expiration date marked on the tube.

Questions regarding this testing should be directed to Suzanne E. Dale, PhD, D(ABMM), Director, Microbiology and Molecular Diagnostics, p: (585) 429-2360 or Edi M. Hewa, MTASCP, Manager of Microbiology and Molecular Diagnostics, p: (585) 429-2205.