Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0406304	(X3) Date Survey Completed 12/30/2022
Name of Provider or Supplier Lake Region Healthcare - Elbow Lake	**Street Address, City, State** 1411 Hwy 79 E, Elbow Lake, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review, observation, and an interview with laboratory personnel, the laboratory failed to retain all quality control (QC) records including the manufacturers' assay information sheets, lot numbers, and expiration dates for QC material for two years. Findings are as follows: ITEM # 1 1. The laboratory performed Coagulation testing under the specialty of Hematology as confirmed by the General Supervisor (GS) during a tour of the laboratory at 9:40 a.m. on 12/29/22. 2. The Instrumentation Laboratory ACL ELITE Coagulation instrument was observed as present and available for use during the tour of the laboratory. 3. Upon request, the laboratory could only produce the manufacturers' assay information sheets for the current lot of control material being used. 4. The current lot of control material was not programmed into the ACL ELITE database and the GS was unable to confirm the exact date the laboratory had changed lots but confirmed in an interview at 1:42 p.m. on 12/2/22, it was sometime between September first and fifth of 2022. The laboratory was unable to provide the manufacturers' assay information sheets prior to when the lot switch occurred in September of 2022. See D5469 5. The laboratory performs approximately 600 coagulation tests annually as confirmed by the GS at 3: 15 p.m. on 12/29/22. ITEM #2 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed the General Supervisor (GS) during a tour of the laboratory at 9:40 a.m. on 12/29/22. 2. The Hema 3 stains and microscope to perform manual blood smears were observed as present and available for use during the tour of the laboratory. 3. The laboratory was not documenting the performance of a quality check of the stain material. See D5473 4. In

	an interview at 11:14 a.m. on 12/30/22, the GS confirmed the laboratory did not retain manufacturers' information containing lot numbers and expiration dates, for the Heme 3 stain used each day a patient testing for the previous 2 years. 5. The laboratory performs approximately 1,200 manual differentials annually as confirmed in an email received from the GS at 2:19 p.m. on 01/03/2023. .
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 document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of the non-graded proficiency testing (PT) results for regulated analytes when the PT program did not obtain the agreement required for scoring in two of 24 PT events reviewed for 2021 and 2022. Findings are as follows: 1. The laboratory performed Bacteriology and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 9:40 a.m. on 12/29/22. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The following analytes were not graded by API due to lack of consensus: One Blood Cell Identification (BCID) result and one Vaginal Wet Preparation (VWP) result from the second 2022 Hematology PT event. One Urine Culture MIC/ZONE Diameter Value (UCMZ) result from the second 2022 Microbiology PT event for 11 antibiotics. Event Sample ID Analyte 2022-2 ECI-09 BCID 2022-2 VA-02 VWP 2022-2 UR-06 UCMZ 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test results. The data summaries were not present, and evaluation of the non-graded results were not found in laboratory records. 5. In an interview at 11:42 a.m. on 12/29/22, the GS confirmed the above finding. **This is a repeat deficiency, cited during the 05/13/21 survey** .
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 laboratory personnel, the laboratory failed to 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 specified in 493.1231 through 493.1236. Findings include: 1. A review of laboratory policy, Quality Assurance Plan, on 12/30/22, at 10:30 a.m., found the laboratory's established quality assurance (QA) policies failed to include monitoring of all areas of the general laboratory system and the policies failed to identify and correct problems in these areas. 2. The laboratory's QA system failed to

	monitor, assess, and when indicated, correct problems identified in the general laboratory systems such as, but not limited to, the following: a. The accuracy of non-graded proficiency test results was not verified. The QA system failed to identify correct this repeat deficiency. See D5215. .
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 a review of laboratory records, direct observation, and an interview with the laboratory personnel, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 and failed to 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. Findings are as follows: 1. Failure to ensure manufacturer's instructions for establishing a normal patient mean and using the correct ISI with each new lot of thromboplastin were followed. See D5411. 2. Failure to ensure blood bank quality control material were not used after expiration date. See D5417. 3. Failure to ensure the reference ranges adopted by the laboratory were obtained by the laboratory during performance verification studies on the epoc system. See D5421. 4. Failure to ensure manufacture established mean and standard deviation were verified prior to patient testing for each new lot of quality control material. See D5469. 5. Failure to ensure stain quality controls were performed and documented for hematology. See D5473, 6. Failure to ensure gram stain QC were performed and documented as established in laboratory procedure. See D5503. 7. Failure to 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 at 493.1251 through 493.1283. See D5791. .
