

**K-ASSAY®**

# ASO (WHO) Calibrator

Lot F761, Exp. 2018-05-31

**Cat. No. KAI-079C****INTENDED USE**

The **K-ASSAY®** ASO (WHO) Calibrator is intended to be used to calibrate the **K-ASSAY®** ASO (WHO) assay for quantifying serum anti-streptolysin O (ASO). FOR *IN VITRO* DIAGNOSTIC USE.

**SUMMARY**

The calibrators in this kit are human serum tested and found negative for HBsAg and HIV Ab. They contain known quantities of anti-streptolysin O (ASO). These are to be used as calibrators with the **K-ASSAY®** ASO (WHO) assay.

**KIT COMPOSITION****Calibrators (Liquid Stable)****MATERIALS PROVIDED**

Calibrators 1-5	Human serum	5 x 1 mL
	Sodium azide	< 0.1%

Calibrators contain pooled human serum with assigned values for anti-streptolysin O.

**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.

Calibrators contain pooled human serum from ASO positive human serum. The serum has been tested and found non-reactive for the presence of HBsAg and HIV antibody by an FDA approved method. However, it is not possible to guarantee that any human source material is free of these 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 Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

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

Calibrators in this kit contain 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 Centers for Disease Control, Atlanta, Georgia.

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

**CALIBRATOR PREPARATION**

The calibrators are ready to use and 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 for one year from the date of manufacturing as indicated on the expiration date on the package and bottle labels.

**CALIBRATOR STABILITY**

Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard. Once opened, the calibrator is stable for 1 month. Store at 2-8°C when not in use.

**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:

- Use or function
- Installation procedures and requirements
- Principles of operation
- Performance characteristics, operating instructions
- Calibration procedures including materials and / or equipment to be used
- Operational precautions, limitations, and hazards
- Service and maintenance information

**PROCEDURE****Materials Supplied**

Calibrators should be used as specified in the **K-ASSAY®** ASO (WHO) assay package insert.

Calibrator A	1 x 1 mL
Calibrator B	1 x 1 mL
Calibrator C	1 x 1 mL
Calibrator D	1 x 1 mL
Calibrator E	1 x 1 mL

## Materials Required But Not Supplied

**K-ASSAY**® ASO (WHO) Assay, Cat. No. KAI-078.

Two-reagent clinical chemistry analyzer capable of accurate absorbance reading at 570 nm, accurately dispensing the required volumes, and maintaining 37°C.

### Details of Procedure

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

**K-ASSAY**® ASO (WHO) Calibrators are assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-ASSAY**® ASO (WHO) assay.

A calibration curve is generated by assaying this series of calibrators with known concentrations of anti-streptolysin O. Concentrations of the patient samples are interpolated from the calibration curve.

### CALIBRATOR VALUES

(Lot: F761)












#### ASO

ASO Calibrator A	0 IU/mL
ASO Calibrator B	125 IU/mL
ASO Calibrator C	250 IU/mL
ASO Calibrator D	500 IU/mL
ASO Calibrator E	1,000 IU/mL

The ASO Calibrators have been standardized against the WHO (World Health Organization) NIBSC Anti-Streptolysin O standard material.

The expected values for the **K-ASSAY**® ASO (WHO) Calibrators are continually being revised through ongoing quality control. 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. 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





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