Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0648109	08/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
State Hygienic Laboratory	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
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observation of the COVID-19 testing room and interview with the Quality Assurance Manager and the technical supervisor (TS) #42, the laboratory failed to have a uni-directional workflow that includes separate areas for positive control and extraction plate storage, separate area for mastermix/reaction plate processing and positive control. Uni-directional workflow refers to the manner in which testing personnel and patient specimens move through the molecular testing process to prevent cross-contamination of patient specimens, and consists of separate areas for reagent preparation, pre-amplification, and post-amplification. Findings: 1. Observation of the COVID-19 testing room showed the positive control being stored in the same refrigerator as the patient extraction plates. 2. Observation of the COVID-19 testing room showed three hoods located next to each other. The middle hood was used for mastermix/reaction plate processing and the two outer hoods were used for the addition of the positive control. The three hoods were located across and next to the Applied Biosystems 7500 Fast Real Time PCR analyzers. The testing personnel used the outer hood to prepare the reaction plates and move to the middle hood for the addition of the positive control. The workflow was not in one direction. 3. Interview on August 26, 2021 at 12:00 PM with the Quality Assurance Manager and TS #42, confirmed the laboratory failed to have a uni-directional workflow to include separate areas to prevent contamination of patient specimens, equipment, instruments, reagents, materials, and supplies.
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 personnel competency records and interview with the laboratory director (LD), the laboratory failed to perform three of three competencies for the positions of general supervisor (GS) and 26 of 26 competencies for the positions of technical supervisors (TS). Findings: 1. Personnel competency records failed to include documentation of evaluations of specific GS and TS responsibilities. 2. Interview with the LD on August 26, 2021 at 4:00 PM confirmed the laboratory failed to perform competency assessments for GS and TS positions.
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 the molecular COVID-19 and non COVID-19 testing rooms, review of manufacturer manuals, and interview with technical supervisors (TS) #24, 42, the laboratory failed to monitor humidity to ensure proper operation of instrumentation. Findings: 1. Observation of the non COVID-19 molecular area used for PCR testing showed six of six Applied Biosystems 7500 PCR analyzers. 2. Observation of the non COVID-19 PCR extraction room showed two of two Thermo Scientific KingFisher analyzers. 3. Observation of the COVID-19 testing laboratory showed four of four Thermo Scientific KingFisher analyzers and five of nine Applied Biosystems 7500 PCR analyzers. 4. Review of the Applied Biosystems 7500 PCR manual revealed to operate with "20-80 percent relative humidity noncondensing." 5. Review of the Thermo Scientific KingFisher manual showed "make sure relative humidity is between 10% and 80% noncondensing." 6. Interview with the TS #24, 42 confirmed the laboratory failed to monitor the humidity in the COVID-19 and non COVID-19 molecular laboratory rooms. Based on observation of the -20 degree Celsius (C) freezer and two of two refrigerators located in the non COVID-19 molecular room and one -80 degree C freezer located in the microbiology hallway, review of temperature charts, review of manufacturer's inserts, and interview with technical supervisors #6, 24, the laboratory failed to define criteria and follow the manufacturer's guidelines for proper storage of reagents. Findings: 1. Observation of the -20 degree C freezer (serial #RH174657) located in the non COVID-19 molecular room showed TaqMan probe kits with a required storage range of -15 to -25 degrees C. 2. Review of the -20 degree C freezer temperature charts revealed two of 54 days the temperature fell outside of the required range of -15 to -25 degrees C. 3. Observation of the refrigerator (serial #K50338B) located in the non COVID

	molecular room, showed 3 boxes Applied Biosystems master mix with the required storage of 2-8 degrees C. 4. Review of the temperature charts for the refrigerator revealed 10 of 54 days the temperature range fell outside the 2-8 degrees C range. 5. Observation of the -80 degree C freezer (serial # 578107) showed storage of quality control organisms for microbiology with a required range of -70 to -90 degrees C. 6. Review of the -80 degree C freezer temperature charts revealed 34 of 235 days the temperature fell outside of the required -70 to -90 degrees C range. 7. Interview with the TS #6, 24 on August 26, 2021 at 4:00 PM confirmed the laboratory failed to monitor and document the freezer and refrigerator temperatures for proper temperature range.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 Personnel Report and interview with the Quality Assurance Manager, the laboratory failed to provide documentation of academic credentials for all Testing Personnel. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the

	military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of personnel records and interview, the laboratory could not provide academic credentials for all Testing Personnel (TP) listed on the CMS-209. Findings: 1. No academic credentials were available to qualify 13 of 88 TP (TP #34, #35, #51, #52, #53, #54, #56, #60, #63, #66, #73, #74, and #82). 2. Confirmed during interview with the Quality Assurance Manager on August 26, 2021 at 1030 AM.