REFERENCES

SHIPPING DAMAGE
Please notify your distributor, if this product was received damaged.

HAZARDOUS MATERIALS
None of the materials in this kit are hazardous and therefore do not require a Safety Data Sheet (SDS) in accordance with the OSHA Hazard Communication Standard.

SYMBOLS KEY

- Expiration date
- Consult Instructions for Use
- Manufacturer
- Catalogue Number
- In Vitro Diagnostic Medical Device
- Lot number
- Temperature limitations

Manufacturer
BÜHLMANN Laboratories AG
Baselstrasse 55
4124 Schönenbuch, Switzerland

BÜHLMANN fCAL® turbo
Calprotectin turbidimetric assay for professional use

Control Kit
B-KCAL-CONSET

BÜHLMANN Laboratories AG
For In Vitro Diagnostic Use Only
Baselstrasse 55
4124 Schönenbuch, Switzerland
Tel.: +41 61 487 1212
Fax: +41 61 487 1234
info@buhlmannlabs.ch

CLIA Complexity: High

INTENDED USE
The BÜHLMANN fCAL® turbo Control Kit is intended for use with the BÜHLMANN fCAL® turbo Reagent Kit, for quality control, in the determination of fecal calprotectin levels in extracted stool samples.
CONTROL VALUE
Control values are assigned according to a value transfer protocol [Ref. 1-2] and are indicated in the enclosed QC-data sheet. The control material comprises blood-derived human calprotectin and is standardised against internal reference material.

REAGENTS SUPPLIED

<table>
<thead>
<tr>
<th>Reagents</th>
<th>Quantity</th>
<th>Code</th>
<th>Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controls Low / High Controls containing an assigned concentration of human calprotectin</td>
<td>3 x 2 vials</td>
<td>B-KCAL-CONSET</td>
<td>Ready to use</td>
</tr>
<tr>
<td></td>
<td>1 mL/vial</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1

REAGENT STORAGE AND STABILITY

Unopened controls

Store at 2-8 °C. Do not use kit past expiration date printed on the labels.

Opened controls

Store for up to 3 months at 2-8 C, capped.

Table 2

MATERIALS REQUIRED BUT NOT PROVIDED

<table>
<thead>
<tr>
<th>Reagents</th>
<th>Quantity</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>BÜHLMANN fCAL® turbo Reagent Kit Reaction Buffer (R1) Immunoparticles (R2)</td>
<td>1 vial/35 mL 1 vial/7 mL</td>
<td>B-KCAL-RSET</td>
</tr>
<tr>
<td>BÜHLMANN fCAL® turbo Calibrator Kit Calibrators 1-6 for instrument calibration</td>
<td>1 x 6 vials 1 mL/vial</td>
<td>B-KCAL-CASET</td>
</tr>
</tbody>
</table>

Table 2

WARNINGS AND PRECAUTIONS

- This test is for in vitro use only.
- Before measuring please equilibrate reagents, controls, calibrators and samples as described in the application note.
- Do not mix controls of different lots or switch caps between reagents.
- Avoid evaporation of the controls.
- The controls contain components of human origin. Although tested and found negative for HBV, HCV and HIV, the controls should be handled as if capable of transmitting infections and should be handled in accordance with Good Laboratory Practices (GLP) using appropriate precautions. Disposal of any discarded materials should be in accordance with local requirements.

ASSAY PROCEDURE

Application notes/ assay installation
The assay procedure for the BÜHLMANN fCAL® turbo has been established on the Roche cobas® c501/502 platforms and will be expanded to other platforms over time. Application notes describing installation and analysis on all validated clinical chemistry analyzers are available from BUHLMANN Diagnostics Corp, BDC at (844) 300-9799 (Mon-Fri 8:00AM-5:00PM EST).

QC controls
The BÜHLMANN fCAL® turbo Control kit must be assayed each day before running patient fecal sample extracts. This is to validate the calibration curve established with the BÜHLMANN fCAL® turbo Calibrator kit. The controls have assigned, lot-specific value ranges indicated on the QC-data sheet enclosed. The control measurements must be within the indicated value ranges to obtain valid results for patient fecal sample extracts.

If the control values are not valid, repeat QC control measurement with fresh controls. If control values remain invalid, recalibrate the instrument. If valid control values cannot be reproduced, after performing the steps described above, contact BUHLMANN Diagnostics Corp, BDC at (844) 300-9799 (Mon-Fri 8:00AM-5:00PM EST),