



In recent years, infectious diseases have become more prevalent, more severe, and more difficult to treat. More often, researchers and clinicians are interested in testing for many pathogens at the same time, and increasingly, they want a quantitative answer. Using the ICEPlex® System, researchers can assay multiple pathogens from the same sample, and receive a qualitative or even a quantitative answer, depending on the application. PrimeraDX can support clinical labs using the ICEPlex System by combining and expanding pathogen assays into a custom panel or Laboratory-Developed Test (LDT).

Multiple Answers In Less Than 4 Hours

- Detection, differentiation, and quantification of multiple targets in a single reaction
- Proven performance on sensitivity and specificity
- Internal controls, DNA quality control and extraction control included in every assay
- Less hands-on time reduces errors and streamlines lab operation
- Expedited turn-around-time to less than 4 hours

The ICEPlex Solution

PrimeraDx has developed a unique platform for detection, differentiation and quantification of multiplexed targets with high specificity and sensitivity from a range of infectious agents. The advanced capabilities of the ICEPlex system allow researchers to get more information from each sample by combining diverse assays in a single well. The combination of PCR and Capillary Electrophoresis enables simultaneous identification and quantitative measurement of pathogen presence along with viability in a rapid assay. The ICEPlex system allows researchers to combine a wide spectrum of assay types into a single test, including:

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| <ul style="list-style-type: none">• Pathogen detection• Strain typing | <ul style="list-style-type: none">• Pathogen quantification• Bacterial viability | <ul style="list-style-type: none">• Drug resistance• Host genetic susceptibility |
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Wide Range of Capabilities Proven Through Customer Collaborations*

We have collaborated with researchers and reference labs to demonstrate the capabilities of the ICEPlex System in pathogen detection and quantification applications including identification of variant strains and drug resistant pathogens.

***Clostridium difficile* Assay**

The *C. difficile* assay targets sites on the toxin B gene. PrimeraDx is conducting a controlled multi-site clinical trial for ICEPlex *C. difficile* assay on the ICEPlex System to offer the accuracy of real-time PCR with the time and cost savings of multiplex technology. At this time, however, the ICEPlex *C. difficile* assay remains for research use only.

Women's Health STI Panel

By taking advantage of the high multiplex capability of the ICEPlex System, we have shown simultaneous detection and discrimination of seven pathogens (two bacteria, two yeasts, two viruses and one parasite) from the same sample in a single well. The PrimeraDx STI panel was able to detect:

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

PrimeraDx has developed a unique platform for detection and differentiation of fungal infectious agents with high specificity and sensitivity. We collaborated to develop a demonstration panel, which simultaneously detects and differentiates nine major fungal pathogens in a single reaction including calibrators and controls. Mitochondrial, ribosomal, and multi-locus genomic sequences are targeted to enhance sensitivity.

- *Candida albicans*
- *Candida tropicalis*
- *Aspergillus flavus*
- *Candida krusei*
- *Candida glabrata*
- *Aspergillus fumigatus*
- *Candida parapsilosis*
- *Cryptococcus neoformans*
- *Aspergillus niger*

Transplant Viral Panel

The PrimeraDx Transplant Viral demonstration panel was developed to quantitate the following viral targets in a single well:

- Cytomegalovirus (CMV)
- Human Herpes virus 6 (HHV-6)
- Epstein-Barr Virus (EBV)
- BK Virus (BKV)
- Human Herpes virus 7 (HHV-7)

Many of these panels will be available as kitted RUO products in the future. Find out more about how we can help you advance your infectious disease research by visiting www.PrimeraDx.com.

*The ICEPlex system and all collaborative panels are for Research Use Only and have not been approved for in vitro diagnostic use by the FDA.