



C. Difficile GDH CLIA Re-Calibrator and Control Set

Instructions for Use (IFU)

For Research Use Only. Not for Use in Diagnostic Procedures.

REF 80-GDHHU-FCSET

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

Customer Service:
Tel: (603) 893-8914
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Intended Use

The *C. Difficile* GDH CLIA Re-Calibrator and Control Set is an accessory used in conjunction with the Clostridium Difficile GDH CLIA Kit (80-GDHHU-FC100) by trained laboratory personnel using the KleeYa platform. For Research Use Only. Not for Use in Diagnostic Procedures.

Reagents Included

Re-Calibrators	Cut-Off Re-calibrator 1 vial containing <i>C. difficile</i> GDH at a fixed concentration. Ready to use.	1 x 1mL
Positive and Negative Controls	Pos and Neg Controls 2 vials, each containing <i>C. difficile</i> GDH at a fixed concentration. Ready to use.	2 x 1mL

Materials Required but Not Provided

Clostridium Difficile GDH CLIA Reagents (80-GDHHU-FC100)
KleeYa Platform
KleeYa Consumables
General laboratory equipment

Precautions and Warnings

1. For Research Use Only.
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. 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-GDHHU-FCSET) must match the lot number for the reagent kit (80-GDHHU-FC100) being run.
5. Routine maintenance of the KleeYa instrument is required for proper performance.
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. 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.
9. 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 4 uses within 28 days. Re-calibrator and controls must be returned to 2-8°C when not in use.

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

Reagent Preparation

All reagents, re-calibrators, and controls are ready to use. Ensure samples are fully thawed and mixed gently before loading on the KleeYa instrument. Mix re-calibrators and controls by gentle inversion and load in appropriate KleeYa sample racks. Ensure no bubbles are present after mixing. If necessary, assign the lot specific assay to the appropriate control(s) on the KleeYa instrument.

Assay Calibration and Quality Control

1. The cut-off re-calibrator must be run each day *C. difficile* GDH testing is performed.
2. Positive and negative controls are to be run each day *C. difficile* GDH testing is performed.
3. Traceability: No international reference material or reference measurement procedures are available for *C. difficile* GDH. The Calibrators and Controls used in the Clostridium difficile GDH CLIA Kit are traceable to internal reference standards made from recombinant *C. difficile* GDH diluted in a buffer containing stabilizers and preservatives.

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