

Application Brief

Women's Health Sexually Transmitted Infections Panel

Unique All-In-One-Well Detection and Differentiation of Multiple Sexually Transmitted Infectious Agents

INTRODUCTION

Sexually Transmitted Infections (STI) can be caused by multiple pathogens including bacteria, viruses, fungi, and parasites. Detecting multiple different classes of microbes in a single well by real-time PCR can be challenging due to variations in sensitivity and reliability. The high multiplexing capabilities of the ICEPlex® system allows inclusion of crucial calibration standards for quantitation and internal controls for the process quality to allow different classes of pathogens to be detected reliably in a single PCR reaction.

The PrimeraDx Women's Health STI Panel was designed to detect:

- *Candida albicans*
- *Candida glabrata*
- *Neisseria gonorrhoeae*
- *Chlamydia trachomatis*
- *Trichomonas vaginalis*
- Herpes Simplex Virus type 1 (HSV-1)
- Herpes Simplex Virus type 2 (HSV-2)

SUMMARY

- Simultaneously detects multiple microbial targets belonging to different classes: virus, fungi, bacteria, and parasites.
- Accurately differentiates HSV-1 from HSV-2.
- Significantly reduces the turnaround time & cost of testing patient samples by combining multiple targets in a single PCR reaction.
- Expedites sample turn-around time to less than 4 hours.

METHOD HIGHLIGHTS

1. Primers were designed using PrimeraDx's exclusive strategy that can selectively amplify unique genomic region for each target in the panel. One of the primers in each primer set was labeled with either FAM- or TYE- dye.
2. Purified microbial genomic DNAs from a commercial source and a small number of clinical isolates were used to generate proof of concept data.
3. The Internal Control served as whole process control.
4. Multiplex PCR reactions were subjected to thermocycling in a standard 96-well PCR plate on the ICEPlex system.
5. Fluorescently labeled amplicons were then automatically injected, separated and detected in the capillary electrophoresis module of the ICEPlex system.
6. Amplification curves for all targets and controls were generated automatically by the ICEPlex software and cycle thresholds (Cts) were calculated.



TYPICAL DATA

The data demonstrated the ability of the Women's Health STI Panel of PrimeraDx to simultaneously detect and differentiate all seven STI-specific targets in one PCR reaction on the ICEPlex system. The results from the tests on ICEPlex system were automatically generated and reported after the end of the run.

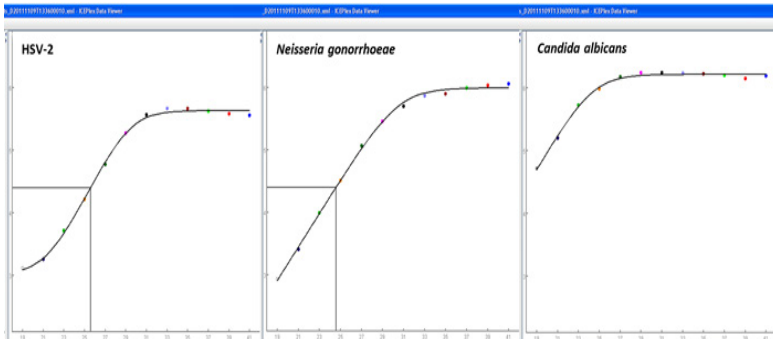


Figure 1. Representative amplification curves for 3 of the Women's Health STI Panel targets on ICEPlex system

		<i>Candida albicans</i>	<i>Candida glabrata</i>	<i>Neisseria gonorrhoeae</i>	<i>Chlamydia trachomatis</i>	<i>Trichomonas vaginalis</i>	HSV-1	HSV-2
Sample 1	Ct							25.2
	Result	No	No	No	No	No	No	Detected
Sample 2	Ct			24.6				
	Result	No	No	Detected	No	No	No	No
Sample 3	Ct	17.9						
	Result	Detected	No	No	No	No	No	No

Table 1. Representative results for three samples on ICEPlex system.

FOR MORE INFORMATION

To find out more about how PrimeraDx can help your lab, please contact us at 508.618.2300 or www.primeradx.com.

The ICEPlex system and ICEPlex Sexually Transmitted Infections Panel are for Research Use Only and have not been approved for in vitro diagnostic use by the FDA. The presented information is for demonstration purposes only.