

Advisory Notice

Date Released: 2022-January-25
Posted By: Quality Assurance
Reagents Affected: FT4 Enzyme (ELISA) & FT4 Tracer (CLIA), Substrates: Sc, Sn, Sub A (ELISA and Signal A (CLIA))
Brief Description: Vial and Cap Change due to PETG Shortage
Amber Vial Substitution (from 10ml Amber PETG)

Due to extended covid-related supply issues and government production contracts, a worldwide shortage persists for PETG vials. Monobind has identified alternative vials and caps which will be used as a replacement of amber PETG vials. Previously Monobind issued an advisory for components dispensed in the 5ml vial size and now it is extending this advisory to reagents dispensed in the 10ml vial size.

Please note: There is no impact on product performance of these changes. This is based on historical packaging, current storage of reagents in these materials as well as performance data. As PETG becomes more available, Monobind will transition back to reagents in this format. The timing of such is variable given the unprecedented conditions caused by the pandemic. Monobind is making all efforts to return to amber PETG vials as soon as possible.

In Summary:

Affected Reagent	Change	Effective
FT4 Enzyme	Amber PETG vials to clear material	Immediately
FT4 Tracer	Amber PETG vials to clear material	Immediately
Substrate A	Amber PETG vials to Amber HDPE	Immediately
Substrate Sc	Amber PETG vials to Amber HDPE	Immediately
Substrate Sn	Amber PETG vials to Amber HDPE	Immediately
Signal A	Amber PETG vials to Amber HDPE	Immediately

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

Sincerely,



Anthony Shatola
Quality Assurance Director