Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0036143	07/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
University Health Service	207 Fletcher Street, Ann Arbor, 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
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 record review and interview with the Laboratory Manager, the laboratory failed to follow its testing personnel competency assessment policies for 1 (Testing Personnel #5) of 35 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's personnel competency records revealed Testing Personnel #5 was employed as a testing personnel starting on 1/10/23. One competency assessment was completed in April 2023. 2. A review of the laboratory's "Competency Assessment" policy revealed a section stating, "Annually, each technologist is observed by another qualified tech for each test performed at UHS. The observer watches the technologist perform the test. If the observer sees that every step is followed correctly, they will sign-off on the Direct Observation sheet with the date, their initials and the order number if applicable." 3. An interview on 7/1/24 at 10: 24 am with the Laboratory Manager confirmed the annual competency assessment for Testing Personnel #5 was not completed in accordance with laboratory policy.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in

	493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on observation, record review, and interviews, the laboratory failed to ensure Potassium Hydroxide (KOH) used to perform KOH preparations was not used when it had exceeded its expiration date (refer to D5417), failed to perform and document calibration verification every six months on the Tosoh AIA for human chorionic gonadotropin and ferritin (refer to D5439), failed to perform controls each date of patient testing fof Shiga toxin and Campylobacter patient testing dates (refer to D5445), and failed to perform and document quality control after changing reagents prior to resuming patient hematology testing using the Sysmex XN-550 (refer to D5461).
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 observation and interview with the Laboratory Manager, the laboratory failed to ensure Potassium Hydroxide (KOH) used to perform KOH preparations was not used when it had exceeded its expiration date for one bottle observed. Findings include: 1. The surveyor observed a bottle of EDM3 Potassium Hydroxide 10% with the expiration date of 4/22/24 near the microscope in the Treatment Center Clinic laboratory area on 7/1/24 at 9:07 am. 2. An interview on 7/1/24 at 9:07 am with the Laboratory Manager confirmed the laboratory performs KOH preparation testing and the bottle observed had exceeded it's expiration date.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent

	calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel 3 (TP3), the laboratory failed to perform and document calibration verification every six months on the Tosoh AIA for human chorionic gonadotropin and ferritin for two (July 2022 to July 2024) of two years reviewed. Findings include: 1. Record review revealed that the laboratory did not perform calibration verification at least every six months from July 2022 to July 2024 for human chorionic gonadotropin and ferritin testing performed using the Tosoh AIA chemistry analyzer. 3. An interview with TP3 on 07/01/2024 at 3:30 pm confirmed calibration verification was not performed for ferritin and human chorionic gonadotropin at least every six months.
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 and interview with Laboratory Manager, the laboratory failed to perform controls each date of patient testing for 186 Shiga toxin patient testing dates and 179 for Campylobacter patient testing dates between July 2022 and July 2024. Findings include: 1. A review of the laboratory's "ImmunoCard STAT! EHEC Rapid test for Shiga toxins 1 and 2 in human stool" manufacturer's instructions revealed a section titled "Quality Control" stating, "This test should be performed per applicable local, state, or federal regulations or accrediting agencies" and "External control reagents should be tested according to the requirements of the laboratory or those of applicable local, state or accrediting agencies." 2. A review of the laboratory's "Campylobacter Quik Chek" manufacturer's instructions revealed a section titled "Quality Control" stating, "The reactivity of the CAMPYLOBACTER QUIK CHEK kit should be verified upon receipt using the Positive Control and negative ocntrol (Diluent). The Positive Control is supplied with the kit (gray-capped bottle). The Positive control confirms the reactivity of the other reagents associated with the assay, and is not intended to ensure precision at the analytical assay cut-off. Diluent is used for the negative control. Additional tests can be performed with the controls to meet the requirements of local, state, and/or federal regulations and/or accrediting organizations." 3. A review of the laboratory's "Microbiology Reagents- Quality Control Logsheets" from July 2022 to July 2024 revealed quality control testing was completed only monthly and with each new lot. 4. A review of patient testing records revealed a total of 186 patient testing dates between July 2022 and July 2024 when Shiga toxin quality control was not performed and 179 patient testing dates when Campylobacter quality control was not performed. 3. An interview with the

	Laboratory Manager on 07/01/2024 at 10:41 am confirmed controls were not performed each day of testing for either Shiga toxin or Campylobacter and there was not an Individualized Quality Control Program (IQCP) in place.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to perform and document quality control after changing reagents prior to resuming patient hematology testing using the Sysmex XN-550 eight times from 05/10/2023 to 06/27/2024. Findings include: 1. A review of the laboratory's "Changing Reagents on the Sysmex XN-550" procedure revealed a lack of control procedure for ensuring reagents changed throughout the testing day were acceptable prior to use in patient testing. 2. An interview with TP1 on 07/01/2024 at 11:35 am revealed that reagents are replaced as needed, either upon expiration or when depleted on the instrument, which alerts the technician in both cases accordingly. TP1 indicated that quality control is not performed after change of reagents. 3. After reviewing Sysmex XN-550 onboard reagent inventory log, it was determined controls were not run after replacement of eight reagents: a. 5 Cellpack DCL reagents, lot number Y4007 (05/10/2024, 05/21/2024, 06/03/2024, 06/13/2024) and lot number Y4014 (06/26/2024). b. 1 Cellpack DFL reagent, lot number A3040 (06/27/2024). c. 1 Flurocell WDF, lot number A3112 (05/30/2024). d. 1 Sulfolyser, lot number A3015 (06/20/2024). 4. A review of the laboratory's "Sysmex Automated Hematology Analyzer XN-550 Basic Operation" manufacturer's instructions revealed a section titled "When QC analysis is performed" stating, "QC is performed at the following times. Before sample analysis, after replacement/replenishment of reagents, after instrument maintenance, and when there is a concern about the accuracy of analysis values." 5. An interview with the LM on 07/01/2024 at 2:20 pm revealed quality controls had not been performed after change of reagents.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Manager, the Technical Consultant failed to evaluate the competency of testing personnel at least semiannually in the first year for 3 (Testing Personnel 8, 29, and 32) of 35 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's testing personnel competency records revealed a lack of semiannual competency

	assessment documentation for personnel that were new since the previous survey: a. Testing Personnel #8 had training and initial competency completed on 4/12/23 and a subsequent competency assessment completed on 5/22/24. b. Testing Personnel #29 had training and initial competency completed on 5/19/22 and a subsequent competency assessment completed on 6/6/23. c. Testing Personnel #32 had training and initial competency completed on 3/27/23 and no other competency assessments performed to date. 2. A review of the laboratory's "Competency Assessment" policy revealed a section stating, "Training checklists are utilized and new employees are allowed to work the bench independently after the training technologist completes the checklist. The new employee is evaluated again 6 months after the initial training." 3. A review of the laboratory's "PPM Competency Assessment" policy revealed a lack of process for semiannual competency assessment performance. 4. An interview on 7/1 /24 at (blank) with the Laboratory Manager confirmed the Technical Consultant had not performed and documented semiannual competency assessments with the testing personnel listed above.