

CLSI publishes new method evaluation guideline

September 2018—The Clinical and Laboratory Standards Institute announced the publication of “EP34—Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, 1st ed.” EP34 provides recommendations for establishing a dilution scheme to be used for patient specimens that contain measurand concentrations in the extended measuring interval above a measurement procedure’s upper limit of quantitation. Guidance is provided on determining, validating, and verifying the appropriate diluent and dilution ratio to be used for such specimens. The guideline also covers creating spiked samples for use during dilution recovery studies and using spiking to determine the suitability of a sample matrix for dilution recovery studies. Intended users of this guideline are manufacturers of in vitro diagnostic tests and medical laboratory scientists, directors, and pathologists.

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