Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0668441	04/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
Federal Medical Center Rochester	2110 East Center St, Rochester, MN	

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 completed on 04/30/2026. The laboratory was found to be NOT in compliance with the following CLIA conditions: D5016 - 42 C.F.R. 493.1210 Condition: Routine chemistry D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of the laboratory's procedures, manufacturer's instructions, and interviews with staff, the laboratory failed to meet the requirements for the subspecialty of routine chemistry as evidenced by: 1. The laboratory failed to define humidity and room temperature according to the manufacturer's instructions. Refer to D5413 I and II. 2. The laboratory failed to have a system in place to detect immediate errors and monitor accuracy and precision over time. Refer to D5441 I and II.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on direct observation, a review of the laboratory's procedures, manufacturer's instructions, and interviews with staff, the laboratory failed to meet the requirements for the overall quality of the Preanalytic system as evidenced by: 1. The laboratory failed to follow the manufacturer's instructions for specimen stability and transport for 19 of 19 boxes received from outside the facility containing patient specimens. Refer to D5311.
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 direct observation, staff interviews, and a review of the laboratory's policies, the laboratory failed to follow the manufacturer's instructions for specimen stability and transport for 19 of 19 boxes containing patient specimens received from outside the facility. Findings: a. On 4/30/2026 at 10:45 AM, a direct observation revealed that 19 boxes containing patient specimens were received from outside the facility. Further observation of Technical Consultant (TC) #3 (as listed on the CMS-209) unpacking boxes revealed 1 box containing 16 specimens packed with a single ice pack that was cool to the touch. Staff did not document the specimen temperature at the time of receipt. b. During an interview on 4/30/2026 at 10:45 AM, TC #3 stated that if the icepack is not cool, the specimens are rejected. c. During an interview on 4/30/2026 at 9:56 AM, TC #1 (as listed on the CMS-209) stated that if a box is not received within 2 days, the laboratory will reject all specimens in the box, and the laboratory did not perform specimen transport studies to confirm that 1 cold pack in a box would maintain the manufacturer's required transport temperature. During a follow-up interview at 2:00 PM, TC #1 stated that the laboratory receives specimens from 37 facilities. d. A review of the laboratory's "Order Choice Catalog" revealed (sampling) Test: Total Bilirubin (TBil) "refrig" [refrigerate]. The refrigerated temperature range was not defined. e. A review of the laboratory's policy DPC LP019g "Specimen Acceptance or Rejection", updated 06/11/19, revealed: "6. Acceptable stability limits will be verified with each specimen by its collection date and time, and storage condition. Specimens outside of the acceptable limits will be rejected and placed in to the biohazardous trash container, comment recorded into the LIS [laboratory information system] and provider notified." f. A review of the laboratory's "Specimen Requirements for Laboratory Testing" revealed "Stabilities @ [at] 2-8C [degrees Celsius]" for all specimen types listed and the number of days specimens may be stored. A sampling of items on the form included: TBil, 7 days at 2-8C [degrees Celsius] g. A review of the manufacturer's package insert "Application Sheet ...Test Name: Bilirubin Total Gen. 3" revealed "Specimen collection and preparation ... Stability if care is taken to prevent exposure to light ...1 day at 20-25C [degrees Celsius] ...7 days at 4-8C [degrees Celsius]." The laboratory's acceptable temperature

	range (2-8 degrees Celsius) exceeded the manufacturer's stability temperature range by 2 degrees Celsius. Instructions to avoid exposure to light were not included on the "Specimen Requirements for Laboratory Testing" form.
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: I. Based on a review of the laboratory's humidity charts, the manufacturer's instructions, and an interview with Technical Consultant (TC) #1, the laboratory failed to define humidity ranges according to the manufacturer's instructions for 1 of 1 month reviewed. Findings: a. A review of the laboratory's April 2026 humidity chart revealed that the laboratory defined the acceptable humidity range as 30-80%. b. A review of the manufacturer's instructions "Sysmex XN series (XN-2000)" revealed: "15.6.3 Installation environment ...Relative humidity should be within the range 20-85%...If ambient temperature and relative humidity are not within the suggested range, air-condition the environment." The laboratory's defined acceptable range exceeded the manufacturer's range by 10%. c. During an interview on 4/30/2026 at 7:45 AM, TC #1 (as listed on the CMS-209) stated the laboratory had just started monitoring humidity. A follow-up interview with TC #1 at 2:00 PM confirmed the laboratory's humidity range exceeded the manufacturer's acceptable range. II. Based on a review of the manufacturer's instructions, the laboratory's April 2026 environmental records, and an interview with Technical Consultant (TC) #1, the laboratory failed to define room temperature according to the manufacturer's instructions for 1 of 1 month reviewed. Findings: a. A review of the laboratory's April 2026 environmental records revealed that the laboratory defined the room temperature as 15-25 degrees Celsius (C). b. A review of the manufacturer's instructions "Application Sheet ...Test Name: Elecsys HIV combi PT" revealed "Test principle and procedure ...Ensure the samples, calibrators and controls are at 20-25C [degrees Celsius] prior to measurement." The laboratory's defined room temperature range exceeded the manufacturer's range by 5 degrees Celsius. c. During an interview on 4/30/2026 at 7:45 AM, TC #1 confirmed the laboratory's room temperature range was defined as 15-25C [degree Celsius].
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:
I. Based on a review of the manufacturer's instructions, the laboratory's quality control (QC) data, the laboratory's procedure, and an interview with staff, the laboratory failed to have a system in place to detect immediate error for 31 of 31 chemistry analytes. Findings: a. A review of the manufacturer's package insert "Liquid Assayed Multiqual, Levels 1, 2 and 3", revision date 10/14/2025, revealed "Assignment Of Values ...The mean values and corresponding +/-3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product." b A review of the manufacturer's package insert "Liquid Assayed Multiqual, Levels 1, 2 and 3", revision date 10/14/2025, the laboratory's QC data "New QC Lot Validation ...Control MultiQual 3 ...Lot: 46043 ... EXP: 05/31/2028" form, reviewed 1/23/2026, and the manually entered Multiqual 3 reference values data retrieved from the Cobas 8000 serial number 18M4-03 revealed: 1. Test: Albumin (ALB), Level 3 i. Package Insert: mean=4.29; Range=3.95-4.63 [The calculated 1SD=0.1133] ii. Laboratory's QC data: Package Insert: mean=4.29; Range=3.95-4.63; SD=0.17, Recovered Data: mean=4.31; STD [standard deviation] =0.09; 1 SD Range=4.14-4.48 The package insert 1SD value (0.17) listed on the New QC Lot Validation form did not match the manufacturer's 1SD value (0.1133) calculated from the "Liquid Assayed Multiqual, Levels 1, 2 and 3" package insert. The laboratory's 1SD range (4.41-4.48), listed on the New QC Lot Validation form, did not reflect the recovered SD of 0.09 (4.22-4.40). iii. Cobas 8000 data: Target value: 4.30, Deviation 0.20; 3s: 3.70-4.90 The Target value (4.30) and deviation (0.20) entered in the Cobas 8000 for ALB did not match the recovered data mean (4.31) or the calculated package insert SD value (0.17) on the "New QC Lot Validation" form. The 3SD range (3.70-4.90) utilized by the laboratory for ALB exceeds the manufacturer's 3SD range (3.95-4.63) and the laboratory's recovered 3SD range (4.04-4.58). The values represent a range greater than 5SD of the manufacturer's calculated SD and greater than 6SD of the laboratory's calculated SD. 2. Test: ALT [alanine transaminase], Level 3 i. Package Insert: mean=192; Range 177-207 [The calculated 1SD=5] ii. Laboratory's QC data: Package Insert: mean=192; Range=177-207; SD=8, Recovered Data: mean=183; STD=4; 1 SD Range=175-190 The package insert 1SD value of 8 listed on the New QC Lot Validation form did not match the manufacturer's 1SD value of 5, calculated from the "Liquid Assayed Multiqual, Levels 1, 2 and 3" package insert. The laboratory's 1SD range (175-190), listed on the New QC Lot Validation, did not reflect the recovered SD of 4 (179-187). iii. Cobas 8000 data: Target value: 183.00, Deviation 8.00; 3s: 159.00-207.00 The 3SD range (159.00-207.00) utilized by the laboratory for ALT exceeds the manufacturer's 3SD range (177-207) and the laboratory's recovered 3SD range (171-195). The value represents a range