

### Intended Use

These C-Reactive Protein Controls are intended for use in C-Reactive Protein (High Sensitivity) Wide Range test systems to validate performance of the assay. The controls may also be useful in assessing test precision or analytical errors.<sup>2</sup> For in vitro diagnostic use only.

### Test Summary

C-reactive protein (CRP) is described in the literature as an acute phase protein that is involved in the activation of complement, acceleration of phagocytosis, and detoxification of substances released from damaged tissue. CRP is one of the most sensitive indicators of inflammation.<sup>1</sup>

In response to an inflammatory stimulus, a rise in CRP may be detected within 6 hours. CRP is a sensitive, non-specific indicator of acute phase reactants. The level of CRP in serum is elevated in patients with arthritis or liver disease such as hepatitis B, or biliary cirrhosis, and after severe infections such as septic shock.

The CRP-HS Wide Range is intended for the quantitative determination of human CRP by latex particle enhanced immunoturbidimetric assay (ITA). ITA methods for the quantitative determination of antibody and antigen immunoprecipitation complexes have been described.<sup>1</sup>

### Reagents

Human serum containing buffers, stabilizers and fillers.

Two levels of the control are provided. Assay values are listed on the vial label.

### Precautions

Human serum was used to manufacture this product. Each donor unit was tested and found negative for HbsAg and HCV and non-reactive for HIV-1/2 antibody. Since no test method can assure that products derived from human blood do not contain HIV-1/2 and Hepatitis B and Hepatitis C viruses, these controls should be handled as though capable of transmitting infectious diseases.

Good laboratory safety practices should be followed when handling any laboratory reagent. Refer to a recognized laboratory safety program for additional information. (See NCCLS document GP17-T, Clinical Laboratory Safety; Tentative Guideline, 1994)

### Materials Provided

#### CRP Control Set (6 x 3mL)

|                        |          |
|------------------------|----------|
| CRP Control – Level I  | 3 x 3 mL |
| CRP Control – Level II | 3 x 3 mL |

### Directions For Use

1. Controls are liquid stable, ready to use.
2. For assay use, remove a suitable aliquot of control for the instrumentation used; cap and refrigerate the vial.

DO NOT dilute these controls. Results from diluted controls will not correspond to the original value in a linear manner.

### Stability and Storage

Unopened, the C-reactive protein Controls are stable until the expiration date listed on the vial if stored at 2-8°C. After opening the controls are stable for 30 days at 2-8°C.

### Limitations of the Procedure

Refer to the "LIMITATIONS" section of the package insert for the C-reactive Protein (HS) Wide Range Reagent Set. Improper handling and/or storage of the control can have an effect on the recovered results. Errors in assay

technique can cause erroneous results. DO NOT use the product if there is visible evidence of microbial growth in the vial.

### Reference Results

For reference value ranges, see table below. The values listed were obtained using in-date reagents at the time of testing. Any modifications in more recent reagent lots may give values different from the printed expected values.

The assay values and ranges provided are derived using the C-reactive Protein (HS) Wide Range Reagent Set. The mean of several assay values may not duplicate the assay value indicated, but should be within the range given. An individual assay value may be outside the range given.

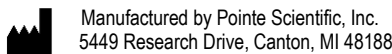

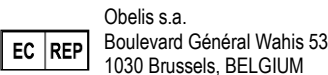
It is recommended that each laboratory establish its own mean and precision parameters with these controls.

#### Control Lot # 417601











| Instrument     | Unit  | Level I            | Level II           |
|----------------|-------|--------------------|--------------------|
|                |       | Exp. Date: 2016-06 | Exp. Date: 2016-06 |
| ACE            | mg/L  | 2.3 ± 0.6          | 47.8 ± 7.6         |
| Cobas Mira     | mg/L  | 1.6 ± 0.4          | 50.2 ± 8.0         |
| Hitachi 717    | mg/L  | 2.4 ± 0.6          | 51.2 ± 8.2         |
| Hitachi 917    | mg/L  | 2.2 ± 0.6          | 51.9 ± 8.3         |
| Olympus AU     | mg/L  | 1.9 ± 0.5          | 48.6 ± 7.8         |
| Mindray BS 480 | mg/dl | 2.3 ± 0.6          | 49.4 ± 7.9         |
| All Other      | mg/L  | 2.1 ± 0.5          | 50.0 ± 8.0         |

### Reference

1. Pointe Scientific, Inc. C-Reactive Protein (High Sensitivity) Wide Range reagent package insert (P803-C7568-01).
2. *Textbook of Clinical Chemistry*, Tietz, N.W., Ed., W.B. Saunders Company, Philadelphia, 1986, p. 424-458.
3. U.S. Patent nos. 6,248,597; 6,828,158.

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### Symbol Key

|   |   |
|---|---|
|  Use by (YYYY-MM)                                    |  Lot and batch code  |
|  Catalog number                                      |  Manufacturer  |
|  <i>In vitro</i> diagnostic medical device           |  Temperature limitation  |
|  Consult instructions for use                        |  CE mark  Caution |
|  Authorized representative in the European Community |   |

Rev. 8/15 P803-C7568-06