

## **Indiana University Health Molecular Pathology Laboratory**

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### *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Qualitative Assay

For in vitro diagnostic use

#### **CERNER ORDERABLE**

Chlamydia PCR, CHLAM PCR 3054

GC PCR 3058

STD Panel GC PCR + CHLAM PCR 7469

#### **CPT CODE**

87491, 87590

#### **CLINICAL UTILITY**

The Cobas CT/NG v2.0 Test is for the in vitro qualitative detection and differentiation of ribosomal RNA (rRNA) from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC) to aid in the diagnosis of chlamydial and/or gonococcal urogenital disease using the automated instrumentation. The Cobas CT/NG v2.0 Test utilizes PCR amplification of target DNA sequences using both CT and NG specific primer pairs and real-time detection of cleaved fluorescent-labeled CT and NG specific oligonucleotide detection probes. IU Health Molecular Laboratory has conducted an in-house validation of rectal and throat swabs<sup>1</sup>.

#### **METHODOLOGY**

The Cobas CT/NG v2.0 Test utilizes PCR amplification of target DNA sequences using both CT and NG specific primer pairs and real-time detection of cleaved fluorescent-labeled CT and NG specific oligonucleotide detection probes.

#### **SPECIMENS**

Cobas PCR Swab Sample Kit (endocervical swab, vaginal swab, cervical swab, throat swab, rectal swab)

Urines in preservative free sterile container (must be received with 24 hours of collection)

#### **SPECIMEN STABILITY**

Store the swab in the swab specimen transport tube at 2°C to 30°C

Urine samples in the collection container must be transported to the lab at 2°C to 30°C

#### **SHIPPING**

Transport and store the swab in the swab specimen transport tube at 2°C to 30°C

Urine samples in the collection container must be transported to the lab at 2°C to 30°C

#### **CAUSES FOR REJECTION**

Probetek tubes, 2 swabs in Cobas tube, no swab in Cobas tube, urine specimen >24 hours since collection, grey urine Cx tubes, male urethral and penile specimens in Cobas tubes.

#### **ASSAY RANGE**

Qualitative Results (CT Positive/Negative and GC Positive/Negative)

#### **TURNAROUND TIME**

1-3 days

1. Reference information can be found in the Indiana University Health Molecular Assay Procedures.