

Bioway Chemistry Reagent Series

Retinol-binding protein Test Kit

Detection of Retinol-Binding Protein in Human serum on Chemistry Analyzers



Cat. No. R048K11

The RBP Test Kit

SUMMARY OF TEST PROCEDURE

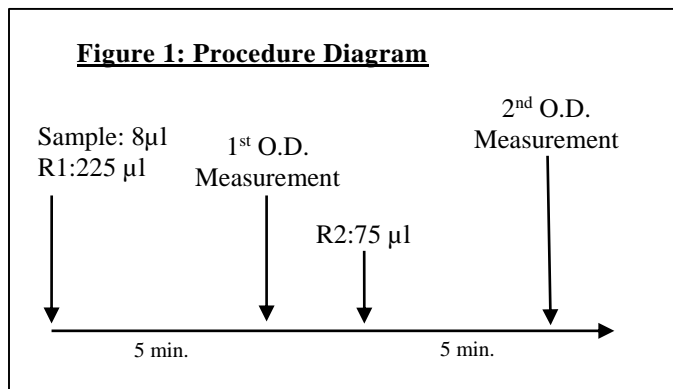


Table 1: Instrument Parameters*

Calibration method	5 point non-linear	Slope of reaction	increase
Wavelength	Dλ : 340nm Sλ : 700nm	Sample volume	8 µl
Test method	2 point end	R1 volume	225 µl
Reaction temperature	37°C	R2 volume	75 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series Retinol-binding protein Reagent Kit (the Kit) is an immunoturbidimetric assay intended for *in vitro* quantitative detection of retinol-binding protein in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Vitamin A deficiency has become a serious problem among women and children in developing countries around the world. A reliable detection method for vitamin A supplementation is needed. Serum retinal concentration is a good indicator of vitamin A status but it is very unstable while exposing to heat or light, and the techniques are also expensive and complicated. An alternative way is to measure the concentration of retinol binding protein, the 1 to 1 carrier of retinol in the blood. Retinol-binding protein is a 21-kDa protein synthesized by the liver and easy to be quantified by routine immunoassay.

TEST PRINCIPLES

The Kit utilizes immunoturbidimetry to measure the retinol-binding protein level in human serum or plasma. During the test, retinol-binding protein in the sample binds with the specific anti-retinol-binding protein antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of retinol-binding protein in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Phosphate buffer, pH 7.2-7.6 Polyethylene glycol 6000 EDTA-Na2	40mmol/L 83mmol/L 10mmol/L
R2	goat anti-human RBP Phosphate buffer, pH 7.2-7.6 EDTA-Na2	6ml 40mmol/L 10mmol/L

MATERIALS NEEDED BUT NOT PROVIDED

- Automated chemistry analyzer
- Retinol-binding protein calibrator set and control set (available for purchase)

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8°C after opening.

PRECAUTIONS

- The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2-8° C for up to 24 hours or at -80° C for up to a months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

Calibration: 5 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

- Add 8 µl of sample and 225 µl of R1, mix well and incubate at 37°C for 5 minutes.
- Take 1st optical density measurement OD at 5 minutes.
- Add 75 µl of R2, mix well and incubate at 37°C for another 5 minutes.
- Take 2nd optical density measurement OD.
- Calculate $\Delta OD = OD 2 - OD 1$

RESULT

The % retinol-binding protein can be obtained by using the calculated ΔOD to find the corresponding % retinol-binding protein on a calibration curve.

EXPECTED VALUES

26.7-70 mg/L in 95% standard deviation of 120 health human beings. It is recommended for each laboratory to establish its own expected values

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QUALITY CONTROL

Commercially available retinol-binding protein controls may be used. It is recommended to use Randox retinol-binding protein Control set (available for purchase) for optimal results.

A control should be tested before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The Kit should not be used for the diagnosis of diabetes mellitus.
3. Samples exceeding 126mg/L should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0.0~126 mg/L ($R \geq 0.99$); linearity deviation $\leq 10\%$

Accuracy: control recovery relative deviation $\leq 10\%$

Precision: Within Run: $CV \leq 6\%$;
Run-to-Run: $CV \leq 10\%$

Interference: no interference detected for: Bilirubin ($<1026 \mu\text{mol/L}$), Hemoglobin ($<4.0 \text{ g/L}$), triglycerides ($<11.3 \text{ mmol/L}$)

Reagent Blank Absorbance: at 340nm wavelength and 10 mm optical diameter, O.D. ≤ 0.5

REFERENCES

1. Blaner W. S. *et al.*, EndocrRev 26:1241-1251 (1989)
2. Naylor H. M. *et al.*, Biochemistry 38:2647-2653 (1999)
3. Blaner W. S. *et al.*, EndocrRev 10:308 (1980)

Not Intended for Sale in the United States.

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