***REVISED** 12/26/2024*

FLO.23325 New Reagent Lot/Shipment Confirmation of Acceptability **Phase II**

The laboratory evaluates performance of new lots/shipments of antibodies and reagents before or concurrently with being placed into service.

NOTE: Evaluation of new lots or shipments of antibodies and reagents for positive and negative reactivity is required to ensure consistent performance. Methods for evaluation include (but are not limited to):

- *Parallel testing of old versus new lots on patient samples or control materials*
- *Testing of new lot/shipment on control material with defined criteria for acceptance*
- *Testing of the new lot/shipment on normal patient material with defined criteria for acceptance.*

Only when there is agreement between the individual old and new lots may the new lot be placed into routine use. Individual antibodies must be evaluated as a single reagent (see FLO.23335 for antibody cocktails). All reagents that interact with or alter patient samples (such as lysing agents and permeabilization reagents) must be evaluated. Inert reagents (such as sheath fluid and cleaning fluids) are exempt from this requirement.

Evidence of Compliance:

✓ Records of confirmation of new antibody and reagent lots

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988, final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1256(e)(1)].

***NEW** 12/26/2024*

FLO.23335 New Antibody Cocktail Confirmation of Acceptability **Phase II**

The laboratory evaluates performance of newly prepared antibody cocktails before or concurrently with being placed into service and assigns an expiration date for the cocktail.

NOTE: Laboratory-prepared or commercially-prepared antibody cocktails require validation to ensure proper composition and consistent performance before or concurrently with being placed into service. The laboratory must establish a stability period for laboratory-prepared cocktails during the validation of the assay for which it is used and assign an expiration date. The stability period of the prepared cocktail may be shorter than the stability of the individual components due to interaction between the components.

Because individual antibody lots/shipments require confirmation of acceptability (per FLO.23325), parallel testing of the old cocktail versus the new cocktail may be performed but is not required. Procedures must include defined criteria to accept new cocktails with both positive and negative controls for each component of the cocktail (with the exception of rare flow antigens such as CD1a, CD30, and/or CD103). Normal cells in patient samples or other standardized control material can be used for confirmation.

If antibodies or stains are not used in a cocktail, they must be evaluated individually (per FLO.23325).

Evidence of Compliance:

✓ Records of confirmation of new antibody cocktails

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Validation of Assays Performed by Flow Cytometry - Approved Guideline-First Edition.* CLSI Document H62. Clinical and Laboratory Standards Institute, Wayne, PA, 2021.
2) Tangri S, Vall H, Kaplan D, et al. Validation of cell-based fluorescence assays: practice guidelines from the ICSH and ICCS - part III - analytical issues. *Cytometry B Clin Cytom*. 2013;84(5):291-308.
3) Wood B, Jevremovic D, Bene MC, et al. Validation of cell-based fluorescence assays: practice guidelines from the ICSH and ICCS - part V - assay performance criteria. *Cytometry B Clin Cytom.* 2013;84(5):315-323.