

Application Note for the Gentian Calprotectin Immunoassay on the AU5800¹

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 <ul style="list-style-type: none"> R1 Assay Buffer (54 mL) R2 Immunoparticles (9 mL) | REF 1201 |
| Gentian GCAL [®] Calprotectin Reagent Kit <ul style="list-style-type: none"> R1 Assay Buffer (30 mL) R2 Immunoparticles (5 mL) | REF 1202 |
| Gentian GCAL [®] Calprotectin Calibrator Kit (6 levels x 1 mL) | REF 1251 |
| Gentian GCAL [®] Calprotectin Control Kit (2 levels x 1 mL) | REF 1219 |

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]. 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 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 GCAL[®] Calprotectin Immunoassay was found to be 0.40 mg/L.

Linearity

The linearity range of the Gentian GCAL[®] Calprotectin Immunoassay was found to be 0.38-20.26 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 100 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 100 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]. 2 serum pools (S1-2), 1 lithium heparin plasma pool (S3) 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 | 0.93 | 3.62 | 3.86 | 5.29 |
| S2 | 9.13 | 0.87 | 1.41 | 1.65 |
| S3 | 12.75 | 0.88 | 0.58 | 1.05 |
| CL | 1.05 | 3.35 | 1.25 | 3.57 |
| CH | 9.66 | 0.90 | 1.20 | 1.49 |

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 103-119 %.

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 | Coefficient | 95% CI |
|----|-------------------------|----------------|-------------|--------------|
| 43 | 0.56-20.33 | Intercept | 0.08 | [0.03, 0.11] |
| | | Slope | 1.04 | [1.02, 1.06] |
| | | R ² | 1.00 | |



Bjornasveien 5
N-1596 Moss
Norway
TEL: +47 99 33 99 05
www.gentian.com

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

- Harmonised analytical measuring range across Beckman Coulter instruments

Date of issue

2024-11-26

Instrument Settings for the Gentian GCAL[®] Calprotectin Immunoassay on the AU5800¹ (serum/plasma)

Reagent ID: 254

| Parameters | | Specific Test Parameters | | | | | | |
|----------------------------------|----------|--------------------------|----------------|----------|-----------------|--------------------------|-------------------|-------------------------|
| General | LIH | ISE | HbA1c | | Calculated Test | Range | | |
| Test Name: | | CAL1G | < | > | Type: | Serum*** | Operation | Yes |
| Sample Volume | 4.0 | μL | Dilution | 0 | μL | OD Limit | | |
| Pre-Dilution Rate | 1 | | Diluent Bottle | OutSide | | Min.OD | | Max.OD |
| Rgt. Volume | R1(R1-1) | 170 | μL | Dilution | 0 | μL | Reagent OD Limit | |
| | R1-2 | | μL | Dilution | | μL | 1 st . | Low -2.0000 High 2.0000 |
| | R2(R2-1) | 25 | μL | Dilution | 15 | μL | Last | Low -2.0000 High 2.0000 |
| Common Rgt. Type | None | | Name | None | | Correlation Factor A | 0.48 | High 19.16 |
| Wavelength | Pri 660 | nm | Sec. | None | nm | Factor for Maker A | 1 | B 0 |
| Method | END | | | | | | 1 | B 0 |
| Reaction Slope | + | | | | | Onboard Stability Period | 28 | Day 0 Hour |
| Measuring Point1 1 st | 9 | | Last | 15 | | LIH Influence Check | No | |
| Measuring Point2 1 st | | | Last | | | Lipemia | + | |
| Linearity Limit | | % | | | | Icterus | + | |
| Lag Time Check | | | | | | Hemolysis | + | |

| Parameters | | Specific Test Parameters | | | | | |
|-----------------------------|----------------------------|--------------------------|-------|------|-----------------|----------|----------------|
| General | LIH | ISE | HbA1c | | Calculated Test | Range | |
| Test Name: | | CAL1G | < | > | Type: | Serum*** | |
| Value/Flag: | | * | | | | | |
| Specific Ranges: | | | Level | Low | -99999.99 | High | 99999.99 |
| | From | | To | | | | |
| | Sex | Year | Month | Year | Month | Low | High |
| <input type="checkbox"/> 1. | * | * | * | * | * | * | * |
| <input type="checkbox"/> 2. | * | * | * | * | * | * | * |
| <input type="checkbox"/> 3. | * | * | * | * | * | * | * |
| <input type="checkbox"/> 4. | * | * | * | * | * | * | * |
| <input type="checkbox"/> 5. | * | * | * | * | * | * | * |
| <input type="checkbox"/> 6. | * | * | * | * | * | * | * |
| 7. | Standard demographics | | | | | * | * |
| 8. | Not within expected values | | | | | * | * |
| Panic Value | Low | * | High | * | Unit | mg/dL | Decimal Places |
| | | | | | | | 2 |

