Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0305356	06/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Medical Center	220 Hospital Drive, Jackson, AL	

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
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records and an interview with the General Supervisor, the laboratory failed to participate in Proficiency Testing for Routine Chemistry. This was noted for one out of four Chemistry events reviewed from November 2021 to the date of the current survey, 6/7/2023. The findings include: 1. A review of American Proficiency Institute PT records revealed the laboratory scored 0% on all analytes for 2023 Chemistry 1st due to failure to submit results within the time frame established by the PT provider. No documentation of additional accuracy verification was available for review. 2. During an interview on 6 /6/2023 at 2:00 PM, the General Supervisor confirmed the above findings.
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 a review of Beckman Coulter Access 2 validation records, a review of American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the General Supervisor, the laboratory failed to verify the accuracy of Vitamin B12 and Folate at least twice annually. This was noted for one out of one Chemistry Proficiency Testing events reviewed since the implementation of these analytes. The findings include: 1. A review of validation records revealed the laboratory added Vitamin D, Vitamin B12, Folate, and Parathyroid Hormone (PTH) to the testing menu of the Beckman Coulter Access 2 as of 11/30/2022. 2. A review of API records revealed Vitamin D and PTH were added to the laboratory's PT menu, however, Vitamin B12 and Folate were not added. 3. During an interview on 6/6/2023 at 2:00 PM, the General Supervisor confirmed Vitamin B12 and Folate were not added to the 2023 PT order, and the laboratory had not implemented another mechanism to verify semi-annually the accuracy of these non-regulated Chemistry analytes.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of OPTI CCA-TS2 Calibration Verification records, a review of RNA Medical CVC 123 Calibration Verification Controls package insert, and an interview with the General Supervisor, the laboratory failed to perform Calibration Verification procedures according to manufacturer's instructions. This was noted for three out of three calibration verifications reviewed. The findings include: 1. A review of OPTI CCA-TS2 Calibration Verification records revealed one run of five levels of CVC 123 controls for pH, pCO2, and pO2 on 6/8/2022, 6/29/2022, and 1/12/2023. 2. A review of the CVC 123 Calibration Verification Controls package insert revealed the following: "...Repeat steps 2 through 5 for the remaining ampoules of Level 1 until

	three replicates are completed...Test Levels 2, 3, 4, and 5 the same way..." 3. During an interview on 6/7/2023 at 11:30 AM, the General Supervisor confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of Personnel records and an interview with the General Supervisor, the Technical Consultant failed to evaluate competency for Testing Personnel at least semiannually within the first year of patient testing. This was noted for one out of two new Testing Personnel that would be eligible to have a semiannual competency assessment performed since the date of the previous survey (11/21/21). The findings include: 1. A review of Personnel records for Testing Personnel #6 revealed only documentation of initial training, dated 10/3/2022. There was no record of the semiannual competency assessment due the first half of 2023 for Testing Personnel #6. 2. During an interview on 6/6/2023 at 12:00 PM, the General Supervisor confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of Personnel records and an interview with the General Supervisor (also Testing Personnel #7), the Technical Consultant failed to perform and document the annual competency for one out of three Testing Personnel previously qualified during the last survey (11/21/21). The findings include: 1. A review of Personnel records for Testing Personnel #7 (also the General Supervisor) revealed no documentation of the 2022 annual competency assessment. The laboratory only provided the most recent competency evalulation, dated 6/5/2023. 2. During an interview on 6/6/2023 at 12:00 PM, the General Supervisor confirmed the above findings.