# Retinol-Binding Protein

## Gentian Retinol-Binding Protein Control Low, Medium, High

REF 11020, 11021, 11022

**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.

## Control kit indication for use

The Gentian Retinol-Binding Protein Controls are intended to monitor and evaluate the quality of the calibration curve established from the Gentian Retinol-Binding Protein Calibrator Kit with the Gentian Retinol-Binding Protein Reagent Kit.

## Control value assignment

The control 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 depending on control level** | |
|---|---|
| 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 |
| **Products required, but not provided** | |
| Gentian Retinol-Binding Protein Calibrator Kit (5 levels x 1 mL) | REF 11051 |
| Gentian Retinol-Binding Protein Reagent Kit<br>• R1 Gentian Retinol-Binding Protein Assay Buffer (1 x 40 mL)<br>• R2 Gentian Retinol-Binding Protein Reagent (1 x 13 mL) | REF 11001 |

*All products are ready for use.*

## Composition

The Gentian Retinol-Binding Protein control is a human biological fluid containing human RBP 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

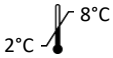
### Application notes

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.

### QC controls

The Gentian Retinol-Binding Protein Controls should be assayed every day the test is in use to validate the calibration curve. The controls are ready to use. 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

| | |
|---|---|
|   | Temperature Limit |
|  | Use by Date |
|  | Consult Instructions for Use |
|  | Manufacturer |
|  | CE Mark |
|   | UKCA mark |
|   | *In Vitro* Diagnostic Medical Device |
|   | Lot Number |
|   | Catalogue Number |
|   | Unique Device Identifier |
|   | Contents |
|   | Control Low |
|   | Control Medium |
|   | Control High |

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## Representatives

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|---|---|
| UK Responsible Person | Emergo Consulting (UK) Limited<br>c/o Cr360 – UL International<br>Compass House, Vision Park Histon<br>Cambridge CB24 9BZ<br>United Kingdom |

## 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].

## Serious incidents

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

## Modifications 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.

## Date of issue

2023-09-27