Order references

Reagents

REF		CONT
RBTUR-B00	*Universal kit*	1x 40 ml R1 + 1 x 13 ml R2
RBTUR-H00	*Universal kit*	2 x 40 ml R1 + 2 x 13 ml R2
RBTUR-L00	*Universal kit*	12 x 40 ml R1 + 12 x 13 ml R2

Other necessary products

REF		CONT
RBREK-000	*RBP Calibrators Kit (5 Levels)*	5 x 1 ml
RBCOS-002	*RBP Low Control*	1 x 2 ml
RBCON-002	*RBP Medium Control*	1 x 2 ml
RBCOX-002	*RBP High Control*	1 x 2 ml

Field of application - Purpose

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

Medical benefit - Scientific validity

Retinol-binding protein (RBP) is an unglycosylated protein synthesised by the liver. The role of RBP is to transport retinol (vitamin A) from the liver to the target tissues (retina, skin, etc.) in the bloodstream. This protein is then metabolised, filtered and reabsorbed in the kidney. RBP is a sensitive marker of undernutrition and the monitoring of its serum concentration allows the monitoring of nutritional status. Decreased RBP serum and plasma levels are also observed in the event of hypovitaminosis A, tubular nephropathies, hepatocellular insufficiency or severe or acute inflammation. An increase in RBP is correlated with of glomerular renal failure, type 2 diabetes or steatosis.

Method 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.

Warning and precautions

- For in vitro diagnostic use only.
- Must be handled by qualified personnel under the responsibility of a biologist.
- The human-origin products have been screened and found negative for HIV 1 and 2 antibodies, HCV antibodies and HBAg, but they must nevertheless be handled as potentially infectious products.
- These products contain sodium azide. Products containing sodium azide must be handled with care: avoid ingestion and contact with the skin or mucous membranes.
- Sodium azide becomes explosive on contact with heavy metals such as copper or lead.

Samples

Collection conditions

Collect specimens using standard laboratory techniques; use only suitable procedures, tubes or collection containers.

Sample type

Serum and fresh plasma

Storage and stability of specimens

Temperature	Stability
-70°C	Indefinitely
- 20 °C	≤ 6 months
4 - 8 °C	≤ 72 hours

This information comes from data originating from “Tietz Clinical Guide to Laboratory Tests” and from “WHO”.

Reagents

Composition and concentrations/Storage

Active components:
Reagent R1: none
Reagent R2: anti-RBP goat anti-serum .

Other components:
Reagent R1: buffer, polymer, inorganic salt and preservative.
Reagent R2: buffer, inorganic salt and preservative.

Conservation temperature:
Reagent R1: 2 - 8 °C.
Reagent R2: 2 - 8 °C.

Preparation

Ready to use.

Storage and stability

Reagents are stable until the expiration date printed on the packaging (months passed), under the following recommended storage and handling conditions:

- Unopened vial stored at temperature indicated on packaging.
- Opened vial: closed immediately after use or placed on closed analyser intended for this purpose, not contaminated by handling and stored at the temperature indicated on the packaging.

Note:

- Do not freeze the reagents.
- Nanoparticle-based reagents can settle over time. It may be necessary to delicately mix by repeated turning.

Other materials required

Usual laboratory equipment including an analytical system equipped with a photometric detector.

Calibration

Calibration

The calibration curve is performed by using the calibration kit indicated in the “Order references” section. The zero point of the calibration curve is performed with physiological saline solution.

Traceability

The method has been standardised with a benchmark method traceable to the international standard as described in the associated calibrators data sheet (see the “Order references” section).
Calibrate the method when the reagent batch number changes or in case of change in performance (contact the manufacturer if the changes persist) or if quality control requires it.

Quality control

The frequency of controls and the confidence limits must be adapted to the laboratory requirements. The results must be within the defined confidence limits. Each laboratory shall establish corrective measures to be taken if results fall outside the defined limits. Comply with current legislation in the country and local guidelines relating to quality control.
The calibration curve and its stability can be validated using the control materials indicated in the “Order references” section**.**

Reference values

	Reference values
Healthy individual	30 - 60 mg/L

International units: mg/L
Conventional units: mg/L

This information coming from data originating from “Clinical guide to laboratory tests”. Each laboratory must check the validity of its values and if necessary establish its own reference values, depending on the population examined.

Analytical performances

The analytical performance data below are given as an indication. The results obtained in the laboratory may differ from these.

