



## CRP Ultra Wide Range Calibrator

CATALOGUE NUMBER: 082B

SIZE: 5 x 2 mL

**Note: Changes are highlighted.**

### INTENDED USE

For the calibration of the CRP Ultra Wide Range assay.

### TEST SUMMARY

See the CRP Ultra Wide Range package insert.

### REAGENTS

The CRP Ultra Wide Range calibrators are prepared by diluting purified C-reactive protein with normal human serum and <0.1% sodium azide.

The 5 calibrators have values of 2.5, 10.0, 20.0, 80.0, and 160.0 mg/L, respectively.

### WARNINGS AND PRECAUTIONS FOR USE

**IVD**

For *in vitro* diagnostic use

**Rx ONLY**

Do not use the calibrators beyond the expiration date printed on the labels.

**Warning:** Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested negative for HBs antigen, HIV 1/2 and HCV antibodies. As no test method can assure the complete absence of HIV, hepatitis B virus, hepatitis C virus or other infectious agents, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions.

**Caution:** CRP Ultra Wide Range Calibrators contain <0.1% sodium azide as an antimicrobial agent. Sodium azide may react with lead and copper plumbing to form potentially explosive metal azide buildup. Flush with copious amounts of water when discarding material. Do not pipette by mouth.

See Safety Data Sheet for additional information.

### PRODUCT PREPARATION, STORAGE AND STABILITY

Liquid, ready to use.

Unopened calibrators are stable until the expiration date shown on the label when stored at 2 - 8°C.

Once opened and capped the calibrators are stable up to 5 weeks at 2 - 8°C.

### PRODUCT DETERIORATION

Presence of turbidity or microbial growth may indicate deterioration.

### DISPOSAL

Product must be disposed of in accordance with all Federal, Provincial, State and local regulations.

### ANALYTICAL PROCEDURE

#### MATERIALS PROVIDED

Description	Configuration	Catalog Number
CRP Ultra Wide Range Calibrator Set	5 x 2 mL vials 2.5 mg/L yellow cap 10.0 mg/L cream cap 20.0 mg/L yellow-green cap 80.0 mg/L pink cap 160.0 mg/L red cap	082B

#### MATERIALS REQUIRED (BUT NOT PROVIDED)

Description	Configuration	Catalog Number
CRP Ultra Wide Range Reagent	R1 1 x 30 mL R2 1 x 20 mL	082

- Physiological saline to be used as zero calibrator (blank solution).
- Quality Control materials.
- Analyzer capable of running two-reagent chemistries.

### CALIBRATION

The values of the CRP Ultra Wide Range calibrators can be found on the calibrator vial labels.

Refer to the instrument operator's manual for analyzer specific calibration procedures and for guidance in determining calibration frequency.

Quality Control values should be within the expected ranges.

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## Symbols

**LOT**

Batch Code



Manufactured for



Consult instructions for use

**IVD**

*In vitro* diagnostic medical device



Use by date  
YYYY-MM-DD or YYYY-MM

**REF**

Catalog number



Temperature limit



Caution, consult accompanying document

**Rx ONLY**

Caution: Federal law restricts this device to sale by or on the order of a physician

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