BioProfile FLEX Verification Material

LEVEL 11

IgG

Lot. No. 18275047  Exp. Date 2019-10

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Constituent</th>
<th>Parameter</th>
<th>Units</th>
<th>Mean</th>
<th>Expected Range</th>
<th>Units</th>
<th>Mean</th>
<th>Expected Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioProfile FLEX</td>
<td>IgG</td>
<td>mg/mL</td>
<td>3.07</td>
<td>2.46-3.68</td>
<td>g/L</td>
<td>3.07</td>
<td>2.46-3.68</td>
<td></td>
</tr>
</tbody>
</table>

Product Information

NOVA BIOPROFILE FLEX VERIFICATION MATERIAL – An assayed aqueous material intended for verifying the measurement of IgG on the BioProfile Flex Analyzer only.

Ingredients: These controls are formulated from a buffered aqueous solution, each with a known amount of human polyclonal IgG. Follow standard laboratory procedures for handling such materials.

Level 10  Catalog No. 48942
Level 11  Catalog No. 48943

Storage: Material must be stored at 2-8°C. Each level has a lot number and expiration date printed on the label.

Directions for Use: Gently invert the bottle two times before dispensing material. Remove cap. Dispense material into sample cups or micro centrifuge tubes for analysis.

Assigned Values: The EXPECTED RANGE for each analyte was determined at Nova by performing multiple determinations on multiple instruments using multiple runs of each level of verification material. The EXPECTED RANGE indicates the maximum deviations from the mean value which may be expected under differing laboratory conditions from instruments which are operating according to specifications. Users may wish to determine MEAN VALUES and EXPECTED RANGES in their own laboratory. Please verify that the lot number appearing on the Assay Data Sheet agrees with the lot number appearing on the material being analyzed.

Limitations: The values appearing in the Assay Data Table are specific for instruments and reagents manufactured by Nova Biomedical.