

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 <ul style="list-style-type: none"> • R1 Gentian Retinol-Binding Protein Assay Buffer (40 mL) • R2 Gentian Retinol-Binding Protein Reagent (13 mL) 	REF 11001
Gentian Retinol-Binding Protein Reagent Kit S <ul style="list-style-type: none"> • R1 Gentian Retinol-Binding Protein Assay Buffer (20 mL) • R2 Gentian Retinol-Binding Protein Reagent (6 mL) 	REF 11002

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 NaN₃ 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

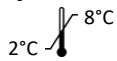
Application notes

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

UK Responsible
Person

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Compass House, Vision Park Histon
Cambridge CB24 9BZ
United Kingdom

References

Not applicable

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 11002 Gentian Retinol-Binding Protein Reagent Kit 5
- References section was corrected