

## Diagnosis of sexually transmitted infections (STI) using the Roche Cobas® 6800 real-time PCR assay

Dear colleagues:

Effective March 12, 2024, DMC University Laboratories will **transition** from the BD Viper Qx XTR system to the Roche cobas® 6800 platform for the diagnosis of sexually transmitted infections caused by *Chlamydia trachomatis* (CT), *Neisseria gonorrhoea* (NG) *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG). The new assay has received FDA clearance.

The cobas® 6800 Systems is an automated system for qualitative in vitro detection of nucleic acids from these pathogens. It utilizes real-time polymerase chain reactions (PCR), for the direct detection of CT, NG, TV and MG DNA in male and female patient specimens. This test is intended as an aid in the diagnosis of the above STIs in both symptomatic and asymptomatic individuals.

In the current format, these tests are offered as a **combo panel CT/NG (*Chlamydia/Gonorrhoea*)** or **CT/NG/TV (*Chlamydia/Gonorrhoea/Trichomonas*)**. After transitioning to the Roche system, they will be offered as stand-alone tests to be compliant with current regulations which do not allow laboratories to provide the diagnostic tests in a panel format.

### **Specimen collection:**

- Endocervical swab specimens should be collected with the cobas® PCR Media Dual Swab Sample Kit.
- Vaginal swab specimens can be collected with either the cobas® PCR Media Uni Swab Sample Kit or cobas® PCR Media Dual Swab Sample Kit.
- Male and female urine should be collected with the cobas® PCR Urine Sample Kit. See attached for detailed instructions for specimen collection; please refer to respective specimen collection guidance and instructions provided by the manufacturer.

**Specimen transport:** All specimen types can be transported at 2-30°C.

### **Sample rejection:**

- Any specimen not collected in the Roche Cobas PCR transport devices
- Urines collected in cups or plain tubes or incorrect urine volume, (acceptable volume is 6 ml, between fill lines)
- Roche Cobas® PCR transport without a swab
- Woven (cleaning ) swab, instead of flocked swab in cobas PCR Dual swab transport
- Leaking samples
- Swab or urine specimens collected in any BD Qx transports
- **Samples from patients under the age of 18 for TV/MG**
- **Samples from patients younger than 14 years for CT/NG**

- **Swabs from male patients for CT/NG/TV test (urine is the only acceptable sample). Meatal swabs from male patients are acceptable for Mycoplasma genitalium only.**

**How to order:**

Depending on the sample type (Swab or urine), health care providers should choose the correct test from Sunquest, Antrim, or Cerner as shown below. Each test should be ordered separately.

Sunquest Test Code	Cerner Test Name	Antrim Unit Code
UGONOA	URINE GONORRHEA AMPLIFICATION	354050
UCHLMA	URINE CHLAMYDIA AMPLIFICATION	354068
UMYCGA	URINE MYCOPL GENITALIUM AMPLIFICATION	354076
UTRICA	URINE TRICHOMONAS AMPLIFICATION	354084
SGONOA	SWAB GONORRHEA AMPLIFICATION	354092
SCHLMA	SWAB CHLAMYDIA AMPLIFICATION	354100
SMYCGA	SWAB MYCOPL GENITALIUM AMPLIFICATION	354118
STRICA	SWAB TRICHOMONAS AMPLIFICATION	354126

Please note that the current test codes (**see below**) will be deactivated immediately after the launch of Roche Cobas 6800 assays.

Test Name	Sunquest Code	Antrim Unit Code
CHLAMYDIA DNA AMPLIF	CHLAMA	315663
GONORRHEA DNA AMPLIF	GONOA	315671
CHLAM/GONO DNA AMPLIF PROFILE	CGAP	315853
TRICHOMONAS AMP	TRCAMP	336206
CT,GC AND TRICH AMP	CGTRCA	336727

**Assay limitations:**

- Reliable results depend on proper sample collection, storage and handling procedures.
- Products containing carbomer(s), including vaginal lubricants, creams and gels may interfere with the test and should not be used during or prior to collecting urogenital specimens.
- The presence of mucus (> 0.5% w/v) in endocervical specimens may cause false negative test results.
- The presence of whole blood (> 5% v/v) in urine may cause false negative and/or invalid test results.
- Assay performance has not been validated for use with other collection media and/or specimen types.
- Detection of the above pathogens is dependent on the number of organisms present in the specimen and may be affected by specimen collection methods, patient factors (i.e., age, history of STI, presence of symptoms), stage of infection and/or infecting C. trachomatis and N. gonorrhoeae strains.
- Though rare, mutations within the PCR target regions may result in failure to detect the presence of the bacterium.

