Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0648109	06/11/2025
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, review of test volume records, and interview with the laboratory's Quality Systems Manager, the laboratory failed to establish proper conditions for specimen transportation (temperature) as part of its written policies and procedures for 1 of 1 policy in the specialty of Chemistry (Maternal Screening Department). Findings Included: 1. A review of the laboratory's policy for the Iowa State Hygienic Laboratory in the Maternal Screening Department in the specialty of Chemistry stated the following under the Specimen Transport (For Clients) section: "4.3.2 Transport Temperature - Samples may be transported to the laboratory at ambient temperature or on ice packs. Both transport temperatures are acceptable and have been validated." 2. A review of the laboratory's test volume records showed an annual test volume of 7,569 for the specialty of Chemistry. 3. In an interview on 6/10/2025 at 10:41 AM, the Quality Systems Manager confirmed that some SOPs had not been updated to reflect defined temperature ranges in specimen transport for clients, and that ambient temperature was not defined.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test

	procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on technical supervisor interview and mycobacteriology quality control record review, the laboratory failed to have a written procedure manual that included quality control protocols for Lowenstein-Jensen (LJ) medium and the maintenance of mycobacteriology quality control organisms. Findings included: 1. In mycobacteriology, it was the practice of the laboratory to culture patient mycobacteriology specimens using LJ medium. Whenever new lots/shipments/batches of LJ medium were received by the laboratory, the laboratory performed LJ medium quality control procedures on the new lot/shipment/batch of LJ medium to ensure the media was appropriate to culture patient mycobacteriology specimens. The laboratory maintained and used mycobacteria quality control organisms to perform LJ medium quality control procedures. 2. The laboratory maintained no written procedures which had been approved by the laboratory director detailing the laboratory's protocols for performing LJ medium quality control procedures and maintaining and using mycobacteria quality control organisms. The technical superviosr confirmed these findings on June 11, 2025 at 09:30 am. 3. According to laboratory records, the laboratory performed and reported approximately 4,000 patient mycobacteriology culture results annually.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 review of the manufacturer's instructions, review of patient records, and confirmed in interview with the Technical Supervisor (TS) of Virology, the laboratory failed to follow manufacturer's instructions in ensuring Trichomonas Vaginalis (TV) specimens were not tested on patients under the age of 14 for 2 of 1,140 Trichomonas Vaginalis specimens run on the Hologic Panther analyzer for 18 months reviewed.

	Findings Included: 1. A review of manufacturers instruction for the Aptima Combo 2 Assay Panther System (502446 Rev. 009) stated the following on page 20: "Limitations: P. The performance of the Aptima Combo 2 Assay has not been evaluated in adolescents less than 14 years of age." 2. A review of the laboratory's Laboratory Information Management System (LIMS) patient report generated from January 2024 to June 2025 showed a total of 1,140 TV tests run and 2 patient specimens whose age demographics fell under the age of 14 at the time of testing. 3. In an interview on 6/3/2025 at 1:57 PM, the TS of Virology confirmed the findings that the lab performed testing on specimens for 2 patients under the age of 14 in 2024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, manufacturer's instructions, review of Reese System temperature ranges, and interview with the laboratory's quality assurance manager, the laboratory failed to define temperature ranges consistent with the manufacturer's instructions, for the general room temperature where 12 of 12 temperature dependent reagents and supplies were stored. Findings Included: 1. During a tour of the laboratory on 6/10/25 at 10:17 AM and 6/11/25 at 11:01 AM, the following temperature dependent reagents and supplies were observed: a. 1 box Qiagen Large 96-Rod Covers 16, Lot #160053548, Manufacturer storage temperature requirements, 