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Advisory Notice

Date Released: 2021-July-8 (Revision one)

Posted By: Vial and CAP Change due to PETG Shortage

Product Affected: All Kits and Controls

Reagents Affected: Calibrators, Controls, Enzyme, Biotin, Buffer, Diluent, Stop Solution

Brief Description of Advisory: Glass Vial Substitution (for 5ml PETG vials)

<u>UPDATED</u> to include WHITE CAP as glass vials require unique plastic polypropylene (PP) caps. In some cases, Monobind reagents use various color PP caps (such as green or red) and in these cases Monobind must switch to white and will continue to inkjet on the caps' top to identify the reagents.

Due to covid-related supply issues and government contracts for vaccine-vial production, a worldwide shortage exists for PETG vials for IVD. Monobind has identified glass vials and related caps which will be used as a replacement for PETG vials. This will affect various components (reagents) of Monobind kits dispensed in the 5ml vial size, as Monobind will shift production based on inventory levels. Should the shortage continue longer than expected, the 10ml vial size and components dispensed in this size may also be replaced with glass vials.

Glass has no impact on product performance and the visual difference will be quite minimal to the user since Monobind kits include clear PETG. The weight of the components (and kit) may increase slightly due to the glass. As PETG becomes more available, Monobind will transition back to reagents in this format. The timing of such is variable due to the unprecedented conditions presented by the pandemic. Monobind is making all efforts to return to PETG vials as soon as possible.

In Summary:

Affected Product	Change	Effective
All ELISA Kits	Various components will be in glass vials	Immediately
All CLIA Kits	Various components will be in glass vials	Immediately
All Control Products	Glass vials will be used on new lots	Immediately

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

Sincerely,

AShatola

Anthony Shatola
Quality Assurance Director