

**K-ASSAY®**

# Beta-2 Microglobulin Serum / Plasma Calibrator

**Cat. No. KAI-281C**

## INTENDED USE

The **K-ASSAY®** Beta-2 Microglobulin Serum / Plasma Calibrator is intended to be used for the calibration of the **K-ASSAY®** Beta-2 Microglobulin assay for the quantitative analysis of Beta-2 Microglobulin ( $\beta$ 2MG) in serum or plasma samples. FOR *IN VITRO* DIAGNOSTIC USE.

## SUMMARY

These are to be used as calibrators for the **K-ASSAY®** Beta-2 Microglobulin assay, **with serum or plasma samples only**. (Use Cat. No. KAI-282C Beta-2 Microglobulin Urine Calibrator for urine samples).

## KIT COMPOSITION

### Calibrators (Liquid Stable)

Calibrator 1-5, Human Beta-2 Microglobulin, 5 x 2 mL

Contain pooled human serum with assigned values for  $\beta$ 2MG.

## WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. Rx only.

Only use application parameters specific for **K-ASSAY®** Beta-2 Microglobulin Serum / Plasma Calibrator with the **K-ASSAY®** Beta-2 Microglobulin assay on serum or plasma samples. When using urine samples, use **K-ASSAY®** Beta-2 Microglobulin Urine Calibrator (Cat. No. KAI-282C). Failure to use application parameters specific for the Beta-2 Microglobulin Serum / Plasma Calibrator may produce erroneous values.

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

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

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

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

Calibrators 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 calibrators 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 Management No. CDC-22 issued by the Center for Disease Control, Atlanta, GA.

Calibrators contain purified human serum. Each donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for HBs antigen and HCV and HIV-1/HIV-2 antibodies. However, it is not possible to guarantee that they are free of hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), or other infectious agents. Therefore, all products containing human serum should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiology and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

## CALIBRATOR PREPARATION

The calibrators are ready to use. They do not require reconstitution.

## STORAGE AND HANDLING

All calibrators should be stored refrigerated (2-8°C). Return all calibrators to 2-8°C promptly after use. Unopened calibrators can be used until the expiration date on the package and bottle labels. Opened bottles of calibrators can be used for 1 month if stored at 2-8°C.

## CALIBRATOR STABILITY

Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

## INSTRUMENT

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 570 nm. 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

Calibrators should be used as specified in the **K-ASSAY®** Beta-2 Microglobulin assay package insert.

## Materials Supplied

|                               |          |
|-------------------------------|----------|
| Calibrator 1 (White Cap)      | 1 x 2 mL |
| Calibrator 2 (Light Blue Cap) | 1 x 2 mL |
| Calibrator 3 (Green Cap)      | 1 x 2 mL |
| Calibrator 4 (Dark Red Cap)   | 1 x 2 mL |
| Calibrator 5 (Dark Brown Cap) | 1 x 2 mL |

## Materials Required But Not Supplied

**K-ASSAY**® Beta-2 Microglobulin assay, Catalog Number KAI-280

Clinical chemistry analyzer: capable of accurate absorbance readings at 570 nm with appropriate cuvettes and calculating rate reactions, capable of accurately dispensing the required volumes, and capable of maintaining 37°C.

Saline solution (0 mg/L calibrator)

## Details of Procedure

NOTE: Allow all reagents and specimens to come to room temperature. Mix all reagents gently before using.

**K-ASSAY**® Beta-2 Microglobulin Serum / Plasma Calibrator is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-ASSAY**® Beta-2 Microglobulin immunoturbidimetric assay.

**Use K-ASSAY® Beta-2 Microglobulin Serum / Plasma Calibrator only with the serum / plasma instrument protocols .**

## CALIBRATOR VALUES

### Beta-2 Microglobulin

|              |           |
|--------------|-----------|
| Calibrator 1 | 1.5 mg/L  |
| Calibrator 2 | 5.0 mg/L  |
| Calibrator 3 | 10.0 mg/L |
| Calibrator 4 | 50.0 mg/L |
| Calibrator 5 | 80.0 mg/L |

### Use saline solution as the 0 mg/L calibrator.

Values are standardized against the WHO (World Health Organization) 1st international standard material for Beta-2 Microglobulin.

The values for the **K-ASSAY**® Beta-2 Microglobulin Serum / Plasma Calibrator are continually being revised through ongoing quality assurance. As a result, the expected values may change from lot to lot. Please refer to the package insert for each lot for the exact calibrator values.

## LABELING SYMBOLS

|   |  |
|---|--|
|  | Lot Number   |
|  | Calibrator   |
|  | Expiration or "Use By" Date                                      |
|  | Catalog Number   |
|  | For <i>In Vitro</i> Diagnostic Use                               |
|  | 2-8°C Temperature Limitation.<br>Store between 2 and 8 degrees C |
|  | Potential Human Biohazard  |
|  | Manufacturer   |
|  | Consult Package Insert for Instructions for Use                  |
|  | Authorized Representative in the European Community              |

## EU AUTHORIZED REPRESENTATIVE





### **Advena Ltd.**

Tower Business Centre, 2<sup>nd</sup> Flr.,  
Tower Street, Swatar, BKR 4013 Malta

## ORDERING / PRICING / TECHNICAL INFORMATION



### **KAMIYA BIOMEDICAL COMPANY**

12779 Gateway Drive  
Seattle, WA 98168 USA  
TEL: (206) 575-8068 / (800) 526-4925  
FAX: (206) 575-8094