

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/08/2021  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  11D0888460	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____	(X3) DATE SURVEY COMPLETED  04/28/2021
NAME OF PROVIDER OR SUPPLIER  SAVANNAH MEDICAL CLINIC			STREET ADDRESS, CITY, STATE, ZIP CODE 120 EAST 34TH STREET SAVANNAH, GA 31401	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D 000	INITIAL COMMENTS	D 000		
D1001	<p>A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 28, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:</p> <p><b>CERTIFICATE OF WAIVER TESTS CFR(e): 493.15(e)</b></p> <p>Laboratories eligible for a certificate of waiver must--</p> <p>(1) Follow manufacturers' instructions for performing the test; and</p> <p>(2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of quality control (QC) logs, observation during the laboratory tour, review of laboratory test package inserts, and staff interview, the laboratory failed to follow current manufacturer's instructions for all waived tests performed by the laboratory as required.</p> <p>Findings include:</p> <p>1. Review of waived test package inserts and observation during the laboratory tour on 04/28/21 at approximately 11:00 a.m. revealed there were no required QC logs available at the time of survey for the following waived tests: Urine Human Chorionic Gonadotropin (hCG) (Henry Schein) and Microhematocrit (Clay Adams Readacrit) for 2019, 2020 or 2021 thus far.</p> <p>2. An interview with staff #3 (CMS 209) in the lab at approximately 11:10 a.m. on 10/28/2021 confirmed the lack of QC documents for the</p>	D1001	<p>1. <u>How the deficient practice will be corrected?</u> Quality Control Logs will be instituted immediately for the Urine Human Chorionic Gonadotropin (hCG) and Microhematocrit (Clay Adams Readacrit)</p> <p>2. <u>Were any patients found to have been affected by the deficient practice?</u> The laboratory determined that no patients test result or care were affected after review using waived test controls monitoring.</p> <p>3. <u>What measure has been put in place to insure the deficient practice does not recur?</u> Quality controls have been instituted for waived tests cited. No patients will be affected going forward due to corrective actions taken.</p> <p>4. <u>What quality controls has been put in place or what systematic changes have been made to ensure that the deficient practice does not recur?</u> QA controls and documentation have been added to QA daily laboratory log sheet. Microhematocrit (Clay Adams Readacrit) will be tested each morning of use. New Urine Human Chorionic Gonadotropin (hCG) box will be tested upon opening. Results will be documented.</p>	05/21/21

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

*Lawrence W. Miller, MD*

TITLE

LABORATORY DIRECTOR

(X6) DATE

5/14/21

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See Instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

Rec'd 5/18/21