TBE Tick-Borne Ehrlichiosis Panel by rPCR - Qual

GA Test Code	**8425**
Method	Real-Time Polymerase Chain Reaction (rPCR) – Qualitative
PCR Targets	▸ ***Anaplasma phagocytophilum*** ▸ ***Ehrlichia chaffeensis*** ▸ ***Ehrlichia ewingii/canis*** ▸ ***Ehrlichia muris*-like** **Note:** The DNA detected from *E. ewingii* and *E. canis* cannot be reliably differentiated by this test. A result of "Detected" for *Ehrlichia ewingii/canis* indicates the presence of either of these two organisms in the specimen.
Specimens	**Whole Blood (ACD or EDTA)**: 1.0 (min 0.5) mL, ambient (4 days), refrigerated (7 days). **CSF**: 1.0 (min 0.5) mL, refrigerated (7 days) or frozen (90 days).
Causes for Rejection	Quantity not sufficient (QNS); time/temperature instructions not followed.
Reference Range	Not Detected
Turnaround Time	24-48 hours
CPT Codes	87798

Description

This test was developed and its performance characteristics determined by Genetic Assays. It has not been cleared nor approved by the U.S. FDA. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Genetic Assays is certified under CLIA as qualified to perform high-complexity testing.This assay uses real-time polymerase chain reaction (rPCR) for the simultaneous and multiplex amplification and detection of the DNA of the following causative pathogens of tick-borne disease (i.e. Anaplasmosis or Ehrlichiosis): *Anaplasma phagocytophilum, Ehrlichia chaffeensis, Ehrlichia ewingii/canis, Ehrlichia muris*-like.

Clinical Utility

Ehrlichia and *Anaplasma* species are tick-borne obligate intracellular bacteria that cause clinically similar febrile disease in humans and domestic animals. In the United States, ehrlichiosis is most commonly caused by *E. chaffeensis*, and to a much lesser extent *E. ewingii*. Infections from *E. canis* and *E. muris*-like subtypes are not as common and seem to be geographically isolated. Anaplasmosis is caused by *Anaplasma phagocytophilum* infecting granulocytes. Anaplasmosis is more common in the upper midwest and northeastern U.S., whereas ehrlichiosis is more common in the southeastern and south-central U.S. These areas correspond with the known geographic range of the host tick, the Lone Star tick *(Amblyomma americanum)*.

PCR has emerged as the the best way to diagnose and ascertain the cause of ehrlichiosis and anaplasmosis. A "Detected" PCR result for any target indicates the presence of the respective organism in the specimen. A "Not Detected" PCR result indicates that target's DNA was below detectable levels or not present in the specimen, but it does not completely rule out infection with these or other non-target pathogens.

www.cdc.gov/ticks/diseases/index.html

Genetic Assays, Inc.

4711 Trousdale Drive, Ste 209 • Nashville, TN 37220 • (615) 781-0709 • (800) 390-5280 • FAX (615) 781-0766

www.geneticassays.com