

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0680088	(X3) Date Survey Completed 05/10/2018
Name of Provider or Supplier Warrington Clinic	Street Address, City, State 551 Medical Drive, Clarksdale, MS	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Cell Dyn Emerald hematology analyzer maintenance form from 7/1/16 to 5/10/18 and interview with staff at 11:30 am on 5/10/18, the laboratory failed to document as performed the Semi Annual maintenance on the Cell Dyn Emerald analyzer as required by the manufacturer. The following maintenance was not documented as performed according to the required maintenance instructions of the manufacturer: Semi Annual Maintenance: Lubricate the pistons (last performed on 11/28/16).</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p>

This STANDARD is not met as evidenced by:
Based on Cell Dyn Emerald calibration documentation and interview with testing personnel at 10:00 am on the day of survey, 5/10/18, the laboratory failed to perform the required calibration on the Medonic Cell Dyn Emerald hematology analyzer at least once every 6 months according to the frequency required by the manufacturer. Since the last survey, 6/28/16, calibration was documented as performed on 4/29/16 and then again on 11/28/16. This time frame exceeds the 6 month manufacturer's calibration requirement.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on surveyor review of written quality assessment (QA) policies and procedures, it was determined the laboratory director failed to ensure that a comprehensive QA program designed to monitor and evaluate the overall quality of the total testing process (general laboratory, preanalytic, analytic and postanalytic systems) was maintained and followed to assure the quality of the laboratory services provided. Findings include: The laboratory director had not ensured that the following parts of the written laboratory QA program were being followed: 1. Proficiency Testing - Technical consultant did not review results within one week of receipt as stated in the QA Plan for the following: 2016--2nd and 3rd events, 2017--all 3 events, and 2018--1st event. 2. Performance and Periodic Review of Quality Control, Proficiency Testing And Patient Results-Technical consultant failed to review and sign every 3 months as stated in the QA policy for the following: quality control, proficiency testing, temperature logs, quality control records, calibration and maintenance from 6 /28/16 through 5/10/18. THIS IS A REPEAT DEFICIENCY

D6049

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

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on review of laboratory records (including quality control, calibrations, temperatures, maintenance and proficiency testing results) since the last survey (6/28 /16) through the day of survey, 5/10/18, and confirmation with staff at 1:30 pm, the technical consultant listed on the CMS(Centers For Medicare & Medicaid) 209 Personnel form before the day of survey, failed to document as reviewed the laboratory records. The following records were not reviewed by the technical consultant appointed during that time: 1. Refrigerator, humidity and room temperature

records from 11/30/16 through 5/10/18 2. Cell Dyn Emerald QC (quality control) 3. Cell Dyn Emerald calibration - 1/10/17 through 12/29/17 4. Cell Dyn Emerald Maintenance - 7/1/16 through 4/3/18 5. Affirm VP III QC, heat block - 11/18/16 through 5/9/18 6. Proficiency testing event results- 1st and 2nd of 2017 and 1st of 2018