

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0313215	(X3) Date Survey Completed 01/21/2020
Name of Provider or Supplier Crockett Medical Clinic, Inc	Street Address, City, State 58 South Bells St, Alamo, TN	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory director / designee failed to sign the attestation statement for 2018 event three. The findings include: 1) Review of the laboratory's proficiency testing records revealed the attestation statement for 2018 event three had not been signed by the laboratory director or designee. 2) Interview with the lead testing personnel on January 21, 2020 at 11:45 a.m. confirmed the laboratory director / designee failed to sign the proficiency testing statement for 2018 event three.</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, proficiency testing records, and interview with the lead testing personnel, the laboratory director failed to ensure the</p>

proficiency testing corrective action plan was followed for unacceptable proficiency testing results in 2018. The findings include: 1) Review of the laboratory procedure manual revealed that corrective action is to be performed for any unacceptable proficiency testing result. 2) Review of the laboratory's proficiency testing records revealed an unacceptable score for 2018 event two, sample number HD-6. The report was signed by the technical consultant. No corrective action was documented for the unacceptable result. 3) Interview with the lead testing personnel on January 22, 2020 at 11:45 a.m. confirmed the laboratory director failed to ensure the proficiency testing corrective action plan was followed for 2018 event two.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of patient test reports, the validation studies for the Beckman Coulter AcT Diff 2, and interview with the lead testing personnel, the technical consultant failed to review and approve validation studies for the Beckman Coulter AcT Diff 2 instrument prior to patient complete blood count (CBC) testing in 2018. The findings include: 1) Observation of the laboratory on January 21, 2020 at 7:45 a.m. revealed the Beckman Coulter AcT Diff 2 CBC instrument (serial number 49482072) in use for patient CBC testing (new since the last survey date.) 2) Review of the first patient reported from the new instrument (patient number one) revealed patient testing began on June 21, 2018. 3) Review of the validation studies performed for the Beckman Coulter AcT Diff 2 CBC instrument revealed the studies had not reviewed or approved by the technical consultant. 4) Interview with the lead testing personnel on January 21, 2020 at 11:45 a.m. confirmed the technical consultant failed to review and approve the validation studies for the Beckman Coulter AcT Diff2 CBC instrument prior to patient testing in 2018.