

Advisory Notice

Date Released: 2016-May-6
Posted By: Quality Control
Effective Date: 2016-February-15
Product Affected: T4 Enzyme (ELISA) & Tracer (CLIA) in Total T4, Free T4, NT4, & Thyroid VAST
Brief Description: New Amber Vial

To whom it may concern,

Recent product improvements to Monobind T4 Assays have shown the use of Amber Vials as a better safeguard for "T4 Enzyme and Tracer" and "Free T4 Enzyme and Tracer" against light sensitivity. Product updates are summarized below:

Reagent	Previous Packaging	New Packaging	Lots Affected
T4 Enzyme	Clear Vial	Amber Vial	2Q1B6 & Newer
T4 Tracer	Clear Vial	Amber Vial	2Q1E6 & Newer
Free T4 Enzyme	Clear Vial	Amber Vial	12Q1C6 & Newer
Free T4 Tracer	Clear Vial	Amber Vial	12Q1C6 & Newer
Strep T4 Enzyme	Clear Vial	Amber Vial	82Q1A6 & Newer
Strep T4 Tracer	Clear Vial	Amber Vial	82Q1A6 & Newer
Strep Free T4 Enzyme	Clear Vial	Amber Vial	72Q1A6 & Newer
Strep Free T4 Tracer	Clear Vial	Amber Vial	72Q1A6 & Newer
Neonatal T4 Enzyme	Clear Vial	Amber Vial	26Q1A6 & Newer

These reagents are present as kit components in the following products:

- Total T4 AccuBind ELISA Item #: 225-300
- Total T4 AccuLite CLIA Item #: 275-300
- Total T4 SBS AccuBind ELISA Item #: 8225-300
- Total T4 SBS AccuLite CLIA Item #: 8275-300
- Free T4 AccuBind ELISA Item #: 1225-300
- Free T4 AccuLite CLIA Item #: 1275-300
- Free Thyroid Panel AccuBind VAST ELISA Item #: 7025-300
- Free Thyroid Panel AccuLite VAST CLIA Item #: 7075-300
- Thyroid Panel AccuBind VAST ELISA Item #: 8025-300
- Thyroid Panel AccuLite VAST CLIA Item #: 8075-300
- Neonatal T4 AccuBind ELISA Item #: 2425-300

All other aspects of the product remain unchanged, including the IFU. The Design Output has been updated to reflect the new packaging.

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

Sincerely, *A Shatola*

Anthony Shatola, Quality Control Director