

N-geneous™ Wide Range CRP Calibrator Set

INTENDED USE

For the calibration of the N-geneous™ Wide Range CRP assay.

SUMMARY AND PRINCIPLE

See the N-geneous™ Wide Range CRP Reagent package insert.

REAGENTS/COMPOSITION

The N-geneous™ Wide Range CRP calibrators are a human serum liquid matrix with assigned concentrations of C-reactive protein.

5 calibrators at approximate values of 3, 6, 30, 170 and 360 mg/L.

Precautions and Warnings

1. For In Vitro Diagnostic Use.
2. Do not use the calibrators after the expiration date printed on the labels.
3. **Warning:** Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA- approved method and found non-reactive for the presence of HBsAg, and antibody to HIV 1 /2 and antibody to HCV. Because no known test method can offer complete assurance that Hepatitis B virus, Human Immunodeficiency virus (HIV) or other infectious agents are absent, all human-based products should be handled in the accordance with good laboratory practices using appropriate precautions.¹
4. **Caution:** N-geneous™ Wide Range CRP 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.

Preparation of Calibrator

Calibrators: Liquid, ready to use.

Storage and Stability

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

Once opened and capped, the calibrators are stable for 4 weeks at 2 - 8°C.

Indications of Deterioration

Presence of turbidity or microbial growth may indicate deterioration.

PROCEDURE

Materials Provided

Description	Configuration	Catalog Number
N-geneous™ Wide Range CRP Calibrator Set	5 Levels x 2 mL vials	80-6655-00

Materials Required but not Provided

Description	Configuration	Catalog Number
N-geneous™ Wide Range CRP Reagent 1	25 mL	80-6640-00
N-geneous™ Wide Range CRP Reagent 2	25 mL	80-6641-00

- Quality Controls materials.
- Analyzer capable of running two reagent chemistries.

Calibration

The N-geneous™ Wide Range CRP assay requires a multipoint calibration curve. The values of the CRP calibrators, which can be found on the calibrator vial labels, are assigned by procedures traceable to CRM470 BCR reference material.²

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.

References

1. Richardson JH and Barkley WE, eds. Biosafety in Microbiological and Biomedical laboratories, U.S. Dept. of Health and Human Services, Public Health Service, HHS Publication No. (CDC) 84-8395, Washington, DC: 1984.
2. Kimberly MM et al., Standardization of Immunoassays for Measurement of High-Sensitivity C-Reactive Protein. Phase I: Evaluation of Secondary Reference Materials. Clin Chem 2003; 49: 611-616.

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Definitions for Symbols



This product fulfills the requirements of the European Directive for In Vitro Diagnostic Medical Devices.



Catalog number



For in vitro diagnostic use



Temperature limitation



Manufactured by



Use by



Batch code



Consult instructions for use



Caution, consult accompanying documents

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