

# Cystatin C



## Application Note for the Gentian Cystatin C Immunoassay on the Thermo Scientific™ Indiko™ Plus<sup>1)</sup>

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](http://www.gentian.com).

### Assay kit components

| Products available                                                                                                                        |          |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------|
| Gentian Cystatin C Reagent Kit <ul style="list-style-type: none"><li>R1 Assay Buffer (58 mL)</li><li>R2 Immunoparticles (10 mL)</li></ul> | REF 1101 |
| Gentian Cystatin C Calibrator Kit (6 levels x 1 mL)                                                                                       | REF 1051 |
| Gentian Cystatin C Control Kit (2 levels x 1 mL), or                                                                                      | REF 1019 |
| Gentian Cystatin C Control Kit (2 levels x 5 mL)                                                                                          | REF 1026 |
| Additional material required but not provided                                                                                             |          |
| Instrument-specific bottles                                                                                                               |          |

All products are ready for use.

### Reagent stability

The in-use stability of the Gentian Cystatin C Reagent Kit was found to be at least 26 days in an on board study based on the CLSI guideline EP25 [1].

### Calibration stability

The calibration curve stability of the Gentian Cystatin C Calibrator Kit was found to be at least 12 days in a study based on the CLSI guideline EP25 [1].

### Performance characteristics

All results refer to validation of the Gentian Cystatin C Immunoassay on one instrument site with one lot of reagents, unless otherwise stated.

### Measuring range

The measuring range of the Gentian Cystatin C Immunoassay was found to be 0.36 – 8.20 mg/L. The exact measuring range is specific to the calibrator lot, please refer to the analytical value sheet available on [www.gentian.com](http://www.gentian.com).

### Analytical sensitivity

The analytical sensitivity of the Gentian Cystatin C 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 Cystatin C Immunoassay was found to be 0.26 mg/L.

### Linearity

The linearity range of the Gentian Cystatin C Immunoassay was found to be 0.36 – 8.43 mg/L in a linearity study based on the CLSI guideline EP06 [3].

### Security zone

No antigen excess effect in samples below 11.60 mg/L was observed for the Gentian Cystatin C Immunoassay in a study based on the CLSI guideline EP34 [4]. Samples with a Cystatin C concentration above the highest calibrator and up to 11.60 mg/L return a value above the highest calibrator and are flagged for rerun.

### Precision

Precision of the Gentian Cystatin C Immunoassay was tested in a 3-day precision study based on the CLSI guideline EP05 [5]. One serum pool, one lithium-heparin plasma pool, one EDTA plasma pool and two controls were measured 5 times with 5 replicates (n=25).

| Sample ID | Mean [mg/L] | Repeatability [%] | Between run CV [%] | Within-lab CV [%] |
|-----------|-------------|-------------------|--------------------|-------------------|
| PR-1      | 0.78        | 2.26              | 0.44               | 2.30              |
| PR-2      | 1.98        | 2.16              | 1.44               | 2.59              |
| PR-3      | 7.85        | 2.74              | 1.80               | 3.28              |
| PR-CL     | 0.91        | 2.46              | 2.66               | 3.63              |
| PR-CH     | 3.22        | 1.77              | 2.63               | 3.17              |

### Analytical specificity and limitations

Interference was tested in a study based on the CLSI guideline EP07 [6]. As the antibodies in the Gentian Cystatin C 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            | 13 g/L                             |
| Intralipid             | 6 g/L                              |
| Bilirubin              | 0.6 g/L                            |

### Instrument variation

Results obtained with the Gentian Cystatin C 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        |
|----|-------------------------|----------------|-------------|---------------|
| 51 | 0.46 – 7.42             | Intercept      | 0.01        | [-0.02, 0.03] |
|    |                         | Slope          | 0.93        | [0.91, 0.95]  |
|    |                         | R <sup>2</sup> | 1.00        |               |



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## References / Bibliography

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. 2<sup>nd</sup> ed. CLSI guideline EP06. Clinical and Laboratory Standards Institute; 2020
4. CLSI. Establishing and verifying an extended measuring interval through specimen dilution and spiking. 1<sup>st</sup> ed. CLSI guideline EP34. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
5. CLSI. Evaluation of Precision of Quantitative Measurement Procedures. 4<sup>th</sup> 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

