



# ORARISK<sup>®</sup> CT/NG

## SAMPLE, REPORT

**Date of Birth:** 09/20/1980 (42 yrs)

**Gender:** Male

**Patient ID:** 920-H

**Patient Location:** Test Site A

## ORDERING PROVIDER

Ronald McGlennen MD  
7400 Flying Cloud Drive  
Suite 150  
Eden Prairie, MN 55344  
855-672-5362

## SAMPLE INFORMATION

**Specimen#:** 5989009001

**Accession#:** 202306-03361

**Specimen:** Oral Rinse(P)

**Collected:** 06/04/2023

**Received:** 06/05/2023 14:26

**Reported:** 06/06/2023 10:47



ORALDNA<sup>®</sup> LABS

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[oraldna.com](http://oraldna.com)

CLIA#: 24D1033809  
CAP#: 7190878

### Sample, Report

**Date of Birth:** 09/20/1980 (42 yrs)  
**Gender:** Male  
**Patient ID:** 92O-H  
**Patient Location:** Test Site A

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<b>Reason for Testing</b>	Evaluation of suspicious lesion	<b>Lesion Size</b>	2mm x 1mm
<b>Related Info</b>	Not Provided	<b>Color</b>	Red
		<b>Lesion Location(s)</b>	Tonsil

## MOLECULAR DETECTION OF C. TRACHOMATIS / N. GONORRHOEAE IN THE OROPHARYNX

### Test Results

<b>Chlamydia trachomatis</b>	Positive
<b>Neisseria gonorrhoeae</b>	Negative



### Signs and Symptoms of Oropharyngeal Infection

#### Symptoms

- Painful swallowing
- Coating or discharge in throat
- Fever, swelling in neck

#### Consequence

- Transmission to sexual partner(s)
- Local spread of infection to neck, joints or respiratory tract

### Interpretation:

This sample is positive for Chlamydia trachomatis DNA and negative for Neisseria gonorrhoeae DNA. See comments.

### Comments:

**Significance:** These molecular genetic findings support the diagnosis of an oropharyngeal infection by Chlamydia trachomatis (CT). The current negative result for Neisseria gonorrhoeae does not exclude the possibility of an infection with that organism not detected due to the presence of inhibitory substances or levels of the organism not detected due to assay sensitivity. The clinical significance of oropharyngeal asymptomatic CT infection is unclear and routine oropharyngeal screening for CT is not yet recommended. Current evidence suggests, however, that oropharyngeal CT can lead to serious consequences locally as well, it can be transmitted to genital sites sexually and by direct contact. Based on this, it is advised that such infections be treated with azithromycin or doxycycline. The effectiveness of other antimicrobial regimens for CT is unknown. In cases of suspected treatment failure, oropharyngeal swabs and testing based on culture to assess antimicrobial drug susceptibility may be indicated for more effective management.

## Sample, Report

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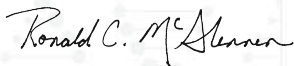
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**Consider:** Infections with *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) are common in extragenital sites in certain populations. Nucleic acid amplification testing (NAAT) also known as DNA testing has not been cleared by the FDA for detection of oropharyngeal infections caused by CT and NG; however, the CDC is recommending NAAT's to test for these extragenital infections based on increased sensitivity, ease of specimen transport and processing. No recommendations exist regarding routine extragenital screening in women because studies have focused on genitourinary screening, but oropharyngeal infections are not uncommon. This test is not recommended for the evaluation of suspected sexual abuse, for other medico-legal indications, or for evaluation of children under the age of consent. In these circumstances culture is the test of choice. Specific recommendations for the frequency and response to these DNA based assays can be reviewed at <http://www.cdc.gov/mmwr/pdf/rr/rr64O3.pdf>

**Methodology:** The Cobas(R) CT/NG Ver 2.0 test involves two major processes: 1) automated nucleic acid extraction for cellular and microbial DNA and 2) simultaneous amplification of CT (cryptic plasmid and chromosomal ompA gene DNA region) and NG (highly conserved direct repeat region DR-9) based on real-time detection PCR, followed by detection of the resulting fluorescent-labeled probes. An Internal Control, based on an exogenous CT and NG DNA species, is added to all samples prior to sample preparation, is co-amplified and detected with any natural occurring analytes, to monitor the performance of each of the assay processes. The Cobas(R) 4800 software renders the results of each sample tested, before transfer of that data to the OralDNA Labs reporting system TeleGene(TM). **Test limitations:** Only cervical specimens collected in PreservCyt Solution, either prior to cytology processing or after processing with the ThinPrep T2000 Processor, are FDA approved for testing. The analytical and performance characteristics of this laboratory-developed test (LDT) was determined by OralDNA Labs pursuant to Clinical Laboratory Improvement Amendments (CLIA 88) requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.



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Medical Director

