



To : CDL Clients
From : The Laboratory
Subject : New procedure for Chlamydia and Gonorrhea analysis by PCR
Date : July 5th 2012

Dear Client,

CDL Laboratories is proud to announce that we recently acquired the fully automated Cobas® 4800 analyzer from its privileged partner, Roche Diagnostics. This state of the art technology requires no manual manipulation (from DNA extraction to the amplification process) and will produce accurate results, with a quick turn around time.

This new instrument, in addition to performing the recently announced HPV testing with genotyping, will also perform Chlamydia and Gonorrhea analysis by utilizing the PCR (*Polymerase Chain Reaction*) technology.

New Instructions for Chlamydia and Gonorrhea Testing:

1) Urine : Male and Female

- **Specimen Required:** Urine Container
- **Instructions:** First stream urine in a sterile urine container with no preservative, properly labeled (first stream). The patient should not have urinated for at least two hours prior to sampling.
- **Specimen Conservation:** 24h between 2°C - 30°C

2) Cobas® PCR Media collection kit: Female (only)

- **Specimen Required:** Cobas® PCR Media collection kit
- **Instructions :** Cervical, vaginal and/or endocervical sample. It is mandatory for the single swab to be broken off and left in the transport media tube.
- **Specimen Conservation:** Endocervical : 12 months between 2°C - 30°C. Vaginal and cervical: 90 days between 2°C - 30°C.

Cobas® PCR specimen tubes with no swabs or with two swabs will not be tested. We will not process endocervical and vaginal swab specimens that appear bloody or have a dark brown color.

Since the vast majority of patients are asymptomatic, it is highly recommended to simultaneously tests for the presence of both sexually transmitted infections.

All clients currently using the Amplicor collection kit (PCR container) must now use the Cobas® PCR Media collection kit.



MEMORANDUM

Specimen type and pricing for Chlamydia and Gonorrhea PCR testing

Specimen type (PCR)	Gender		Patient price and CDL code	
	Male	Female	1 test	2 tests
Chlamydia	Urine (first stream)	<u>Urine (first stream)</u> or Cobas® PCR Media collection kit.	Code : CMPC	Code : CGPCR
Gonorrhea	Urine (first stream)	<u>Urine (first stream)</u> or Cobas® PCR Media collection kit.	Code : GONO	

Please contact us for the prices.

For scientific information, please contact Melanie Painchaud at (514) 344-8022 ext. 250. To order supplies, please fax your supply order form to (514) 341-9509. Please see the attached procedure for Chlamydia and Gonorrhea.

We wish to thank you for your continued support.

The Laboratory

Please take note that this is the same procedure as the Gonorrhea by PCR.

MEDICAL SUPPLIES

- Men : sterile urine container only.
- Women : sterile urine container or Cobas® PCR collection kit.

- Sterile urine container or Cobas® PCR collection kit;
- Biohazard bag;
- Stability:
 - Urine : 24 hours between 2°C and 30°C
 - Cobas® PCR collection kit
 - 1) Vaginal sample : 90 days between 2°C and 30°C
 - 2) Endocervical and cervical sample : 12 months between 2°C and 30°C

Sterile Urine Container

PREPARATION

- 1) It is recommended to use the first stream of the first morning urine.
- 2) Do not urinate at least two (2) hours before specimen collection.
- 3) Women:
 - Inform your physician if you are having your period.
 - Do not clean the labial area before the specimen collection.

MALE AND FEMALE COLLECTION PROCEDURE

- 1) Wash your hands with soap and water;
- 2) Open the sterile container;
- 3) Urinate in the container. A minimum volume of 10 mL is mandatory for analysis. If need be, continue to urinate in the toilet once you have filled up the container;
- 4) Tightly close the container;
- 5) Identify the container:
 - First name, last name
 - Date of birth or medicare card number
 - Date and time of collection
- 6) Promptly return the container to your physician or the laboratory.

COBAS® PCR COLLECTION KIT (WOMEN ONLY)

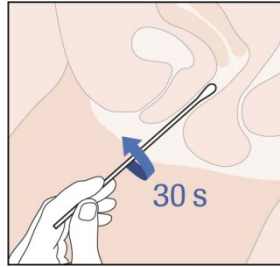
PREPARATION

- 1) Do not wet the swab in the Cobas® PCR Media tube before collecting the sample.
- 2) Wear gloves.