2026-08-18

# Instrument Settings for the Gentian Cystatin C Immunoassay on the Thermo Scientific™ Indiko™ Plus<sup>1)</sup>

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

|                |            |
|----------------|------------|
| Name           | Cystatin C |
| Tag            | ***        |
| Version number | ***        |
| Full name      | Cystatin C |
| Online name    | Cystatin C |

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

## Sample type

|                                            |                                       |                   |     |
|--------------------------------------------|---------------------------------------|-------------------|-----|
| <input checked="" type="checkbox"/> Serum  | <input type="checkbox"/> Oral fluid   | Test version ID   | *** |
| <input checked="" type="checkbox"/> Plasma | <input type="checkbox"/> Whole blood  | Last time changed | *** |
| <input type="checkbox"/> Urine             | <input type="checkbox"/> Hemol. Blood | User name         | *** |
| <input type="checkbox"/> CSF               | <input type="checkbox"/> Other        |                   |     |

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

|            |     |                     |     |
|------------|-----|---------------------|-----|
| Blank type | Yes | Primary dilution 1+ | 0   |
|            |     | Dispensed volume    | 197 |

|                |                       |                   |        |
|----------------|-----------------------|-------------------|--------|
| Reagent        | Reagent               | Reagent           | R1     |
| Sample         | Sample                | Volume (µL)       | 160    |
| 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 |                   |        |

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

Blank type

Yes

Primary dilution 1+

0

Dispensed volume

197

|                |
|----------------|
| 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

197

|                |
|----------------|
| 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)

300

Actual time (sec)

297

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

Blank type

Yes

Primary dilution 1+

0

Dispensed volume

197

|                |
|----------------|
| 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

197

|                |
|----------------|
| 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)

18

Actual time (sec)

18

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

Blank type

Yes

Primary dilution 1+

0

Dispensed volume

197

|                |
|----------------|
| 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)

0.000

Actual time (sec)

\*\*\*

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

Blank type

Yes

Primary dilution 1+

0

Dispensed volume

197

|                |
|----------------|
| 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)

150

Actual time (sec)

144

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

|            |     |  |  |  |                                         |          |
|------------|-----|--|--|--|-----------------------------------------|----------|
| Blank type | Yes |  |  |  | Primary dilution 1+<br>Dispensed volume | 0<br>197 |
|------------|-----|--|--|--|-----------------------------------------|----------|

|                |                       |                       |       |
|----------------|-----------------------|-----------------------|-------|
| Reagent        | Reagent               | Main wavelength (nm)  | 540   |
| Sample         | Sample                | Side wavelength (nm)  | None  |
| Incubation     | Mix                   | Residual net abs. (A) | 0.000 |
| 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 |
|------|------|----------|--------|------------------|-------------|----|
|------|------|----------|--------|------------------|-------------|----|

dilution with

Primary dilution 1+

Neat sample

Dispense with   
Volume (µL)

Diluent

Sample Diluent ID

Dispense with   
Volume (µL)

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

|                    |           |                   |     |
|--------------------|-----------|-------------------|-----|
| Calibration type   | Spline    | Abs. error (A)    | *** |
| Repeat time (days) | 12        | Rel. error (%)    | *** |
| Point/calibrator   | Duplicate | Factor limit min. | *** |
| Acceptance         | *         | Factor limit max. | *** |
| Concentration axis | Linear    | Bias limit min.   | *** |
| Response axis      | Linear    | Bias limit max.   | *** |

| Nbr | Calibrator | Curent lot | Concentration | Dilution 1+ |
|-----|------------|------------|---------------|-------------|
| 1   | CysC1      | **         | **            | 0           |
| 2   | CysC2      | **         | **            | 0           |
| 3   | CysC3      | **         | **            | 0           |
| 4   | CysC4      | **         | **            | 0           |
| 5   | CysC5      | **         | **            | 0           |
| 6   | CysC6      | **         | **            | 0           |

Factor   
Bias

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](http://www.gentian.com)

\*\*\* Instrument default