Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408762	04/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dakota Regional Medical Center Hospital Laboratory	107 12th St S, Cooperstown, ND	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory director or designee failed to sign the attestation statements for 4 of 10 (Events 2 and 3 chemistry, Event 3 alcohol, and Event 2 endocrinology) College of American Pathologists (CAP) and Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing events reviewed from 2023. Findings include: 1. Reviewed at 8:40 a.m. on 04 /09/24, the following 2023 proficiency testing records failed to include attestation statements signed by the laboratory director or designee: - CAP Events 2 and 3 chemistry - CAP Event 3 alcohol - WSLH Event 2 endocrinology 2. During interview at 11:20 a.m. on 04/09/24, the laboratory manager (#1) confirmed the laboratory director had not signed the attestation statements for CAP Events 2 and 3 chemistry, CAP Event 3 alcohol, and WSLH Event 2 endocrinology in 2023. 3. Reviewed at 3:45 p.m. on 04/09/24, the policy "Laboratory Proficiency Testing," dated, 07/2023, failed to include a requirement for the laboratory director to sign the proficiency testing attestation statements.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to twice annually verify the accuracy of 2 of 3 non-regulated microscopy analytes (wet preparation and potassium hydroxide [KOH] preparation) in 2023. The laboratory performed approximately fifteen wet preparation and five KOH preparation patient tests in 2023. Findings include: 1. Reviewed at 8:15 a.m. on 04/09/24, the laboratory's test menu listed wet preparation and KOH preparation microscopy tests available for patient testing. 2. Reviewed at 8:40 a.m. on 04/09/24, the 2023 proficiency testing records indicated the laboratory did not participate in proficiency testing for wet preparation and KOH preparation analytes. 3. Reviewed at 11:50 a.m. on 04/09/24, the 2023 verification records failed to include evidence of a second accuracy verification in 2023 for wet preparation and KOH preparation analytes. 4. Upon request, the laboratory failed to provide evidence of a second accuracy verification in 2023 for wet preparation and KOH preparation analytes. 5. During interview at 12:00 p.m. on 04/09/24, the laboratory manager (#1) confirmed the laboratory performed patient testing for wet preparation and KOH preparation analytes in 2023 and did not verify the accuracy of these tests a second time in 2023. 6. Review of the following policies/procedures occurred on 4/09/24: - "Wet Prep Examination," dated 05/2017, stated, ". . . Comparison Testing: Every 6 months a comparison wet prep is done between 2 techs. . . ." - "Direct KOH Examination," dated 05/2017, stated, ". . . Comparison Testing: Every 6 months, a comparison KOH is done between 2 techs. . . ."
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, staff interview, policy/procedure review, and manufacturer's instructions review, the laboratory failed to verify calibration at least every six months for 1 of 1 analyte (procalcitonin) calibrated with less than three calibrators on the Biomerieux Vidas 3 analyzer in 2023. The laboratory performed approximately 50

	procalcitonin patient tests in 2023. Findings include: 1. Reviewed on 04/09/24, the 2023 procalcitonin calibration records indicated the use of two standards for calibration of procalcitonin. 2. Upon request on 04/09/24, the laboratory failed to provide evidence of calibration verification at least twice annually for procalcitonin in 2023. 3. During interview at 3:10 p.m. on 04/09/24, the laboratory manager (#1) confirmed the laboratory had failed to verify calibration at least twice annually for procalcitonin in 2023. 4. Reviewed at 3:45 p.m. on 04/09/24, the following policies, procedures, and instructions failed to include a requirement for at least twice annual calibration verification for procalcitonin: - Policy: "Laboratory Quality Control, Preventive Maintenance, Policies and Procedures . . . VII. Procalcitonin (Biomerieux Vidas 3) . . .," dated 07/2023. - Procedure: "Vidas 3 Procalcitonin (PCT) Testing," dated 02/2022. - Manufacturer's instructions: "Vidas 3 System Overview Instrument Overview," dated 2021.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy/procedure review, the laboratory failed to twice annually compare and evaluate test results using different methodologies for white blood cell differential for 1 of 1 year reviewed (2023). The laboratory performed approximately 1700 automated and 100 manual white blood cell differential patient tests in 2023. Findings include: 1. Reviewed at 8:15 a.m. on 04/09 /24, the laboratory's test menu listed automated and manual white blood cell differential testing available for patient testing. 2. Reviewed at 8:40 a.m. on 04/09/24, the 2023 proficiency testing records indicated the laboratory did not participate in proficiency testing for manual white blood cell differentials. 3. Reviewed at 11:50 a. m. on 04/09/24, the 2023 testing comparison records failed to include evidence of a second comparison for white blood cell differentials in 2023. 4. Upon request, the laboratory failed to provide evidence of a second comparison for white blood cell differentials in 2023. 5. During interview at 12:00 p.m. on 04/09/24, the laboratory manager (#1) confirmed the laboratory performed automated and manual white blood cell differential patient testing and did not perform a second comparison in 2023. 6. Reviewed at 3:45 p.m. on 04/09/24, the following policies/procedures failed to include a requirement for twice annual comparison and evaluation of test results using different methodologies for white blood cell differentials: - Policy: "Laboratory Quality Control, Preventive Maintenance, Policies and Procedures . . . I. Hematology . . .," dated 07/2023. - Procedure: "Sysmex XN-550 Automated Hematology Analyzer . . .," dated 10/09/19. - Procedure: "Manual Differential Leukocyte [white blood cell] Count Wright's Stain," dated 05/2017.