

§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies

(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

Interpretive Guidelines §493.1252(e)

“Kit” means all components of a test that are packaged together.

§493.1253 Standard: Establishment and verification of performance specifications

(a) Applicability. Laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

Interpretive Guidelines §493.1253(a)

The requirements of §493.1253 apply to each nonwaived test system (i.e., moderate and high complexity) introduced into the laboratory on or after April 24, 2003. This includes the following:

- A test system that is introduced into the laboratory for the first time to measure an analyte that the laboratory has not previously measured;
- A test system introduced for the first time into the laboratory for a test that the laboratory currently performs on an alternative test system (e.g., instrument A has been used to perform cholesterol testing, now instrument B will be used);
- An analyte added to a test system that can measure multiple analytes which the laboratory has been using for patient testing but has not previously reported patient results for this particular analyte; and
- A modification to a test system that the laboratory has been using for patient testing (e.g., the laboratory reduces the specimen and/or reagent volumes).

When multiple instruments (including the same make and model, e.g., point-of-care instruments) are used to perform the same test, the laboratory must verify or establish, as applicable, performance specifications for each instrument.

Refer to requirements in subpart M, for training and competency of personnel.

Specific information regarding testing for agents of emergent public health significance and alternative methods /procedures for establishing performance specifications may be found at www.aphl.org.

NOTE: Public health testing performed on environmental (non-human) samples is not subject to CLIA.