Luminex® Performance Assay
Human C-Reactive Protein/CRP Kit

Catalog Number: LUCB1707
Pack Size: 100 Tests

SPECIFICATIONS AND USE

Recommended Sample Types
- Serum, plasma, and platelet-poor plasma.

Microparticle Region
- Region-04

Components
- Microparticle Concentrate (Part 893989) is supplied as a 100X concentrated stock (0.075 mL) with preservatives.
- Biotin-Antibody Concentrate (Part 893992) is supplied as a 100X concentrated stock solution (0.075 mL) with preservatives.

Other Supplies Required
- Luminex Performance Assay Human Cardiac Base Kit B (Catalog Number LUCB000).

Storage
- Store the unopened kit at 2-8 °C. Do not use past the expiration date on the label.
- Avoid freezing microparticles.
- Protect microparticles from light.

Instructions for Use
- Refer to the Base Kit insert for the Luminex Performance Assay procedure.

TYPICAL DATA

This human CRP standard curve is provided only for demonstration. A standard curve must be generated each time an assay is run, utilizing values from the Standard Value Card included in the Base Kit.

![Human CRP Standard Curve](image)

<table>
<thead>
<tr>
<th>Standard</th>
<th>pg/mL</th>
<th>MFI</th>
<th>Average</th>
<th>Corrected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blank</td>
<td>0</td>
<td>10.0</td>
<td>10.0</td>
<td>—</td>
</tr>
<tr>
<td>1</td>
<td>105,000</td>
<td>7436</td>
<td>7604</td>
<td>7594</td>
</tr>
<tr>
<td>2</td>
<td>35,000</td>
<td>4968</td>
<td>4977</td>
<td>4967</td>
</tr>
<tr>
<td>3</td>
<td>11,667</td>
<td>2094</td>
<td>2122</td>
<td>2112</td>
</tr>
<tr>
<td>4</td>
<td>3889</td>
<td>620</td>
<td>629</td>
<td>619</td>
</tr>
<tr>
<td>5</td>
<td>1296</td>
<td>187</td>
<td>194</td>
<td>184</td>
</tr>
<tr>
<td>6</td>
<td>432</td>
<td>66.3</td>
<td>69.3</td>
<td>59.3</td>
</tr>
<tr>
<td>7</td>
<td>144</td>
<td>28.8</td>
<td>29.1</td>
<td>19.1</td>
</tr>
</tbody>
</table>

PERFORMANCE CHARACTERISTICS

All data were collected with assays run as a multiplex.

Sensitivity - The Minimum Detectable Dose (MDD) was determined by adding two standard deviations to the mean MFI of twenty zero standard replicates and calculating the corresponding concentration.

Twenty-six assays were evaluated, and the MDD of human CRP ranged from 7.68-39.0 pg/mL. The mean MDD was 14.7 pg/mL.
Samples were spiked with natural or recombinant human CRP and evaluated for recovery and were serially diluted to evaluate assay linearity.

Recovery and Linearity - Samples were spiked with natural or recombinant human CRP and evaluated for recovery and were serially diluted to evaluate assay linearity.

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Recovery</th>
<th>Linearity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>102</td>
<td>88-115</td>
</tr>
<tr>
<td>EDTA plasma</td>
<td>92</td>
<td>90-95</td>
</tr>
<tr>
<td>Heparin plasma</td>
<td>93</td>
<td>85-100</td>
</tr>
<tr>
<td>Platelet-poor EDTA plasma</td>
<td>97</td>
<td>91-104</td>
</tr>
<tr>
<td>Platelet-poor heparin plasma</td>
<td>97</td>
<td>94-98</td>
</tr>
</tbody>
</table>

Intra-assay Precision (precision within an assay) - Three samples of known concentration were tested twenty times on one plate to assess precision within an assay.

Inter-assay Precision (precision between assays) - Three samples of known concentration were tested in fifty-three separate assays to assess precision between assays.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Intra-assay Precision</th>
<th>Inter-assay Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>n</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Mean (pg/mL)</td>
<td>834</td>
<td>2090</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>540</td>
<td>138</td>
</tr>
<tr>
<td>% CV</td>
<td>6.5</td>
<td>6.6</td>
</tr>
</tbody>
</table>

Recovery
- Three samples of known concentration were tested in fifty-three separate assays.
- Three samples of known concentration were tested twenty times on one plate.
- The average recovery was calculated for each sample type.
- The range of recovery values was calculated for each sample type.

Linearity
- The range of linearity was calculated for each sample type.
- The average % of Expected was calculated for each sample type.

Specificity - This assay recognizes natural and recombinant human CRP. The assay was tested for cross-reactivity and interference with the following factors. Less than 0.5% cross-reactivity and interference was observed.

Recombinant human:
- Cathepsin A
- Cathepsin B
- Cathepsin C
- Cathepsin D
- Cathepsin E
- Cathepsin F
- Cathepsin G
- Cathepsin H
- Cathepsin L
- Cathepsin M
- Cathepsin N
- Cathepsin O
- Cathepsin P
- Cathepsin Q
- Cathepsin R
- Cathepsin S
- Cathepsin T
- Cathepsin U
- Cathepsin V
- Cathepsin W
- Cathepsin X
- Cathepsin Y
- Cathepsin Z

Recombinant mouse:
- MPO
- P-Selectin/CD62P
- Serpin A1
- Serpin A2
- Serpin A3
- Serpin A4
- Serpin A5
- Serpin A6
- Serpin B1
- Serpin B2
- Serpin B3
- Serpin B4
- Serpin B5
- Serpin B6
- Serpin C1
- Serpin C2
- Serpin C3
- Serpin C4
- Serpin D1
- Serpin D2
- Serpin D3
- Serpin D4
- Serpin E1
- Serpin E2
- Serpin E3
- Serpin F1
- Serpin F2
- Serpin F3
- Serpin F4
- Serpin F5
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- Serpin FD
- Serpin FE
- Serpin FF
- Serpin FG
- Serpin FH
- Serpin FI
- Serpin FJ
- Serpin FK
- Serpin FL
- Serpin FM
- Serpin FN
- Serpin FO
- Serpin FP
- Serpin FQ
- Serpin FR
- Serpin FS
- Serpin FT
- Serpin FU
- Serpin FV
- Serpin FW
- Serpin FX
- Serpin FY
- Serpin FZ

Natural proteins:
- human Vitronectin

Recombinant human multiplex partners:
- Cystatin C
- MPO
- P-Selectin/CD62P
- Serpin E1/PAI-1

Technical Hints
- Protect the microparticles and streptavidin-PE from light at all times.
- Refer to the appropriate Base Kit Standard Value Card for reconstitution volume and value of the reconstituted standard.
- Diluted microparticles cannot be stored. Make a fresh dilution of microparticles each time the assay is run.
- The use of a vacuum manifold device made to accommodate a microplate is necessary for washing. Adjust the vacuum on the plate washer to between 15 and 40 cm Hg.
- Discrepancies may exist in values obtained for the same analyte utilizing different technologies.

Luminex Performance Assays afford the user the benefit of multianalyte analysis of cytokines in a complex sample. For each sample type, a single, multipurpose diluent is used to optimize recovery, linearity, and reproducibility. Such a multipurpose, single diluent may not optimize any single analyte to the same degree that a unique diluent selected for analysis of that analyte can optimize conditions. Therefore, some performance characteristics may be more variable than those for assays designed specifically for single analyte analysis.

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