

## Intended Use

The Pointe CRP (HS) Wide Range Multi-Standard Set is intended to be used for the calibration of the manufacturer's CRP (High Sensitivity) Wide Range immunoturbidimetric assay. For *in vitro* diagnostic use only.

## Rx Only

## Summary

The standards in this kit contain known quantities of human C-reactive protein. These reagents are to be used as standards with the manufacturer's CRP (HS) Wide Range immunoturbidimetric assay.

## Kit Composition

Standard (2.5 – 160.0 mg/L)	Human CRP 0.1% Sodium Azide	5x2ml
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## Precautions

1. This reagent is for *in vitro* diagnostic use only.
2. Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.
3. Standards contain purified human CRP isolated from human serum which was tested and found negative for HbsAg and HIV antibodies by an FDA cleared method. However, all products which contain human source material should be handled in accordance with good laboratory practices and appropriate control. See the National Institute of Health Manual, "Biosafety in Microbiology and Biomedical Laboratories", 2<sup>nd</sup> ed., 1988.
4. Do not mix or use reagents from one test kit with those from a different lot number.
5. Do not use reagents past the expiration date stated on each reagent container label.
6. Do not pipette by mouth. Avoid ingestion and contact with skin.
7. Reagents in this kit contain sodium azide as a preservative. Sodium azide may form explosive compounds in lead drain lines. When disposing of reagents through plumbing fixtures, flush with copious amounts of water.

## Interfering Substances

Dust particles or other particulates in the reaction may result in extraneous light-scattering resulting in variable results.

## Preparation

The standards are ready to use and do not require reconstitution.

## Storage and Handling

All reagents should be stored refrigerated (2-8°C). Return all reagents to 2-8°C promptly after use. Unopened reagents can be used until the expiration date on the package and bottle labels. Opened bottles of reagents can be used for 1 month if stored at 2-8°C.

## Reagent Stability

Discard reagents if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

## Instruments

Measurements of absorbance are to be made with a spectrophotometer able to accurately read absorbance at 570 and 700 nm. Refer to the instrument manual from the manufacturer regarding the following:

- a) Use or function
- b) Installation procedures and requirements
- c) Principles of operation
- d) Performance characteristics
- e) Operation instructions
- f) Calibration procedures including materials and/or equipment to be used
- g) Operational precautions and limitations
- h) Hazards
- i) Service and maintenance information

## Materials Provided

Standards should be used as specified in the manufacturer's CRP (HS) Wide Range immunoturbidimetric assay package insert.

Standard (2.5 mg/L)	1x2ml
Standard (10.0 mg/L)	1x2ml
Standard (20.0 mg/L)	1x2ml
Standard (80.0 mg/L)	1x2ml
Standard (160.0 mg/L)	1x2ml

## Materials Required but not Provided

1. CRP(HS) Wide Range immunoturbidimetric assay kit
2. Accurate pipetting devices.
3. Test tubes/rack
4. Spectrophotometer capable of accurate absorbance reading at 570 and 700 nm with appropriate cuvettes.
5. Heating Block/bath (37°C).

## Procedure

The CRP Multi-Standards are assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the manufacturer's CRP (HS) Wide Range immunoturbidimetric assay kit. Note: Allow all reagents and specimens to come to room temperature. Mix all reagents gently before using.

## Standard Values

The values for the CRP (HS) Wide Range Multi-Standard Set are continually being revised through ongoing quality assurance. As a result, the expected values may change from lot to lot. Please refer to the vial labels for each lot for the exact standard values.

## Symbol Key

Use by (YYYY-MM-DD)	<b>LOT</b> Lot and batch code
<b>REF</b> Catalog number	Manufacturer
<b>IVD</b> <i>In vitro</i> diagnostic medical device	Temperature limitation
Consult instructions for use	<b>Rx Only:</b> Prescription Use Only
CE mark	<b>EC REP</b> Authorized representative in the European Community

**REF** C7568-STD Manufactured for HORIBA Instruments Incorporated - Pointe Brand  
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2°C - 8°C **IVD**

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## Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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