Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0305356	11/03/2021
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the Form CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification and an interview with the General Supervisor, the laboratory failed to enroll in a proficiency testing (PT) program for Chemistry - Endocrinology Human Chorionic Gonadotropin (hCG) (this is a regulated moderate-complexity test). This was noted from the previous survey (January 2019) to the current survey (November 2021). The findings include: 1. A review of the Form CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification revealed the test menu included Human Chorionic Gonadotropin (hCG) performed on the Beckman Coulter Access II analyzer. 2. During an interview on 11 /02/2021 at 02:20 PM, the General Supervisor confirmed the laboratory was not enrolled in PT for hCG; patient testing was performed, starting in 2019 thru November 2021.
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 laboratory records and an interview with the Laboratory Director, the laboratory failed to verify the accuracy of Urine Sediment, Vaginal Wet Prep, Vaginal Wet Prep KOH (potassium hydroxide), and direct antiglobulin test (DAT) at least twice annually. This was noted from the previous survey in 2019 thru November 2021. The findings include: 1. A review of the Urine Sediment records, Vaginal Wet Prep records, Vaginal Wet Prep KOH records, and DAT records revealed a lack of accuracy verification performed at least twice annually. 2. During an interview on 11/02/2021 at 2:20 PM, the General Supervisor confirmed the above test did not have accuracy verification at least twice annually from the previous survey in 2019 thru November 2021.
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 the OPTI CCA-TS2 Blood Gas calibration verification records and an interview with the General Supervisor, the laboratory failed to perform calibrations verifications at least every six months as per CLIA regulations. The laboratory missed performing one of three calibration verifications due during the review period of 06/19/2020 (installation of the instrument) thru November 2021. The findings include: 1. A review of the OPTI CCA-TS2 Blood Gas calibration verification records revealed no calibration verification in July of 2021. The previous calibration verifications were performed on 06/19/2020 and 01/11/2021. 2. During an interview on 11/02/2021 at 4:00 PM, the General Supervisor confirmed the laboratory had not performed calibration verification since 01/11/2021.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Chemistry quality control (QC) records for the Access 2 analyzer, Coagulation QC for the ACL Elite analyzer, and an interview with the General Supervisor, the laboratory failed to ensure at least two levels of quality control were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted two days out of 6 months reviewed from March 2019 to August 2021 for Coagulation. For Chemistry this was noted ten days out of 5 months reviewed from March 2019 to September 2021. The findings include: 1. A review of the QC records for the Access 2 analyzer revealed the following: a) Free Thyroxine (FRT4) i) 10/28/2019 (6 patients run) and 10/31/2019 (4 patients run); Level 1 control was not run ii) 01/20/2020 (4 patients run), 01/21/2020 (2 patients run), 01/28/2020 (1 patient run), and 01/31/2020 (2 patients run); Level 1 was not run (except 01/28/2020 when Level 1 was unacceptable) iii) 09/09/2021 (1 patient run); Level 2 was unacceptable b) Human Chorionic Gonadotropin (hCG) i) 10/12/2019 (1 patient run); Level 1 was not run ii) 01/22/2020 (1 patient run); Level 1 was not run c) Prostate-Specific Antigen (PSA) i) 10/28/2019 (4 patients run); Level 1 was not run ii) 01/20 /2020 (1 patient run), 01/21/2020 (2 patients run), 01/28/2020 (3 patients run), and 01 /31/2020 (3 patients run); Level 1 was not run (except 01/28/2020 when Level 1 was unacceptable) iii) 09/04/2021 (1 patient run); Level 2 was unacceptable d) Thyroid-Stimulating Hormone (TSH) i) 01/20/2020 (11 patients run), 01/21/2020 (9 patients run), 01/28/2020 (15 patients run), and 01/31/2020 (7 patients run) Level 1 was not run (except 01/28/2020 Level 1 was unacceptable). 2. A review of the QC records for ACL Elite analyzer revealed the following: a) 03/24/2019-Partial thromboplastin time (PTT) Level 1 was unacceptable (two patients run) b) 08/07/2021-Partial thromboplastin time (PTT) Level 1 was unacceptable (one patient run). 2. During an interview on 11/03/2021 at 11:35 AM, the General Supervisor confirmed the above findings.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on a review of personnel records and interview with the General Supervisor, the Laboratory Director failed to ensure semi-annual and annual competency evaluations assessed the six specific skills required by CLIA for testing personnel in the laboratory. This was noted on eight of eight Testing Personnel (TP) listed on the CMS-209 Form. The findings include: 1. A review of personnel records revealed

	competency for laboratory testing personnel was assessed using the "Position Description / Performance Evaluation". This form was a general Human Resources assessment form; there was no semi-annual and annual competency evaluation of skills required by CLIA for testing personnel for each testing system used in the laboratory. The 6 skills required by CLIA are the following: a) direct observation of routine patient test performance, b) monitoring the recording and reporting of test results, c) review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records, d) direct observation of performance of instrument maintenance and function checks, e) assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples, and f) assessment of problem solving skills. 2. During an interview on 11/02/2021 at 12:45 AM, the General Supervisor confirmed the above findings.