

# Gentian Calprotectin Immunoassay

**For Research Use Only (ROU). Not for use in diagnostic procedures. The RUO kits cannot be used to compare the quality of the Gentian assay to other assays without our approval.**

## Principle of the Procedure

The Gentian Calprotectin Immunoassay is an immunoturbidimetric assay intended for the *in vitro* quantitative determination of calprotectin in human lithium heparin plasma and serum samples.

The Gentian Calprotectin Immunoassay is a particle-enhanced turbidimetric immunoassay (PETIA). The lithium heparin plasma or serum sample is mixed with Calprotectin Immunoparticles. Calprotectin from the sample and the anti-calprotectin antibodies from the immunoparticles solution bind to form aggregates that increase the turbidity of the solution. The degree of turbidity is proportional to the concentration of calprotectin, which can be quantified via an established standard calibration curve.

## Hazards Identification



Hazard pictograms (CLP):

GHS07

Signal word (CLP): Warning

Contains: 2-methylisothiazol-3(2H)-one

### Hazard statements (CLP):

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

### Precautionary statements (CLP):

P280 - Wear eye protection, protective gloves, protective clothing.  
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

To obtain the SDS (safety data sheet), please contact Gentian at [marketing@gentian.com](mailto:marketing@gentian.com).

## Warnings and Precautions

1. Contains substances from human or animal origin and should be considered as potentially infectious material. Handle with caution and discard following local regulations.
2. Reagents containing MOPS/Tween (R1) and EDTA (R2) can be irritating to eyes, respiratory tract and skin. Handle with due caution and do not ingest.
3. R1 contains avian proteins. Handle with due caution to avoid allergic skin reaction.

## Additional Handling Instructions

1. This test is for *in vitro* use only and must be handled by qualified personnel.
2. Use only validated and approved instrument applications.
3. Do not use products after the expiration date has passed.
4. Do not mix reagents of different lots or interchange caps of reagents, controls, calibrators, and lots.

5. Tighten caps carefully back on after use of reagents, calibrators, and controls to avoid evaporation.

## Storage instructions

All products provided for the Gentian Calprotectin Immunoassay must be stored at 2-8°C. The expiry date is printed on the labels.

## Procedure

### Reagent Preparation

The reagents are ready for use. Mix the reagents gently before placing them into the assigned reagent positions. The reagent bottles may fit directly into the instrument.

## Assay Kit Components

Products available	
Gentian Calprotectin Reagent Kit <ul style="list-style-type: none"> <li>• R1 Assay Buffer (54 mL)</li> <li>• R2 Immunoparticles (9 mL)</li> </ul>	REF 1201-RUO
Gentian Calprotectin Reagent Kit S <ul style="list-style-type: none"> <li>• R1 Assay Buffer (30 mL)</li> <li>• R2 Immunoparticles (5 mL)</li> </ul>	REF 1202-RUO
Gentian Calprotectin Calibrator Kit (6 levels x 1 mL)	REF 1251-RUO
Gentian Calprotectin Control Kit (2 levels x 1 mL)	REF 1219-RUO

*All products are ready for use.*

## Calibration Curve Establishment

The calibration curve can either be created from a dilution series that is automatically prepared by the instrument or by using a 6-point pre-diluted calibrator kit as specified in the instrument manual. Calibrator values are lot specific, and calibration must be performed whenever a new lot is used. The values assigned to the calibrators are provided in the analytical value sheet. A new calibration should be performed according to instrument specific calibration curve stability or when a new reagent lot is used.

## QC Controls

The Gentian Calprotectin Controls should be assayed every day that the test is in use to verify the calibration curve. The controls have lot specific concentration ranges that must be met before measuring samples. The assigned value ranges are given in the analytical value sheet. If the control values measured are not valid, repeat the control measurements. Recalibrate if necessary.

## Control and Calibrator Value Assignment

The control and calibrator values are given in the analytical value sheet.

## Measuring Samples

When a valid calibration curve has been established and the control values are within the valid range, the lithium heparin plasma or serum sample may be measured. Ensure that the minimum sample volume is present in the sample cups/tubes and assay the samples according to the instructions given in the instrument manual.

## Application Notes

Contact [marketing@gentian.com](mailto:marketing@gentian.com) for detailed application notes describing the procedures for installation and analysis on specific instruments. For instructions on how to install a new application, consult the instrument manual. Maintenance, operation, and precautions must be handled in accordance with the specific instrument manual.

## Results

The results are calculated automatically by the instrument. The results are presented in mg/L.

## Gentian AS

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## Date of issue

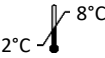



















2022-08-23

## Modification from the Previous Version

This version has been updated with

- Renamed section "Principle of the procedure"
- Removal of "Summary"
- Structural changes

## Symbols Key

	Temperature Limit
	Use by Date
	Consult Instructions for Use
	Manufacturer
	Research Use Only
	Lot Number
	Catalogue Number
	Contents
	R1 Assay Buffer
	R2 Immunoparticles
	Control Low
	Control High
	Calibrator
	Calibrator Level 1
	Calibrator Level 2
	Calibrator Level 3
	Calibrator Level 4
	Calibrator Level 5
	Calibrator Level 6
	Warning