




EDI™ Human Anti-Mullerian Hormone Calibrators

Consumable Reagent for Chemiluminescence Immunoassays (CLIA) in the ECL100 System

REF L0544 – L0545 CE IVD   

INTENDED USE

The EDI™ Human Anti-Mullerian Hormone Calibrators are intended for use in the conjunction with Chemiluminescence Immunoassay (CLIA) kits using the ECL100 Immunoassay analyzer.

For in-vitro diagnostics use only

REAGENT PRINCIPLE

The reagents are designed, developed, and produced for validating the master curve of the EDI™ Human Anti-Mullerian Hormone CLIA Kit (CL0812) and to validate the immunoassay against the master curve and ensure reliability and consistency of assay results.

REAGENTS: PREPARATION AND STORAGE

The reagent must be stored at 2 – 8°C upon receipt. For the expiration date of the reagent, refer to the label on the product.

1. EDI™ AMH Calibrators (L0544 – L0545)

Lyophilized Human Anti-Mullerian Hormone in a bovine serum albumin-based matrix with a non-azide preservative. Refer to vials for exact concentration.

Qty: 2 x vials

Storage: 2 – 8°C before reconstitution, <-20°C after reconstitution; Do not exceed 6 freeze-thaw cycles.

Preparation: Must be reconstituted with 0.5 mL of demineralized water, allowed to sit for 10 minutes, and then mixed by inversions or gentle vortexing. Make sure that all solids are dissolved completely prior to use.

SAFETY PRECAUTIONS

The reagent must be used in a professional laboratory environment and are for in vitro diagnostic use. Wear gloves while performing this assay and handle these reagents as if they were potentially infectious. Do not get into eyes, on skin, or clothing. Do not ingest or inhale fumes. On contact, flush with copious amount of water for at least 15 minutes. Exercise Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED

- Immunoassay Analyzer (ECL100)
- EDI™ Human Anti-Mullerian Hormone CLIA Kit (CL0812)

LIMITATIONS OF THE PROCEDURE

- This product is for use on the ECL100 Immunoanalyzer only. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, operation, system performance, instructions, calibration, precautions, hazards, maintenance, and troubleshooting.
- Reagents from different lots cannot be mixed.

WARRANTY

This product is warranted to perform as described in its labeling and literature when used in accordance with all instructions. Epitope Diagnostics, Inc. DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, and in no event shall Epitope Diagnostics, Inc. be liable for consequential damages. Replacement of the product or refund of the purchase price is the exclusive remedy for the purchaser. This warranty gives you specific legal rights and you may have other rights, which vary from state to state

TRACEABILITY


Since there is no internationally recognized primary reference material available, EDI calibrates using the manufacturer's selected measurement procedure as the secondary reference measurement procedure as per ISO 17511:2003. The calibrators and controls were standardized with a primary master reference. Traceability between calibrators and controls are maintained with cross-over studies for each lot. Each cross-over study tests at least 6 freshly reconstituted sets of the new calibrators and controls in six individual assays, and uses at least 3 secondary reference sets for each test.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For technical assistance or to place an order, please contact Epitope Diagnostics, Inc. at +1 (858) 693-7877 or fax to +1 (858) 693-7678 or email at cs@epitopediagnostic.com

This product is developed and manufactured by
Epitope Diagnostics, Inc.
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Please visit our website at www.epitopediagnostics.com to learn more about our products and services.

 MDSS GmbH
Schiffgraben 41,
30175 Hannover, Germany

GLOSSARY OF SYMBOLS (EN 980/ISO 15223)

 In Vitro Diagnostic Device

 European Conformity


 Lot Number

 Catalog Number

 Use by

 Manufacturer

 Authorized Representative in Europe

 Read Instructions before Use

 Keep Away from Heat and Direct Sun light

 Store at