SUMMARY AND EXPLANATION OF THE TEST

Glial Fibrillary Acidic Protein (GFAP) is a class-III intermediate filament majorly expressed in astrocytic glial cells in the central nervous system. Astrocytes play a variety of key roles in supporting, guiding, nurturing, and signaling neuronal architecture and activity. Monomeric GFAP is about 55kD. It is capable of forming both homodimers and heterodimers; GFAP can polymerize with other type III proteins or with neurofilament protein (such as NF-L). GFAP is involved in many important CNS processes, including cell communication and the functioning of the blood brain barrier. GFAP, as a potential biomarker has been shown to associate with multiple diseases such as traumatic brain injury, stroke, brain tumors, etc. Decreases in GFAP expression have been reported in Down’s syndrome, schizophrenia, bipolar disorder, and depression.

Healthy donors

Table 1: General characteristics of Simoa Human GFAP immunoassay

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration range</td>
<td>0-1,000 pg/mL</td>
</tr>
<tr>
<td>Dynamic range</td>
<td>0-4,000 pg/mL</td>
</tr>
<tr>
<td>Lower limit of detection</td>
<td>0.211 pg/mL</td>
</tr>
<tr>
<td>Lower limit of quantification</td>
<td>0.686 pg/mL</td>
</tr>
<tr>
<td>Spike-recovery (serum/plasma)</td>
<td>92.8%</td>
</tr>
<tr>
<td>Dilution Linearity (serum)</td>
<td>106.2%</td>
</tr>
<tr>
<td>Dilution Linearity (CSF)</td>
<td>90.1%</td>
</tr>
<tr>
<td>Typical sample volume – serum/plasma</td>
<td>46 µL</td>
</tr>
<tr>
<td>Minimum sample volume – serum/plasma</td>
<td>3 µL</td>
</tr>
<tr>
<td>Sample volume – CSF</td>
<td>4.6 µL</td>
</tr>
</tbody>
</table>

Table 2: Precision characteristics of Simoa Human GFAP immunoassay. Representative precision was estimated with repeated assay of serum panels using three instruments and one reagent lot. Within-run and between-run CVs are depicted in the following table. Within-run CVs reflect average CVs across 5 experiments of 3 replicates each.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean GFAP (pg/mL)</th>
<th>Within Run %CV (n=5)</th>
<th>Between Run %CV (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum panel 1</td>
<td>31.75</td>
<td>6.3</td>
<td>5.7</td>
</tr>
<tr>
<td>Serum panel 2</td>
<td>317.6</td>
<td>10.9</td>
<td>13.0</td>
</tr>
<tr>
<td>Serum panel 3</td>
<td>2,282</td>
<td>8.2</td>
<td>13.6</td>
</tr>
</tbody>
</table>

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