

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1098464	(X3) Date Survey Completed 04/09/2019
Name of Provider or Supplier Alabama Cancer Care	Street Address, City, State 171 Town Center Dr Suite 6, Anniston, 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
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 a review of the Medonic Hematology analyzer quality control (QC) records, and an interview with the Testing Personnel, the surveyor determined the laboratory failed to retain the manufacturer's QC assay sheets (package inserts) for two years (2017-2018) as per CLIA regulatory requirements. The findings include: 1. A review of the Medonic Hematology analyzer QC records revealed no retention of the manufacturer's QC assay sheets (package inserts) for two years (2017-2018) except for the current lot number of QC in use. 2. During an interview on 4/9/2019 at 3:10 PM, the Testing Personnel confirmed the above noted findings. .</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 reviews of the Medonic Hematology analyzer calibration records and the Medonic Procedure Manual, and an interview with the Testing Personnel, the surveyor determined the laboratory failed to perform two out of three calibrations in 2018 and 2019 as frequently as required by the manufacturer. The findings include: 1. A review of the Medonic M Series Hematology Analyzer Procedure Manual on page 18 revealed, "...Calibration: Required every six months...". 2. A review of the Medonic Hematology analyzer records revealed calibrations were performed as follows: A) 6/8/2017 (during installation of the new analyzer) B) 2/2/2018 (eight months after the previous calibration) C) 7/11/2018 D) 3/1/2019 (eight months after the previous calibration) 3. During an interview on 4/9/2019 at 3:00 PM, the Testing Personnel (TP) confirmed the calibrations in early 2018 and 2019 were performed later than required by the manufacturer since calibrations should be performed every six months. The TP further stated the laboratory had experienced multiple problems with their vendor delivering calibrators and quality controls late or to the wrong location. .

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on reviews of the Hematology quality control (QC) records and the patient logs, and an interview with the Testing Personnel, the laboratory failed to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results on two days in August 2017. The findings include: 1. A review of the QC records for the Medonic Hematology analyzer revealed all three levels of QC were outside acceptable ranges on 8/1/2017 and 8/2/2017. 2. A review of the patient logs revealed eight patient CBCs (Complete Blood Counts) were performed on 8/1/2017, and thirteen CBCs were run on 8/2/2017. 3. During an interview on 4/9/2019 at 3:05 PM, the Testing Personnel reviewed and confirmed the above noted findings. .

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a review of patient results reports and an interview with the Testing Personnel, the laboratory failed to ensure reports included the correct address of the laboratory performing the testing. The findings include: 1. On 4/9/2019 at 3:25 PM, the Testing Personnel (TP) was asked about the post-analytical process in the facility, and how patients can obtain copies of their test results for themselves or a consulting physician. The TP explained laboratory results may be printed from the Cure MD electronic medical record (EMR) upon request. An example of a CBC (Complete Blood Count) report was provided for review. 2. As the interview continued on 4/9/2019, the surveyor and the TP reviewed the report from the EMR which listed a Gadsden address in the upper left hand corner. The TP then confirmed the address was for the Alabama Cancer Care's Gadsden location, not the Anniston location where this CBC had been performed. Thus the above noted findings were confirmed.

SURVEYOR ID #32558 Licensure and Certification Surveyor