Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385556	08/28/2024
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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 10:27 am on 08/28/2024, the laboratory failed to perform a self evaluation when the laboratory received three ungraded PT scores from two out of five PT testing events from 01/01/2023- 08/28/2024. The findings include: 1. For 2024 Microbiology 1st event, the laboratory received ungraded PT test scores for the following: * Urine Culture Susceptibility Testing, MIC Testing/CLSI/Trimethoprim/Sulfamethoxazole- specimen UR-01 * Gram Stain Morphology- specimen GS-02 2. For 2024 Microbiology 2nd event, the laboratory received ungraded PT test scores for the following: * Gram Stain- specimen GS-08 6. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores listed above.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by:

	Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 10:27 am on 08 /28/2024, the laboratory failed to take and document corrective action for four unacceptable PT scores from three out of five PT testing events from 01/01/2023- 08 /28/2024. The findings include: 1. For 2023 testing event 1, the laboratory received unacceptable PT test scores for the following: *2023 Immunology /Immunohematology 1st event- Rheumatoid Factor (specimen RF-04) 2. For 2023 testing event 2, the laboratory received unacceptable PT scores for the following: *2023 Core Chemistry 2nd event- Vancomycin (specimen CH-09) *2023 Core Chemistry Verification 2nd event- Partial Pressure of Carbon Dioxide (PCO2) (specimen IB-08) 3. For 2023 testing event 3, the laboratory received unacceptable PT test scores for the following: *2023 Microbiology 3rd event- Shiga Toxin 2 (specimen SHG-03) 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores listed above.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on review of quality control (QC) records, the Human Chorionic Gonadotropin (HCG) Qualitative Serum Individualized Quality Control Plan (IQCP), and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 3:23 pm on 8/28/2024, the laboratory failed to follow its IQCP for performing qualitative serum HCG QC for two out of eight months from 01/01/2024- 08/28/2024. The findings include: 1. The HCG Qualitative Serum IQCP stated the following for external QC: "Number and frequency: Two levels of control run with each new lot or shipment of product, monthly, and with each new operator." 2. Review of HCG Kit Quality Control Record logs indicated that the laboratory did not perform two levels of QC in April 2024 or August 2024. 3. At the time of the survey, the laboratory did not have additional qualitative serum HCG QC records available from April 2024 or August 2024. B. Based on review of quality control (QC) records, the C Difficile Toxin A/B procedure, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 3:23 pm on 8/28/2024, the laboratory failed to follow its procedure for performing Clostridium difficile (C diff) QC for seven out of eight months from 01/01/2024- 08/28/2024. The findings include: 1. The C Difficile Toxin A/B procedure stated the following for external QC: "The reactivity of the TOX A/B QUIK CHEK test should be verified on receipt and monthly using the positive control and negative control." 2. Review of Quality Control Logsheet for C diff indicated that the laboratory did not perform two levels of QC for the following months: January- March 2024 and May- August 2024. 3. At the time of the survey, the laboratory did not have additional C diff QC records available from January- March 2024 and May- August 2024. C. Based on review of quality control (QC) records, the i-STAT Individualized Quality Control Plan (IQCP), and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 4:34 pm on 8/28/2024, the laboratory failed to follow its IQCP for performing QC on 12 analytes for eight out of eight months from 01/01/2024- 08/28/2024. The findings include: 1. The laboratory uses the following test cartridges on two i-STAT analyzers

	(serial numbers 386030 and 407453): * EG6+ [pH, partial pressure of carbon dioxide (PCO2), and partial pressure of oxygen (PO2)] * cTnI (troponin I) * Chem 8+ (sodium, potassium, chloride, ionized calcium, total carbon dioxide, glucose, blood urea nitrogen, and creatinine) 2. The i-STAT IQCP stated the following for external QC: "Number and frequency: Two levels of liquid quality control is run at least monthly and on each new lot/shipment of cartridges." 3. Review of i-STAT QC logs for both analyzers indicated the laboratory did not perform two levels of QC at least monthly and on each new lot/shipment of cartridges from 01/01/2024- 08/28/2024. Refer to D5447. 4. At the time of the survey, the laboratory did not have additional i-STAT QC records available.
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 lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 3:23 pm on 08/28/2024, the laboratory failed to develop an IQCP for the following test systems: Quik Chek Complete Clostridium difficile, Immunocard STAT Crypto-Giardia, Alere Determine HIV 1/2 Antibody/Antigen, Qiagen Amnisure Rupture of Membranes, Microscan Panel weekly Antimicrobial Susceptibility Testing (AST), Microscan Panel Streamlined QC, and Microbiology Prepared Media. Laboratory personnel identifier #1 indicated that the laboratory intended to follow the manufacturer's instructions for performing QC for each of the listed test systems. At the time of the survey, the laboratory did not have an IQCP for any of the test systems previously listed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, the i-STAT Individualized Quality Control Plan (IQCP), and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 4:34 pm on 8/28/2024, the laboratory failed to perform and document two levels of QC for each lot number of cartridges and on each i-STAT analyzer for eight out of eight months from 01/01/2024- 08/28/2024. The