greater than 6SDs of the manufacturer's and is equivalent to 6SD of the laboratory's calculated SDs. 3. Test: Blood Urea Nitrogen (BUN), Level 3 i. Package Insert: mean=67.0; Range 61.1-73.0 [The calculated 1SD=1.9833] ii. Laboratory's QC data: Package Insert: mean=67, Range= 61.1-73.0, SD=3.0, Recovered Data: mean=67.9; STD=1.9; 1 SD Range=64.9-70.9 The package insert 1SD value of 3 listed on the New QC Lot Validation did not match the manufacturer's 1SD value of 1.9833, calculated from the "Liquid Assayed Multiqual, Levels 1, 2 and 3" package insert. The laboratory's 1SD range (64.9-70.9), listed on the New QC Lot Validation, did not reflect the recovered SD of 1.9 (66-69.8). iii. Cobas 8000 data: Target value: 67.90, Deviation 3.00; 3s: 58.90-76.90 The 3SD range (58.90-76.90)

	utilized by the laboratory for BUN exceeds the manufacturer's 3SD range (61.1-73.0), and the laboratory's recovered 3SD range (62.2-73.6). The values represent a range greater than 5SD on the low end and 4SD on the high end of the manufacturer's calculated SD, and a range greater than 4SD of the laboratory's calculated SD. c. Footnotes on the laboratory's QC data, "New QC Lot Validation", added to the package insert range revealed: "Per Package Insert: +/-2SD ranges calculated from supplied +/- 3SD ranges." Footnote added to 1SD Range revealed, "Range based on Recovered Mean from Manufacturer SD." d. During an interview on 04/30/2026 at 8: 50 AM, Technical Consultant (TC) #1 and TC #2 (as listed on the CMS-209) stated that the laboratory calculates its own mean but uses the manufacturer's 3SD range to calculate a 1SD value because its own calculated 1SD would be too narrow. TC #2 further stated that the 1SD was calculated by subtracting the laboratory's mean from the low end value, then dividing by 3, and the calculation was done in the spreadsheet. e. During a follow-up interview on 5/4/2026 at 11:46 AM, TC #1, TC #2, and Testing Personnel (TP) #5 (as listed on the CMS-209) stated there was no written procedure for the establishment of chemistry QC ranges. The laboratory calculates the mean by using a combined average of 10 data points from both chemistry instruments. The package insert SD value on the New QC Lot Validation form is calculated by treating the manufacturer's 3SD range as a 2SD range. The calculated SD value is then used as the 1SD value, along with the laboratory's calculated mean, to establish QC ranges. The mean and SD are manually entered into the Cobas 8000 instrument. f. A review of the laboratory's CMS-116 revealed that the annual chemistry test volume=601,144. II. Based on a review of the laboratory's QC data, the laboratory's procedure, and an interview with staff, the laboratory failed to have a system in place to monitor accuracy and precision over time for 31 of 31 chemistry analytes. Findings: a. A review of the laboratory's Levy-Jennings (L-J) QC data (sampling) retrieved from the Cobas 8000 serial number 18M4-03 revealed: 1. Test: ALB: i. MultiQual 1 Target Value 2.60. From 3/2026 to the date of the survey, the range of values shifted below the established mean. ii. MultiQual 2 Target Value 3.50. From 3/2026 to the date of the survey, the range of values shifted below the established mean. iii. MultiQual 3 Target Value 4.30. The value entered into the instrument does not match the laboratory's recovered mean of 4.31. From 3/2026 to the date of the survey, the range of values shifted below the established mean. 2. Test: ALT: i. MultiQual 1 Target Value 27.00. From 3/2026 to the date of the survey, the range of values shifted above the established mean. ii. MultiQual 2 Target Value 88.00, From 3/19/2026-4/8/2026, the range of values shifted below the established mean, and from 4/8/2026-date of the survey, the range of values shifted above the established mean. iii. MultiQual 3 Target Value 183.00, From 3/19/2026 to 4/8/2026, the range of values shifted below the mean, and from 4/8/2026 to the date of the survey, the values shifted above the established mean. b. A review of the laboratory's procedure DOC LP244d "Cobas 8000 Chemistry Analyzer Operation", updated 02/01/2024, revealed "B. Quality Control ...3iv.4 Select Graph visible check box to view a Levy-Jennings graph." c. During an interview on 4/30/2026 at 8:50 AM, TC #2 (as listed on the CMS-209) stated QC was monitored over time using a multi-review process, monthly submission to Unity, and addressing flags in the Unity report. If drift is identified, TC #2 will check the mean and the laboratory data and possibly recalculate the mean. Additionally, the testing personnel (TP) review the L-J charts daily. TC #1 and TC #2 (as listed on the CMS-209) confirmed the observed shifts. TC #2 confirmed the procedure did not provide detailed instructions for resolving shifts and trends, but stated that if the shift is within 1SD, staff would consult the Clinical Director and check the Unity peer data and method. d. A review of the laboratory's CMS-116 revealed that the annual chemistry test volume=601,144.

