

SARS-CoV-2 Total Antibody



Gentian SARS-CoV-2 Total Antibody Calibrator Kit

REF 1851

For *in vitro* diagnostic use by laboratory professionals.

This document describes the general use of the product above. For instrument specific settings, please refer to the application notes available upon request from marketing@gentian.com.

Intended Purpose

The Gentian SARS-CoV-2 Total Antibody Immunoassay is a turbidimetric assay intended for the *in vitro* quantitative detection of total antibodies to the SARS-CoV-2 spike protein (S1-subunit) in human plasma and serum samples. The Gentian SARS-CoV-2 Total Antibody Immunoassay is intended for use on automated clinical analysers by laboratory professional users.

The Gentian SARS-CoV-2 Total Antibody Immunoassay is intended as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, or a successful response to vaccination. The Gentian SARS-CoV-2 Total Antibody Immunoassay should not be used to diagnose acute SARS-CoV-2 infection.

Calibrator Kit Indication for Use

The Gentian SARS-CoV-2 Total Antibody Calibrator Kit is intended to be used to establish a calibration curve for measuring anti-S1 SARS-CoV-2 antibody concentration in human lithium heparin plasma and serum samples with the Gentian SARS-CoV-2 Total Antibody Immunoassay.

Calibrator Value Assignment

The calibrator value, given in the analytical value sheet, is assigned according to Gentian's value transfer protocol as recommended in ISO 17511 for calibrators and controls. The allowable lot-to-lot variation of the highest calibrator level is within the range 1000 - 1455 BAU/mL. For lot specific concentrations, please consult the analytical value sheet.

Calibrator Standardisation

The Gentian SARS-CoV-2 Total Antibody Calibrator is standardised against the WHO International Standard for anti-SARS-CoV-2 IgG (NIBSC code 20/136).

Assay Kit Components

Products provided	
Gentian SARS-CoV-2 Total Antibody Calibrator Kit (6 levels x 0.5 mL)	REF 1851
Products required, but not provided	
Gentian SARS-CoV-2 Total Antibody Control Kit (2 levels x 0.5 mL)	REF 1819
Gentian SARS-CoV-2 Total Antibody Reagent Kit <ul style="list-style-type: none">R1 Assay Buffer (25 mL)R2 Immunoparticles (4.5 mL)	REF 1801

All products are ready for use.

Composition

The Gentian SARS-CoV-2 Total Antibody Calibrator consists of avian anti-SARS-CoV-2 S1 antibodies in PSA buffer. ProClin® 950 is used as preservation. For lot specific concentrations, please consult the analytical value sheet.

Hazards identification



Hazard pictograms (CLP):

GHS07

Signal word (CLP): Warning

Contains: 2-methylisothiazol-3(2H)-one

Hazard statements (CLP):

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP):

P280 - Wear eye protection, protective gloves, protective clothing.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

To obtain the SDS (safety data sheet), please contact Gentian at marketing@gentian.com.

Warnings and Precautions

- Contains substances from human or animal origin and should be considered as potentially infectious material. Handle with caution and discard following local regulations.
- Contains avian proteins. Handle with due caution to avoid allergic skin reaction.

Additional Handling Instructions

- This test is for *in vitro* use only and must be handled by qualified personnel.
- Use only validated and approved instrument applications.
- Do not use products after the expiration date has passed.
- Do not mix reagents of different lots or interchange caps of reagents, controls, calibrators, and lots.
- Tighten caps carefully back on after use of reagents, calibrators, and controls to avoid evaporation.

Reagent Storage and Stability

All products provided for the Gentian SARS-CoV-2 Total Antibody Immunoassay must be stored at 2-8°C. The expiry date is printed on the labels. Using an BS240 instrument (Mindray), the in-use stability of the Gentian SARS-CoV-2 Total Antibody Calibrators was found to be at least 8 weeks in a study using a protocol based on the CLSI guideline EP25. For calibration curve stability, please refer to the instrument specific application notes.

Procedure

Application Notes

Applications of the Gentian SARS-CoV-2 Total Antibody Immunoassay have been established on several clinical chemistry analysers. Detailed, validated application notes describing the procedures for installation and analysis on specific instruments are available upon request from marketing@gentian.com. For instructions on how to install a new

application, consult the instrument manual. Maintenance, operation, and precautions must be handled in accordance with the specific instrument manual.

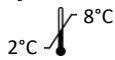















Establishment of the Calibration Curve

The calibrator levels 1 to 6 are used to establish a 6-point standard curve as defined in the instrument manual. The calibrators are ready to use. Do not program dilution. Calibrator values are lot specific, and calibration must be performed whenever a new lot is used. The values assigned to the calibrators are provided in the analytical value sheet. A new calibration should be performed according to the instrument specific calibration curve stability or when a new reagent lot is used.

QC Controls

The Gentian SARS-CoV-2 Total Antibody Controls should be assayed every day the test is in use to validate the calibration curve. The controls have lot specific concentration ranges that must be met before measuring samples. The assigned value ranges are given in the analytical value sheet. If the control values measured are not valid, repeat the control measurements. Recalibrate if necessary. If the calibration cannot be performed without error, or valid control values cannot be reproduced, contact the local distributor for support.

Symbols Key

	Temperature Limit
	Use by Date
	Consult Instructions for Use
	Manufacturer
	CE Mark
	<i>In Vitro</i> Diagnostic Medical Device
	Lot Number
	Catalogue Number
	Unique Device Identifier
	Contents
	Calibrator
	Calibrator Level 1
	Calibrator Level 2
	Calibrator Level 3
	Calibrator Level 4
	Calibrator Level 5

CAL 6

Calibrator Level 6



Warning

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Serious Incidents

Please notify the manufacturer and your competent authority if any serious incidents have occurred in relation to the device.

Changes from previous version

First version

Date of issue

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