



**EDN CLIA  
Re-Calibrator and Control Set  
Instructions for Use (IFU)**

**For Research Use Only.**

**REF** 80-EDNHU-FCSET

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

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

The EDN CLIA Re-Calibrator and Control Set is an accessory used in conjunction with the EDN CLIA Kit (80-EDNHU-FC100) by trained laboratory personnel. For Research Use Only. Not for Use in Diagnostic Procedures.

## Reagents Included

<b>Re-Calibrators</b>	<b>Re-Calibrators</b> 2 vials of EDN at fixed concentrations. Provided in a lyophilized form.	2 vials
<b>Controls</b>	<b>Controls</b> 2 vials of EDN at fixed concentrations. Provided in a lyophilized form. The range of acceptable values for each control level are printed on the lot-specific Certificate of Analysis.	2 vials

## Materials Required but Not Provided

EDN CLIA Reagents (80-EDNHU-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-EDNHU-FCSET) must match the lot number for the reagent kit (80-EDNHU-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](mailto: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 2 uses within 24 hours. Re-calibrator and controls must be returned to 2-8°C when not in use. They cannot be frozen and thawed.

## Reagent Preparation

1. Controls and re-calibrators are provided in a lyophilized form. Please refer to the Certificate of Analysis provided with each kit for the appropriate volume of deionized water for reconstitution. Close the vial with the rubber stopper and cap, gently swirl the vial, invert the vial several times, and allow it to stand for 10 minutes. The contents of the vial should be in solution with no visible particulates. Make sure no bubbles are present after mixing, then transfer to the designated bar code-labeled tube and load in the appropriate sample rack on the KleeYa system.

**Note: Ensure that the component name and number match when transferring from the glass vial to the labeled plastic vial.**

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

## Assay Calibration and Quality Control

1. Re-calibrator must be run each day EDN testing is performed.
2. Controls are to be run each day EDN testing is performed.
3. Traceability: No international reference material or reference measurement procedures are available for EDN. The Calibrators and Controls used in the EDN CLIA Kit are traceable to internal reference standards made from EDN diluted in a buffer containing stabilizers and preservatives.

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