

Application Note for the Gentian Calprotectin Immunoassay on the Siemens Atellica CH 930¹

For *in vitro* diagnostic use by laboratory professionals.

This document describes the instrument specific settings and performance of the product on the instrument above. For assay information, please refer to the IFU available on www.gentian.com.

Assay kit components

Products available	
Gentian GCAL [®] Calprotectin Reagent Kit	REF 1201
- R1 Assay Buffer (54 mL) - R2 Immunoparticles (9 mL)	
Gentian GCAL [®] Calprotectin Reagent Kit S	REF 1202
- R1 Assay Buffer (30 mL) - R2 Immunoparticles (5 mL)	
Gentian GCAL [®] Calprotectin Calibrator Kit (6 levels x 1 mL)	REF 1251
Gentian GCAL [®] Calprotectin Control Kit (2 levels x 1 mL)	REF 1219
Additional equipment but not provided	
Instrument-specific bottles	

All products are ready for use.

Reagent stability

The in-use stability of the Gentian GCAL[®] Calprotectin Reagent Kit was found to be at least 30 days in an on board a study based on the CLSI guideline EP25 [1]. If the instrument remains unused for more than a week, please ensure the reagents are gently inverted every 7 days.

Calibration stability

The calibration curve stability of the Gentian GCAL[®] Calprotectin Calibrator Kit was found to be at least 7 days in a study based on the CLSI guideline EP25 [1].

Performance characteristics

All results refer to validation of the Gentian GCAL[®] Calprotectin Immunoassay on one instrument site with one lot of reagents, unless otherwise stated.

Measuring range

The measuring range of the Gentian GCAL[®] Calprotectin Immunoassay was found to be 0.44-19.62 mg/L. The exact measuring range is specific to the calibrator lot, please refer to the analytical value sheet available on www.gentian.com.

Analytical sensitivity

The analytical sensitivity of the Gentian GCAL[®] Calprotectin Immunoassay was tested in a study based on the CLSI guideline EP17 [2]. The limit of quantification (LoQ) is defined as the lowest concentration of an analyte that can be reliably detected and at which the total error meets the requirements for accuracy. The LoQ of the Gentian Calprotectin Immunoassay was measured as 0.42 mg/L lithium heparin plasma and 0.44 mg/L in serum samples.

Linearity

The linearity range of the Gentian GCAL[®] Calprotectin Immunoassay was found to be 0.44-19.62 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 65 mg/L was observed for the Gentian GCAL[®] Calprotectin Immunoassay in a study based on the CLSI guideline EP34 [4]. Samples with a calprotectin concentration above the highest calibrator and up to 65 mg/L return a value above the highest calibrator and are flagged for rerun.

Precision

Precision of the Gentian GCAL[®] Calprotectin Immunoassay was tested in a 3-day precision study based on the CLSI guideline EP05 [5]. 3 serum pools and 2 controls were measured 5 times with 5 replicates (n=25).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
S1	0.79	3.58	2.27	4.24
S2	4.93	0.37	1.00	1.07
S3	15.29	0.60	1.07	1.23
CL	0.97	2.36	3.45	4.18
CH	9.91	0.71	0.52	0.88

Recovery

Recovery was analysed by spiking a low analyte sample with a high analyte sample according to Westgard [6]. The Gentian GCAL[®] Calprotectin Immunoassay had a recovery of 89-102 %.

Analytical specificity and limitations

Interference was tested in a study based on the CLSI guideline EP07 [7]. As the antibodies in the Gentian GCAL[®] Calprotectin Immunoassay are of avian origin, there is no interference due to Rheumatoid Factor in the samples [8]. No clinically relevant difference was detected at the tested interferent concentrations.

Potential interferents	Concentration with no interference
Haemoglobin	2.5 g/L
Intralipid	10 g/L
Bilirubin	0.6 g/L

Instrument variation

Results obtained with the Gentian GCAL[®] Calprotectin Immunoassay were compared using Passing-Bablok regression with results from the Cobas c501 instrument (Roche) in a study based on the CLSI guideline EP09 [9].

n	Range of samples [mg/L]	Term	Co-efficient	95% CI
46	0.39-20.75	Intercept	0.15	[0.07, 0.27]
		Slope	1.03	[0.99, 1.06]
		R ²	0.99	

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References

1. CLSI. Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI document EP25-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.
2. CLSI. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition. CLSI document EP17-A2. Wayne, PA: Clinical and Laboratory Standards Institute ;2012.
3. CLSI. Evaluation of Linearity of Quantitative Measurement Procedures. 2nd ed. CLSI guideline EP06. Clinical and Laboratory Standards Institute; 2020.
4. CLSI. Establishing and Verifying and Extended Measuring Interval Through Specimen Dilution and Spiking. 1st ed. CLSI guideline EP34. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
5. CLSI. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI document EP05-A3. Wayne, PA: Clinical Laboratory Standards Institute; 2014.
6. Westgard JO. Basic Method Validation, 3rd Edition. 2008; ISBN13: 9781886958258
7. CLSI. Interference Testing in Clinical Chemistry. 3rd ed. CLSI guideline EP07. Wayne, PA: Clinical Laboratory Standards Institute; 2018.
8. Larsson A, et al. Poultry Science 1993;72:1807-12.
9. CLSI. Measurement Procedure Comparison and Bias Estimation Using Patient Samples. 3rd ed. CLSI guideline EP09c. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

