Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405305	10/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Murray County Medical Center	2042 Juniper Avenue, Slayton, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to verify the accuracy of all tests performed at least twice annually. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/30/18 at 8:05 a.m. 2. A Beckman Coulter AU680 chemistry analyzer was observed as present and available for use during the tour. 3. The laboratory performed Transferrin testing as confirmed by the GS. 4. The laboratory utilized American Association of Bioanalysts (AAB) as the Proficiency Testing (PT) provider. Twice annual verification of accuracy documents for Transferrin were not found during review of PT records from 2016, 2017, and 2018. The laboratory was unable to provide these documents upon request. 5. In an interview on 10/30/18 at 10:15 a.m., the GS confirmed the above findings. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other

	materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure instructions for instrument calibration, reportable ranges and reference ranges were included in the procedure manual. Findings are as follows: A) Hematology 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/30/18 at 8:05 a.m. 2. A Beckman Coulter Unicel DxH 600 hematology analyzer was observed as present and available for use during the tour. 3. Review of the Hematology Procedure - DxH 600 procedure, located in the on-line Policies and Procedure manual, did not provide evidence that the calibration process for the instrument was included in the procedure. 4. In an interview on 10/30/18 at 2:30 PM, the GS confirmed the above finding. B) Chemistry 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/30/18 at 8:05 a.m. 2. An OPTI CCA TS2 blood gas analyzer was observed as present and available for use during the tour. 3. Review of the Blood Gas Procedure - OPTI CCA TS2 Critical Care Analyzer procedure, located in the on-line Policies and Procedure manual, did not provide evidence that reportable ranges and reference ranges were included in the procedure. 4. In an interview on 10/30/18 at 2: 30 PM, the GS confirmed the above finding. .
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 establish a system to evaluate and define the relationship between test results obtained from different analyzers or methodologies at least twice annually. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/30/18 at 8:05 a. m. 2. Beckman Coulter Access 2 and Alere Triage immunoassay analyzer were observed as present and available for use during the tour. 3. The GS indicated the laboratory used the Triage as back up testing to the Access 2 for the following methods:. - Troponin - CKMB 4. The laboratory's procedure manuals did not include a system to define and evaluate the relationship between test results obtained from

	different test methodologies or analyzers at least twice annually. Documentation of such an evaluation was not found during review of laboratory records. 5. In an interview on 10/30/18 at 12:30 PM, the GS confirmed the above finding. .
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 accurate reference ranges were listed on Urinalysis and Hematology test reports reviewed during the survey. Findings are as follows: A) Urinalysis 1. The laboratory performed Urinalysis testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/30/18 at 8:05 a.m. 2. A Siemens Clinitek Status urinalysis analyzer and a Nikon Eclipse 200 microscope were observed as present and available for use during the tour. 3. The reference ranges found in the Urinalysis procedure, located in the on-line Policies and Procedure manual, were not consistent with that included on the test report (Female - 94 years, Date of testing = 12/2/17) reviewed on the date of survey, as follows: Parameter: Procedure: Test Report: Specific Gravity 1.003-1.029 1.005-1.030 pH 4.5 - 7.8 5.0 - 9.0 Urobilinogen 0.1 - 1.0 0.2 - 1.0 WBC / hpf* 0 - 4 None Seen RBC / hpf* Male 0 - 3 None Seen Female 0 - 5 Casts / hpf 0 - 4 None Seen 5. In an interview on 10/30/18 at 3:15 p.m., the GS confirmed the above findings. B) Hematology 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/30/18 at 8:05 a.m. 2. A Beckman Coulter Unicel DxH 600 hematology analyzer was observed as present and available for use during the tour. 3. The reference ranges found in the Hematology Procedure - DxH 600 procedure, located in the on-line Policies and Procedure manual, were not consistent with that included on the test report (Male - 75 years, Date of testing = 10/9/18) reviewed on the date of survey, as follows: Parameter: Procedure: Test Report: MCH* 25.5 - 34.0 30 - 37 MCHC* 31.5 - 36.5 28 - 37 Granulocyte % 45 - 77 44 - 76 Monocyte % 3 - 10 3 - 11 Eosinophil % 0.0 - 6.0 1 - 4 5. In an interview on 10/30/18 at 3:15 p.m., the GS confirmed the above findings. * WBC/ hpf = White Blood Cells per high power field * RBC/ hpf = Red Blood Cells per high power field * MCH = Mean Corpuscular Hemoglobin * MCHC = Mean Corpuscular Hemoglobin Concentration