¹ Registered trademark of Beckman Coulter
Application Note for Gentian GCAL[®] Calprotectin Immunoassay on the AU5800

| Parameters | | Calibration Parameters | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|------------------------|--|----------------------|---|--|-------------------------|--|-------------------|--|-------------|--|--|--|--|--|--|--|--|------------|----|------|-----|------|----------|---------|----------------------|----|----------------------|----------------------|----------|---------|----------------------|----|----------------------|----------------------|----------|---------|----------------------|----|----------------------|----------------------|----------|---------|----------------------|----|----------------------|----------------------|----------|---------|----------------------|----|----------------------|----------------------|----------|---------|----------------------|----|----------------------|----------------------|----------|------------------------|----------------------|----------------------|----------------------|----------------------|----------|------------------------|----------------------|----------------------|----------------------|----------------------|----------|------------------------|----------------------|----------------------|----------------------|----------------------|-----------|------------------------|----------------------|----------------------|----------------------|----------------------|-----------------|--|---|--|---|--|---|--|--|--|--|--|--|------------|----|------|-----|------|---------|------------------------|----------------------|----------------------|----------------------|----------------------|---------|------------------------|----------------------|----------------------|----------------------|----------------------|--|--|--|--|--------------------------------------|--|
| Calibrators | Calibration Specific | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| General | ISE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Test Name: | CAL1G ▾ | < ▢ > ▢ | Type | Serum*** ▾ | Cuvette . ▾ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Use Serum Cal. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">Calibration Type: 6AB ▾</td> <td colspan="2">Formula: Spline ▾</td> <td colspan="2">Counts: 2 ▾</td> </tr> <tr> <td colspan="6" style="text-align: center;"><Calibrator Parameters> Range</td> </tr> <tr> <td></td> <td style="text-align: center;">Calibrator</td> <td style="text-align: center;">OD</td> <td style="text-align: center;">Conc</td> <td style="text-align: center;">Low</td> <td style="text-align: center;">High</td> </tr> <tr> <td>Point 1:</td> <td style="text-align: center;">Cal 1 ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;">**</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>Point 2:</td> <td style="text-align: center;">Cal 2 ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;">**</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>Point 3:</td> <td style="text-align: center;">Cal 3 ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;">**</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>Point 4:</td> <td style="text-align: center;">Cal 4 ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;">**</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>Point 5:</td> <td style="text-align: center;">Cal 5 ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;">**</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>Point 6:</td> <td style="text-align: center;">Cal 6 ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;">**</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>Point 7:</td> <td style="text-align: center;"><input type="text"/> ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>Point 8:</td> <td style="text-align: center;"><input type="text"/> ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>Point 9:</td> <td style="text-align: center;"><input type="text"/> ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>Point 10:</td> <td style="text-align: center;"><input type="text"/> ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td colspan="2"><Point Cal. For</td> <td colspan="2">No. of Correction Points ▾</td> <td colspan="2">Use Master Curve ▾</td> </tr> <tr> <td colspan="6" style="text-align: center;">Master Curve> OD Range</td> </tr> <tr> <td></td> <td style="text-align: center;">Calibrator</td> <td style="text-align: center;">OD</td> <td style="text-align: center;">Conc</td> <td style="text-align: center;">Low</td> <td style="text-align: center;">High</td> </tr> <tr> <td>Point-1</td> <td style="text-align: center;"><input type="text"/> ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>Point-2</td> <td style="text-align: center;"><input type="text"/> ▾</td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td colspan="2">MB Type Factor: </td> <td colspan="2">1-Point Calibration Point ▾</td> <td colspan="2"><input type="checkbox"/> with Conc-0</td> </tr> </table> | | | | | | Calibration Type: 6AB ▾ | | Formula: Spline ▾ | | Counts: 2 ▾ | | <Calibrator Parameters> Range | | | | | | | Calibrator | OD | Conc | Low | High | Point 1: | Cal 1 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | Point 2: | Cal 2 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | Point 3: | Cal 3 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | Point 4: | Cal 4 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | Point 5: | Cal 5 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | Point 6: | Cal 6 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | Point 7: | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | Point 8: | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | Point 9: | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | Point 10: | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <Point Cal. For | | No. of Correction Points ▾ | | Use Master Curve ▾ | | Master Curve> OD Range | | | | | | | Calibrator | OD | Conc | Low | High | Point-1 | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | Point-2 | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | MB Type Factor: | | 1-Point Calibration Point ▾ | | <input type="checkbox"/> with Conc-0 | |
| Calibration Type: 6AB ▾ | | Formula: Spline ▾ | | Counts: 2 ▾ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <Calibrator Parameters> Range | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Calibrator | OD | Conc | Low | High | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point 1: | Cal 1 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point 2: | Cal 2 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point 3: | Cal 3 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point 4: | Cal 4 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point 5: | Cal 5 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point 6: | Cal 6 ▾ | <input type="text"/> | ** | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point 7: | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point 8: | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point 9: | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point 10: | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <Point Cal. For | | No. of Correction Points ▾ | | Use Master Curve ▾ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Master Curve> OD Range | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Calibrator | OD | Conc | Low | High | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point-1 | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Point-2 | <input type="text"/> ▾ | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| MB Type Factor: | | 1-Point Calibration Point ▾ | | <input type="checkbox"/> with Conc-0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Slope Check | None ▾ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Allowance Range Check | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | <input type="checkbox"/> Reagent Blank | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | <input type="checkbox"/> Calibration | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Advanced Calibration Operation | No ▾ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Interval (RB/ACAL) | <input type="text"/> ▾ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | <input type="checkbox"/> Lot Calibration | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Stability | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Reagent Blank | 7 Day 0 Hour | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Calibration | 7 Day 0 Hour | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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