15 to 25 degrees C b. 1 bottle Roche MagNA Pure External Lysis Buffer, Lot #84717200, Manufacturer storage temperature requirements, 15 to 25 degrees C c. 5 boxes MagNA Pure 24 Processing Cartridge, Lot #21011330, Manufacturer storage temperature requirements, 15 to 25 degrees C d. 3 boxes Qiagen QuantiFERON-TB Gold Plus Blood Collection Tubes, Lot #58103080, Manufacturer storage requirements, 4 to 25 degrees C. e. 2 Roche Cobas CREJ2 box, Ref #05401755190, Manufacturer storage requirements, 15 to 25 degrees C 2. A review of the laboratory's Reese temperature monitoring system showed the laboratory temperature threshold set to a high of 30 degrees C. 3. In an interview on 6/10/2025 at 10:41 AM, the Quality Systems Manager confirmed that the Reese temperature monitoring system had a high temperature alert threshold at 30 degrees C, instead of the having the most stringent settings in accordance to what was stored within the laboratory.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on direct observation, manufacturer instructions, and confirmed in interview with the Technical Supervisor (TS) -7 according to the Form CMS-209, the laboratory failed to ensure the labeling of new expiration dates for 3 of 6 Bio-Rad Liquicheck Maternal Serum Control bottles in use. Findings Included: 1. During a tour of the laboratory on 6/10/2025 at 10:19 AM, 6 Bio-Rad Liquicheck Maternal Serum Control bottles were found in storage. The following open bottles, did not have new expiration dates written: a. 1 Bio-Rad Liquicheck Maternal Serum Control 1, Lot #1002111 b. 1 Bio-Rad Liquicheck Maternal Serum Control 2, Lot #1002112 c. 1 Bio-Rad Liquicheck Maternal Serum Control 3, Lot #1002113 2. A review of the manufacturer's instructions stated, "Liquichek Maternal Serum Control II is a multi-constituent control: 30 day thawed open-vial stability at 2 to 8 degrees C. Available in three individual levels". 3. In an interview on 6/10/25 at 10:19 AM, TS-7 confirmed the bottles did not have new expiration dates written on them after opening.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on technical supervisor interview and mycology lactophenol cotton blue stain quality control record review, the laboratory failed to ensure that lactophenol cotton blue stain had not been used when it had exceeded its expiration date. Findings included: 1. In mycology, the laboratory stained each patient specimen received using lactophenol cotton blue stain. 2. On June 11, 2025 at 09:40 am, the technical supervisor read the labeling of the laboratory's lactophenol cotton blue stain in use as having lot number 798851 and expiration date February 12, 2025. No additional information was provided to indicate that the laboratory had not been using this lactophenol cotton blue stain that had not expired to stain patient specimens. 3. According to the technical supervisor, the laboratory performed and reported approximately 8 patient mycology test results weekly.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on technical supervisor interview and bacteriology whole genome sequencing instrument maintenance record review, the laboratory failed to perform weekly Qiagen EZ1 Advanced XL instrument maintenance as defined by the manufacturer. Findings included: 1. In bacteriology whole genome sequencing, the laboratory used the Qiagen EZ1 Advanced XL instrument for nucleic acid purification from isolates derived from patient specimens. 2. From January 1, 2025 to May 31, 2025, laboratory Qiagen EZ1 Advanced XL instrument maintenance records indicated that weekly

	manufacturer required maintenance had not been performed for 3 of 21 weeks of patient testing. 3. On June 10, 2025 at 04:15 pm, the technical supervisor confirmed these findings and stated that the Qiagen EZ1 Advanced XL instrument was used for approximately 15 isolates from patient specimens weekly. II. Based on review of manufacturer's instructions, laboratory maintenance records, test volume records, and interview with the Technical Supervisor (TS)-3 of Virology, as per the Form CMS-209, the laboratory failed to follow the operator's manual for the Hologic Panther System for daily maintenance requirements and cleaning for 3 of 3 months (random review). Findings included: 1. A review of manufacturer's instructions (AW-20220-001 Rev. 001) for the Hologic Panther revealed the following maintenance requirements for the mag wash cleaning: "As part of system maintenance, it is required that this task be performed after each testing day. For example, if processing test orders on Monday-Friday, schedule the Mag Wash Clean task to be run after working hours on Monday-Friday." 