GCAL®

Application Note for the Gentian Calprotectin Immunoassay on the Vitros® 5600/XT 7600[1]

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 • R1 Assay Buffer (54 mL) • R2 Immunoparticles (9 mL)	REF 1201
Gentian GCAL® Calprotectin Reagent Kit S • R1 Assay Buffer (30 mL) • R2 Immunoparticles (5 mL)	REF 1202
Gentian GCAL® Calprotectin Calibrator Kit (6 level x 1 mL)	REF 1251
Gentian GCAL® Calprotectin Control Kit (2 levels x 1 mL)	REF 1219
Additional material required 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 4 weeks in an on board study based on the CLSI guideline EP25 [1].

Calibration stability

The calibration curve stability of the Gentian GCAL® Calprotectin Calibrator Kit was found to be at least 1 week 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 0.41-19.85 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. The LoQ of the Gentian GCAL® Calprotectin Immunoassay was found to be 0.30 mg/L.

Linearity

The linearity range of the Gentian GCAL® Calprotectin Immunoassay was found to be 0.41-19.85 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 78 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 78 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]. 1 serum pool, 2 lithium-heparin plasma 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 [%]
PR-1	0.88	4.11	5.18	6.61
PR-2	7.16	1.14	1.40	1.81
PR-3	11.87	1.21	1.24	1.73
PR-CL	1.05	2.87	1.50	3.23
PR-CH	10.27	1.45	0.88	1.70

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 82-101 %.

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 Vitros® 5600 instrument (QuidelOrtho) in a study based on the CLSI guideline EP09 [9].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
42	0.42-19.98	Intercept	0.13	[0.07, 0.18]
		Slope	0.91	[0.90, 0.94]
		R^2	1.00	

[1] Registered trademark of QuidelOrtho

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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 an 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 the previous version

- First version.

Date of issue

2025-01-30

Instrument Settings for the Gentian GCAL® Calprotectin Immunoassay on the Vitros® 5600/XT 7600[1]

CONFIGURATION

	Full Assay Name	Gentian Calprotectin*	
	Short Assay Name	GCAL*	
	Fluid Type	Serum****	
	Assay Model Type	2 Point Rate	
	Template	*2PT R1-S-R2	
	Cal Model Type	Cubic Spline	
Calibrators Bottles	6	**Replicates Per Cal**	2

DILUTION PARAMETERS

Diluent	None	**Standard Dilution Factor**	1.0
	REFLEX DILUTION		
Reflex Dilution	Off		

RESULTS PARAMETERS

Reporting Type	Quantitative					
Units	mg/L					
					RANGES	
Significant digits	4	**Precision digits**	2	**Reference**	*	*
				Supplementary	*	*
				Measuring (reportable)	0.41	19.85
Slope	1.00	**Intercept**	0.00			
Cuve Tip Expiration Time	35					
Temperature sensitive	no					

[1] Registered trademark of QuidelOrtho

ADDITIONAL PARAMETERS

Initial Absorbance Limits	
-0.200	2.700
Blank Absorbance Limits	
-0.200	2.700
Antigen Excess Factor	
9.0000	

Monotonicity	Increased		
Max. Response – High	3.000 **	**Max. Response – Low**	-3.000 **
Min. Response – High	3.000 **	**Min. Response – Low**	-3.000 **
		Calibration interval	999

	Measuring Conc. (reportable)	Triple Read Limit
Measuring Min. (reportable)	0.00	400.0
Critical Conc.	5000	8.00
Measuring Max. (reportable)	9999	8.00

CALIBRATORS

Kit Lot Number	Bottle Number	Dilution Factor	Calibrator Value	Response Area
***	1	1.0	***	0.20000
***	2	1.0	***	0.20000
***	3	1.0	***	0.20000
***	4	1.0	***	0.20000
***	5	1.0	***	0.20000
***	6	1.0	***	0.20000

PROTOCOL

1.	**Reagent**	Volume (µL)	170.0	Pack/Bottle = UD01 / A
2.	**Incubation**	Seconds	0.00	
3.	**Sample**	Volume (µL)	2.5	
4.	**Incubation**	Seconds	304.00	
5.	**Reagent**	Volume (µL)	20.0	Pack/Bottle = UD01 / B
6.	**Incubation**	Seconds	0.00	
7.	**Read**	Wavelength (nm)	660	
8.	**Incubation**	Seconds	76.00	
9.	**Read**	Wavelength (nm)	660	

* User defined
** Default by instrument
*** Lot specific. See analytical value sheet available on www.gentian.com
**** Valid for serum and lithium-heparin plasma

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.