

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0045094	(X3) Date Survey Completed 08/15/2024
Name of Provider or Supplier Massac Memorial Hospital	Street Address, City, State 28 Chick Street, Metropolis, IL	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of AccuTest proficiency testing (PT) records, lack of documentation, and interview with laboratory testing personnel (TP) #9; the laboratory failed to attest to the routine integration of PT samples into the patient workload for six of six PT events reviewed for blood gas testing. Findings Include: 1. Review of AccuTest PT records found no attestation statements for Routine Chemistry - Blood Gas /Electrolytes (ID: BGAS435) for six of six events: Event: Year: 2 2022 3 2022 1 2023 2 2023 3 2023 1 2024 2. On survey date 08-15-24, at 3:24 pm, TP #9 confirmed the laboratory failed to attest to the routine integration of PT samples for the Accutest Routine Chemistry - Blood Gas/Electrolytes events reviewed.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, lack of documentation, and</p>

interview with technical consultant (TC), the laboratory failed to have a system in place that twice yearly evaluates and defines the comparison of test results between the two Sysmex Hematology instruments for seven of seven analytes including reticulocyte count, white blood cell count, red blood cell count, hemoglobin, hematocrit, platelet count, and automated white blood cell differential. Findings Include: 1. Upon a tour of the laboratory on 08-15-2024, at 11:50 AM, direct observation identified two Sysmex instruments: a XN-350 (serial number:15141) and a XN-1000 (serial number:16838). 2. Review of laboratory test menu identified the seven above hematology analytes performed on the two Sysmex analyzers. 3. Review of laboratory records revealed a lack of instrument-to-instrument comparison documentation for seven of seven hematology analytes performed on the two Sysmex hematology analyzers. 4. On survey date 08-15-2024, at 11:53 am, the TC confirmed no instrument-to-instrument comparison had been completed for the seven of seven hematology analytes on the two Sysmex hematology analyzers.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(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 review of employee competency assessments and interview with testing personnel (TP) #9; the technical consultant (TC) failed to ensure semi-annual competency assessments were performed by a qualified TC for two of two TP responsible for moderate complexity arterial blood gas (ABG) testing during the first year the individuals tested patient specimens. Findings: 1. Upon record review, two of two ABG TP (#13 and #16) semi-annual competency assessments were not performed by a qualified technical consultant. TP13's 03-21-2024 ABG assessment was performed by TP #10. TP13's 07-30-2024 ABG assessment was performed by TP #9 and TP #10. TP16's 06-24-2023 ABG assessment was performed by TP #10. TP16's 11-24-2023 ABG assessment was performed by TP #10. 2. An interview with TP #9 on 08-15-2024, at 03:24 pm, confirmed that two of two of the testing personnel's semi-annual competency assessments were not performed by a qualified technical consultant.