

Ketone Body Calibrator

For Research Use Only. Not for use in diagnostic procedures.

Intended use

The Ketone Body Calibrators are intended to be used with the Autokit Total Ketone Bodies and the Autokit 3-HB test kits to establish points of reference that are used in the determination of the values in the measurement of Total Ketone Bodies and 3-HB in human serum or plasma.

Reagents

- | | |
|--------------------------------|----------|
| (1) Ketone Body Calibrator 300 | 4 × 5 mL |
| 300 μmol/L 3-HB | |
| 0.025% Sodium azide | |
| 17% Polyethylene glycol | |
| (2) Ketone Body Calibrator 40* | 4 × 5 mL |
| 40 μmol/L 3-HB | |
| 0.025% Sodium azide | |
| 17% Polyethylene glycol | |

*Ketone Body Calibrator 40 should be used only for the high sensitivity method.

Each unopened vial is stable until the expiration date printed on the label when stored at 2-10°C.

This product is not FDA approved for clinical use.

Warning and precautions

- (1) For Research Use Only. Not for use in diagnostic procedures.
- (2) Do not use the calibrators in any procedures other than those described herein. Performance cannot be guaranteed if the calibrators are used in other procedures or for other purposes. Read instruction sheets for Autokit Total Ketone Bodies and Autokit 3-HB assay.
- (3) Store the calibrators under the specified conditions. Do not use calibrators past the expiration date stated on each calibrators container label.
- (4) Do not use the calibrators which were frozen in error. Such the calibrators may give false results.
- (5) After opening the reagents, it is recommended to use them immediately. When the opened reagents are stored, cap the bottles and keep them under the specified conditions.
- (6) Do not use the containers and other materials in the package for any purposes other than those described herein.
- (7) When discarding the calibrators, dispose of them according to local or national regulations.
- (8) The Ketone Body Calibrators contain 0.025% sodium azide as a preservative. Sodium azide may react with copper or lead plumbing to form explosive compounds. Even though the reagents contain minute quantity of sodium azide, drains should be flushed well with a large amount of water, when discarding the reagents.
- (9) If the reagents come in contact with the mouth, eyes or skin, wash off immediately with a large amount of water. Consult a physician if necessary.

Physical or chemical indications of instability

The presence of precipitates in the calibrators or values of control sera outside the manufacturer's acceptable range may be an indication of reagent instability.

Reagent preparation

Ketone Body Calibrator 300 : Use the Calibrator as supplied. After opening the bottle, store at 2-10°C and use within one month.

Ketone Body Calibrator 40 : Use the Calibrator as supplied. After opening the bottle, store at 2-10°C and use within one month.

Assigned Values

The Ketone Body Calibrators values are assigned by using the molar extinction coefficient (K-factor) of NADH. There are no traceability standards available for this analyte. Therefore, Wako uses our internal reference standards to control lot to lot differences.

Ordering information

Code No.	Product	Package
412-73791	Ketone Body Calibrator 300	4 × 5 mL
418-73891	Ketone Body Calibrator 40	4 × 5 mL

Revision date ; Apr. 1, 2018

412-73791F

Manufactured by
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