

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0706982	(X3) Date Survey Completed 05/09/2018
Name of Provider or Supplier Warrington Clinic - Shelby	Street Address, City, State 1209 1/2 Broadway, Shelby, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Cell Dyn Emerald analyzer records from last survey, 6/15/16, through day of this survey and confirmation with staff at 3:00 pm, the laboratory failed to retain the quality control (QC) assay sheets to include but not limited to acceptable ranges, storage requirements, lot numbers and standard deviations for at least 2 years. Findings include: Review of the Cell Dyn Emerald QC assay sheet in use the day of survey and other hematology records, it was determined the laboratory did not retain all QC assay sheets with the change of a new lot number of hematology low, normal and high controls. On the day of survey the following lot numbers of QC assay sheets were not available: Cell Emerald Control Lot Numbers: #6130, #7352, #7268, #7184, #6298 and #6214.</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</p>

acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on Cell Dyn Emerald calibration documentation and interview with testing personnel at 4:00 pm on the day of survey, 5/9/18, 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, 6/15/16, calibration was documented as performed on 7/14/16 and 4/21/17. 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. 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 6/15/16 through 5/9/18. 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 results) since the last survey on 6/15/16, through the day of survey, 5/9/18, and confirmation with staff at 4:30 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 5/16/16 through 5/9/18. 2. Cell Dyn Emerald QC (quality control), calibration, maintenance - 6/15/16 through 5/9/18. 3. Proficiency testing event results- 3rd event of 2016, 1st and 2nd events of 2017 and 1st event of 2018.