Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0011492	06/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Corry Memorial Hospital	965 Shamrock Lane, Corry, PA	

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
D0000	An announced CLIA Recertification survey was conducted at the Corry Memorial Hospital on 06/11/2024 - 06/12/2024 by the PA Department of Health. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: D5405, D5423, and D5559.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with the techical supervisor (TS #1), the laboratory failed to have a complete written procedure for the analyte Creatinine on the Siemens Dimension EXL from 10/19/2022 to the day of survey. Findings include: 1. On the day of the survey, 06/11/2024 at 09:30 am, review of the procedure manuals for Chemistry revealed the operators manual were used to perform testing on the following from 10/19/2022 to day of survey: - Creatinine on the Siemens Dimension EXL. 2. Review of the operators manual revealed that the test system instructions used failed to include the following requirements: - Step by step performance of the procedure including test calculations and interpretation of results. - Control procedures. - Corrective action to take when calibrations or control results fail to meet the laboratory criteria for acceptability. - 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. - Reference intervals (normal values). -The reportable range for test results for the test system as established or verified. 3. TS #1 confirmed the findings on 06/11/2024 around 03:00 pm.

D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the technical supervisor (TS#1), the laboratory failed to establish performance specifications before reporting patient test results when modifying an FDA-cleared/approved test system for white blood cell (WBC) and platelet (PLT) counts performed on the Sysmex 550 Hematology analyzer from 10/19/2022 to 06/11/2024. Findings include: 1. The laboratory's procedure for Sysmex 550 states, "There are different methods for handling samples with platelet clumping or "platelet satllitism". These methods inculude vortexing of the original sample and reanalyzing, recollection of the specimen, use of a different anticoagulant" 2. The Sysmex 550 manufacturer's instructions states, " whole blood should be collected in K2 or K3 EDTA anticoagulants." 3. On the day of the survey, 06/011/2024 at 2:31 pm, the laboratory could not provide documentation for the performance specifications established when performing WBC and PLT counts using sodium citrate anticoagulant (blue top tube) for Sysmex 550 analyzer from 10/19/2022 to 06/11/2024. 4. TS#1 confirmed the findings above on 06/11/2024 at 02:31 pm.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of transfusion reaction records, blood bank procedures, and interview with the technical supervisor (TS) #1, the laboratory failed to ensure transfusion reaction investigations were completed and documented per the laboratory's established procedures from 02/24/2021 to 06/12/2024. Findings Include: 1. The laboratory's transfusion reaction procedure states, "Do not give out another unit

	of blood on the patient without first completing a transfusion workup and the pathologist has reviewed it." "In all suspected transfusion reactions, complete the first six steps in the investigation record before going forward. These steps are : A Check identification of patient and of donor blood. B Clerical Check on unit card,log book, and container label for errors. C Check for visible hemolysis or icterus in reciepient pre-and post-transfusion blood sample. D Repeat ABO and Rh tests on pre-transfusion sample and on blood from the bag or from a segment still attached to the unit. Test post-reaction sample for ABO and Rh. E Direct antiglobulin test on pre-and post-tranfusion blood sample. F. Examine post-reaction urine specimen for the presence of free hemoglobin." 2. On the day of survey, 06/12/2024, at 09:30 am, a review of 1 of 1 (32956) transfusion reaction record revealed the laboratory failed to ensure transfusion reaction investigations were completed and documented per the laboratory' established procedures from 02/21/2021 to 06/12/2024. 3. The laboratory failed to provide documentation for the following steps in the transfusion reaction workup performed on 02/24/2021: - Pathologist review of the post transfusion workup. - Examination of the post reaction urine specimen for the presence of hemoglobin 4. TS #1 confirmed the findings above on 06/12/2024 at 10:30 am.