Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0896256	01/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
South Oakland County Health Division Laboratory	27725 Greenfield, Southfield, MI	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the technical supervisor, the laboratory failed to perform and evaluate performance specifications for two (Alere Determine HIV-1/2 Ag/Ab Combo and Chembio DPP HIV 1/2) of two new test methods. The findings include: 1. On January 29, 2019 at 1:45 PM, the surveyor requested performance verification studies for the Alere Determine HIV-1/2 Ag/Ab Combo and Chembio DPP HIV 1/2 tests which includes accuracy, precision, reportable range, and normal reference ranges for the two new tests put into use September 17 and 24, 2018 respectfully. 2. During the interview on January 29, 2019 at approximately 2:00 PM, the technical supervisor stated the performance specifications were not completed for this location.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through

	493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review, procedure review, and interview with the technical supervisor, the laboratory failed to perform quality control as required for the immunology testing for ten (2610113845, 2610113673, 2610126166, 2610151642, 2610126141, 2610152023, 2610152497, 2610176917,2610176963, and 2610176973) of 12 patients tested. Findings include: 1. Record review for the immunology serum "Chembio DPP HIV-1/2 Client Log" compared to the "Chembio DPP HIV-1/2 Quality Control Log Sheet" revealed the laboratory did not run external quality control material each day of patient testing as follows: a. August 8, 2018 - two patients tested b. August 16, 2018 - one patient tested c. August 30, 2018 - one patient tested d. September 4, 2018 - one patient tested e. September 21, 2018 - one patient tested f. October 17, 2018 - one patient tested g. November 26, 2018 - one patient tested h. November 27 2018 - two patients tested 2. On January 29, 2019 at 1:45 PM when requested, the technical supervisor was not able to provide the surveyor with the quality control documentation for each day of patient testing. 3. On January 29, 2019 at 2:00 PM, procedure review for "Chembio DPP Procedure" revealed kit controls are to be run "Monthly for each month there is testing performed". 4. During the interview on January 29, 2019 at approximately 2:00 PM, the technical supervisor confirmed two different levels of external controls had not been performed each day of patient testing and that an individualized quality control plan had not been implemented to decrease the number or frequency of running external controls for the testing location.