Retinol-Binding Protein

Gentian Retinol-Binding Protein Reagent Kit

REF 11001

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 to 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.

Summary and explanation of test

Retinol-Binding Protein (RBP) is a transport protein for retinol (alcohol derivate of vitamin A) in blood. RBP is a single polypeptide chain protein with molecular mass of around 21 kDa and a member of the lipocalin family. It is the only know specific transport protein for retinol. RBP is synthesized and stored in the liver before binding to retinol in addition to prealbumin to stabilize the complex (in a 1:1:1 complex) and avoid renal filtration. In the circulation RBP is mostly saturated with retinol; around 85% under healthy conditions. Retinol-free RBP in the circulation is filtrated by the kidney and almost completely reabsorbed by the proximal renal tubule. The concentration of RBP in blood remains mostly constant in healthy individuals, though the levels can be altered in many conditions. Decreased RBP serum and plasma levels are observed under vitamin A deficiency and undernutrition, impaired hepatic biosynthetic capacity and severe or acute inflammation. An increase in RBP is observed in glomerular desease, obesity, insulin resistance and type 2 and gestational diabetes. [1-5]

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.

Relevant calculations

The evolution of analyte concentration (Conc) dependence of absorbance variation (A_{conc}) is described by asymmetric sigmoidal function:

$$A_{(conc)} = \frac{A_{max}}{1+exp-(a+b.\log(Conc))}$$

A_0 is blank sample absorbance, A_{Max} is the highest absorbance of the curve, a and b are inflexion parameters of the curve.

Assay principle

The retinol-binding protein contained in the sample to assay reacts specifically with anti-human retinol-binding protein antiserum and the turbidity induced by the formation of the antigen-antibody immune complex is measured at 340 nm and 700 nm. The measured turbidity is proportional to the retinol-binding protein concentration contained in the sample.

Assay kit components

Products provided	
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

Products required, but not provided	
Gentian Retinol-Binding Protein Calibrator Kit (5 levels x 1 mL)	REF 11051
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

All products are ready for use.

Composition

Reaction Buffer 1 (R1, 40 mL inactive ingredient): Phosphate buffer, polymer, inorganic salt and preservative (0.09 % Sodium azide).
Reaction Buffer 2 (R2, 13 mL): Active component: anti-RBP goat anti-serum. Other components: buffer, inorganic salt and preservative.

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. Use only validated and approved instrument applications.
2. Do not use products after the expiration date has passed.
3. Do not mix reagents of different lots or interchange caps of reagents, controls, calibrators, and lots.
4. Tighten caps carefully back on after use of reagents, calibrators, and controls to avoid evaporation.
5. Do not freeze the reagents.

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.

Specimen collection and handling

Collect specimens using standard laboratory techniques; use only suitable procedures, tubes, or collection containers. Recommended sample material is fresh plasma or serum. It is recommended to sample after 12 hours of fasting and drug intake, and to analyse the samples as fresh as possible. Sample stability data from “Tietz Clinical Guide to laboratory Tests” [6] and from “WHO” [7] testing showed that RBP was stable indefinitely stored at -70 °C, and up to 6 months -20 °C, and up to 72 hours at 4 to 8 °C. Mix samples well before analysing.

Performance characteristics

The results refer to the main validation of the Gentian Retinol-Binding Protein Immunoassay on a Cobas c501 instrument (Roche) at one instrument site with one lot of reagents, unless otherwise stated. For the instrument specific performance characteristics, please refer to the instrument specific application notes.

Measuring range

The measuring range of the Gentian Retinol-Binding Protein Immunoassay is approximately 7.8-139 mg/L. The exact measuring range is calibrator- and instrument specific, please refer to the analytical value sheet for the lot specific calibrator values (available on www.gentian.com) and the instrument specific application notes.

Analytical sensitivity

The analytical sensitivity of the Gentian Retinol-Binding Protein Immunoassay was tested in a study based on the CLSI guideline EP17 [8]. 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 was measured to be 7.81 mg/L. For the instrument specific LoQ, please refer to the instrument specific application notes.

Precision

The total precision of the Gentian Retinol-Binding Protein Immunoassay was measured with a CV <5% in a study based on the CLSI guideline EP05 [9]. For the instrument specific total precision, please refer to the instrument specific application notes.

Analytical specificity and limitations

No interference is detected for this product with triglycerides, haemoglobin, bilirubin, sodium citrate, EDTA, heparin or sodium fluoride at the tested concentrations in a study based on the CLSI guideline EP07 [10]. For the instrument specific interference, please refer to the instrument specific application notes.

Assay 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 to 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.

Reagent preparation

The reagents are ready for use. Mix the reagents gently before placing them into the assigned reagent positions. The reagent bottles may fit directly into the instrument unless otherwise stated in the application notes.

Establishment of the calibration curve

Please refer to the instruction for use of the Gentian Retinol-Binding Protein Calibrator Kit (REF 11051) available at www.gentian.com.

QC controls

Please refer to the instruction for use of the Gentian Retinol-Binding Protein Control Kit (REF 11020, 11021, 11022) available at www.gentian.com.

Measuring patient samples

When a valid calibration curve has been established and the control values are within the valid range, the fresh plasma or serum sample may be measured. Ensure that the minimum sample volume is present in the sample cups/tubes and assay the samples according to the instructions given in the instrument manual.

Results

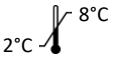
The results are calculated automatically by the instrument for all applications established for the Gentian Retinol-Binding Protein Immunoassay. The results are presented in mg/L.

Clinical performance

Reference intervals

The reference interval is 30 - 60 mg/L. This information coming from data originating from "Clinical guide to laboratory tests" [11]. Each laboratory must check the validity of its values and if necessary, establish its own reference values, depending on the population examined.

Symbols key

	Temperature Limit
	Use by Date
	Consult Instructions for Use
	Manufacturer
	CE Mark
	UKCA mark
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	Catalogue Number
UDI	Unique Device Identifier
CONTENTS	Contents
R1	R1 Assay Buffer
R2	R2 Immunoparticles

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References

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10. CLSI. Interference Testing in Clinical Chemistry. 3rd ed. CLSI guideline EP07. Wayne, PA: Clinical Laboratory Standards Institute; 2018.
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Serious incidents

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

Modification from the previous version

- Updates on Summary and explanation of test, Specimen collection and handling, Measuring range, Analytical specificity and limitations and References sections.
- Included the information about the SDS available on the Gentian website.
- Included UKCE mark and the Representative section.

Date of issue

2023-09-28