Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0663079	08/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Shelby County Health Department Laboratory	814 Jefferson Avenue Rm 124, Memphis, TN	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the employee competency checks procedure, the personnel records and interview with the general supervisor, the laboratory failed to follow the employee competency checks procedure in 2018. The findings include: 1) Review of the employee competency checks procedure revealed, "1. Annually, one (or more) Competency Assessment Worksheet ("Direct Observation of Test Performance"-COMPASS>DOC) will be prepared for each employee for each procedure to be assessed. Initial, Six Month, and Annual assessments will be documented." 2) Review of the eight testing personnel records revealed the competency assessment worksheet was not completed for the 2018 training or annual competency documentation. 3) Interview on August 20, 2019 at 2:00 p.m. with the general supervisor confirmed the competency assessment worksheet was not completed for the eight testing personnel training or annual competency documentation. The procedure was not followed.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, the form for recording HIV 1/2 rapid test quality control, and interview with the laboratory director, the laboratory failed to perform negative and positive controls for HIV 1/2 antibody each day of patient testing in 2017. The findings include: 1) Review of the laboratory's procedure titled "OraQuick ADVANCE Rapid HIV-1/2 Antibody Test" revealed that external quality control is performed with each new operator, new lot number, new shipment, problems with storage or testing temperature, and "At periodic intervals as dictated by the user facility." There was no individualized quality control plan (IQCP) present in the procedure manual for reduced quality control frequency. 2) Review of the laboratory's form used for documenting OraQuick Rapid HIV 1/2 antibody quality control revealed the following statement: "***DAILY CONTROLS ARE NOW PERFORMED MONTHLY (AS OF 1 MAR 2017)***. 3) Interview with the laboratory director on August 20, 2019 at 4:00 pm confirmed the laboratory did not perform negative and positive external controls each day of patient testing for OraQuick HIV 1/2 in 2017, 2018, and 2019, and did not have an IQCP for reduced quality control frequency.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's quality assessment (QA) plan, the pipette calibration and verification procedure, the 2018 pipette calibration records, interview with testing personnel number six and the general supervisor, the laboratory failed to include review of pipette calibration records in the QA plan. The findings include: 1) Observation on August 20, 2019 at 9:15 a.m. revealed a total of ten pipettes on various counters in use for patient testing. 2) Review of the laboratory's QA plan revealed review of the pipette calibration records was not included in the plan. 3) Review of the pipette calibration and verification procedure revealed, "pipettes will be calibrated annually. 4) Review of the 2018 pipette calibration records revealed six pipette were calibrated. The six pipette calibration records contained the same identification number for all pipettes. 5) Interview on August 20, 2019 at 4:00 p.m. with testing personnel number six confirmed the six pipette calibration records contained the same identification number for all six pipettes. All ten pipettes are in use for patient testing. All ten pipettes were not calibrated in 2018 and none in 2019. 6) Interview on August 20, 2019 at 4:15 p.m. with the general supervisor confirmed the QA plan does not include review of the pipette calibration records. The 2018 calibration records were not reviewed and contain the incorrect identification number for the pipettes.