2. A review of the laboratory's onboard Panther Fusion Maintenance Log Report from April 2025 through June 2025 revealed the laboratory failed to follow manufacturer's instructions to perform daily Mag Wash Clean maintenance after each day testing was performed on the following Hologic Panther Fusion Analyzers: Serial Numbers # 1010910224, 2090002472. The Mag Wash Clean maintenance tasks were set to run at 6:55 AM, instead of the end of the each testing day. 3. A review of the laboratory's test volume records showed the following 2024 Annual Test Volume run on the Hologic Panther Fusion analyzers: Chlamydia/Gonorrhoeae - 28,545 Annual Test Volume Hepatitis C Virus Quantitative - 177 Annual Test Volume Candida auris - 1523 Annual Test Volume Herpes Simplex Virus 1 and 2 - 544 Annual Test Volume Monkey Pox - 137 Annual Test Volume 2019 Novel Coronavirus - 40 Annual Test Volume 4. In an interview on 6/10/25 at 2: 47 PM, the TS-3 of Virology confirmed the Mag Wash settings were not set to run after each testing day in accordance with the manufacturer's instructions. III. Based on review of manufacturer's instructions, laboratory maintenance records, test volume records, and interview with the Technical Supervisor (TS)-3 of Virology, as per the Form CMS-209, the laboratory failed to follow the operator's manual for the Hologic Panther System for quarterly cleaning maintenance requirements for 6 of 6 months (random review). Findings Included: 1. The manufacturer's instructions for the Hologic Panther System (AW-20220-001 Rev. 001) listed the following cleaning requirements of the thermocycler: "Clean Thermocycler - Perform the Thermocycler Clean Maintenance task at least every 3 months and as needed to remove debris that may be inside the thermocycler wells." 2. A review of the laboratory's onboard Panther Fusion Maintenance Log Report from January 2025 to June 2025 revealed the laboratory failed to follow manufacturer's instructions to perform quarterly Thermocycler cleaning maintenance on the following Hologic Panther Fusion Analyzers: Serial Numbers # 1010910224, 2090002472. 3. A review of the laboratory's test volume records showed the following 2024 Annual Test Volume run on the Hologic Panther Fusion analyzers: Chlamydia/Gonorrhoeae - 28,545 Annual Test Volume Hepatitis C Virus Quantitative - 177 Annual Test Volume Candida auris - 1523 Annual Test Volume Herpes Simplex Virus 1 and 2 - 544 Annual Test Volume Monkey Pox - 137 Annual Test Volume 2019 Novel Coronavirus - 40 Annual Test Volume 4. In an interview on 6/10/25 at 2:47 PM, the TS-3 of Virology confirmed the onboard thermocycler cleaning cycle was set to a quarterly interval, however the instrument maintenance log did not record the performance of cleaning.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

	This STANDARD is not met as evidenced by: Based on technical supervisor interview and bacteriology catalase quality control record review, the laboratory failed to include a negative and positive catalase quality control material at least once each day patient specimens were assayed. Findings included: 1. In bacteriology, it was the practice of the laboratory to perform a catalase test on bacteria cultured/isolated from patient specimens to aid in the identification of the isolate. 2. According to laboratory catalase quality control records, the laboratory had not tested negative and positive catalase quality control materials at least once each day isolates from patient specimens were tested since August 3, 2023. 3. The technical supervisor confirmed these findings on June 10, 2025 at 02:45 pm and stated that the catalase test was used on patient specimen isolates at least once each day the laboratory conducted patient testing. 4. On June 10, 2025, the laboratory was using catalase reagent (hydrogen peroxidase) lot number 245512, expiration date March 3, 2026, which was made by the laboratory on March 3, 2025. The laboratory maintained no documentation to indicate that any catalase quality control procedures had been performed on this lot of catalase reagent even though the catalase reagent had been used to test isolates from patient specimens. 5. According to laboratory records, the laboratory performs and reports the test results of approximately 1200 patient bacteriology cultures annually.
