Intended use
The Ketone Body Calibrators are intended to be used with the AutoK1 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
300 umol/L 3-HB
0.025% Sodium azide
17% Polyethylene glycol
(2) Ketone Body Calibrator 40*
40 umol/L 3-HB
0.025% Sodium azide
17% Polyethylene glycol

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

Reagent preparation
Ketone Body Calibrator 300: Use the Calibrator as supplied. After open-
ing the bottle, store at 2-10°C and use within
one month.
Ketone Body Calibrator 40: Use the Calibrator as supplied. After open-
ing 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 extinc-
tion coefficient (K-factor) of NADH. There are no traceability standards avail-
able for this analyte. Therefore, Wako uses our internal reference standards
to control lot to lot differences.

Ordering information

<table>
<thead>
<tr>
<th>Code No.</th>
<th>Product</th>
<th>Package</th>
</tr>
</thead>
<tbody>
<tr>
<td>412-73791</td>
<td>Ketone Body Calibrator 300</td>
<td>4 × 5 mL</td>
</tr>
<tr>
<td>418-73891</td>
<td>Ketone Body Calibrator 40</td>
<td>4 × 5 mL</td>
</tr>
</tbody>
</table>

Revision date: Apr. 1, 2018

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 Au-
tokit Total Ketone Bodies and AutoK1 3-HB assay.
(3) Store the calibrators under the specified conditions. Do not use calibra-
tors past the expiration date stated on each calibrators container label.
(4) Do not use the calibrators which were frozen in error. Such the calibra-
tors 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 preser-
 vative. Sodium azide may react with copper or lead plumbing to form ex-
 plosive 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 im-
mediately 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 out-
side the manufacturer’s acceptable range may be an indication of reagent
instability.