

Advisory Notice

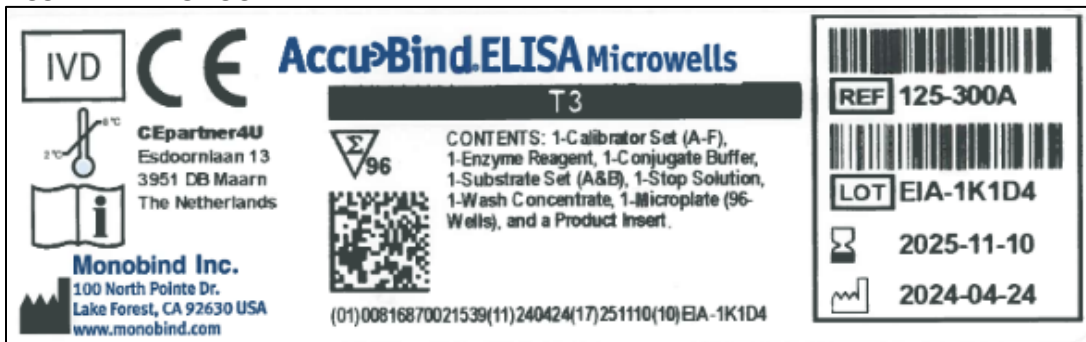
Date Released: 2025-September-30
Posted By: Quality Assurance
Product Affected: All Finished Monobind Kits
Brief Description of Advisory: Updated Primary Packaging, Box Label, Vial Label, IFU

Monobind has updated the **Primary Packaging** used in AccuBind® ELISA and AccuLite® CLIA products to accommodate additional product and regulatory information, including a new EU Rep. New **Sample Label Sheets** are available for each product. Specific changes:

Product Labels (Outside Label - Kit Box)

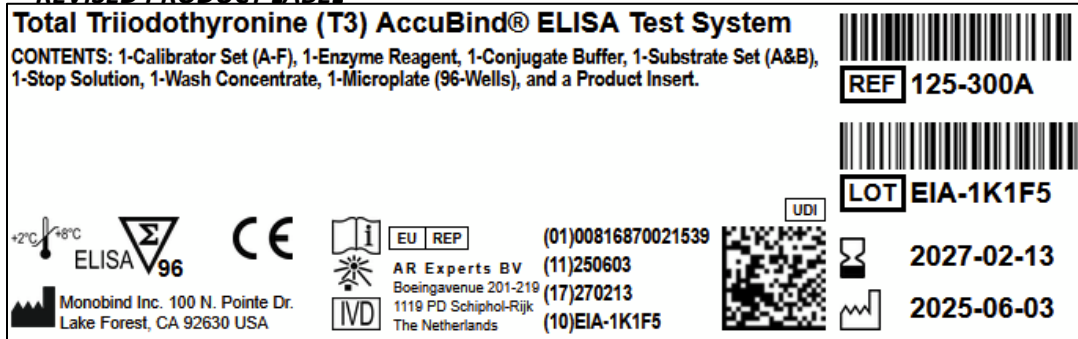
- Longer product names with the formal analyte name and short name for better identification
 - o Harmonizes with the IFU product name
 - o Harmonizes with DoC (formal + short product name) and FDA/ FSC (short product name), due to limited character restrictions (contact Monobind for certificate requests)
- Updated ISO 15223-1 Symbols, with additional (ELISA or CLIA) identifiers near the Σ of wells
- Updated EU Rep (for CE products), now AR Experts BV (from CEpartner 4U after merger)
- Sample labels for T3 ELISA product are shown below:

CURRENT PRODUCT LABEL



IVD **CE** **AccuBind ELISA Microwells**
T3
CEpartner4U
 Esdoornlaan 13
 3951 DB Maarn
 The Netherlands
Monobind Inc.
 100 North Pointe Dr.
 Lake Forest, CA 92630 USA
 www.monobind.com
Σ96
 CONTENTS: 1-Calibrator Set (A-F),
 1-Enzyme Reagent, 1-Conjugate Buffer,
 1-Substrate Set (A&B), 1-Stop Solution,
 1-Wash Concentrate, 1-Microplate (96-
 Wells), and a Product Insert.
REF 125-300A
LOT EIA-1K1D4
 2025-11-10
 2024-04-24
 (01)00816870021539(11)240424(17)251110(10)EIA-1K1D4

REVISED PRODUCT LABEL



Total Triiodothyronine (T3) AccuBind® ELISA Test System
 CONTENTS: 1-Calibrator Set (A-F), 1-Enzyme Reagent, 1-Conjugate Buffer, 1-Substrate Set (A&B),
 1-Stop Solution, 1-Wash Concentrate, 1-Microplate (96-Wells), and a Product Insert.
REF 125-300A
LOT EIA-1K1F5
 2027-02-13
 2025-06-03
ELISA Σ96 **CE** **EU REP** **UDI**
 (01)00816870021539
 (11)250603
 (17)270213
 (10)EIA-1K1F5
AR Experts BV
 Boeingavenue 201-219
 1119 PD Schiphol-Rijk
 The Netherlands
Monobind Inc. 100 N. Pointe Dr.
 Lake Forest, CA 92630 USA



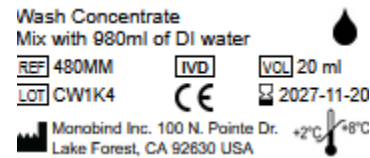
Vial Label

- Vial labels contain the same information but in an updated layout for better space utilization
 - o Icon will be reduced to one placement (from two) and on right side
 - o Print will be entirely in black (blue eliminated, as well as graphic bars at top)

CURRENT



REVISED



Labels for Review

One drive link contains all revised Sample Label Sheets: [Customers - Revised Labels](#)

IFU

- Will include updated glossary of ISO 15223-1 symbols and new EU Rep info
- Will include specific section '16.0 Available Configurations' with current detail on pack sizes and contents, as well as the associated SKUs (Item #s) and production descriptions which appear on the website and sales order/ invoice

Net Steps

Please review, perform any required regulatory update with your MOH, and offer any feedback you may have to Monobind at regulatory@monobind.com

Effective Date

Updated Product (Outside Box + Vials) labels will be used for lots manufactured starting Nov 1, 2025. Note, older lots held in inventory may contain earlier version labels, and a mix of label presentation on different reagent types, as well as the outside kit label. IFUs will undergo updates (to new revisions) and be made available on Trails and Monobind's website.

Trails

As a reminder, Distributors may access Technical Files from the [Trails website](#) in Documents > Kit or Controls, Instruments or Company Certifications. For access, please contact customerservice@monobind.com. Trails will be updated with the revised Sample Labels and IFU, as well as the Monobind website, once they go into effect Nov 1, 2025.

As an official of the company, I verify this information to be true and correct.

A Shatola

Anthony Shatola | Quality Control Director
On behalf of: regulatory@monobind.com

