

The β 2-Microglobulin Turbidimetric Immunoassay Reagent Kit

Catalogue number: 51680

For the quantitative determination of β 2-Microglobulin
in human serum and plasma

This package insert must be read in its entirety before using this product
Use only the current version of product data sheet enclosed with the kit

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**FOR RESEARCH USE ONLY
NOT FOR USE IN DIAGNOSTIC PROCEDURES**

Version: 5.22

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PACKING SPECIFICATION

Cat. No.	Size	Approximately tests
51680-05	R1: 15ml, R2: 5ml	100
51680-10	R1: 30ml, R2: 10ml	200
51680-20	R1: 60ml, R2: 20ml	400
51680-50	R1: 150ml, R2: 50ml	1000
51680-100	R1: 300ml, R2: 100ml	2000

INTRODUCTION

β 2-Microglobulin(β 2-MG), is a small-molecule globulin produced by lymphocytes, platelets, and polymorphonuclear leukocytes, with a molecular weight of 11,800 and a single-chain polypeptide consisting of 99 amino acids. It is the β chain (light chain) portion of the human leukocyte antigen (HLA) on the cell surface. It contains a pair of disulfide bonds in the molecule and contains no sugar; similar to the structure of the immunoglobulin stable region. It is widely found in plasma, urine, cerebrospinal fluid, saliva, and colostrum. Normal human β 2-microglobulin synthesis rate and release from the cell membrane are fairly constant. B2-microglobulin can be freely filtered from the glomerulus, 99.9% is absorbed in the proximal tubules, and in renal tubular epithelial cells Decomposition and destruction; therefore, the emission of β 2-microglobulin is very small under normal circumstances. β 2-MG mainly reflects glomerular filtration dysfunction, urine β 2-MG mainly reflects renal tubular reabsorption function impairment. It also can be used as a tumor marker for some people with blood cell cancers (multiple myeloma, lymphoma) to give information about their likely prognosis. The health reference of β 2-MG is 0.8-2 mg/L in blood and 0.11-0.32 mg/L in urine.

PRINCIPLE OF THE ASSAY

This assay is a turbidimetric immunoassay for the quantitative measurement of β 2-MG in human serum and plasma. A standard or sample is added into a cuvette and mixed with the reaction buffer R1. After a short incubation, the test reagent R2, which is a suspension of microparticles coated with β 2-MG antibodies, is added into the cuvette and mixed. The presence of β 2-MG in the

standard or sample causes the immune-particles to aggregate. The extent to which the microparticles aggregate is quantified by the amount of light scattering measured as absorbance by a chemistry analyzer. The concentration of β 2-MG in unknown samples can be interpolated from a reference curve using the standards provided.

REAGENTS SUPPLIED

R1 – Reaction buffer, 30 ml, a ready-to-use buffer solution containing salt, polyether compound and preservative

R2 – Test reagent, 10 ml, a ready-to-use suspension of polymer microparticles coated with rabbit anti- β 2-MG polyclonal antibodies in storage buffer

OTHER MATERIALS REQUIRED

1. Clinical chemistry analyzer
2. β 2-Microglobulin Calibrator (provided separately, Cat. #51680-S1)
3. β 2-Microglobulin Control (optional, provided separately, Cat. #51680-C1)
4. Deionized water
5. Analyzer-specific reagent containers for R1 and R2

STORAGE

The kit should be stored at 2-8°C upon receipt. Once opened, the reagents may be stored at 2-8°C for up to 4 weeks.

SAMLE HANDLING

This kit can be used to determine β 2-Microglobulin in human serum and plasma samples. Blood specimens should be collected aseptically into appropriate tubes. Plasma should be prepared by standard techniques for laboratory testing. The prepared specimens should be stored in closed vessels. If the assay cannot be performed within 24 hours or specimens are to be shipped, the specimens should be frozen at -20°C or below. For long-term storage of specimens, -70°C or below is recommended. To avoid freeze-thaw cycles, specimens should be aliquoted. Do

not use hemolyzed, hyperlipemia, heat-treated or contaminated specimens. No dilution of the sample is required in this assay.

ASSAY PROCEDURE

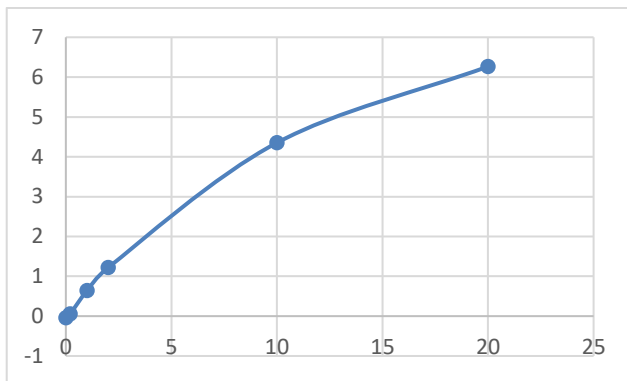
Assay procedures may vary depending on the automated chemistry analyzer to be used. A general example of assay procedures is stated as follow:

1. Dispense 180µl of R1 into a clean cuvette
2. Add 2µl of sample and incubate at 37°C for 5 minutes
3. Further add 60µl of R2
4. Read change of absorbance at Main Wavelength 570 nm for 8 minutes after the addition of R2
5. Calculate the concentration of β2-Microglobulin in unknown sample by interpolation from a reference curve using the standards provided

TYPICAL STANDARD CURVE

The following standard curve is provided for demonstration only. A standard curve should be generated for each assay.

β2-MG (mg/L)	Absorbance
0	-0.042
0.2	0.055
1	0.640
2	1.217
10	4.353
20	6.265



CALCULATION

1. Subtract the absorbance of the blank from that of standards and samples.
2. Generate a standard curve by plotting the absorbance obtained (y-axis) against β 2-Microglobulin concentrations (x-axis). The best fit line can be generated with any curve-fitting software by regression analysis. 4-parameter curve fitting can be used for calculation.
3. Determine β 2-Microglobulin concentration of samples from standard curve.

ASSAY CHARACTERISTICS

A. Sensitivity

The sensitivity is defined as the lower limit of detection and is estimated as the mean of the blank sample plus three times the SD obtained from the blank sample. The sensitivity of β 2-Microglobulin assay is 0.042 mg/L.

B. Precision

The precision of the β 2-Microglobulin assay is < 10% CV. Two samples consisting of serum-based panels were assayed 20 times separately.

Sample	Mean β 2-MG (mg/L)	SD (mg/L)	CV
Panel 1	1.41	0.008	0.58%
Panel 2	1.73	0.022	3.00%

C. Linearity

The β 2-Microglobulin assay is linear between 0.2 mg/L to 20 mg/L.

D. Interference

No interference was detected with hemoglobin up to 5 g/L, conjugated bilirubin up to 300 mg/L, free bilirubin up to 300 mg/L, and up to 5g/L lipid emulsion.