

§484.100(c) Standard: Laboratory services.

(1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter. The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests.

Interpretive Guidelines §484.100(c)(1)

If an HHA nurse or other HHA employee only *assists* a patient who has her or his own glucose meter, then a Clinical Laboratory Improvement Amendment (CLIA) certificate is not required. If the HHA nurse or HHA employee conducts the test, regardless of whether the patient's equipment or the HHA's equipment is used, then a CLIA certificate (specifically a Certificate of Waiver) is required.

The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests, except that an HHA may allow a patient to use HHA testing

equipment for a short, defined period of time until the patient has obtained his or her own testing equipment. As a part of the care planning process, HHAs are expected to help patients identify and obtain resources to secure the equipment needed for self-testing.