K-*ASSAY*®

Beta-2 Microglobulin

For the Quantitative Determination of Human Beta-2 Microglobulin in Serum / Plasma or Urine

Cat. No. KAI-280

INTENDED USE

For the quantitative determination of human Beta-2 Microglobulin in serum / plasma or urine by immunoturbidimetric assay. FOR *IN VITRO* DIAGNOSTIC USE.

INTRODUCTION AND SUMMARY

Beta-2 Microglobulin (β2MG) is a low molecular weight protein (M.W.: 11,800) which is found in minute quantities in various body fluids such as blood and urine. The measurement of β2MG is useful in the diagnosis of functional renal disorders and various malignant tumors, in treatment assessment and disease prognosis for myeloma, and also in monitoring the activity of chronic lymphocytic leukemia and AIDS.[1] The **K-*ASSAY*®** Beta-2 Microglobulin assay is intended for the quantitative determination of human β2MG in serum / plasma or urine by latex-enhanced immunoturbidimetric assay.

PRINCIPLE OF TEST

When an antigen-antibody reaction occurs between β2MG in a sample and β2MG antibody that has been adsorbed to latex particles, agglutination results. This agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of β2MG in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

KIT COMPOSITION

Reagents (Liquid Stable)

R1: Buffer Reagent 1 x 45 mL
Glycine buffer solution (170 mM)

R2: Latex Suspension 1 x 20 mL
Latex particles coated with rabbit anti-human β2MG antibodies (0.30% w/v)

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. Rx only.

Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.

Do not mix or use reagents from one test kit with those from a different lot number.

Do not use reagents past their expiration date stated on each reagent container label.

Do not pipette by mouth. Avoid ingestion and contact with skin.

Reagents in this kit contain < 0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of reagents through plumbing fixtures, flush with copious amounts of water. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts," in the Manual Guide-Safety Guide Management No. CDC-22 issued by the Center for Disease Control, Atlanta, Georgia.

REAGENT PREPARATION

Reagents are ready to use and do not require reconstitution.

STORAGE AND STABILITY

All reagents should be stored at 2-8°C and protected from light. Unopened reagents can be used until the expiration date on the package and bottle labels. Discard reagents if they become contaminated. Evidence of obvious precipitation in reagent 2 (R-2) solution is cause to discard. Once the reagent bottle has been opened, store tightly capped at 2-8°C and use within 1 month.

SPECIMEN COLLECTION AND PREPARATION

The sample may be serum, plasma, or urine (depending on calibrator used).

For serum samples, centrifuge after clotting fully.

Plasma samples should be collected using heparin, EDTA, or sodium citrate as the anticoagulatant.

Urine samples that contain any floating substances should be centrifuged and the supernatant tested.

It is recommended that specimen collection be carried out in accordance with NCCLS document M29-A2 and H2-A2. No method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood samples should be considered potentially infectious.

Testing should be performed immediately. If this is not possible, the sample should be placed in a tightly sealed container and stored at -20°C. Avoid repeat freeze/thaw cycles.

AUTOMATED ANALYZER APPLICATION

Suitable for two-reagent automated analyzers that can measure a rate reaction at an absorbance at 570 nm. Each user should validate assay functionality on their instrument. Refer to the instrument manual from the manufacturer regarding the following:

a) Use or function
b) Installation procedures and requirements
c) Principles of operation
d) Performance characteristics, operating instructions
e) Calibration procedures including materials and / or equipment to be used
f) Operational precautions, limitations, and hazards
g) Service and maintenance information

PROCEDURE

Materials Supplied

Reagent 1 (R-1) Buffer Reagent 1 x 45 mL
Reagent 2 (R-2) Latex Suspension 1 x 20 mL

Materials Required But Not Supplied

Calibrators:
Serum or Plasma samples:
K-*ASSAY*® Beta-2 Microglobulin Serum/Plasma Calibrator, Cat. No. KAI-281C

Urine samples:
K-*ASSAY*® Beta-2 Microglobulin Urine Calibrator, Cat. No. KAI-282C

Two Reagent Clinical Chemistry Analyzer:
Capable of accurate absorbance readings at 570 nm
Capable of accurately dispensing the required volumes
Capable of maintaining 37°C

Assay Procedure

Note: Allow all reagents and specimens to warm to room temperature. Mix all reagents gently before using.

