

**K-ASSAY**<sup>®</sup>

# UIBC Calibrator

Lot A123, Exp. 2020-04-30

Cat. No. KAI-302C

## INTENDED USE

The **K-ASSAY**<sup>®</sup> UIBC Calibrator is intended to be used for the calibration of the **K-ASSAY**<sup>®</sup> UIBC assay for quantifying Unsaturated Iron Binding Capacity of serum specimens. FOR *IN VITRO* DIAGNOSTIC USE.

## SUMMARY

The calibrator in this kit contains a known quantity of iron. Using saline as the first point, the UIBC calibrator is to be used to make a 2 point calibration for the **K-ASSAY**<sup>®</sup> UIBC assay.

## KIT COMPOSITION

Ferrous ammonium sulfate, liquid 1 x 5 mL

## 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 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.

## 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 until the expiration date on package and bottle labels.

## CALIBRATOR STABILITY

Opened bottles of calibrators can be used for 1 month if stored at 2-8°C. Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

Calibrator transferred to the instrument sample cup may

concentrate over time. Therefore, calibrators should be capped and stored at 2-8°C when not in use. Otherwise, fresh calibrators should be used for each calibration.

## PROCEDURE

### Materials Supplied

Calibrators should be used as specified in the **K-ASSAY**<sup>®</sup> UIBC assay package insert.

Ferrous ammonium sulfate, liquid 1 x 5 mL

### Materials Required But Not Supplied

**K-ASSAY**<sup>®</sup> UIBC assay

Isotonic saline or DI water for use as 0 calibrator.

Two-Reagent Clinical Chemistry Analyzer:

Capable of accurate absorbance reading at ~ 750 nm

Capable of accurately dispensing the required volumes

Capable of maintaining 37°C

### Details of Procedure

The **K-ASSAY**<sup>®</sup> UIBC Calibrator is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-ASSAY**<sup>®</sup> UIBC assay.

This assay has been adjusted so that isotonic saline or DI water will result in a 0 µg/dL calibration point. Isotonic saline or DI water should be used as the first calibration point. When paired with the **K-ASSAY**<sup>®</sup> UIBC Calibrator, you will then create a reliable 2 point calibration.

### CALIBRATOR VALUE

<b>Lot A123</b>
200 µg/dL

The **K-ASSAY**<sup>®</sup> UIBC Calibrator has been standardized against NIST SRM 937 (Standard Reference Material).

The values for **K-ASSAY**<sup>®</sup> UIBC Calibrator are continually being revised through on going 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
	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
	Consult Package Insert for Instructions for Use
	Authorized Representative in the European Community

## EU AUTHORIZED REPRESENTATIVE





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## ORDERING / PRICING / TECHNICAL INFORMATION



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