Modification from previous version

- Added CH 930 to instrument name

Date of issue

2026-09-18

Instrument Settings for the Gentian GCAL[®] Calprotectin Immunoassay on the Siemens Atellica CH 930¹

Definition	Sample/Reagent	Calculation	Calibration	Mitigation																																															
Assay Name GCAL* ID Units mg/L Test version * Display Name GCAL* Print Name GCAL* LIS Code GCAL* LOINC ☐ Investigation Only ☐ Kinetic Mode	<table border="1"> <thead> <tr> <th>Serum</th> <th>Plasma</th> <th>Urine</th> <th>CSF</th> <th>RBC</th> </tr> </thead> <tbody> <tr> <td colspan="5"> Measuring Interval ☒ Serum <table> <tr> <td>Low</td> <td>High</td> </tr> <tr> <td>Assay Range 0.4 </td> <td> 19.6 </td> </tr> </table> </td> </tr> <tr> <td colspan="5"> Sample Predilution <table> <tr> <th>Sample Volume</th> <th>Dilution Factor</th> <th>Total Volume</th> </tr> <tr> <td> 25 μL</td> <td> 2 </td> <td>50 μL</td> </tr> </table> </td> </tr> <tr> <td colspan="5"> Below Measuring Interval Configuration <table> <tr> <th>Sample Volume</th> <th>Dilution Factor</th> <th>Total Volume</th> </tr> <tr> <td> 0 μL</td> <td> </td> <td>0 μL</td> </tr> </table> </td> </tr> <tr> <td colspan="5"> Above Measuring Interval Configuration <table> <tr> <th>Sample Volume</th> <th>Dilution Factor</th> <th>Total Volume</th> </tr> <tr> <td> 10 μL</td> <td> 5 </td> <td>50 μL</td> </tr> </table> </td> </tr> </tbody> </table>				Serum	Plasma	Urine	CSF	RBC	Measuring Interval ☒ Serum <table> <tr> <td>Low</td> <td>High</td> </tr> <tr> <td>Assay Range 0.4 </td> <td> 19.6 </td> </tr> </table>					Low	High	Assay Range 0.4	19.6	Sample Predilution <table> <tr> <th>Sample Volume</th> <th>Dilution Factor</th> <th>Total Volume</th> </tr> <tr> <td> 25 μL</td> <td> 2 </td> <td>50 μL</td> </tr> </table>					Sample Volume	Dilution Factor	Total Volume	25 μL	2	50 μL	Below Measuring Interval Configuration <table> <tr> <th>Sample Volume</th> <th>Dilution Factor</th> <th>Total Volume</th> </tr> <tr> <td> 0 μL</td> <td> </td> <td>0 μL</td> </tr> </table>					Sample Volume	Dilution Factor	Total Volume	0 μL		0 μL	Above Measuring Interval Configuration <table> <tr> <th>Sample Volume</th> <th>Dilution Factor</th> <th>Total Volume</th> </tr> <tr> <td> 10 μL</td> <td> 5 </td> <td>50 μL</td> </tr> </table>					Sample Volume	Dilution Factor	Total Volume	10 μL	5	50 μL
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Definition	Sample/Reagent	Calculation	Calibration	Mitigation
Calculation	High-dose Hook Effect	HIL Calculation		
Analysis Method End Point (EPA)				
Primary Wavelength 545 Blank Wavelength --- Main Start Time 268 Main End Time 427 Absorbance Offset 5 Decreasing Reaction Absorbance ☐ ☐ Start-Point Estimation Blank Start Time Blank End Time 				

Definition	Sample/Reagent	Calculation	Calibration	Mitigation			
Specimen Type	Serum*	☐ Automatically Order Calibration	1	☐ C0 Adjust			
Standard Curve	Spline	☐ Lot Calibration Expiration (Days)	1	☐ Semi Quant			
Lot Calibration Interval (Days)	7	☐ Pack Calibration Expiration (Hours)		Calibrator Onboard Stability (Hours)			
Pack Calibration Interval (Days)	7	☐ New Lot		Refrigerated **			
		☐ IFU Changed		Unrefrigerated **			
Calibrator Levels and Predilution		☐ Perform QC with Calibration					
Levels 6							
Level	Weight	Replicates	Dilution Factor	Sample	Sample Volume	Total Volume	
1	1	2	2	1	25 µL	50 µL	☐ CH Diluent Only
2	1	2	2	2	25 µL	50 µL	
3	1	2	2	3	25 µL	50 µL	
4	1	2	2	4	25 µL	50 µL	
5	1	2	2	5	25 µL	50 µL	
6	1	2	2	6	25 µL	50 µL	

Disclaimer: The specific settings above is what used to validate the application on the specific instrument. For any instrument specific settings, please refer to the instrument manual. Please be aware that illustrations or settings might be affected in case of an instrument software update.

* User defined

** Store at 2-8 °C. The expiry date is printed on the labels.