Measurement range

7,81-141 mg/L
Linearity was assessed according to Clinical and Laboratory Standards Institute (CLSI) protocol EP06-A. The method has been demonstrated to be linear up to 141 mg/L.
The Limit of Quantitation was determined in accordance with the CLSI EP17-A2 requirements, based on 126 determinations and a TE goal of 20 % calculated using the Westgard model. The associated bias and precision components were 0,4 mg/L and 7,5 %, respectively.
The measurement range is bounded by the quantification and linearity limits. Samples having a concentration greater than the upper limit must be diluted.

Lower limits of measurement

Limit of Blank = 0,65 mg/L
Limit of Detection = 1,25 mg/L
The Limit of Blank was determined in accordance with the CLSI EP17-A2 requirements, based on 120 determinations of blank samples. The Limit of Blank is the 95th percentile of the standard normal distribution of the blank samples determination.
The Limit of Detection was determined in accordance with the CLSI EP17-A2 requirements and with a proportion of false positive (α) less than 5 % and false negative (β) less than 5 %, based on 120 determinations with low level replicates.

Interferences (Analytical specificity)

Icterus: No significant interference up to a bilirubin concentration of 500 µmol/L (< 10 % or 2 SD).
Hemolysis: No significant interference up to a hemoglobin concentration of 6,9 g/L (< 10 % or 2 SD).
Lipemia: No significant interference up to a triglycerides concentration of 32 g/L (< 10 % or 2 SD).

Precision

Precision was evaluated with 3 quality controls following the CLSI protocol EP05-A3. Within-run precision was determined using 2 runs per day with 2 replicates per run. Within-lab precision was determined using a single lot of reagent and at least 4 calibrations. These results are guidelines. Variables (e.g. instrument maintenance, environment, sample handling) can affect the reproducibility of test results.

	Number of days	Number of measures	Mean concentration	Within-run CV	Within-lab CV
Control 1	22	88	33.80 mg/L	2.53 %	3.53 %
Control 2	22	88	50.49 mg/L	1.80 %	2.81 %
Control 3	22	88	62.93 mg/L	1.30 %	2.56 %

Trueness - Accuracy

Trueness, quantified by the bias, is estimated by comparing the mean obtained in the intermediate precision study, based on internal quality control samples, with the expected target value equated to the “true” value of the tested sample.
Accuracy is defined as the closeness of agreement between a measured value and a true value of a measurand (quantity to be measured).
DiAgam allows a bias of 5% compared to the international standard or compared to a reference method traceable to the international standard when it exists.

Limitations of the method

The results of this test should always be interpreted in relation to the patient’s medical history, clinical signs and other findings.

Prozone

By limiting the linearity to the value of the upper limit of the measurement range, no excess antigen effect was observed for samples with a concentration up to 600 mg/L.

Matrix effect

The inter-laboratory control samples and controls can yield different results from those obtained with other assay methods because of a matrix effect. In this case, an analysis of the results according to specific target values of the method utilised may be necessary. If in doubt, contact the manufacturer.

Utilisation procedure

If the application corresponding to the barecode is not installed on your analyzer, please contact DiAgam. Indeed CE validated applications are available from the manufacturer.
For a detailed description on how run an assay, please refer to the operating instructions for your system.

Literature

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. CLSI. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition. CLSI document H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2007.
5. 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.

Symbols legend

The following symbols may appear on the packaging and the label:

LOT	*Batch code*	BUF	*Buffer*
	Use until	CAL	*Calibrator*
	Manufacturer	H	*High*
IVD	*In vitro diagnostic medical device*	M	*Moderate*
	Temperature (Storage at)	L	*Low*
REF	*Catalogue reference*	4 LEV	*4 levels*
	Read the usage instructions	5 LEV	*5 levels*
REAG	*Reagent*	6 LEV	*6 levels*
KIT	*Kit*	CONTROL	*Control*
CONT	*Content*	CE	*This product meets the requirements of European Directive 98/79 EC concerning in vitro diagnostic medical devices*
Ab	*Antibody or Antisera*		

	DiAgam Belgium: Rue du Parc Industriel 40, 7822 Ghislenghien, Belgium
DiAgam Headquarters	*Avenue Louis Lepoutre 70, 1050 Bruxelles, Belgique*
Distributed by	*DiAgam France: Boulevard de la Liberté 130, 59000 Lille, France*