- CT/NG is not recommended for evaluation of suspected sexual abuse and for other medico-legal indications.
- CT/NG should not be used to determine therapeutic success as nucleic acids may be present after antimicrobial therapy.
- CT/NG has not been evaluated in patients younger than 14 years of age.
- TV/MG has not been evaluated in patients younger than 18 years of age.
- In less than 5% of GC and CT coinfections, the detection of *N. gonorrhoeae* present at concentrations near the lower limit of detection (LoD) may be impacted.

**Testing for STI in young patients:**

For testing patients younger than 14 years for CT and NG or for testing patients younger than 18 years of age for TV and MG, please collect sample in Aptima collection kit and order Aptima tests.

**Testing other sample types for GC or CT**

Samples from sources such as eye, throat or anorectal area will continue to be sent out to a reference laboratory for these pathogens.

**Obtaining collection/transport kits:**

- Hospital floors, ED and Clinics: call the DMC warehouse for your site and request the following Roche cobas® collection kits :

**cobas® PCR Media Dual Swab Sample Kit**

**cobas® PCR Urine Sample Kit**

- Outreach clients: contact sales (Peggy Predhomme) at 313-966-7666)

Thank you,

**For technical inquiries please contact:**

**Virology lab, 313-993-0710**

**Peggy Predhomme, Sales representative, 313-966-7666**

**Fadi Gammou, Lab manager, 313-745-2314**

**Dr. Hossein Salimnia, Technical Director, 313-745-2130**

**Dr. Marilyn Fairfax, Medical Director, 313-745-4188**

**Dr. Tim Kennedy, CLIA Director, 313-745-4571**

## Specimen Collection Best Practices – Extragenital



- **Patients should refrain from using over-the-counter hygiene and/or prescription products in the throat or rectum for 24 hours before their appointment.**
  - This helps to ensure a quality specimen is collected and minimizes potential for test interference.
- **When collecting an anorectal specimen: if the swab is grossly contaminated with feces, discard and repeat the collection procedure.**

## cobas® PCR Media Sample Kits

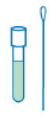


100 packets per kit



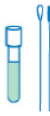
### cobas® PCR Urine Sample Kit

- 1 **cobas®** PCR media tube
- 1 disposable pipette for transferring urine from collection cup to tube
- Validated for use with **cobas®** CT/NG, **cobas®** CT/NG v2.0 and **cobas®** TV/MG Tests



### cobas® PCR Media Uni Swab Sample Kit

- 1 **cobas®** PCR media tube
- 1 polyester woven swab
- For the collection and transport of human specimens
- Validated for use with **cobas®** CT/NG, **cobas®** CT/NG v2.0, **cobas®** TV/MG and **cobas®** Cdiff Tests



### cobas® PCR Media Dual Swab Sample Kit

- 1 **cobas®** PCR media tube
- 1 polyester woven swab for cleaning prior to endocervical specimen collection or for the collection of an anorectal, meatal, oropharyngeal, or vaginal specimen (same swab as in Uni-swab sample kit)
- 1 flocked swab for endocervical specimen collection
- Validated for use with the **cobas®** CT/NG, **cobas®** CT/NG v2.0 and **cobas®** TV/MG Tests

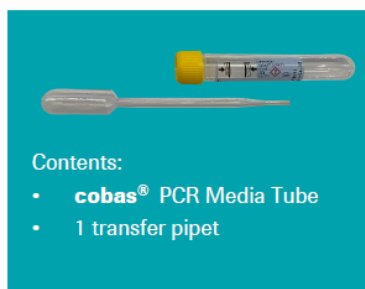
### Specimen Stability

Specimens collected and transported for testing with the **cobas®** CT/NG, **cobas®** CT/NG v2.0 and **cobas®** TV/MG tests in the **cobas®** PCR Media tube are stable at 2 – 30° C for up to 1 year.

Stool specimens for testing with the **cobas®** Cdiff Test mixed with the **cobas** PCR Media is stable at 2 – 8° C for 60 days or at 30° C for 7 days before testing on the **cobas®** 4800 System.

