

**NEW!**

# Culture Testing Now Available!

Culture testing is widely considered to be the “gold standard” for diagnosis of tick-borne illnesses. For many years, tick-borne disease cultures were too expensive and tedious to be practical for laboratory use. Until now. After many years of research and development, IGeneX is pleased to introduce cePCR™ (Culture-Enhanced PCR) for all of the major tick-borne illnesses. IGeneX is currently the only lab that can culture all of the major tick-borne illnesses.

## Advantages of Culture-Enhanced PCR (cePCR)

- Provides higher sensitivity than standard PCR testing
- The only 100% specific method for identification of a tick-borne disease.
- Available for seven tick-borne diseases: Lyme disease, Tick-Borne Relapsing Fever, Bartonella, Babesia, Anaplasma, Ehrlichia, and Rickettsia
- Obtaining cultures before antibiotic use improves the chances of identifying the offending microorganism, which improves patient care.

## HOW cePCR WORKS?

In culturing, a clinical sample from the body (e.g. blood) is incubated in media. During this incubation period, micro-organisms in the sample grow and multiply. The sample is then tested by PCR to identify the pathogens.



### Step 1

An aliquot of whole blood is placed into a proprietary culture media.



### Step 2

The culture media is incubated for several days.



### Step 3

PCR tests are performed on the cultured samples.

# cePCR VALIDATION STUDIES

During the development of cePCR, IGeneX performed two validation studies that verified the accuracy of the test.

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## Real-time PCR followed by sequencing

IGeneX cultured 1200 samples for two weeks. 57 samples were positive, spread across six diseases listed in the table below. The 57 samples were then sent for DNA sequencing to confirm the species. Some of the species that were detected, such as *A. platys*, are rarely found in the US, and likely would not be detected with traditional PCR.

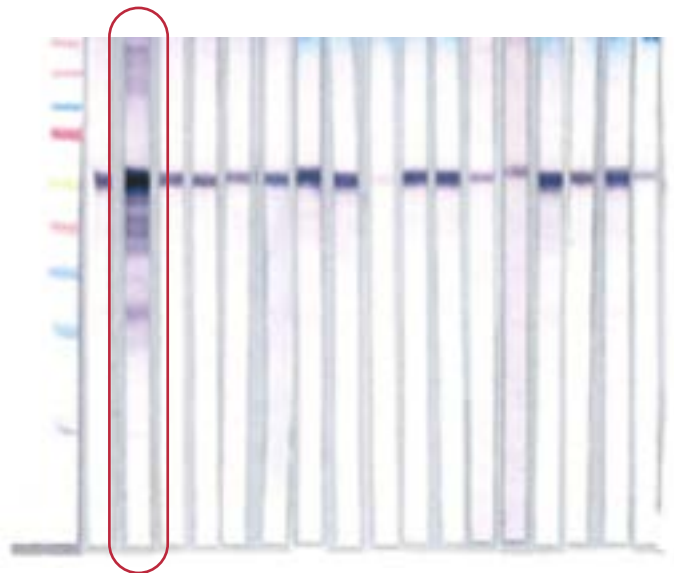
### Total Samples Tested (1200) – 58 Samples Positive

	Positive	Species (based on sequence analysis)
Lyme Borreliae	23	17 <i>B. burgdorferi</i>
		2 <i>B. garinii</i>
		4 <i>B. mayonii</i>
Relapsing Fever Borreliae	5	4 <i>B. miyamotoi</i>
		1 <i>B. miyamotoi</i>
Babesia	20	12 <i>B. microti</i>
		7 <i>B. duncani</i>
		1 <i>Babesia sp.</i>
Bartonella	7	5 <i>B. henselae</i>
		1 <i>B. elizabethae</i>
		1 <i>B. tribocrum</i>
Anaplasma	2	1 <i>A. phagocytophilum</i>
		1 <i>A. platys</i>
Samples	57	4.75%

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## Reverse Western blotting using pathogen-specific antibodies

IGeneX cultured patients' blood for 16 weeks and prepared Western blots from the culture pellets. The blots were tested against antibodies to four tick-borne disease groups: Lyme disease, Tick-Borne Relapsing Fever, Babesia, and Bartonella. The blot below clearly shows the detection of a pathogen.



## HOW TO ORDER cePCR TEST PANELS?

Patients can culture each disease separately, or choose between three test panels.

- ◆ **Borreliosis cePCR Test Panel**  
Includes two-week culture, plus real-time PCR for Lyme and TBRF.
- ◆ **Co-infection cePCR Test Panel**  
Includes two-week culture, plus real-time PCR for Babesia, Bartonella, HME, HGA, and Rickettsia.
- ◆ **Tick-Borne Disease cePCR Test Panel**  
Includes two-week culture, plus real-time PCR for Lyme, TBRF, Babesia, Bartonella, HME, HGA, and Rickettsia.

## SENSITIVITY AND SPECIFICITY

- ◆ **Sensitivity**
  - IGeneX was able to grow multiple pathogens in culture
  - If a pathogen grows in culture, it is guaranteed to be active and not a remnant of a pathogen
- ◆ **Specificity**
  - All sequencing results matched the initial PCR determination
  - All reverse western blots matched exactly the results of sequencing