D5517	MYCOLOGY CFR(s): 493.1263(a)(c) (a) The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s). This STANDARD is not met as evidenced by: Based on technical supervisor interview and mycology lactophenol cotton blue stain quality control record review, the laboratory failed to check each lot number and shipment of lactophenol cotton blue when opened for intended reactivity with at least one quality control organism. Findings included: 1. In mycology, the laboratory stained each patient specimen received using lactophenol cotton blue stain. 2. The laboratory maintained no documentation to indicate that each lot number and shipment of lactophenol cotton blue stain had been checked for intended reactivity with at least one quality control organism. On June 11, 2025 at 09:40 am, the technical supervisor confirmed these findings and indicated that no lactophenol cotton blue stain quality control procedures had been performed. 3. On June 11, 2025, the laboratory was using Remel lactophenol cotton blue stain, lot number 798851, expiration date 02/12/2025. 4. According to the technical supervisor, the laboratory performed and reported approximately 8 patient mycology test results weekly.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable

	patient test results. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory quality control records, and confirmed in interview with the Technical Supervisor (TS)-7, according to the Form CMS-209, the laboratory failed to take corrective action necessary to ensure the evaluation of all patient test results obtained since the last acceptable test run, after 2 of 2 unacceptable quality control (QC) failures requiring recalibration from May 1, 2025 to June 10, 2025 (random review). Findings Included: 1. During a tour of the laboratory on 6/10/2025 at 2:47 PM, two Beckman Coulter UniCel Dxl 800 Access Immunoassay analyzers were observed in use in the Maternal Screening Department. 2. A review of the laboratory's QC records showed the following repeat control failures where recalibration was required, and patient test results since the last acceptable QC run were not evaluated: a. Beckman Coulter UniCel DxL (S/N #608823), QC failure requiring recalibration on 5/22/25, 27 AFP tests run on 5/21 to the last acceptable QC run. b. Beckman Coulter UniCel DxL (S/N #608823), QC failure requiring recalibration on 6/4/25, 3 PAPP-A tests run on 5/29 to the last acceptable QC run. 3. In an interview on 6/10/2025 at 1:28 PM, the TS-7 confirmed that the patient evaluation to the last acceptable QC run was not performed after the aforementioned QC failures which required recalibration.
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. This STANDARD is not met as evidenced by: Based on quality manager interview and bacteriology quality control and instrument maintenance records review, the laboratory failed to establish 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. Findings included: 1. For the records review at D5429 (the laboratory failed to perform weekly Qiagen EZ1 Advanced XL instrument maintenance as defined by the manufacturer) and D5449 (the laboratory failed to include a negative and positive catalase quality control material at least once each day patient specimens were assayed), the laboratory maintained no documentation to indicate that these records had been monitored and assessed to ensure laboratory protocols were followed. 2. According to the quality manager on June 10, 2025 at 05:00 pm, laboratory technical supervisors were to review laboratory testing records periodically. The laboratory maintained no written procedures that defined this periodic review. 3. According to laboratory records, the laboratory performed and reported 84,614 patient test results annually.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system;

	This STANDARD is not met as evidenced by: Based on direct observation, review of twice annual laboratory instrument comparison /correlation records, and confirmed in interview with the Technical Supervisor (TS) -3, according to the Form CMS-209, the TS failed to verify the laboratory's test performance characteristics including the precision and accuracy of the test system for 2 of 2 Hologic Panther Analyzers. Findings Included: 1. During a tour of the laboratory on 6/10/2025 at 2:47 PM, two Hologic Panther Analyzers (S/N#s 1010910224, 2090002472) were observed in use in the Molecular Biology Department. 2. A review of the laboratory section's twice annual instrument comparison data, showed no review or signature from the TS to ensure proper review, technical oversight and approval of the laboratory section's twice a year instrument correlations. 3. In an interview on 6/10/2025 at 3:15pm, the TS-3 confirmed that the instrument correlation was performed, but not signed by the TS to signify any review and approval of the correlation data performed.