An example of automated application (Hitachi 917):

Serum / Plasma Sample 2 µL
↓
• ←R1 (Buffer Reagent) 180 µL
↓ 37 °C, 5 min.
• ←R2 (Latex Suspension) 80 µL
↓ 37 °C, 5 min.
2-point endpoint, 570 nm / 800 nm (primary/sub if available)

Urine Sample 9 µL
↓
• ←R1 (Buffer Reagent) 135 µL
↓ 37 °C, 5 min.
• ←R2 (Latex Suspension) 60 µL
↓ 37 °C, 5 min.
2-point endpoint, 570 nm / 800 nm (primary/sub if available)

Automated Method (Example)

Chemistry Parameters for Automatic Analyzer

Serum / Plasma Samples

INSTRUMENT	Roche / Hitachi 917
TEMPERATURE	37°C
TEST	(B2MG)
ASSAY CODE	(2 POINT END)(10) (18)(34)(0)(0)
WAVELENGTH	(800) (570)
SAMPLE VOLUME	(2.0) (0.0) (0)
REAGENT VOL (R1)	(180) (0)
REAGENT VOL (R2)	(0) (0)
REAGENT VOL (R3)	(80) (0)
REAGENT VOL (R4)	(0) (0)
ABS. LIMIT (SLOPE)	(32000) (INCREASE)
PROZONE LIMIT	(-32000)(0)(LOWER)
CALIB. TYPE	(SPLINE)
POINT	(5)
SPAN POINT	(5)
SD LIMIT	(999.9)
DUPLICATE LIMIT	(32000)
SENSITIVITY LIMIT	(0)
S1ABS RANGE	(-32000) (32000)
INSTRUMENT FACTOR	a=(1.0) b=(0.0)
UNIT	(mg/L)
STD.(1) Conc.-POS.	(*1) - (1)
STD.(2) Conc.-POS.	(*2) - (2)
STD.(3) Conc.-POS.	(*3) - (3)
STD.(4) Conc.-POS.	(*4) - (4)
STD.(5) Conc.-POS.	(*5) - (5)
STD.(6) Conc.-POS.	( ) - ( )

*1-5: Input concentration of calibrators.

Parameters for other automated analyzers are available.

CALIBRATION

It is recommended that Beta-2 Microglobulin levels be determined using a multi-point calibration curve prepared using the **K-*ASSAY*®** Beta-2 Microglobulin Serum/Plasma Calibrator or **K-*ASSAY*®** Beta-2 Microglobulin Urine Calibrator. Please be sure to use the proper instrument application for the calibrator you are using. It is recommended that the user determine calibration curve frequency as this depends on the instrument and number / type of other assays being performed. Initially, calibration should be performed each day.

QUALITY CONTROL

Normal and abnormal controls of known concentration should be included in each assay performed. These controls should fall within the stated values assigned to the controls. The validity of the assay is in question if the value for the controls generated by the assay's calibration curve does not fall within the stated range. Recalibrate if the value determined for the controls falls outside the stated recovery range.

LIMITATIONS OF PROCEDURE

The β2MG assay is suitable for measuring in the range of:

Serum and Plasma:	0.2 - 80.0 mg/L
Urine:	30 - 8,000 µg/L or 0.03 - 8.00 mg/L

Reagents should not be used after the expiration date indicated on the kit label. Do not mix reagents from different lot numbers.

If the β2MG concentration is greater than highest calibrator value, dilute one part sample with four parts isotonic saline and re-assay. Multiply results by 5 to compensate for the dilution.

PERFORMANCE

Precision

When a sample containing a known level of β2MG is tested 10 times, the CV of the test should typically be under 7%.

Accuracy / Correlation

A comparison of the **K-*ASSAY*®** Beta-2 Microglobulin assay and the latex agglutination method of another company provided the following data:

Serum (mg/L)

y = 0.985x + 0.235
r = 0.999
n = 65
x = Company A's latex assay
y = **K-*ASSAY*®** Beta-2 Microglobulin assay

Urine (µg/L)

y = 0.960x + 6.177
r = 1.000
n = 50
x = Company A's latex assay
y = **K-*ASSAY*®** Beta-2 Microglobulin assay

Assay Range

Serum and Plasma:	0.2 - 80.0 mg/L
Urine:	30 - 8,000 µg/L or 0.03 - 8.00 mg/L

INTERFERENCE

Bilirubin F and C	No interference up to 30 mg/dL
Hemoglobin	No interference up to 500 mg/dL

EXPECTED VALUES

It is recommended that each laboratory establish its own expected range to reflect its patient population.

Serum[1]: < 2.0 mg/L

Urine[2]: ≤ 300 µg/L (≤ 0.3 mg/L)

REFERENCES

1. Jacobs, David S., *et al., Laboratory Test Handbook, 4th Edition* (Lexi-Comp Inc, 1996), p. 371.
2. Moriguchi, J., Ezaki, T., Tsukahara, T., *et al.*, "Comparative evaluation of four urinary tubular dysfunction markers, with special references to the effects of aging and correction for creatinine concentration", Toxicol Lett, 2003: Aug 28; 143(3): 279-290.

LABELING SYMBOLS

LOT	Lot Number
RGT	Reagent
	Expiration or "Use By" Date
REF	Catalog Number
IVD	For *In Vitro* Diagnostics Use
2-8 °C	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
	Consult Package Insert for Instructions for Use
EC REP	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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