D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) (d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedures, the manufacturer's instructions, and an interview with staff, the laboratory failed to titer the positive control material for the ASI RPR (rapid plasma reagin) Card Test for 1 of 1 month reviewed. Findings: a. A review of the laboratory's procedure DOC LP193e "Rapid Plasma Reagin (RPR) Titer-ASI", updated 4/15/2025, revealed "Quality Control: ASI provided controls utilizing all three levels: Reactive, Weak Reactive (moderate to minimal), Non-reactive ...On a testing card, place a drop of each control onto separate circles on the testing card. See steps 4 through 8 below to process the control ...Procedure ...9. Report results in terms of the highest dilution observed to be reactive." The steps did not include instructions for titering the positive quality control (QC). b. A review of the manufacturer's instructions "RPR Card Test For Syphilis", page 3, revealed "Quality Control ...Quality control requirements must be performed in accordance with applicable local, state, and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls with graded reactivity should be included." c. During an interview on 4/30/2026 at 12:55 PM, Technical Consultant (TC) #3 (as listed on the CMS-209) stated that quality control is reported as "Non-reactive," "Weak Reactive," and "Reactive"; patient results are titered up to 1:256, and QC is not titered. d. During an interview on 4/30/2026 at 2:00 PM, TC #1 (as listed on the CMS-209) confirmed RPR positive QC is not titered. e. A review of the laboratory's CMS-116 revealed that the annual diagnostic immunology test volume=90,875.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Hematology Scheduled Maintenance form, the laboratory's procedures, and an interview with staff, the laboratory failed to define staining characteristics for 1 of 1 month reviewed. Findings: a. A review of the laboratory's Hematology Scheduled Maintenance form from April 2026 revealed stain quality was documented as "Acceptable" by placing a check mark in the column. b. A review of the laboratory's procedure DOC LP 209C "Quick Slide Plus Stainer" updated 4/11/2025, revealed "QUALITY CONTROL: 1. Quality Control is performed by visual examination of processed blood film to determine if cellular elements are adequately stained, without excessive artifact; 2. Stain Quality is documented in the Heme Scheduled Maintenance_Form_04." c. A review of the laboratory's procedure DOC LP 133d "Sysmex Scan/ Differential Procedure" updated 4/6/2026 revealed "QUALITY CONTROL: Quality Control is performed by visual examination of processed blood film to determine if cellular elements are adequately stained without excessive artifact. Document in Daily Hematology Checklist if stain is acceptable." d.

	During an interview on 4/30/2026 at 2:00 PM, TC #1 (as listed on the CMS-209) confirmed that "acceptable" and "adequate" were not defined in the laboratory's procedures. e. A review of the laboratory's CMS-116 revealed that the annual hematology test volume=213,638.
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 a review of the laboratory's quality control (QC) records, absence of documented corrective action, and an interview with staff, the laboratory failed to evaluate 17 of 17 patient test results back to the last acceptable QC when Blood Urea Nitrogen (BUN) QC exceeded the laboratory's acceptable limits and test system adjustments were made. Findings: a. A review of the laboratory's BUN QC retrieved from the Cobas 8000 serial number 18M4-03 revealed that on 4/28/2026 at 8:12 AM, QC results exceeded the laboratory's acceptable limits; the reagent pack was replaced, and the instrument was recalibrated. The last acceptable QC was performed on 4/27 /2026 at 9:32 AM. b. The laboratory was asked to provide documentation of corrective action (evaluation of patient results) for the 17 BUN tests performed since the last acceptable QC on 4/27/2026. No documentation was provided. c. During an interview on 4/30/2026 at 8:05 AM, Testing Personnel #6 and Technical Consultant #2 (as listed on the CMS-209) confirmed that the laboratory did not evaluate patient results.