OraRisk® CT/NG

FINAL REPORT

ORALDNA LABS
Innovations in Salivary Diagnostics

Sample, Report

Date Of Birth: 03/03/1980 (35 yrs)
Gender: Female
Patient Id: 0303
Patient Location:

Ordering Provider

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

Sample Information

Specimen#: 99997712
Accession#: 201509-10805
Specimen: Oral Rinse
Body Site: Oropharyngeal

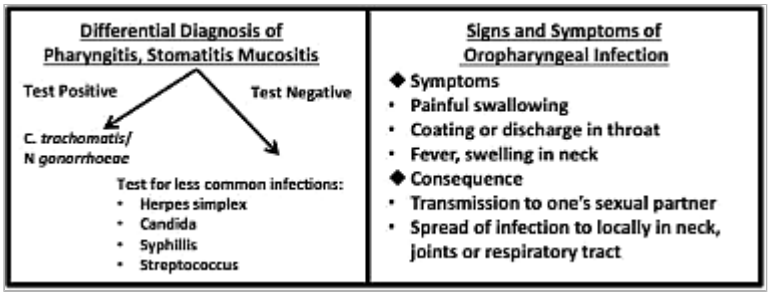
Collected: 09/16/2015 05:20
Received: 09/18/2015 15:24
Reported: 09/20/2015 09:15

Reason for Testing: Ulceration in oropharynx
Related info: Not Provided
Patient History: Not Provided

Lesion Size: Not Provided
Lesion Color: Not Provided
Lesion Location(s): Not Provided

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

Test Results	
Chlamydia trachomatis	Negative
Neisseria gonorrhoeae	Negative



Interpretation:

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

Comments:

- Significance: The current negative result does not exclude the possibility of an oropharyngeal infection with Chlamydia trachomatis and/or Neisseria gonorrhoeae not detected due to the presence of inhibitory substances or levels of the organism not detected due to assay sensitivity. If clinical suspicion of infection remains, repeat collection and testing is recommended.

- Consider: Infections with C. trachomatis and N. gonorrhoeae 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 C. trachomatis and N. gonorrhoeae; 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/rr6403.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 Access Genetics 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. All other acceptable sample types were validated by OralDNA Labs, A Service of Access Genetics, LLC pursuant to Clinical Laboratory Improvement Amendments (CLIA 88) requirements. The FDA has determined that such clearance or approval is not a requirement prior to off-label use for clinical purposes.

Ronald McGlennen MD, FCAP, FACMG, ABMG
Medical Director