Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0400625	01/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Meeker Memorial Hospital	612 S Sibley Ave, Litchfield, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish and follow a written competency assessment procedure for General Supervisor and Technical Supervisor. Findings are as follows: 1. The laboratory performed Chemistry, Coagulation, Hematology, Immunology, Immunohematology, Microbiology, Parasitology, Urinalysis, Virology and Toxicology testing as by Testing Personnel 1 (TP1) during a tour of the laboratory on 01/16/19 at 10:05 a.m. 2. A competency assessment procedure for General Supervisor and Technical Supervisor was not found during review of laboratory policies and procedures. The laboratory was unable to provide a competency assessment procedure upon request. 3. Competency assessments for the General Supervisor and Technical Supervisor for 2017 and 2018 were not found during review of laboratory records. The laboratory was unable to provide the documentation upon request. 4. In an interview on 01/16/19 at 11:15 am., TP1 confirmed the above findings. .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by:

	. Based on document review and interview with laboratory personnel, the laboratory failed to investigate an unacceptable Endocrinology proficiency testing (PT) result for 1 analyte in 2018. Findings are as follows: 1. The laboratory performed Endocrinology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 01/16/19 at 10:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) as PT provider. 3. The laboratory received an unacceptable PT result from API for the survey event, sample and analyte listed below. Survey Event: 2018 Chemistry Core / 2nd Sample: HCG-10 Analyte: HCG* (Serum Quantitative) 4. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 5. In an interview on 01/16/19 at 12:30 p. m., TP1 confirmed the above findings. * HCG = human chorionic gonadotropin .
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, Toxicology and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 01/16/19 at 10:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) as PT provider. 3. The laboratory received non-graded results from API due to no consensus for the survey events, samples and analytes listed below. Event: 2017 Chemistry Core / 2nd Sample ID: CM-07 Test: Troponin I Event: 2017 Chemistry Misc / 2nd Sample ID: IA-04 & IA-06 Test: Folate Event: 2018 Chemistry Misc / 1st Sample ID: UDS-02 Test: Urine Drug Screen / Opiates Event: 2018 Hematology / Coagulation / 1st Sample ID: CYS-02 Test: Body Fluid Crystals 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 01/16/19 at 12:30 p.m., TP1 confirmed the above findings. .
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 to establish and follow a procedure for the ongoing monitoring of

	the effectiveness of 3 Individualized Quality Control Plans (IQCP). Findings are as follows: A. Chemistry - Arterial Blood Gases (ABG's) 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 01/16/19 at 10:05 a.m. 2. An Abbott i-Stat analyzer was observed as present and available for use during the tour of the laboratory. 3. An Individualized Quality Control Plan (IQCP) to reduce the frequency of QC performance from each day of patient testing for ABG's (established March, 2015) was located in the IQCP Manual. 4. An annual review of the ABG IQCP for 2017 and 2018 was not found in laboratory records. The laboratory was unable to provide the documentation upon request. 5. In an interview on 1/17/19 at 10:05 am., TP1 confirmed the above findings. B. Chemistry - Microalbumin (M/Alb) 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 01/16/19 at 10:05 a.m. 2. An Alere Affinion analyzer was observed as present and available for use during the tour of the laboratory. 3. An Individualized Quality Control Plan (IQCP) to reduce the frequency of QC performance from each day of patient testing for M/Alb (established August, 2015) was located in the IQCP Manual. 4. An annual review of the M/Alb IQCP for 2017 and 2018 was not found in laboratory records. The laboratory was unable to provide the documentation upon request. 5. In an interview on 1/17/19 at 10:05 am., TP1 confirmed the above findings. C. Immunology - Amniosure 1. The laboratory performed Immunology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 01/16/19 at 10:05 a.m. 2. Qiagen Amniosure Rupture of Fetal Membranes (ROM) test kits were observed as present and available for use during the tour of the laboratory. 3. An Individualized Quality Control Plan (IQCP) to reduce the frequency of QC performance from each day of patient testing for the Amniosure test kits (established September, 2015) was located in the IQCP Manual. 4. An annual review of the Amniosure IQCP for 2017 and 2018 was not found in laboratory records. The laboratory was unable to provide the documentation upon request. 5. In an interview on 1/17/19 at 10:05 am., TP1 confirmed the above findings. .
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. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 01/16/19 at 10:05 a.m. 2. A Roche C6000 immunoassay analyzer was observed as present and available for use during the tour. 3. The reference interval for Vitamin B12 listed in procedures was not consistent with those on the patient test report (Male - 66 years, Date performed = 2-16-18) reviewed on date of survey as indicated below: Procedure: Roche Cobas Vitamin B12 Application Sheet Version = 2016-07, v7.0 Reference Range: 211 - 946 Procedure: Roche Cobas Vitamin B12 II Instruction for Use (IFU) Version = 2017-04, v1.0 English Reference Range: 22 - 1245 Patient Report Reference Range: 213 - 816 4. In an interview on 1 /17/19 at 9:15 am., TP1 confirmed the above findings. .

D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to provide documentation of review and approval by the laboratory director of Performance Verification results prior to implementation of a revised Chemistry test method. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 01/16/19 at 10:05 a.m. 2. A Roche C6000 immunoassay analyzer was observed as present and available for use during the tour. 3. A Performance Verification (PV) data binder (established July, 2017) with precision and accuracy verification for a revised Vitamin B12 test method on the Roche C6000 immunoassay analyzer analyzer was found during review of laboratory records. 4. The Laboratory Director (LD) failed to sign and date the documents found in the Performance Verification (PV) data binder . 5. In an interview on 1/17/19 at 9:15 am., TP1 confirmed the above findings. .