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Advisory Notice

Date Released: 2022-May-10 (Revision to 2022-January-25)

Posted By: Quality Assurance

Brief Description: Vial and Cap Change due to PETG Shortage

Amber Vial Substitution (from 5ml and 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. Please note the replacement vial size and dimensions could vary however the reagent volume dispensed remains the same.

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 (10ml) vials to clear material glass or | Immediately |
| | Natural HDPE (15ml) | |
| FT4 Tracer | Amber PETG (10ml) vials to clear material glass or | Immediately |
| | Natural HDPE (15ml) | |
| T3/T4 Buffer | Amber PETG (10ml) vials to Amber HDPE (15ml) | Immediately |
| Thyroid VAST Buffer | Amber PETG (10ml) vials to Amber HDPE (15ml) | Immediately |
| Steroid Enzyme | Amber PETG (5ml) vials to Amber HDPE (8ml) | Immediately |
| - Cortisol | | |
| - Testosterone | | |
| - 17-OHP - 17-OHP-SI | | |
| Steroid Tracer | Amber PETG (5ml) vials to Amber HDPE (8ml) | Immediately |
| - Cortisol | | , |
| - Testosterone | | |
| - 17-OHP | | |
| - 17-OHP-SI | | |
| Substrate A | Amber PETG (10ml) vials to Amber HDPE (15ml) | Immediately |
| Substrate Sc | Amber PETG (10ml) vials to Amber HDPE (15ml) | Immediately |
| Substrate Sn | Amber PETG (10ml) vials to Amber HDPE (15ml) | Immediately |
| Signal A | Amber PETG (10ml) vials to Amber HDPE (15ml) | Immediately |

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

Sincerely,

AShatola

Anthony Shatola, Quality Assurance Director