



Recommendations for Use Bartonella ePCR™

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The following test protocol for *Bartonella* spp. infections was developed by our Chief Medical Officer, Dr. B. Robert Mozayeni, based on his direct and independent clinical experience in the diagnosis and management of *Bartonella* spp. infection in human patients with chronic symptoms. The protocol was reviewed and approved by our Chief Scientific Officer, Dr. Edward B. Breitschwerdt, based on his direct and independent clinical experience in veterinary medicine and research on human *Bartonella* spp. infection.

	Triple Blood Draw Bartonella ePCR™	Bartonella IFA Titers
Pre-Treatment	<u>Triple Blood ePCR</u> To confirm active infection by presence of <i>Bartonella</i> spp. DNA	<u>IFA Serology, IgG (Bh, Bq)</u> To provide baseline antibody titers for later evaluation of antibody response; to confirm exposure, if ePCR negative
During Treatment, every 1-2 months	<u>Triple Blood ePCR</u> To detect potential resistance to antibiotic regimen	<u>IFA Serology, IgG (Bh, Bq)</u> To monitor possible seroconversion or increase of titers for confirmation of treatment response
After Treatment, 1, 3 and 6 months post-treatment	<u>Triple Blood ePCR</u> To detect relapse early	<u>IFA Serology, IgG (Bh, Bq)</u> To detect relapse early

Pretreatment: Bartonella ePCR Triple Draw plus Bartonella IFA Serology

All Galaxy Diagnostics ePCR results are confirmed by DNA sequencing, thus, a positive ePCR result confirms the presence of *Bartonella* DNA in the patient sample tested. Post-enrichment PCR positive would be most consistent with active infection. *Bartonella* DNA amplified from original sample could reflect dead bacteria secondary to antibiotic administration as it is not known how long DNA amplification will remain positive after treatment is started.

Negative results do not rule out a diagnosis of bartonellosis and should not over-ride clinical suspicion.

Titers for Bartonella IFA serology should be obtained to establish baseline for possible seroconversion during antibiotic treatment.

During treatment: Bartonella IFA Serology.

Positive antibody titers may develop during treatment if negative prior to starting antibiotics. *Bartonella* antibodies tend to increase (within weeks to months) in patients after starting antibiotic treatment for the infection as immune system recovers. During treatment, increasing or persistent antibody titers do not indicate active or persistent infection.

Mid-treatment: Bartonella ePCR Single Draw

If ePCR positive, it may be necessary to add an additional antibiotic or change antibiotics.

Post-treatment: Bartonella ePCR Triple Draw

Test by Bartonella ePCR™ at 1, 3 and 6 months after end of treatment, or upon recurrence of symptoms. Post-treatment testing is recommended to support therapeutic elimination of the infection. Most patients successfully eliminate *Bartonella* spp. infections with antibiotic treatment. However, a subset of patients for reasons that remain unclear, suppress the infection and do not eliminate the infection. After treatment, antibody titers may persist or decline gradually and should not be relied upon as an indication of recurrence or persistence.

Antibiotic Administration and Bartonella ePCR™ Testing

When contemplating a diagnosis of bartonellosis, testing for *Bartonella* spp. infections in blood, cerebrospinal fluid or joint fluids, pathological effusions or aseptically-obtained tissue biopsies using the Bartonella ePCR should be requested prior to administration of a long duration antibiotic course.

Because bartonellosis is an emerging infectious disease for which standardized treatment regimens have not been validated, it is important that the patient's infection be confirmed by Bartonella ePCR or the diagnosis be supported by IFA serology.

For patients who are already being treated with antibiotics, there are two options:

- 1) Proceed with testing as antibiotic therapy may increase the likelihood of detecting *Bartonella* spp. DNA in the blood or serum. However, concurrent administration of antibiotics may suppress bacterial growth, thereby decreasing the likelihood that the enrichment blood culture will be PCR *Bartonella* positive.
- 2) If the physician elects to do so, stop antibiotics for a period of time (at least two weeks is recommended) prior to obtaining patient samples for Bartonella ePCR testing.

For other questions relative to the timing or submission of samples for Bartonella ePCR and IFA serology, contact Galaxy Diagnostics at www.galaxydx.com.