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with laboratory personnel, the laboratory failed to follow the manufacturer's instructions to establish a normal patient Prothrombin (PT) time mean and incorporate the lot specific International Sensitivity Index (ISI) for each new lot of thromboplastin ensuring the laboratory provided test results within stated performance specifications for Coagulation testing performed under the specialty of Hematology. Findings are as follows: 1. The laboratory

	performed Coagulation testing under the specialty of Hematology as confirmed by the General Supervisor (GS) during a tour of the laboratory at 9:40 a.m. on 12/29/22. 2. The Instrumentation Laboratory ELITE Coagulation instrument was observed as present and available for use during the tour of the laboratory. 3. The package insert for the HemosIL RecombiPlasTin 2G (lot # N0623655) directed the laboratory to enter the ISI value from the insert and establish a normal patient PT mean with each new lot. 4. Documentation showing the new normal patient PT mean had been established with the most recent lot change was requested at 12:15 p.m. on 12/29 /2022. The laboratory was unable to provide the documentation. 5. The ISI programmed into the ELITE database was 1.03 for a previous lot (# N0916546). The ISI for the current, in use, HemosIL RecombiPlasTin 2G lot (# N0623655) was 1.07. 6. In an interview at 1:42 p.m. on 12/29/22, the GS confirmed the new lot had been put into use sometime in the beginning of September 2022 and the laboratory had not performed a mean normal range study or entered the current ISI into the database. The GS confirmed the laboratory performs approximate 600 coagulation tests annually. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on obervation, document review, and interview with laboratory personnel, the laboratory failed to ensure Immunohematology quality control materials were not used after the expiration date had been exceeded on one of 20 patient testing days over a period of six months in 2022. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the general supervisor (GS) during a tour of the laboratory at 9:40 a.m. on 12/29/22. 2. Ortho Clinical Diagnostics Immunohematology test systems were observed as present and available for use during the tour of the laboratory. 3. Reagent Logs for June 2022- December 2022 were reviewed the day of survey. It was found on one of 20 patient testing days, 06/05 /22, expired Selectogen 0.8% (S), Affirmagen 0.8% (A), and Ortho Confidence Cells (OCC) were used past their expiration dates. See below: Reagent Lot Exp. Date S VS430 05/17/22 A 8A412 05/03/22 OCC CNF265 08/03/22 On the day the expired reagents were documented as being used, 06/05/22, one patient had Immunohematology testing performed. 4. In an interview on at 10:30 a.m. on 12/30 /22, the GS confirmed expired quality control material was documented as used as indicated above. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure the reportable ranges obtained during performance verification (PV) activities for four of four chemistry analytes reviewed on date of survey were adopted by the laboratory in 2021 and 2022. Findings are as follows: 1. The laboratory performed Blood Gas analysis which falls under the specialty of Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 9:40 a.m. on 12/29/22. 2. A Siemens epoc Blood Analysis System was observed as present and available for use during the tour of the laboratory. 3. PV activities for the epoc were completed and the laboratory began testing patient specimens in June 2021, as indicated by the GS. 4. The adopted upper and lower limits of the reportable range for Total Carbon Dioxide (TCO2), partial pressure of Oxygen (PO2), partial pressure of Carbon Dioxide (PCO2), and PH did not reflect the actual reportable range values obtained by the laboratory during the PV. See below: Analyte PV Adopted PH 6.628-7.886 6.5-8.0 TCO2 5.400-30.40 5.0-50.0 PO2 43.90-571.5 5.0-750.0 PCO2 2.800-123.3 5.0-250.0 5. In an interview at 12:08 p.m. on 12/29/22, the GS confirmed she used the manufacturers established reportable ranges in the procedure and that they were not the actual values the laboratory had verified during performance verification. The laboratory performs approximately 18 patient tests annually on the epoc analyzer. **This is a repeat deficiency, cited during the 05/13/21 survey** .
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of laboratory records, observation, and interview with laboratory personnel, the laboratory failed to establish or verify the criteria for acceptability for coagulation quality control (QC) material for 2021 and 2022. Findings are as follows: 1. The laboratory performed Coagulation testing under the specialty of Hematology as confirmed by the General Supervisor (GS) during a tour of the laboratory at 9:40 a.m. on 12/29/22. 2. The Instrumentation Laboratory ACL ELITE Coagulation instrument was observed as present and available for use during the tour of the laboratory. 3. Documents for the most current QC lot change were requested at 1:42 p.m on 12/29/22. 4. Documentation showing the laboratory had established their own statistical parameters, or verified the manufacturers statistical parameters (mean and standard deviation{SD}), for the current QC material could not be provided. 5. Per request, it was asked by the surveyor to see the current QC lots programmed into the ACL

	ELITE database. The incorrect lot number, expiration dates, and statistical parameters were programmed into the ELITE database as follows: HemoSIL Normal 1 QC Programmed lot #/Exp. date N1118207/Feb.28.25 Current lot #/Exp. date N0320941 /March.30.25 HemoSIL Abnormal High QC Programmed lot #/Exp. date N0320575 /Mar.31.25 Current lot #/Exp. date N0623655/Jun.30.25 6. In an interview at 1:42 p. m. on 12/29/22, the GS confirmed the laboratory had not established verified the manufacturers mean and SD prior to patient testing. The GS further confirmed the current lot was not programmed into the instrument database. .
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to document Hematology quality control (QC) procedures performed to test Hema 3 stain for intended reactivity each day of use in 2021 and 2022. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed the General Supervisor (GS) during a tour of the laboratory at 9:40 a.m. on 12/29/22. 2. The Hema 3 stains and microscope to perform manual blood smears were observed as present and available for use during the tour of the laboratory. 3. The Blood Smear Laboratory procedure found in the Hematology Procedure Manual, established QC requirement for the Hema 3 stain as follows: Quality Control, Stain quality is evaluated and documented on each patient smear review and documented as "stain ok" on the CBC printout. 4. The CBC printout for patient XXX089 who had a blood smear performed on 11/30/22, was reviewed on the day of survey 12/29/22. Documentation of the Hema 3 stain QC check could not be found on the CBC printout as indicated it should by procedure. 5. QC documentation for the day of patient testing was requested and could not be provided by the laboratory. 6. In an interview at 1:39 p.m. on 12/29/22, the GS confirmed the laboratory was not following their established procedure and that the Hema 3 stain QC check was not getting documented on the CBC patient printouts or elsewhere in the laboratory. 7. The laboratory performs approximately 1,200 manual differentials annually as confirmed in an email received from the GS at 2:19 p.m. on 01/03/2023. CBC = Complete blood cell count .
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: . Based on document review, observation, and an interview with laboratory personnel, the laboratory failed to perform and document positive and negative Gram stain quality control (QC) performance each week of patient testing. Findings are as

	follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on at 9:40a.m. on 12/29/22. 2. A Gram Staining set-up was observed as present and available for use during the tour. 3. The Gram Stain Laboratory procedure found in the Microbiology Procedure Manual, established quality control (QC) frequency to be performed each day of Gram staining, more stringent than regualation. 4. Gram Stain QC was documented by the laboratory on the monthly manual Microbiology QC Log's. The Microbiology QC logs were reviewed for October 2021, November 2021, and December 2021. Gram Stain QC was documented as being performed zero of 61 days (or zero of ~nine weeks) in October 2021 and November 2021. Gram stain QC was documented as follows for December 2021: 12/7/21, 12/10/21, 12/13/21, 12/17/21, 12/30/21, five of 17 patient testing days, (or three of four weeks) in December 2021. 5. In an interview at 9:36 a.m. on 12/30/22, the GS confirmed the above finding. .
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on laboratory record review, procedure manuals, direct observation, and an interview with laboratory personnel, the laboratory failed to 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. Findings are as follows: 1. A review of laboratory policy, Quality Assurance Plan, on 12/30/22, at 10:30 a.m., found the laboratory's established quality assurance (QA) policies failed to include monitoring of all areas of the analytic system and the policies failed to identify and correct problems in these areas. 2. The laboratory's QA system failed to monitor, assess, and when indicated, correct problems identified in the analytic systems such as, but not limited to, the following: a. The laboratory failed to ensure it followed manufacturer's instructions for coagulation lot changes. See D5411. b. The laboratory failed to ensure it did not use expired quality control material. See D5417. c. The laboratory failed to ensure the reference ranges adopted by the laboratory were obtained by the laboratory during performance verification studies on the epoc system. The QA system failed to identify correct this repeat deficiency. See D5421. d. The laboratory failed to ensure manufacture established mean and standard deviation were verified prior to patient testing for each new lot of quality control material. See D5469. e. The laboratory failed to ensure stain quality controls were performed and documented for hematology. See D5473. f. The laborartory failed to ensure gram stain QC were performed and documented as established in laboratory procedure. See D5503. .
