Retinol-Binding Protein

Gentian Retinol-Binding Protein Calibrator Kit

REF 11051

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

In vitro diagnostic reagent for the quantitative determination of retinol-binding protein in samples of human origin by immunoturbidimetry on photometric systems

Calibrator kit indication for use

The Gentian Retinol-Binding Protein Calibrator Kit is intended to be used to establish a calibration curve for measuring retinol-binding protein (RBP) concentration in human serum and fresh plasma samples with the Gentian Retinol-Binding Protein Immunoassay.

Calibrator value assignment

The assigned lot specific calibrator values are given in the analytical value sheet available on www.gentian.com.

Calibrator standardisation

No international standard is available for Retinol-Binding Protein. The calibrator values for the Gentian Retinol-Binding Protein Calibrator Kit are established based on internal reference material.

Assay kit components

Products provided	
Gentian Retinol-Binding Protein Calibrator Kit (5 levels x 1 mL)	REF 11051
Products required, but not provided	
Gentian Retinol-Binding Protein Control Low (1 x 2 mL)	REF 11020
Gentian Retinol-Binding Protein Control Medium (1 x 2 mL)	REF 11021
Gentian Retinol-Binding Protein Control High (1 x 2 mL)	REF 11022
Gentian Retinol-Binding Protein Reagent Kit • R1 Gentian Retinol-Binding Protein Assay Buffer (1 x 40 mL) • R2 Gentian Retinol-Binding Protein Reagent (1 x 13 mL)	REF 11001

All products are ready for use.

Composition

Gentian Retinol-Binding Protein Calibrator are human biological fluids containing human Retinol-Binding Protein at fixed values and sodium azide (<1g/L) as preservative. For lot specific concentrations, please consult the analytical value sheet available on www.gentian.com.

Warnings and precautions

1. Contains substances from human or animal origin and should be considered as potentially infectious material. Handle with caution and discard following local regulations.
2. The sodium azide concentration of this product is not characterised as hazardous. Although, accumulated NaN_3 in lead and copper pipes may cause generation of explosive metal azides. To prevent this, rinse thoroughly if discarded into the drain.
3. Contains a sensitizing substance below concentration limit. May produce an allergic reaction in some people and may cause respiratory irritation if inhaled.
4. Exposure may result in irritation of skin and eyes.
5. Avoid contact with incompatible materials.
6. Avoid exposure to heat and direct sunlight.

For additional safety information, please refer to the SDS (Safety Data Sheet) available on www.gentian.com.

Additional handling instructions

1. This test is for *in vitro* use only and must be handled by qualified personnel.
2. Use only validated and approved instrument applications.
3. Do not use products after the expiration date has passed.
4. Do not mix reagents of different lots or interchange caps of reagents, controls, calibrators, and lots.
5. 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 Retinol-Binding Protein Immunoassay must be stored at 2-8°C. The expiry date is printed on the labels.

Procedure

Application notes

Applications of the Gentian Retinol-Binding Protein 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 5 are used to establish a 6-point standard curve as defined in the instrument manual. The zero point of the calibration curve is performed with physiological saline solution. 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 available on www.gentian.com. 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 Retinol-Binding Protein Controls must be tested each day before any samples are measured 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 available on www.gentian.com. 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

2°C 8°C	Temperature Limit
	Use by Date
	Consult Instructions for Use
	Manufacturer
CE	CE Mark
UK CA	UKCA mark
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	Catalogue Number
UDI	Unique Device Identifier
CONTENTS	Contents
CAL	Calibrator
CAL 1	Calibrator Level 1
CAL 2	Calibrator Level 2
CAL 3	Calibrator Level 3
CAL 4	Calibrator Level 4
CAL 5	Calibrator Level 5

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References

1. Tietz Textbook of Clinical chemistry and molecular Diagnostics, fourth edition, edited by Carl A. Burtis, Edward R. Ashwood, David E. Bruns, 2006
2. Use of Anticoagulants in Diagnostic Laboratory Investigations & Stability of blood, plasma and serum samples. Publication WHO/DIL/LAB/99.1 Rev. 2. Jan. 2002.
3. Clinical guide to laboratory tests, second edition, edited by Norbert W. Tietz, 1990.
4. NCCLS. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Fifth Edition. NCCLS document H4-A5 [ISBN 1-56238-538-0]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004

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

- Included the information about the SDS and analytical value sheet available on the Gentian website.
- Included UKCE mark and the Representative section.

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