Toxoplasma gondii Quantitative Real-time PCR

Test Code: 2200

Clinical and Procedure

Clinical Utility
Toxoplasma gondii is highly problematic when primary infection occurs during the first trimester of pregnancy, often leading to fetal death or when reactivation occurs in immunocompromised patients, leading to life-threatening disease including encephalitis and extracerebral toxoplasmosis. Onset of disease in most patients is preceded by an increase in parasite load. Monitoring blood levels of Toxoplasma gondii DNA correlates well with treatment.

Procedure
Extraction of Toxoplasma gondii DNA from specimen followed by amplification and detection using real-time, quantitative PCR. An internal control is added to ensure the extraction was performed correctly and the PCR reaction was not inhibited. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Specificity
The primers and probes used in this assay are specific for known Toxoplasma gondii strains based on similarity search algorithms. Additionally, no cross reactivity was detected with any viral or protozoa pathogens.

Turnaround Time
Same day (within 8 - 12 hours from receipt of specimen), Monday through Saturday.

Specimen Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>amniotic fluid</td>
<td>2207</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>266 copies/mL to 1x10^8 copies/mL</td>
</tr>
<tr>
<td>aqueous fluid</td>
<td>2245</td>
<td>87799</td>
<td>Yes</td>
<td>1 mL (min. 0.05 mL)</td>
<td>1,423 copies/mL to 1x10^8 copies/mL</td>
</tr>
<tr>
<td>BAL</td>
<td>2209</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>212 copies/mL to 1x10^8 copies/mL</td>
</tr>
</tbody>
</table>

Special Instructions
- Collect 2 mL in sterile, screw top tube.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped ambient temperature must be received within 96 hours of collection.

- Transfer collected amount to sterile, screw top tube for shipment.
- Do not add water, saline or other fluid media to container.
- Do not ship specimen in syringe.
- Store frozen and ship on dry ice.

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</thead>
<tbody>
<tr>
<td>bronch wash</td>
<td>2226</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>212 copies/mL to $1 \times 10^8$ copies/mL</td>
</tr>
<tr>
<td>CSF</td>
<td>2203</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>$183$ copies/mL to $1 \times 10^8$ copies/mL</td>
</tr>
<tr>
<td>pericardial fluid</td>
<td>2212</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>$266$ copies/mL to $1 \times 10^8$ copies/mL</td>
</tr>
<tr>
<td>pleural fluid</td>
<td>2211</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>$266$ copies/mL to $1 \times 10^8$ copies/mL</td>
</tr>
<tr>
<td>trach asp</td>
<td>2219</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>$212$ copies/mL to $1 \times 10^8$ copies/mL</td>
</tr>
<tr>
<td>trach wash</td>
<td>2248</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>$212$ copies/mL to $1 \times 10^8$ copies/mL</td>
</tr>
<tr>
<td>vitreous fluid</td>
<td>2214</td>
<td>87799</td>
<td>Yes</td>
<td>1 mL (min. 0.05 mL)</td>
<td>$1,423$ copies/mL to $1 \times 10^8$ copies/mL</td>
</tr>
<tr>
<td>whole blood</td>
<td>2216</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>$376$ copies/mL to $1 \times 10^8$ copies/mL</td>
</tr>
</tbody>
</table>

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- Specimens shipped at ambient temperature must be received within 96 hrs. of collection.

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- Collect in EDTA tube.

- Transfer collected amount to sterile, screw top tube for shipment.
- Do not add water, saline or other fluid media to container.
- Do not ship specimen in syringe.
- Store frozen and ship on dry ice for overnight delivery.
Specimen Type | Order Code | CPT Code | NY Approved | Volume | Assay Range
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- Specimens shipped at ambient temperature must be received within 7 days of collection.

**Shipping**
Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086

**Causes for Rejection**
Specimens beyond their acceptable length of time from collection as listed in the specimen handling, specimens received in trap containers or specimen types other than those listed.

**Disclaimer**
Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.