



LAB INFORMATION	PATIENT INFORMATION	SPECIMEN INFORMATION
Name: Precision Health Solutions Address: 9675 4th St N St Petersburg, FL 33702 Phone: 727-235-0886 Fax: 833-288-9397 Medical Director: Fatemeh Mousavi, MD CLIA: 10D2181177	Patient: Mickey Mouse DOB: 04/03/1995 Age: 28 Years Gender: Male Patient Address: 123 Main Street City: Toontown State: FL Zipcode: 33659	Acc #: D232780002 Doctor: Donald Duck Facility: Toontown Medical Clinic Provider: Donald Duck Collection Date: 1/29/2024 Received in Lab: 1/29/2024 Resulted Date: 1/29/2024 Specimen Type: Genital Swab

STI Ulcer Panel

Result Summary

Organism(s)	Patient Result	Reference Range
Human herpes virus I	Detected	Not Detected
Human herpes virus II	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. The organism(s) detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, and immunofluorescence) and clinical presentation must be taken into consideration in the final diagnosis. A false negative result may occur if a specimen is improperly collected, transported, or handled. False negative results may also occur if amplification inhibitors are present in the specimen.



The following organisms and resistance genes were tested using this STI Ulcer Panel panel test and are **NOT DETECTED**

Organism(s)	Patient Result	Reference Range
Bacteria		
Treponema pallidum	Not Detected	Not Detected
Virus		

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.