GCAL®



Application Note for the Gentian Calprotectin Immunoassay on the DxC 700 AU¹

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 Assa	y Buffer (54 mL)			
R2 Imm	unoparticles (9 mL)			
Gentian GCAL® Calprotectin Reagent Kit S		REF 1202		
R1 Assa	y Buffer (30 mL)			
R2 Imm	unoparticles (5 mL)			
Gentian GCAL® Calprotectin Calibrator Kit (6 levels x		REF 1251		
1 mL)				
Gentian GCAL® Calprotectin Control Kit (2 levels x 1		REF 1219		
mL)		1213		

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 performed as an on board study based on 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 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 a DxC 700 AU instrument at 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 0.48-19.16 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 found to be 0.45 mg/L in serum and 0.48 mg/L in lithium heparin plasma.

Linearity

The linearity range of the Gentian GCAL® Calprotectin Immunoassay was found to be 0.44-24.53 mg/L in lithium heparin plasma and 0.45-19.16 mg/L in serum in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 106 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 106 mg/L return a value above the highest calibrator and are flagged for rerun with automatic dilution.

Precision

Precision of the Gentian GCAL® Calprotectin Immunoassay was tested in a 3-day precision study based on the CLSI guideline EP05 [5]. 3 lithium heparin plasma (P1-3) and 3 serum pools (S1-3), 2 controls were measured 5 times with 5 replicates (n=25).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
P1	0.90	17.60	2.98	17.85
P2	5.17	1.10	1.58	1.93
Р3	13.04	0.67	0.70	0.97
S1	0.85	5.37	3.75	6.55
S2	4.63	1.43	0.61	1.55
S3	13.06	1.99	0.00	1.99
CL	1.02	4.89	2.42	5.45
СН	10.09	0.87	0.36	0.94

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 96-114 %.

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 on DxC 700 AU instrument were compared using Passing-Bablok regression with results from the AU480 instrument (Beckman Coulter) in a study based on the CLSI guideline EP09 [9].

n	Range of samples [mg/L]	Term	Coefficient	95 % CI
		Intercept	0.07	[0.03, 0.11]
50	0.30-22.40	Slope	0.97	[0.94, 0.99]
		R^2	1.00	





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References

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Modification from the previous version

 Harmonised analytical measuring range across Beckman Coulter instruments

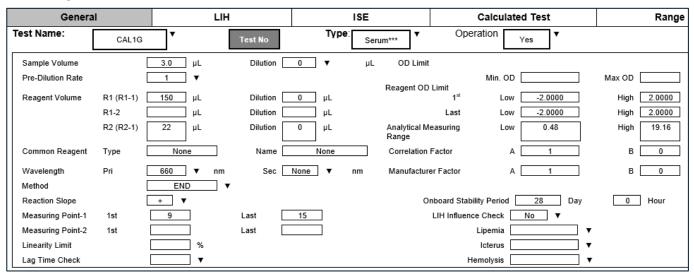
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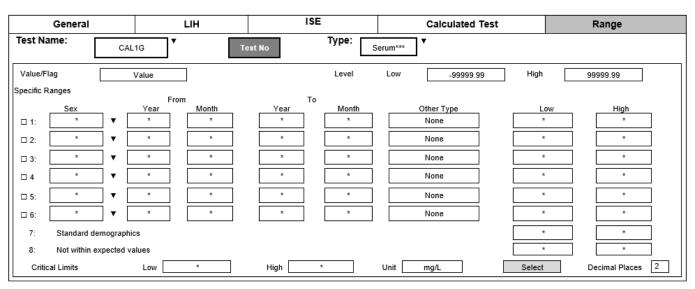
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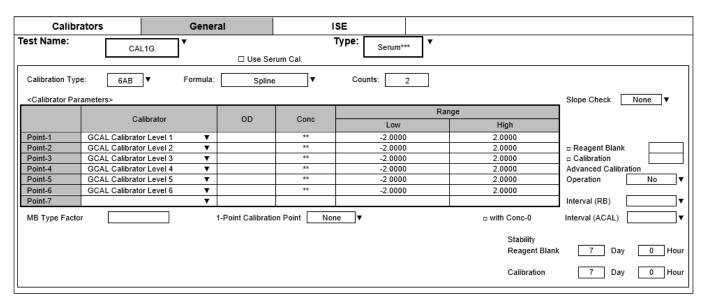
Instrument Settings for the Gentian GCAL® Calprotectin Immunoassay on the DxC 700 AU¹ (serum/plasma)

Reagent ID: 254









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

^{**}Lot specific, see analytical value sheet available on www.gentian.com

^{***}Valid for both serum and lithium heparin plasma