Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385556	07/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
Lakes Regional Healthcare	2301 Highway 71 South, Spirit Lake, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 review of chemistry calibration verification records and confirmed by interview with technical supervisor identifier #1 (TS #1) at 10:49 am on 7/30/2026, the laboratory failed to perform calibration verification every six months for one out of four time periods from 12/25/2024 - 7/30/2026 for the analytes: sodium, potassium, chloride and glycosylated hemoglobin. The findings include: 1. The laboratory performed calibration verification on the analytes: sodium, potassium, chloride and glycosylated hemoglobin on 12/25/24, 8/11/2025, and 7/2/2026. 2. TS #1 confirmed

	at the time of the survey, the laboratory had not performed calibration verification for the analytes: sodium, potassium, chloride and glycosylated hemoglobin for the six month time period between 8/11/2025 and 7/2/2026.
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 review of the Laboratory Test List & Annual Volume form, performance specification records, and quality control (QC) records, lack of an Individualized Quality Control Plan (IQCP), and confirmed by interview with technical supervisor identifier #1 (TS #1) at 1:08 pm on 7/30/2026, the laboratory failed to have an IQCP for the Cepheid GeneXpert test system. The findings include: 1. The Laboratory Test List & Annual Volume stated the laboratory performed Influenza A, Influenza B, respiratory syncytial virus (RSV), SARS-CoV-2, Streptococcus group A, and Clostridium difficile testing using the Cepheid GeneXpert. 2. The performance specification records indicated the laboratory started performing patient testing using the Cepheid GeneXpert on 1/23/2026. 3. QC records for Influenza A, Influenza B, respiratory syncytial virus (RSV), SARS-CoV-2, Streptococcus group A, and Clostridium difficile indicated the laboratory performed QC with each new lot and/or shipment of test cartridges for the Cepheid GeneXpert. 4. TS #1 confirmed at the time of the survey, the laboratory did not have an IQCP for the Cepheid GeneXpert.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on lack of policies and procedures, review of the Laboratory Personnel Report and confirmed by technical supervisor identifier #1 (TS #3) at 12:15 pm on 7/30/2026, the laboratory director failed to ensure the laboratory had policies and procedures established for monitoring individuals who conduct preanalytical, analytical and post analytical phases of testing. In addition, the laboratory director failed to ensure that testing personnel maintained their six month competency for one out of three new testing personnel. The findings include: 1. The laboratory did not have a policy or

	procedure used to specify the need for semiannual and annual competency assessments. 2. The laboratory did not perform semiannual competency assessments on one out of three new testing personnel. Refer to D6127. 3. TS #1 confirmed at the time of the survey, the laboratory did not have a competency policy and the laboratory did not perform competency as required for the above testing personnel.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report and personnel records and confirmed by interview with the technical supervisor identifier #1 (TC #1) at 12:15 pm on 7/30/2026, the technical supervisor failed to ensure the laboratory performed a semi-annual competency assessment on one out of three new high complexity testing personnel hired since the last survey on 8/28/2024. The findings include: 1. The Laboratory Personnel Report stated testing personnel identifier #14 performed high complexity testing. 2. Personnel records confirmed testing personnel identifier #14 started performing patient testing on 4/10/2025. 3. TC #1 confirmed at the time of the survey, the laboratory did not have a semi-annual competency assessment for testing personnel identifier #14. THIS IS A REPEAT DEFICIENCY FROM THE SURVEY ON 8/28/2024.