Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403629	11/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Community Memorial Hospital	512 Skyline Blvd, Cloquet, 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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records for at least 2 years. Findings are as follows: 1. The laboratory performed Chemistry & Hematology testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/04/20 at 10: 05 a.m. 2. The laboratory performed PT using the College of American Pathologists (CAP) provider. 3. The following PT documentation was not present in laboratory records on date of survey. The laboratory was unable to provide these documents upon request. Event: Urine Drug Testing (UDS-C 2018) Missing Item(s): Attestation Statement Event: Hematology / Auto Diff (FH9-A 2019) Missing Item(s): Lab results, Attestation Statement & Laboratory Director Review Event: Cerebrospinal Fluid Chemistry (M-A 2019) Missing Item(s): Lab results, Attestation Statement & Laboratory Director Review 4. In an interview on 11/05/20 at 8:15 a.m., GS1 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 Chemistry proficiency testing (PT) result for 1

	analyte in 2020. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/04/20 at 10:05 a.m. 2. The laboratory performed PT using the College of American Pathologists (CAP) provider.. 3. The laboratory received an unacceptable PO2* result on Specimen AQ-06 in the CAP Blood Gases (AQ-B 2020) event. 4. Investigation of unacceptable PT results was required as established in the Proficiency Testing Process procedure located in the laboratory's Quality Assurance manual. 5. 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. 6. In an interview on 11/05/20 at 8:15 a.m., GS1 confirmed the above findings. *PO2 = Partial pressure of oxygen .
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 five 2018, five 2019, and seven 2020 proficiency testing (PT) scores when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Immunology, Chemistry, Toxicology, and Urinalysis testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/04/20 at 10:05 a.m. 2. The laboratory performed PT using the College of American Pathologists (CAP) provider. 3. The following results were not graded by CAP due to lack of consensus. See below. Event: Diagnostic Immunology (S-C 2018) Sample ID: CRP-05 Analyte: C Reactive Peptide Event: Diagnostic Immunology (S-C 2018) Sample ID: HCG-13 Analyte: Qualitative Serum HCG* Event: Procalcitonin (PCT-B 2018) Sample ID: PCT-06 Analyte: Procalcitonin Event: Diagnostic Immunology (S-B 2018) Sample ID: CRP-03 Analyte: C Reactive Peptide Event: Clinical Microscopy (CM-B 2018) Sample ID: USP-04 Analyte: Urine Sediment ID Event: General Chemistry / TDM* (C-A 2019) Sample ID: CHM-01 thru CHM-05 Analyte: Alkaline Phosphatase Event: General Chemistry / TDM* (C-A 2020) Sample ID: CHM-01 thru CHM-05 Analyte: Alkaline Phosphatase Event: Urine Drug Testing (UDS-B 2020) Sample ID: UDS-07 Analyte: Benzodiazapine Group Event: Plasma Cardiac Markers (PCARM-A 2020) Sample ID: PCAR-09 Analyte: Troponin - I 4. The CAP report referred the laboratory to the expected result data summary for evaluation of the non-graded test results. The data summary for the above analytes were not present in laboratory records. Evaluation of the non-graded results were not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded results upon request. 5. In an interview on 11/05/20 at 8:15 a.m., GS1 confirmed the above findings. * HCG = Human Chorionic Gonadotropin TDM = Therapeutic Drug Monitoring .
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 a Microbiology Individualized Quality Control Plan (IQCP) in 1 of 12 months reviewed . Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/04 /20 at 10:05 a.m. 2. An Abbott Binax NOW analyzer was observed as present and available for use during the tour of the laboratory. Legionella Antigen testing was performed on this analyzer. 3. Legionella Antigen Quality Control (QC) performance was required with each new lot number and/or new shipment as established in the laboratory's IQCP for the test. 4. Documentation on the Patient Testing Log for the Legionella Antigen test indicated that QC was not performed with the change in reagents from lot # 093663 (Exp date: 7/28/19) to lot # 100099 (Expiration date: 4/28 /20) on 1/21/19. 5. In an interview on 11/05/20 at 10:15 a.m., GS1 confirmed the above findings. .
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 observation, document review and interview with laboratory personnel, the laboratory failed to evaluate and define the relationship between test results obtained from different Chemistry analyzers at least twice annually in 2020. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/04/20 at 10:05 a.m. 2. Siemens RAPIDPoint 500 and EPOC blood gas analyzers were observed and available for use during the tour of the laboratory. 3. GS1 indicated the laboratory used the EPOC blood gas analyzer for back up testing to the RAPIDPoint 500. 4. A system to evaluate and define the relationship between test results obtained from different analyzers or methodologies at least twice annually was established in the Method Comparison procedure located in the General Lab Procedures manual. Documentation of such an evaluation in 2020 for the blood gas analyzers was not found during review of laboratory records. The laboratory was unable to provide these documents upon request. 6. In an interview on 11/05/20 at 10:15 a.m., GS1 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 a reference interval was consistent between a Chemistry procedure and a patient test report. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/04/20 at 10:05 a.m. 2. A Siemens Dimension EXL chemistry analyzer was observed and available for use during the tour of the laboratory. 3. The Phosphorus reference intervals listed in the Siemens Dimension EXL Phosphorus procedure, located in the Chemistry Procedure Manual, were not consistent with those included on a patient test report reviewed on date of survey, as indicated below. Patient: Adult female, aged 75 years, tested on 3/23/19 Procedure: 2.5 - 4.9 mg/dl Patient Report: 2.6 - 4.7 mg/dl 4. In an interview on 11/05 /20 at 10:15 a.m., GS1 confirmed the above findings. .
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Supervisor failed to ensure 10 of 10 testing personnel (TP) received competency assessments for three test procedures performed in 2019. Findings are as follows: 1. The laboratory performed Immunology and Microbiology testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/04/20 at 10:05 a.m. 2. Competency assessment documents for 10 of 10 fully trained TP in 2019 did not include an evaluation of the following tests: Legionella Antigen Streptococcus Pneumoniae Antigen Fetal Rupture of Membranes 3. The laboratory was unable to provide the missing competency assessments upon request. 4. In an interview at 11:25 a.m. on 11/04/20, GS1 confirmed the above findings. .
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 document review and interview with laboratory personnel, the Technical Supervisor failed to ensure 3 of 5 new testing personnel received a competency evaluation at least semiannually during the first year of patient specimen testing. Findings are as follows: 1. The laboratory performed Chemistry, Toxicology, Hematology, Urinalysis, Microbiology, Parasitology, Immunology, and Immunohematology testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/04/20 at 10:05 a.m. 2. New Testing Personnel (TP) were hired with the following start dates: TP Hire Date TP7 3/26/19 TP9 5/21/19 TP14 10/2 /18 3. Documentation of the semiannual competency assessment for all tests in the noted specialties were not found for TP7, TP9 and TP14 during review of laboratory personnel records. The laboratory was unable to provide the missing semiannual competency assessments upon request. 4. In an interview at 11:25 a.m. on 11/04/20, GS1 confirmed the above findings.