Precision Health Solutions

Final Report

LAB INFORMATION	PATIENT INFORMATION	SPECIMEN INFORMATION
Name: Precision Health Solutions **Address:** 9675 4th St N St Petersburg, FL 33716 **Phone:** 727-235-0886 **Fax:** 833-288-9397 **Medical Director:** Fatemeh Mousavi, MD **CLIA:** 10D2181177	Patient: Minnie Mouse DOB: 01/03/1955 Age: 70 Years Gender: Female Patient Address: 1111 Rain Forest Cafe Street City: Toontown State: FL Zipcode: 33333	Acc #: D548466152 Facility: Toontown Clinic Provider: Donald Duck APRN Collection Date: 01/15/2024 17:00 P.M Received in Lab: 01/15/2024 Resulted Date: 01/16/2024 10:18 A.M Specimen Type: Urine + Clean Catch Color: Yellow Clarity: Clear

Chlamydia and Gonorrhea Panel

Result Summary

Organism(s)	Patient Result	Reference Range
Neisseria gonorrhoeae	**Detected**	Not Detected

Lab Comment:

Limitations

Negative results do not preclude infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Positive results do not rule out infection, or co-infection with other pathogens not on our panel. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence and radiography) and clinical presentation must be taken into consideration in the final diagnosis.

The following organisms and resistance genes were tested using this Chlamydia and Gonorrhea Panel test and are **NOT DETECTED**

Organism(s)	Patient Result	Reference Range
Bacteria		
Chlamydia trachomatis	Not Detected	Not Detected
	Not Detected	Not Detected

Calling Notes:

Methodology and Intended Use

Real-Time PCR was performed on genomic DNA extractions using the King Fisher and analyzed on a QuantStudio 7 and 12 Flex Platform. Data was obtained for each assay to detect species specific sequences within a sample, During amplification, sequence specific oligonucleotides probes (dually labeled with a fluorophore and quencher) hybridize to a specific DNA template. The 5'-3' exonuclease activity of DNA polymerase during elongation cleaves the fluorophore from being quenched on the oligonucleotide probe, causing the fluorophore to be excited; emitting fluorescence. The accumulation of fluorescence for each sample, in each well is measured by the instrument software during each cycle of amplification, directly corresponding to amplification of target sequence. The Applied Biosystems™ QuantStudio 7 and 12 Flex system software analyzes the data generated, producing quality scores and confidence values for each assay in each well, for each sample. The Applied Biosystems ™ QuantStudio 7 and 12 Flex system software provides a qualitative and quantitative result, the presence or absence of the pathogens or drug resistance markers contained in the panel, along with the internal controls, based upon whether the amplification is above or below the threshold of detection, in conjunction with the quality and confidence values.

The detection and identification of specific pathogens and drug resistance markers from individuals exhibiting signs and symptoms of an infection. This test aids in the diagnosis of STI if used in conjunction with other clinical and epidemiological information. This test is a Laboratory Derived (LDT) qualitative nucleic acid multiplex diagnostic test intended for use on an Applied Biosystems ™ QuantStudio 7 and 12 Flex Real-Time PCR System for the simultaneous detection and identification of multiple pathogen nucleic acids in STI samples obtained from individuals exhibiting signs and symptoms of an STI.