

D5415

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

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

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:

(1) Identity and when significant, titer, strength or concentration.

(2) Storage requirements.

(3) Preparation and expiration dates.

Interpretive Guidelines §493.1252(c)(3)

Expiration dates for test kits and/or reagents may differ due to date opened or storage conditions (e.g., refrigerator, room temperature). Verify that laboratory personnel are aware of these differences and document the appropriate expiration date.

(4) Other pertinent information required for proper use.