

Document number: PSM MOLECULAR BIOLOGY BACTERIOLOGY Issue number: 1.01	Effective date: 04/04/2024	Page 1 of 4
Title: Primary Sample Manual: Molecular Biology - Bacteriology		

Author: *Etain O'Rourke*

Approved By: *Michael Louw, Loretto Pilkington, Margaret Hannan, Diana Selaru*

Title: Primary Sample Manual: Molecular Biology - Bacteriology

Changes made since previous version: Original. Replacement for PSM MOLECULAR BIOLOGY – VIROLOGY.

Note: *Please refer to the document record on QPulse for the revision history of this document*

**THIS DOCUMENT IS CONTROLLED. PRINTED DOCUMENTS ARE DEEMED CONTROLLED
WHEN STAMPED 'IF THIS IS GREEN IT IS AN APPROVED ISSUE'.**

Document number: PSM MOLECULAR BIOLOGY BACTERIOLOGY Issue number: 1.01	Effective date: 04/04/2024	Page 2 of 4
Title: Primary Sample Manual: Molecular Biology - Bacteriology		

CONTENTS:

1. CHLAMYDIA TRACHOMATIS & NEISSERIA GONORRHOEAE (CT/NG)..... 3

**THIS DOCUMENT IS CONTROLLED. PRINTED DOCUMENTS ARE DEEMED CONTROLLED
WHEN STAMPED 'IF THIS IS GREEN IT IS AN APPROVED ISSUE'.**

Document number: PSM MOLECULAR BIOLOGY BACTERIOLOGY Issue number: 1.01	Effective date: 04/04/2024	Page 3 of 4
Title: Primary Sample Manual: Molecular Biology - Bacteriology		

1. CHLAMYDIA TRACHOMATIS & NEISSERIA GONORRHOEAE (CT/NG)

Chlamydia trachomatis (CT) is the second most leading cause of sexually transmitted diseases worldwide, with approximately 89.1 million cases occurring annually. CT is the causative infectious agent for a variety of diseases in men, including urethritis, proctitis, conjunctivitis and epididymitis. In women, the consequences of infection with CT are severe if left untreated. Infection can lead to endometriosis, salpingitis (with subsequent infertility and ectopic pregnancy) and perihepatitis. Additionally, infants from infected mothers can develop conjunctivitis, pharyngitis, and pneumonia.

Neisseria gonorrhoeae (NG) is the causative agent of gonorrhoeae. Acute urethritis is seen in the majority of men with gonorrhoeae, and acute epididymitis is the most common complication, particularly in young men. In women, the primary site of infection is the endocervix, there's a high prevalence of co-infections with CT, *Trichomonas vaginalis*, and bacterial vaginosis. Many women remain asymptomatic; when symptoms do occur, the most common are increased discharge, dysuria, and intermenstrual bleeding. Additionally, NG may cause pelvic inflammatory disease, endometriosis, tubo ovarian abscess, and pelvic peritonitis.

Preparation of patient: Prior to the collection of urine, the patient should not have urinated for at least one hour. For best results, female patients should not cleanse the labial area prior to collection. There is no physical preparation for the vaginal swab.

Precautions: None for patient. Media contains Guanidine Thiocyanate, adequate PPE for the person taking the sample.

Accredited	Yes
Method	The cobas® 4800 CT/NG Test is an in vitro nucleic acid amplification test for the qualitative detection of <i>Chlamydia trachomatis</i> (CT) and/or <i>Neisseria gonorrhoeae</i> (NG) in patient specimens. The test allows for detection of CT/NG DNA in endocervical and vaginal swab specimens, and male and female urine in cobas® PCR Media. The intended targets for the cobas® 4800 CT/NG Test include all fifteen major <i>Chlamydia trachomatis</i> serovars, the Swedish <i>C. trachomatis</i> mutant (nvCT), and both wild-type and variant DR-9 sequences of <i>N. gonorrhoeae</i> . SOP: MB52
Sample Requirements	Sample Type: Urine or urine in cobas PCR Urine Media (cobas® PCR Urine Sample Kit). Endocervical or Vaginal swabs in cobas PCR Media (cobas® Media Dual Swab Kit).
Turnaround Time	4 working days from sample receipt
Stability	Urine specimens should be transferred into the cobas PCR media tube as soon as possible. If specimens cannot be transferred immediately, they can be stored at 2-30°C for up to 24 hours. Stabilised urine specimens are stable at 2-30°C for up to 12 months. Swabs collected with the cobas PCR Media Swab Kit may be stored at 2-30°C for up to 12 months.
Units - Reference Ranges	CT and/or NG Detected Not Detected Invalid

THIS DOCUMENT IS CONTROLLED. PRINTED DOCUMENTS ARE DEEMED CONTROLLED WHEN STAMPED 'IF THIS IS GREEN IT IS AN APPROVED ISSUE'.

Document number: PSM MOLECULAR BIOLOGY BACTERIOLOGY Issue number: 1.01	Effective date: 04/04/2024	Page 4 of 4
Title: Primary Sample Manual: Molecular Biology - Bacteriology		

Notes	<i>Chlamydia trachomatis</i> and <i>Neisseria Gonorrhoeae</i> are notifiable diseases under the Infectious Diseases (Amendment) Regulations 2020 (S.I. No. 53/2020).
--------------	--

Consultant Responsible: Prof M. Hannan
Eurofins Biomnis: +353-1-295-8545

**THIS DOCUMENT IS CONTROLLED. PRINTED DOCUMENTS ARE DEEMED CONTROLLED
WHEN STAMPED 'IF THIS IS GREEN IT IS AN APPROVED ISSUE'.**