Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0863151	04/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Warren Community Hospital	300 West Good Samaritan Drive, Warren, 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
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 six 2020 proficiency testing (PT) results when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Hematology and Immunohematology testing as confirmed by General Supervisor 1 (GS1) during a tour of the laboratory at 8:05 a.m. on 04/22 /21. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. Six results were not graded by API due to lack of consensus. See below. Survey Event: Hematology / Coagulation - 1st Sample ID: HCA-04, HCA-05 Analyte: activated Partial Thromboplastin Time Survey Event: Hematology / Coagulation - 2nd Sample ID: HCA-07, HCA-09, HCA-10 Analyte: activated Partial Thromboplastin Time Survey Event: Immunology / Immunohematology - 3rd Sample ID: SER-11 Analyte: Antibody Screening for Transfusion 4. The API 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. Evaluations of the non-graded results were not found in laboratory records. 5. Investigation of non-graded PT results was required as established in the Proficiency Testing Procedure located in the North Valley Health Center - Laboratory Manual. The laboratory was unable to provide evaluations of the non-graded results upon request. 6. In an interview at 10:15 a.m., on 04/22/21, GS1 confirmed the above finding. .

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 document review and interview with laboratory personnel, the laboratory failed to verify the accuracy at least twice annually of 1 test performed in 2019 and 2020. Findings are as follows: 1. The laboratory performed Urine Drug Sceening testing under the specialty of Chemistry as confirmed by General Supervisor 1 (GS1) during a tour of the laboratory at 8:05 a.m. on 04/22/21. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) provider. 3. Documentation of twice annual accuracy verification of Urine Drug Sceening was not found in laboratory records from 2019 and 2020. The laboratory was unable to provide verification documents for calendar year 2019 and 2020 upon request. 4. In an interview at 10:15 a.m., on 04/22/21, GS1 confirmed the above finding. .
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 include Hematology reportable ranges and reference ranges in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by General Supervisor 1 (GS1) during a tour of the laboratory at 8:05 a.m. on 04/22/21. 2. A Sysmex CA-600 coagulation analyzer and an Alcor Scientific miniSED analyzer were observed as present and available for use during the tour of the laboratory. 3. The reportable range and reference range for the Prothrombin Time (PT) test and the activated Partial Thromboplastin Time (aPTT) test were not found in the respective test procedures located in the North Valley Health Center - Laboratory Manual. 4. The reference range for the Erythrocyte Sedimentation Rate (ESR) was not found in the ESR procedure, also located in the

	North Valley Health Center - Laboratory Manual. 5. The missing reportable ranges and reference ranges were not found elsewhere within laboratory documentation. 6. In an interview at 14:15 p.m., on 04/22/21, GS1 confirmed the above findings. .
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 General Supervisor 1 (GS1) during a tour of the laboratory at 8:05 a.m. on 04/22/21. 2. An Ortho Clinical Diagnostics Vitros 350 chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification activities for Ammonia testing were acceptable and the laboratory began patient specimen testing in July 2020 as indicated in laboratory records. 4. The Laboratory Director did not approve, sign, or date the performance verification documents prior to use of the Ammonia test. 5. In an interview at 14:15 p.m., on 04/22/21, GS1 confirmed the above findings. .
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish in procedure and perform function checks for all general laboratory equipment . Findings are as follows: 1. The laboratory performed Chemistry, Endocrinology, Hematology, Coagulation, Urinalysis, Immunology, and Immunohematology as confirmed by General Supervisor 1 (GS1) during a tour of the laboratory at 8:05 a.m. on 04/22/21. 2. Requirements for periodic function checks of mechanical pipettes were not included in the Laboratory Quality Assurance procedures, located in the North Valley Health Center - Laboratory Manual. 3. In an interview on 04/22/21, at 13:25 p.m., GS1 stated that accuracy checks for mechanical pipettes had not been completed since November, 2018. .
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 testing personnel (TP)received competency assessments for all test procedures performed in 2019 and 2020. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by General Supervisor 1 (GS1) during a tour of the laboratory at 8:05 a.m. on 04/22/21. 2. MedTox Laboratories Profile II - ER urine drug screening test kits were observed as present and available for use during the tour of the laboratory. 3. Competency assessment documents for 6 of 6 fully trained TP in 2019 and 2020 did not include an evaluation of the MedTox Laboratories Profile II - ER urine drug screening test method 4. The laboratory was unable to provide the missing competency documents upon request. 5. In an interview at 14:15 p.m., on 04/22/21, GS1 confirmed the above findings, and stated that she was unaware that the test method above was a Moderate Complexity test, and thus required Competency Assessment. .