## cobas® PCR Media Sample Kits

Urine Sample Kit



### Contents:

- **cobas®** PCR Media Tube
- 1 transfer pipet

- The **cobas®** PCR Urine Sample Kit is used to collect and transport urine specimens
- The **cobas®** PCR Media serves as a nucleic acid stabilizing transport and storage medium for urine specimens
- Validated for use with **cobas®** CT/NG, **cobas®** CT/NG v2.0 and **cobas®** TV/MG Tests
- Urine specimens transferred to **cobas®** PCR Media are stable at 2 – 30° C for up to 1 year
- If the urine specimen cannot be transferred immediately, it can be stored at 2°C to 30°C for up to 24 hours
- Store kits at 15 – 30°C

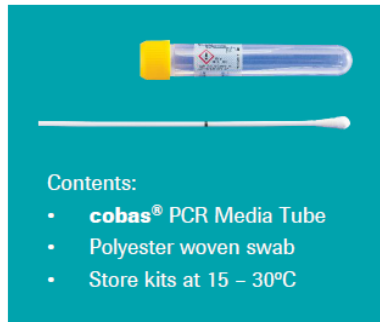
*The University Difference*

4201 St. Antoine • Detroit, MI 48201 • 313-745-4100 / 1-800-456-2154

[www.dmcu.org](http://www.dmcu.org)

## cobas® PCR Media Sample Kits

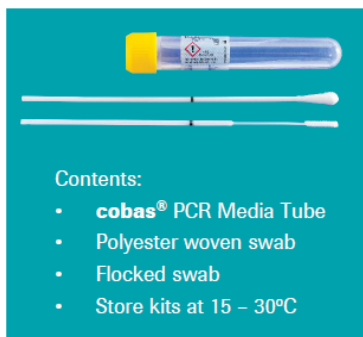
### Uni Swab Sample Kit



- The **cobas®** PCR Media Uni Swab Sample Kit is used to collect and transport human specimens, including anorectal, meatal, oropharyngeal, and vaginal swab specimens
- Validated for use with **cobas®** CT/NG, **cobas®** CT/NG v2.0, **cobas®** TV/MG, and **cobas®** Cdiff Tests
- The **cobas®** PCR Media serves as a nucleic acid stabilizing transport and storage medium for human specimens
- Once in the **cobas®** PCR media tube the sample is stable for 12 months at 2 – 30°C

## cobas® PCR Media Sample Kits

### Dual Swab Sample Kit



- The **cobas®** PCR Media Dual Swab Sample Kit is used to collect and transport anorectal, endocervical, meatal, oropharyngeal, and vaginal swab specimens
- Use this collection kit with the **cobas®** CT/NG, **cobas®** CT/NG v2.0 and **cobas®** TV/MG Tests
- The **cobas®** PCR Media serves as a nucleic acid stabilizing transport and storage medium for various specimen types
- Once in the **cobas®** PCR media tube the sample is stable for 12 months at 2 – 30°C

## cobas® PCR Media Sample Kits

### Dual Swab Sample Kit – Specimen collection

The Dual Swab Collection kit is validated for anorectal, endocervical, meatal, oropharyngeal, and vaginal specimen collection

- **Endocervical Specimens:** Woven swab is used for **cleaning and discarded**, specimen is **collected with the flocked swab**
- **Anorectal, Meatal, Oropharyngeal, and Vaginal Specimens:** Cleaning is not necessary, the specimen is **collected with the woven swab** and the **flocked swab is discarded**



## Why Uni vs Dual swab kit for cobas CT/NG and TV/MG Testing



- Uni swab kit can be used for other applications designed to be used for the collection and storage of human specimens.
- No throwing away a swab, patients wondering if they are reading the directions correctly!
- Minimize the risk of the patient collecting 2 swabs which can result in a rejected specimen.
- Using the dual swab kit may result in the patient using the flocked swab for a self-collected vaginal or meatal specimen, impact unknown.

## cobas® PCR Media Disposable Tube Stand Kit



*Disposable, one time use tube stand*



Disposable, one time use tube stand that can be used to hold a **cobas**® PCR Media Tube as sample is being added to the tube

Primary use for patient who is self-collecting vaginal or meatal specimen (in a clinical setting) for **cobas**® CT/NG and TV/MG testing