

Application Note for the Gentian Calprotectin Immunoassay on the Thermo Fisher Indiko Plus¹

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 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 29 days in an on board 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 29 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 0.38-21.76 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 GCAL[®] Calprotectin Immunoassay was found to be 0.38 mg/L.

Linearity

The linearity range of the Gentian GCAL[®] Calprotectin Immunoassay was found to be 0.37-23.68 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 117 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 117 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 plasma pools and 2 controls were measured 6 times with 5 replicates (n=30).

Sample ID	Mean [mg/L]	Repeatability [%]	Between			
			run CV [%]	day CV [%]	Within day [%]	Within -lab CV [%]
Pr-1	0.94	2.92	0.00	3.28	2.92	4.39
Pr-2	5.54	1.85	3.74	2.73	4.17	4.99
Pr-3	10.73	5.20	2.14	0.00	5.62	5.62
Pr-CL	1.02	4.18	0.00	4.99	4.18	6.51
Pr-CH	10.04	3.08	0.70	4.40	3.16	5.42

Analytical specificity and limitations

Interference was tested in a study based on the CLSI guideline EP07 [6]. As the antibodies in the Gentian GCAL[®] Calprotectin Immunoassay are of avian origin, there is no interference due to Rheumatoid Factor in the samples [7]. No clinically relevant difference was detected at the tested interferent concentrations.

Potential interferents	Concentration with no interference
Haemoglobin	4 g/L
Intralipid	20 g/L
Bilirubin	0.6 mg/L

Instrument variation

Results obtained with the Gentian GCAL[®] Calprotectin Immunoassay were compared using Passing-Bablok regression with results from the Beckman Coulter DxC 700 AU instrument (Beckman Coulter) in a study based on the CLSI guideline EP09 [8].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
53	0.49-21.59	Intercept	0.13	[0.06, 0.21]
		Slope	0.95	[0.89, 1.02]
		R ²	0.99	

¹Registered trademark of Thermo Fisher



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References

1. CLSI. Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline. CLSI document EP25-Ed2. 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. 4th ed. CLSI guideline EP05. Clinical and Laboratory Standards Institute; 2025
6. CLSI. Interference Testing in Clinical Chemistry. 3rd ed. CLSI guideline EP07. Wayne, PA: Clinical Laboratory Standards Institute; 2018.
7. Larsson A, et al. Poultry Science 1993;72:1807-12
8. 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

2026-07-02

Instrument Settings for the Gentian GCAL[®] Calprotectin Immunoassay on the Thermo Fisher Indiko Plus¹

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

Name	GCAL
Tag	***
Version number	***
Full name	Calprotectin
Online name	Calprotectin

Type	Photometric	Number of decimals	2
In use	Yes	Correction factor	1.000
Acceptance	*	Correction bias	0.000
Result unit	mg/l		

Sample type

☒ Serum	☐ Oral fluid	Test version ID	***
☒ Plasma	☐ Whole blood	Last time changed	***
☐ Urine	☐ Hemol. Blood	User name	***
☐ CSF	☐ Other		

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

Blank type	Yes	Primary dilution 1+	0
		Dispensed volume	207

Reagent	Reagent	Reagent	R1
Sample	Sample	Volume (µL)	170
Incubation	Mix	Dispense with	Extra
Mix	Incubate	Extra volume (µL)	5
End point	Reagent	Syringe speed	Normal
Kinetic	Mix	Replacing reagent	None
System water	Incubate		
Antigen excess	End-point blank		
	Incubate		
	End-point measurement		

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Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

Blank type

Yes

Primary dilution 1+

0

Dispensed volume

207

Reagent
Sample
Incubation
Mix
End point
Kinetic
System water
Antigen excess

Reagent
Sample
Mix
Incubate
Reagent
Mix
Incubate
End-point blank
Incubate
End-point measurement

Volume (µL)

2

Dispense with

Extra

Extra volume

2

Extra wash

No

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

Blank type

Yes

Primary dilution 1+

0

Dispensed volume

207

Reagent
Sample
Incubation
Mix
End point
Kinetic
System water
Antigen excess

Reagent
Sample
Mix
Incubate
Reagent
Mix
Incubate
End-point blank
Incubate
End-point measurement

Time (sec)

304

Actual time (sec)

297

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

Blank type

Yes

Primary dilution 1+

0

Dispensed volume

207

Reagent
Sample
Incubation
Mix
End point
Kinetic
System water
Antigen excess

Reagent
Sample
Mix
Incubate
Reagent
Mix
Incubate
End-point blank
Incubate
End-point measurement

Reagent

R2

Volume (µL)

35

Dispense with

Extra

Extra volume (µL)

3

Syringe speed

Normal

Replacing reagent

None

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

Blank type	Yes				Primary dilution 1+	0
					Dispensed volume	207

Reagent	Reagent				Time (sec)	18
Sample	Sample				Actual time (sec)	18
Incubation	Mix					
Mix	Incubate					
End point	Reagent					
Kinetic	Mix					
System water	Incubate					
Antigen excess	End-point blank					
	Incubate					
	End-point measurement					

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

Blank type	Yes				Primary dilution 1+	0
					Dispensed volume	207

Reagent	Reagent				time (sec)	0.000
Sample	Sample				Actual time (sec)	***
Incubation	Mix					
Mix	Incubate					
End point	Reagent					
Kinetic	Mix					
System water	Incubate					
Antigen excess	End-point blank					
	Incubate					
	End-point measurement					

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

Blank type	Yes				Primary dilution 1+	0
					Dispensed volume	207

Reagent	Reagent				Time (sec)	50
Sample	Sample				Actual time (sec)	45
Incubation	Mix					
Mix	Incubate					
End point	Reagent					
Kinetic	Mix					
System water	Incubate					
Antigen excess	End-point blank					
	Incubate					
	End-point measurement					

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

Blank type

Yes

Primary dilution 1+

0

Dispensed volume

207

Reagent
Sample
Incubation
Mix
End point
Kinetic
System water
Antigen excess

Reagent
Sample
Mix
Incubate
Reagent
Mix
Incubate
End-point blank
Incubate
End-point measurement

Main wavelength (nm)

660

Side wavelength (nm)

None

Residual net abs. (A)

0.000

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

dilution with

Water

Primary dilution 1+

0

Neat sample

Dispense with

Extra

Volume (µL)

0

Diluent

Sample Diluent ID

Dispense with

Extra

Volume (µL)

0

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
------	------	----------	--------	------------------	-------------	----

Calibration type

Spline

Repeat time (days)

29

Point/calibrator

Duplicate

Acceptance

*

Concentration axis

Linear

Response axis

Linear

Abs. error (A)

Rel. error (%)

Factor limit min.

Factor limit max.

Bias limit min.

Bias limit max.

Nbr	Calibrator	Curent lot	Concentration	Dilution 1+
1	GCAL1	**	**	0
2	GCAL2	**	**	0
3	GCAL3	**	**	0
4	GCAL4	**	**	0
5	GCAL5	**	**	0
6	GCAL6	**	**	0

Factor

1.000

Bias

0.0000

* User defined

** Lot specific. See analytical value sheet available on www.gentian.com

*** Instrument default

The specific settings above were 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.