Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0687071	(X3) Date Survey Completed 10/08/2020
Name of Provider or Supplier Hennepin County Public Health Clinic	**Street Address, City, State** 525 Portland Avenue, Mc 952, Minneapolis, MN	
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 document review and interview with laboratory personnel, the laboratory failed to verify performance specifications for 1 of 1 new tests implemented in 2019. Findings are as follows: 1. The laboratory performed General Immunology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 10/08/20 at 8:05 a.m. 2. An INSTi HIV-1/HIV-2 Antibody test kit was observed as present and available for use during the tour. 3. A review of the INSTi HIV-1/HIV-2 Antibody Instruction for Use (bioLytical Laboratories, Document # 51-1080 [I], 11Feb2019) revealed that use of the test with fingerstick whole blood carries a Waived complexity, whereas use of the test with venous whole blood and plasma samples (EDTA) carries a Moderate complexity. 4. Testing Personnel 4 (TP4) indicated HIV-1/HIV-2 Antibody patient testing on EDTA whole blood by venipuncture was initiated in May 2019. 5. Performance verification (PV) documentation for comparison of fingerstick whole blood versus venous whole blood using the INSTi HIV-1/HIV-2 Antibody test was not found in laboratory records. The laboratory was unable to provide PV documents upon request. 6. In an interview on 10/08/20 at 11:30 a.m., TP4 confirmed a PV had not been performed for INSTi HIV-1/HIV-2 Antibody test kit using venous whole blood. .

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 observation, document review and interview with laboratory personnel, the laboratory failed to perform minimum quality control activities as required for a Virology test system. Findings are as follows: 1. The laboratory performed General Immunology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 10/08/20 at 8:05 a.m. 2. An INSTi HIV-1/HIV-2 Antibody test kit was observed as present and available for use during the tour. 3. A review of the INSTi HIV-1/HIV-2 Antibody Instruction for Use (bioLytical Laboratories, Document # 51-1080 [I], 11Feb2019) revealed that use of the test with fingerstick whole blood carries a Waived complexity, whereas use of the test with venous whole blood and plasma samples (EDTA) carries a Moderate complexity. 4. Testing Personnel 4 (TP4) indicated HIV-1/HIV-2 Antibody patient testing on EDTA whole blood by venipuncture was initiated in May 2019. 5. Quality control (QC) performance was required with each new lot and shipment of INSTi HIV-1/HIV-2 Antibody test kit as established in the Instruction for Use. 5. Laboratory records indicated HIV-1/HIV-2 Antibody QC was performed with new lots and/or shipments of test devices since the start of patient testing on EDTA whole blood by venipuncture in May 2019. 6. The laboratory did not establish an Individualized Quality Control Plan (IQCP) to reduce the frequency of HIV-1/HIV-2 Antibody QC required each day of patient testing. 7. In an interview on 10/08/20 at 11:30 a.m., TP4 confirmed the above finding. .