

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0303490	(X3) Date Survey Completed 04/19/2018
Name of Provider or Supplier Gadsden Medical Clinic	Street Address, City, State 601 South 3rd Street, Gadsden, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2016 - 2018 CAP (College of American Pathologists) Proficiency Testing records and an interview with Testing Personnel #1, the laboratory failed to document reviews of six of six of the returned survey evaluations results, and failed to document corrective action for two of six surveys with results less than 100 % (percent). The findings include: 1. A review of the CAP Proficiency Testing records revealed no documentation of review (as indicated by the signature of the Laboratory Director) of the returned evaluations for five Hematology surveys in 2016-2017 or the first survey in 2018. 2. A review of the survey results revealed no documentation of investigation or corrective action for two surveys with results less than 100% as follows: A) 2017 FH2-C Hematology: MCH (Mean Corpuscular Hemoglobin) and MCHC (Mean Corpuscular Hemoglobin Concentration) with scores of 80% each B) 2018 FH2-A Hematology: MCH with a failing score of 60% 3. In an interview on 4/20/2018 at 9:55 AM, Testing Personnel #1 was asked if the Laboratory Director reviewed the returned proficiency testing results and if the laboratory had performed corrective action for the analytes with scores less than 100%. Testing Personnel #1 stated she did not know this was required, thus confirming 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</p>

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.

This STANDARD is not met as evidenced by:

Based on reviews of the Beckman Coulter AcT diff 2 calibration and quality control records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC), for three out of four calibrations of the Hematology analyzer performed in 2016 - 2018. The findings include: 1. A review of calibration records for the Beckman Coulter AcT diff 2 revealed the instrument was calibrated on the following dates: A.) 9/14/2016 at 12:25 PM B.) 3/22/2017 at 11:31 AM, and C.) 4/05/2018 at 2:54 PM However, there was no documentation QC was run after the calibrations. 2. A review of the Coulter AcT diff Operator's Guide, under the CALIBRATION section on page 5-18 revealed, "...17. Verify calibration by running 4C PLUS Cell Control. ..." 3. During an interview and review of the QC records on 4/19/2018 at 12:05 PM, TP #1 confirmed controls were only run in the morning on the above calibration dates. 4. During the exit summation on 4/19/2018 at approximately 1:45 PM with TP #1, the manufacturer's direction to perform QC after calibration of the Hematology analyzer were reviewed in the operator's manual. TP #1 stated she had not previously known of this requirement, thus the above noted findings were confirmed. .

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 a review of the Beckman Coulter AcT diff 2 Hematology analyzer quality control (QC) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure at least two levels of Hematology QC were within acceptable limits before patient testing began. This was noted on two days of patient CBC (Complete Blood Count) testing in 2016 and 2017. The findings include: 1. A review of the Hematology cumulative QC report revealed the following days when QC was outside acceptable ranges on days of patient testing: A) 5/23/2016: Low and Normal QC out with 6 patient CBCs tested B) 7/10/2017: Low and Normal QC out with 8 patient CBCs tested 2. During an interview and review of the QC records on 4/19/2018 at 12:05 PM, Testing Personnel #1 confirmed two out three controls were out of acceptable ranges without being repeated on the above dates. .

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an

ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of quality assurance documentation and interviews with the Testing Personnel #1, the surveyor determined the laboratory failed to implement effective timely quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance documentation revealed the laboratory performed quality assurance activities, however the reviews were inadequate to discover and perform corrective action in a timely manner for problems found during the survey in the following areas: A.) Failure to ensure there was documentation of the Laboratory Director/Technical Consultant's review of the returned results evaluations with investigation and corrective actions for scores less than 100% (Refer to D5221.) B) Failure to ensure testing personnel verified calibrations on the Hematology analyzer by running quality controls as specified by the manufacturer's instructions (Refer to D5437.) C) Failure to ensure Hematology QC was reviewed monthly to ensure two levels of Hematology QC were performed and within acceptable ranges each day of patient testing (Refer to D5481.) D) Failure to ensure annual competency assessments were performed and documented for two testing personnel who performed moderate complexity patient testing (Refer to D6054.) 2. The laboratory also failed to document problems (in a problem log or other mechanism) and corrective actions taken when problems occurred. 3. During the exit summation on 4/19/2018 at approximately 1:50 PM, the surveyor's concern that the lab processes (proficiency testing, calibrations, QC and competency assessments) were not being regularly reviewed and documented in a timely manner by the Laboratory Director was discussed with Testing Personnel #1. .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a lack of documentation in the personnel files and an interview with Testing Personnel (TP) #1, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to ensure annual competency evaluations were performed and documented for two of two testing personnel in 2016-2018. The findings include: 1. A review of the Form CMS-209 revealed two testing personnel who had performed moderate complexity testing in Hematology since the previous survey on 3/15/2016. However, the laboratory did not provide documentation of the annual competency assessments during the survey. 2. During the exit summation on 4/19/2018 at approximately 1:50 PM, TP #1 was asked if there was any documentation of competency assessments for the testing personnel; TP #1 stated the Laboratory Director had observed them performing the tests, but they had no formal documentation of the annual assessments. Thus the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor