Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406287	07/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lake Region Healthcare Barnesville	209 2nd Street Se, Barnesville, 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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. 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 non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 07/24 /19 at 9:00 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The laboratory received non-graded results from API for the events and tests listed below. The Data Summaries from API with the expected results for these tests were not included in laboratory records. Event Sample ID Test* 2017 Chemistry-3 CH-11 to CH-15 LDL 2018 Hematology -1 BCI-01 BCID 2018 Hematology-2 BCI-10 BCID 2019 Hematology-1 US-02 USED 2019 Hematology-1 VKP-01 VWP 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 07/24/19 at 11:15 a.m., the GS confirmed the above finding. 6. This issue was also cited during the 08/31/17 survey. See D6014. *Note LDL - Low Density Lipoprotein BCID - Blood Cell Identification USED - Urine Sediment VWP - Vaginal Wet Preparation
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure a Chemistry procedure (performance verification) was approved, signed, and dated by the laboratory director prior to use. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 07/24/19, at 9:00 a.m. 2. An Abbott Piccolo Xpress chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification activities for the analyzer were acceptable and the laboratory began patient specimen testing in May 2018 as indicated in laboratory records. 4. The laboratory Director did not approve, sign, or date the performance verification documents prior to use of the analyzer. 5. In an interview on 07/24/19, at 12:00 p.m., TC1 confirmed the above finding.
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 range obtained during performance verification of a new Chemistry analyzer was accurate in the procedure manual. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 07/24/19 at 9:00 a.m. 2. An Abbott Piccolo Xpress chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory completed performance verification (PV) activities and began testing patient specimens using this analyzer in May 2018 as indicated by TC1 and confirmed via laboratory records. 3. The reportable ranges listed in the Piccolo Blood Chemistry Analyzer - Specimen Processing procedure, located in the Lab Procedure Manual, for the analytes listed below did not reflect the actual reportable range values obtained by the laboratory during the PV. Analyte* Procedure PV Na 110-170 115-160 K 1.5-8.5 2.2-7.5 CO2 5.0-40 10-33 Cl 80-135 86-134 Glu 10-700 29-637 Ca 4.0-16.0 4.3-15.2 BUN 1.0-180 3-104 Crea 0.2-20 0.5-16 ALP 5.0-2400 24-1823 ALT 5.0-2000 16-1504 AST 5.0-2000 21-1506 TBil 0.1-30 0.4-4.3 Alb 1.0-6.5 1.9-5.9 TP 2.0-14 3.3-10.0 4. In an interview on 07/24/19, at 12:10 p.m., TC1 confirmed the above finding and indicated the laboratory had included the manufacturer's analytical measurement ranges as the reportable ranges in the procedure. *Note Na - Sodium K - Potassium CO2 - Carbon Dioxide CL - Chloride Glu - Glucose Ca - Calcium BUN - Blood Urea Nitrogen Crea - Creatinine ALP - Alkaline Phosphatase ALT - Alanine Transaminase AST - Aspartate Aminotransferase TBil - Total Bilirubin Alb - Albumin TP - Total Protein
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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) activities as established in the Individualized Quality Control Plan (IQCP) for a chemistry test. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 07/24/19, at 9:00 a.m. 2. A Biosite Triage Meter chemistry analyzer was observed as present and available for use during the tour of the laboratory. Troponin testing was performed on this analyzer. 2. Troponin QC performance was required with new lots and shipments of testing devices and every 30 days as established in the laboratory's IQCP for the test. 3. The time interval between Troponin QC performance exceeded that established in the IQCP on 6 occasions in the timeframe reviewed, 11/01/17 - 07/24/19, potentially affecting 38 patient test results (Pt). See below. QC date QC date Interval Pt 11/01/17 01/29/18 90 days 3 01/29/18 04/20/18 82 days 5 04/20/18 08/16/18 119 days 9 08/16 /18 01/15/19 153 days 10 01/15/19 04/29/19 105 days 7 04/29/19 none* 87 days 4 4. In an interview on 07/24/19, at 1:35 p.m., TC1 confirmed the above finding. *Note Date of survey, 07/24/19, used for calculation
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory director failed to ensure non-graded proficiency testing (PT) results were evaluated to identify problems that required corrective action. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 07/24/19, at 9:00 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The laboratory received non-graded PT results from API for Low Density Lipoprotein (LDL), Blood Cell Identification (BCID), Urine Sediment (USED), and Vaginal Wet Preparation (VWP) for the PT events listed below. Event Test 2017 Chemistry-3 LDL 2018 Hematology-1 BCID 2018 Hematology-2 BCID 2019 Hematology-1 USED, VWP 4. An evaluation of the non-graded PT results was not

	found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 07/24/19, at 11:15 a.m., TC1 confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical consultant failed to ensure competency was assessed at least semiannually during the first year of patient specimen testing for 1 of 1 new testing personnel hired in 2017. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry and Hematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 07/24/19, at 9:00 a.m. 2. Laboratory records indicated Testing Personnel 1 (TP1) was trained and initially assessed for testing competency in August 2017. A semiannual competency assessment for TP1 was not found in laboratory records. 3. The laboratory was unable to provide the missing semi-annual competency documents upon request. 4. In an interview on 07/24/19, at 9:30 a.m., TC1 confirmed the above findings.