

Intended use

The CRP-HS LT Calibrator Set is designed to be used with the CRP-HS II LT reagent for the determination of C-Reactive Protein (CRP).

Reagents and ingredients

There are two different Calibrator Sets available:

CRP-HS LT Calibrator Set HO 5 concentration x 2 mL
(for automated analyzers like Hitachi, AU and Advia Systems)

Product	Concentration	Package
CRP-HS LT Calibrator HO 1	0.2 mg/dL	CAL 1: 1 x 2 mL
CRP-HS LT Calibrator HO 2	1.0 mg/dL	CAL 2: 1 x 2 mL
CRP-HS LT Calibrator HO 3	4.0 mg/dL	CAL 3: 1 x 2 mL
CRP-HS LT Calibrator HO 4	18.0 mg/dL	CAL 4: 1 x 2 mL
CRP-HS LT Calibrator HO 5	35.0 mg/dL	CAL 5: 1 x 2 mL

CRP-HS LT Calibrator Set T 7 concentration x 2 mL
(for automated analyzers like Architect and Aeroset Systems)

Product	Concentration	Package
CRP-HS LT Calibrator T 1	0.3 mg/dL	CAL 1: 1 x 2 mL
CRP-HS LT Calibrator T 2	0.8 mg/dL	CAL 2: 1 x 2 mL
CRP-HS LT Calibrator T 3	3.5 mg/dL	CAL 3: 1 x 2 mL
CRP-HS LT Calibrator T 4	8.0 mg/dL	CAL 4: 1 x 2 mL
CRP-HS LT Calibrator T 5	16.0 mg/dL	CAL 5: 1 x 2 mL
CRP-HS LT Calibrator T 6	28.0 mg/dL	CAL 6: 1 x 2 mL
CRP-HS LT Calibrator T 7	35.0 mg/dL	CAL 7: 1 x 2 mL

Determination of assigned values

The CRP concentration was determined by Latex Immunoassay using ERM-DA 470 (IRMM) as primary standard.

Reagent preparation

Use the calibrators as supplied. After opening the calibrators, it is recommended to use them immediately. When the opened calibrators are stored, cap the bottles to keep from drying out and store them at 2–10 °C.

Warnings and precautions

- For *in-vitro*-diagnostic use.
- The usage and application of this test is reserved for professional use only.
- Not to be used internally in humans or animals.
- Do not use the calibrators for any other procedures than described herein. Refer to the package insert for CRP-HS II LT reagent before use of the calibrators!
- Do not use the calibrators for any other purpose than described herein.
- Do not use the containers and other materials in the package for any purposes other than those described herein.
- Store the calibrators under the specified conditions. Do not use calibrators past the expiration date stated on each calibrator container label.
- If the calibrators come in contact with mouth, eyes or skin, wash off immediately with a large amount of water. Consult a physician if necessary.
- The calibrators are prepared from human sera which were found to be negative for HbsAg, anti-HIV antibody and anti-HCV antibody. Because no test can offer complete assurance that products derived from human blood will not transmit infectious agents, it is recommended that the calibrators should be handled with the same precautions used for patient specimens.
- The calibrators contain 0.09 % sodium azide as a stabilizer. Sodium azide may react with copper or lead plumbing to form explosive compounds. Even though the reagent contains minute quantity of sodium azide, drains should be flushed well with a large amount of water, when discarding the reagent.
- When discarding the calibrators, dispose of them according to local or national regulations

Additional information

- EUH208 Contains Mixture of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.

Quality control

A quality control program is recommended for all clinical laboratories.

Ordering information

Code No.	Product	Package
460-25801	CRP-HS LT Calibrator Set HO (for automated analyzers like Hitachi, AU and Advia Systems)	CAL: 5 conc. x 2 mL
on request	CRP-HS LT Calibrator Set T (for automated analyzer like Architect and Aeroset Systems)	CAL: 7 conc. x 2 mL