FINAL REPORT

ORARISK® CT/NG

ORALDNA® LABS

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CLIA#: 24D1033809
CAP#: 7190878

SAMPLE, REPORT

Date of Birth: 09/20/1980 (42 yrs)
Gender: Female
Patient ID: 920-L
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#: 5989009000
Accession#: 2023060336O
Specimen: Oral Rinse(P)

Collected: 06/03/2023
Received: 06/04/2023 14:23
Reported: 06/06/2023 10:42

Sample, Report

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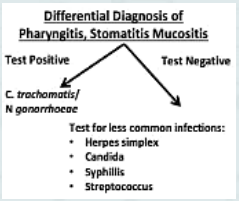
Specimen#: 5989009000
Accession#: 230306-03360
Specimen: Oral Rinse(P)

Collected: 06/03/2023
Received: 06/04/2023 14:23
Reported: 06/06/2023 10:42

Reason for Testing Ulceration in oropharynx
Related Info Not Provided

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

Test Results	
Chlamydia trachomatis	Negative
Neisseria gonorrhoeae	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 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.

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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/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 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.

Ronald C. McGlennen

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Medical Director