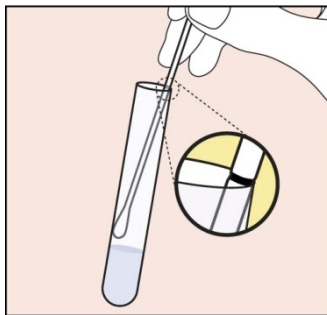
VAGINAL SAMPLE COLLECTION

- 1) Insert swab at a 5 cm depth in the vaginal opening.
- 2) Slowly rotate swab during 30 seconds while touching the vaginal wall.

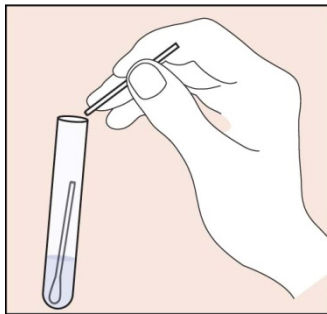
3)



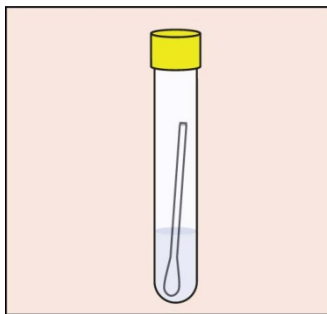
- 4) Slowly remove the swab.
- 5) Make sure that the swab does not come in contact with any other surface before putting it back in the tube.
- 6) Remove the cap from the cobas® PCR tube and lower the swab specimen into the tube until the visible dark line on the swab shaft is aligned with the tube rim. The tip of the swab should be just above the media surface near the hexagonal Roche logo.



- 7) Carefully leverage the swab against the tube rim to break the swab shaft at the dark line; discard the top portion of the swab.



- 8) Tightly re-cap the cobas® PCR Media tube. The specimen is now ready for transport.



- 9) The sample will be rejected if :
- There is no swab in the tube;
 - There are two (2) swabs in the tube;

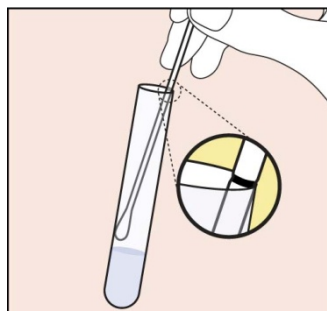


- The sample is dark or bloody.

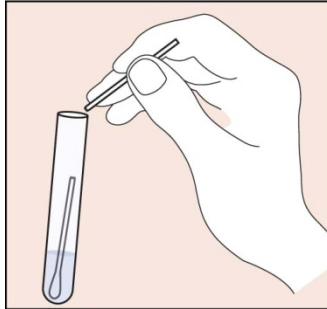


ENDOCERVICAL SPECIMEN COLLECTION

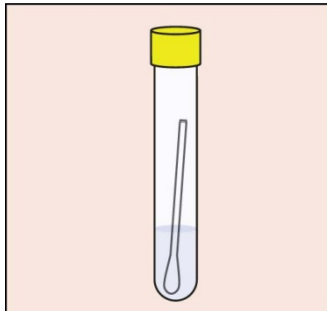
- Using one of the swabs (provided), remove excess mucus from the cervical os and surrounding mucosa. Discard the swab after use.
- To collect the specimen, insert the other provided swab into the endocervical canal.
- Gently rotate the swab 5 times in one direction in the endocervical canal. Do not over-rotate. Carefully withdraw the swab, avoiding any contact with the vaginal mucosa.
- Remove the cap from the cobas® PCR Media tube and lower the swab specimen into the tube until the visible dark line on the swab shaft is aligned with the tube rim. The tip of the swab should be just above the media surface near the hexagonal Roche Logo.



- 5) Carefully leverage the swab against the tube rim to break the swab shaft at the dark line; discard the top portion of the swab.



- 6) Tightly re-cap the cobas® PCR Media tube. The specimen is now ready for transport.



- 7) The sample will be rejected if :
- a. There is no swab in the tube;
 - b. There are two (2) swabs in the tube;



- c. The sample is dark or bloody.