	findings include: 1. The laboratory uses the following test cartridges on two i-STAT analyzers (#1 serial number 386030 and #2 serial number 407453): * EG6+ [pH, partial pressure of carbon dioxide (PCO2), and partial pressure of oxygen (PO2)] * cTnI (troponin I) * Chem 8+ (sodium, potassium, chloride, ionized calcium, total carbon dioxide, glucose, blood urea nitrogen, and creatinine) 2. The laboratory's i-STAT IQCP stated the following for external QC: "Number and frequency: Two levels of liquid quality control is run at least monthly and on each new lot/shipment of cartridges." 3. For the EG6+ cartridges, the laboratory did not perform and document QC for the following months, lot numbers, and analyzers: * January, March, and April 2024- No QC performed on any lot numbers or analyzers * May 2024- No QC performed for lot N24068A on i-STAT #2 4. For the cTnI cartridges, the laboratory did not perform and document QC for the following months, lot numbers, and analyzers: * January 2024- No QC performed for lot B23232 on i-STAT #1 * March 2024- No QC performed for lot B23232 on i-STAT #2 * May 2024- No QC performed for lot 5240099214 on i-STAT #2 * June 2024- No QC performed for lots 5240099214, S24047, and S24009A on i-STAT #1 * July 2024- No QC performed for lot S24047 on i-STAT #1 * August 2024- No QC performed for lot S24047 on i-STAT #1 5. For the Chem 8+ cartridges, the laboratory did not perform and document QC for the following months, lot numbers, and analyzers: * January 2024- No QC performed for lot H23226 on i-STAT #2 and no QC performed for lots H23305 and H23296 on i-STAT #1 * February 2024- No QC performed for lot H23305 on i-STAT #1 * March 2024- No QC performed for lot H23351 on i-STAT #1 * April 2024- No QC performed for lots H23351 and H24035 on i-STAT #1 * May 2024- No QC performed for lot H24035 on i-STAT #2 and lot H24061 on i-STAT #1 * July 2024- No QC performed for lot H24061 on i-STAT #2 * August 2024- No QC performed for lot H24153 on i-STAT #2 6. At the time of the survey, the laboratory did not have additional i-STAT QC records available.
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 lack of comparison testing records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 4:34 pm on 08/28/2024, the laboratory failed to perform and document comparison activities twice annually between two i-STAT analyzers and the Siemens Dimension EXL analyzer for seven out of seven analytes from three out of three time periods from 01/01/2023 - 08/28 /2024. The findings include: 1. The laboratory performed the following analytes on i-STAT analyzer #1 (serial number 386030), i-STAT analyzer #2 (serial number 407453), and the Siemens Dimension EXL analyzer: sodium, potassium, total carbon dioxide, chloride, glucose, blood urea nitrogen (BUN), and creatinine. 2. At the time of the survey, the laboratory had not performed and documented comparison activities for the analytes listed above for the two i-STAT analyzers and the Siemens Dimension EXL analyzer.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) The technical supervisor is responsible for 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 personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 8:37 am on 08/28/2024, the technical supervisor failed to assess the competency of individuals performing high complexity testing at least semiannually during the first year the individual tests patient specimens for one out of six new testing personnel hired since the last survey on 09/21/2022 (laboratory personnel identifier #11). The findings include: 1. Laboratory personnel identifier #11 began performing patient testing in January 2023. 2. At the time of the survey, the laboratory did not have a semiannual competency evaluation for laboratory personnel identifier #11.