Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0648109	(X3) Date Survey Completed 03/23/2023
Name of Provider or Supplier State Hygienic Laboratory	**Street Address, City, State** University Of Iowa Research Park, Coralville, IA	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of three of three Illumina MiSeq analyzers located in the microbiology sequencing room, review of Illumina manufacturer's manual, review of Illumina patient reports, lack of temperature documentation, and interview with the technical supervisor (TS) #19, the laboratory failed to monitor and document the room temperature and relative humidity. Findings include: 1. Observation of the laboratory on 03/21/2023 at 1:00 PM, showed that the temperature and relative humidity in the microbiology sequencing room was not monitored and documented. 2. Review of The Illumina MiSeq analyzer operating conditions revealed, "maintain a lab temperature of 19C to 25C and 30% to 75% non-condensing relative humidity." 3. The laboratory reported out approximately 839 patient reports in 2021 and 970 in 2022 for bacteriology identification sequencing. 4. Interview with TS #19 on 03/21/2023 at 3: 00 PM confirmed the laboratory failed to monitor and document the room temperature and relative humidity.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of 48 of 48 boxs of Bio-Rad Liquichek Maternal Serum II quality control levels 1, 2, and 3 stored in the freezer, review of manufacturer's instructions, procedure manual, documentation of freezer temperatures and patient volumes, and interview with the technical supervisor (TS) #18, the laboratory failed to follow the manufacturer's instructions for storage of control material for 15 of 55 testing days for January 1, 2023, through March 22, 2023. Findings include: 1. Observation of the laboratory freezer showed 48 boxes of Bio-Rad Liquichek Maternal Serum II quality control levels 1, 2, and 3 available for use in the laboratory. 2. Review of the manufacturer's instructions for Bio-Rad Liquichek Maternal Serum II quality control levels 1, 2, and 3 showed controls must be stored at minus 20 degrees Celsius (C) to minus 70 degrees C. 3. Review of the procedure manual revealed, "reagents will be stored according to manufacturer's instructions." 4. Review of the laboratory's temperature chart showed a defined acceptable range of greater than minus 15 degrees C to minus 25 degrees C. 15 of 55 testing days for January 1, 2023, through March 22, 2023, the laboratory failed to meet the manufacturer's required minus 20 to minus 70 degrees C range. 5. The laboratory reports approximately 8000 tests annually for maternal screening. 6. Interview with TS #18 on March 22, 2023, at 1:00 PM confirmed the laboratory failed to properly monitor the freezer and store quality control materials per manufacturer's instructions.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on a review of personnel records, and an interview with the laboratory director (LD), the LD failed to ensure competency for 24 of 24 technical supervisors and 26 of 26 general supervisor positions for 2022. Findings include: 1. Personnel and laboratory records showed no competency evaluations performed in the calendar year 2022 for 24 of 24 technical supervisors and 26 of 26 general supervisors. 2. Interview with the LD on 03/24/2022 at 11:30 AM confirmed the LD failed to ensure competency for 24 of 24 technical supervisors and 26 of 26 general supervisor positions for 2022.