



Calprotectin CLIA Re-Calibrator and Control Set

Instructions for Use (IFU)

For In Vitro Diagnostic Use in Canada.

REF **80-CALHU-FCSET**

Manufactured By:
ALPCO
26-G Keewaydin Drive
Salem, NH 03079

Customer Service:
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Intended Use

The Calprotectin CLIA Re-Calibrator and Control Set is an accessory used in conjunction with the Calprotectin CLIA kit (80-CALPHU-FC100 or 80-CALPHU-FC600) by trained laboratory personnel. For *in vitro* diagnostic use in Canada.

Reagents Included

| | | |
|---------------------------|---|---------|
| Re-Calibrators 1-2 | 1 Set of Re-Calibrators 2 vials, each containing calprotectin at a fixed concentration. Ready-to-use. | 2 x 1ml |
| Controls 1-2 | 1 Set of Controls 2 vials, each containing calprotectin at a fixed concentration. Ready-to-use. The range of acceptable values for each control level are printed on the lot-specific Certificate of Analysis. | 2 x 1ml |

Materials Required but Not Provided

Calprotectin CLIA Reagents (80-CALHU-FC100 or 80-CALHU-FC600)
KleeYa Platform
General laboratory equipment

Precautions and Warnings

1. For *in vitro* diagnostic use in Canada.
2. Follow universal precautions. Materials of human origin used in this kit have been tested and confirmed negative for HBsAg and anti-HIV I and II and anti-HCV antibodies. They should be treated as a potential biohazard and handled and disposed of according to local laboratory legislation.
3. All reagents contain ProClin 300 as a preservative agent (< 0.10%).
4. Additional safety information on hazardous substances included in the kit and actions to take in the event of direct contact or ingestion is provided within the Safety Data Sheet (SDS) for this product. To obtain an SDS, please contact our customer service department at (800) 592-5726 or email: ts@alpc.com.
5. Re-calibrators and controls may only be run with corresponding reagents. If purchased separately, the lot number for the re-calibrator and control set (80-CALHU-FCSET) must match the lot number for the reagent kit (80-CALHU-FC100 or 80-CALHU-FC600) being run.
6. Re-calibrators and controls are only compatible with KleeYa sample racks containing the white spacers.
7. Ensure that no bubbles are present before loading re-calibrators and controls into sample racks.
8. Dispose of unused reagents according to local and federal regulations.

Storage and Transport Conditions

1. Reagents are shipped on cold packs but do not require specific temperature control. Reagents should be stored at 2-8°C. Unopened reagents are stable until the expiration date on the box label.
2. The expiration date is printed on all component labels.

Reagent Stability

| Re-calibrators and Controls |
|---|
| Store at 2-8°C. Un-opened re-calibrators and controls are stable until the expiration date printed on the label. Opened re-calibrators and controls are stable for up to 7 uses within 30 days. Re-calibrators and controls must be returned to 2-8°C when not in use. |

Note: Ensure caps are placed on the correct vials after each use. Switching caps for re-calibrators and controls can negatively impact results.

Reagent Preparation

1. Controls and re-calibrators are ready-to-use. Mix by gentle inversion and load in appropriate KleeYa sample racks. Make sure no bubbles are present after mixing. If necessary, assign the lot specific assay to the appropriate control(s) on the KleeYa instrument. Deselect the default sample dilution in the dilution tab for controls 1 and 2.

Assay Calibration and Quality Control

1. Re-calibrators must be run every 24 hours in order to generate a new calibration curve.
2. Controls 1 and 2 are to be run each day calprotectin testing is performed. Calprotectin control results reported by the KleeYa software must be multiplied by 50 prior to comparison to the control range reported in the enclosed Certificate of Analysis.
3. Traceability: No international reference material or reference measurement procedures are available for calprotectin. The Calibrators and Controls used in the ALPCO Calprotectin CLIA are traceable to internal reference standards made from native calprotectin antigen diluted in a buffer containing stabilizers and preservatives.

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