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure reference intervals were consistent between a Chemistry procedure and a patient test report. The laboratory performed approximately 18 blood gas Chemistry tests on patient specimens annually. Findings are as follows: 1. The laboratory performed Blood Gas analysis which falls under the specialty of Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 9:40 a.m. on 12/29/22. 2. A Siemens epoc Blood Analysis System was observed as present and available for use during the tour of the laboratory. 3. The Total Carbon Dioxide (TCO2), reference intervals listed in the EPOC Blood Gas Laboratory procedure located in the Chemistry General Manual, was not consistent with that included on the test report for patient XXX845, tested on 09/06/21, reviewed on date of survey, 12/29/22. See below Analyte Procedure Report TCO2 23-27 22.0-28.0 4. In an interview at 12:08 p.m. on 12/29/22, the GS confirmed the reference interval discrepancy between the procedure and the patient test report. .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 laboratory record review, direct observation, and an interview with laboratory personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the post-analytic systems specified in 493.1291. Findings include: 1. A review of laboratory policy, Quality Assurance Plan, on 12/30/22, at 10: 30 a.m., found the laboratory's established quality assurance (QA) policies failed to include monitoring of all areas of the post-analytic system and the policies failed to identify and correct problems in these areas. 2. The laboratory's QA system failed to monitor, assess, and when indicated, correct problems identified in the post-analytic systems such as, but not limited to, the following: a. The laboratory reference intervals were not consistent between the procedure and the final test report. See D5807. .
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on review of proficiency testing (PT) records, laboratory procedures, laboratory documents, patient testing logs and reports, quality control (QC) records, and interview with the laboratory personnel, the Laboratory Director failed to provide overall management and direction in accordance with 42 C.F.R. 493.1445 of this subpart. Findings are as follows: 1. Failure to ensure previously cited deficiencies were corrected. See D6079. 2. Failure to ensure that the LD directed no more than five

	laboratories. See D6081. 3. Failure to ensure the laboratory establish and maintain quality control and quality assessment programs to identify failures in quality as they occur. See D6094. 4. Failure to ensure that an approved procedure manual is available to all personnel for any aspect of the testing process. See D6106. .
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on record review, observation, and interview with laboratory personnel, the Laboratory Director failed to ensure previously cited deficiencies were corrected. Findings are as follows: The following deficiencies were cited during the previous survey and were found to be out of compliance again during the most recent survey performed on December 29-30, 2022. 1. D5215 - the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) results for regulated analytes. Found to be out of compliance on 05/13/21. 2. D5421 - the laboratory failed to ensure the reportable range obtained during performance verification activities were adopted by the laboratory. Found to be out of compliance 05/13/21. .
D6081	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(d) Each individual may direct no more than five laboratories. This STANDARD is not met as evidenced by: . Based on document review and CMS database inquiry, the laboratory director failed to ensure he directed no more than five laboratories. Findings are as follows: 1. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification Form CMS-116 and the Laboratory Personnel Report Form CMS-209 indicated the Lake Region Healthcare - Elbow Lake Campus laboratory director role was held by Dr. Scott Pauley. 2. Review of the CMS database indicated that Dr. Scott Pauley was concurrently directing the following five Certificate of Accreditation laboratories. 24D0406290 Lake Region Healthcare Battle Lake Clinic 24D0406358 Lake Region Healthcare Walkin Clinic - Fergus Falls 24D0935418 Prairie Ridge Hospital and Health Services - Morris 24D0691046 St. Francis Healthcare Campus - Breckenridge 24D0406241 Tri County Hospital Laboratory - Wadena 3. The maximum allowable number of laboratories directed by one individual was exceeded by Dr. Scott Pauley. .
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: . Based on a review of laboratory policy, laboratory records, and an interview with laboratory personnel, the Laboratory Director failed to ensure established quality assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred. Findings are as follows: 1. Failure to ensure quality control records are retained including lot numbers and expirations dates. See D3031. 2. Failure to establish and follow a general laboratory systems quality assurance program that assured quality laboratory services and identified failures as they occurred. See D5291. 3. Failure to establish and follow an analytic systems quality assurance program that assured quality laboratory services and identified failures as they occurred. See D5791. 4. Failure to establish and follow a post-analytic systems quality assurance program that assured quality laboratory services and identified failures as they occurred. See D5891. .
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: . Based on document review and an interview with laboratory personnel. the laboratory director (LD) failed to approve approximately half of the current laboratory procedures reviewed on the days of survey. Finding are as follows: 1. While reviewing policies and procedures on the days of survey it was noted that many of the procedures were signed by a previous LD that is no longer employed by the laboratory. They were not signed by the current acting LD. 2. In an interview at 10:10 a.m. on 12/30/22, the General Supervisor confirmed the procedures were not physically signed by the current acting LD nor were they electronically signed by him in the laboratory's electronic database of procedures. .