Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2268409	11/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Um Health-Sparrow	2446 Jolly Road Suite A, Okemos, 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
D0000	A validation survey was performed on November 24, 2025 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition-level deficiency: 493.1250 Condition: Analytic systems.
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 technical consultant #1, the laboratory failed to establish policies to assess technical consultant and clinical consultant competency for two (November 2023 to November 2025) of two years reviewed. Findings include: 1. A review of competency assessments for the clinical consultant and technical consultants revealed a lack of competency assessments used to assess their performance of consultant duties. 2. The surveyor requested the laboratory's staff competency assessment policy on 11/24/25 at 8:53 am and was provided with the "Point of Care Testing (POCT) Procedure for Updating Roster of Testing Personnel". This policy did not address assessing clinical or technical consultants. 3. An interview on 11/24/25 at 9:33 am with technical consultant #1 confirmed the laboratory had not established a policy to assess consultant competency.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview with technical consultant #1, the laboratory failed to follow quality assessment policies and procedures to assess general laboratory system requirements for one (2024) of two years reviewed. Findings include: 1. A review of the laboratory's "Lab- POCT: Quality Assurance/Process Improvement" policy revealed a section stating, "Quality Assurance is the comprehensive, ongoing process for monitoring and evaluating every step of the laboratory's testing process from patient identification and specimen collection through test analysis and test result reporting. Proces Improvement emphasizes the need to redesign policies and procedure to improve the laboratory process. The following procedure ensures quality results are generated ny competent personnel." This policy included a section titled "Evaluation of Quality Assurance" stating, "the following mechanisms are used a part of Process Improvement [sic]: Monthly: Quality control records Patient result logs Corrective action logs Maintenance logs Bi-annually On-line Microscope Review -Provider competency assessment & proficiency Annually Chart Review Test comparisons Team member competency assessment." 2. A review of the laboratory's quality assessment records revealed a lack of documentation of reviews described above performed in 2024. 3. An interview on 11 /24/25 at 2:15 pm with technical consultant #1 confirmed that general laboratory quality assessment documentation was not available for 2024.
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 observation, record review, and interview with technical consultant #1, the laboratory failed to follow its specimen labeling policy for one of three total urine specimen cups observed. Findings include: 1. The surveyor observed three specimen containers with urine inside on 11/24/25 at 8:01 am. One specimen observed did not have the label on the specimen container and was instead on the lid. 2. A review of the laboratory's "Macroscopic Urinalysis" policy included a section titled "Specimen Requirements" stating, "Label the specimen container with the computer-generated label, or with the patient's name and date of birth or history number (two patient identifiers)." 3. An interview on 11/24/25 at 8:09 am with technical consultant #1 confirmed the urine specimen did not have the label on the container.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: . Based on record review and interview with technical consultant #1, the laboratory failed to follow quality assessment policies and procedures to assess preanalytic system requirements for one (2024) of two years reviewed. Findings include: 1. A review of the laboratory's "Lab- POCT: Quality Assurance/Process Improvement" policy revealed a section stating, "Quality Assurance is the comprehensive, ongoing process for monitoring and evaluating every step of the laboratory's testing process from patient identification and specimen collection through test analysis and test result reporting. Proces Improvement emphasizes the need to redesign policies and procedure to improve the laboratory process. The following procedure ensures quality results are generated ny competent personnel." This policy included a section titled "Evaluation of Quality Assurance" stating, "the following mechanisms are used a part of Process Improvement [sic]: Monthly: Quality control records Patient result logs Corrective action logs Maintenance logs Bi-annually On-line Microscope Review - Provider competency assessment & proficiency Annually Chart Review Test comparisons Team member competency assessment." 2. A review of the laboratory's quality assessment records revealed a lack of documentation of reviews described above performed in 2024. 3. An interview on 11/24/25 at 2:15 pm with technical consultant #1 confirmed that preanalytic quality assessment documentation was not available for 2024.
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 record review and interviews, the laboratory failed to perform quantitative beta-human chorionic gonadotropin (bhCG) controls in accordance with its procedure (refer to D5445) and failed to follow quality assessment policies and procedures to assess analytic system requirements (refer to D5791).
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

	This STANDARD is not met as evidenced by: . Based on record review and interview with technical consultant #1, the laboratory failed to perform quantitative beta-human chorionic gonadotropin (bhCG) controls in accordance with its procedure for two (April and May 2024) of 11 months reviewed. Findings include: 1. A review of the laboratory's "i-STAT Point of Care Testing" procedure used for quantitative bhCG testing revealed a section titled "Quality Control" stating, "Control Frequency Wet QC, levels 1-3 with every new lot and shipment of cartridges, monthly, for each type of cartridge in use at each location, by the staff at each site...for bhCG and cTnI cartridges, run all three levels of the respective controls." 2. A review of the laboratory's quantitative bhCG control results revealed a lack of documentation for testing performed in April and May 2024. 3. A review of patient test records revealed a total of 225 patients received quantitative bhCG testing in April and May 2024. 4. An interview on 11/24/25 at 12:53 pm with technical consultant #1 confirmed quantitative bhCG controls had not been performed in accordance with the laboratory's procedure.
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 record review and interview with technical consultant #1, the laboratory failed to follow quality assessment policies and procedures to assess analytic system requirements for one (2024) of two years reviewed. Findings include: 1. A review of the laboratory's "Lab- POCT: Quality Assurance/Process Improvement" policy revealed a section stating, "Quality Assurance is the comprehensive, ongoing process for monitoring and evaluating every step of the laboratory's testing process from patient identification and specimen collection through test analysis and test result reporting. Proces Improvement emphasizes the need to redesign policies and procedure to improve the laboratory process. The following procedure ensures quality results are generated ny competent personnel." This policy included a section titled "Evaluation of Quality Assurance" stating, "the following mechanisms are used a part of Process Improvement [sic]: Monthly: Quality control records Patient result logs Corrective action logs Maintenance logs Bi-annually On-line Microscope Review - Provider competency assessment & proficiency Annually Chart Review Test comparisons Team member competency assessment." 2. A review of the laboratory's quality assessment records revealed a lack of documentation of reviews described above performed in 2024. 3. An interview on 11/24/25 at 2:15 pm with technical consultant #1 confirmed that analytic quality assessment documentation was not available for 2024.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: . Based on record review and interview with technical consultant #1, the laboratory failed to follow quality assessment policies and procedures to assess postanalytic system requirements for one (2024) of two years reviewed. Findings include: 1. A review of the laboratory's "Lab- POCT: Quality Assurance/Process Improvement" policy revealed a section stating, "Quality Assurance is the comprehensive, ongoing process for monitoring and evaluating every step of the laboratory's testing process from patient identification and specimen collection through test analysis and test result reporting. Proces Improvement emphasizes the need to redesign policies and procedure to improve the laboratory process. The following procedure ensures quality results are generated ny competent personnel." This policy included a section titled "Evaluation of Quality Assurance" stating, "the following mechanisms are used a part of Process Improvement [sic]: Monthly: Quality control records Patient result logs Corrective action logs Maintenance logs Bi-annually On-line Microscope Review - Provider competency assessment & proficiency Annually Chart Review Test comparisons Team member competency assessment." 2. A review of the laboratory's quality assessment records revealed a lack of documentation of reviews described above performed in 2024. 3. An interview on 11/24/25 at 2:15 pm with technical consultant #1 confirmed postanalytic quality assessment documentation was not available for 2024.