Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0313215	05/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Crockett Medical Clinic, Inc	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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the 2016 and 2017 proficiency testing (PT) records and interview with testing personnel number one, the laboratory failed to maintain the 2016 and 2017 events three attestation records. The findings include: 1) Review of the 2016 and 2017 PT records revealed no attestation records for 2016 event three and 2017 event three. 2) Interview on May 18, 2018 at 10 am with testing personnel number one confirmed the 2016 and 2017 events three attestation records could not be located.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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. This STANDARD is not met as evidenced by: Based on review of the 2016 PT records, the quality assessment (QA) plan and interview with the technical consultant, the laboratory director failed to ensure the corrective action plan is following with unacceptable PT scores. The findings include: 1) Review of the 2016 and 2018 PT records revealed the 2016 event two platelet score of 60% with no corrective action performed, the technical consultant signed review on 8-10-16. 2) Review of the QA plan revealed corrective action is to be performed and documented for unsatisfactory scores. 3) Interview on May 18, 2018 at 11:30 a.m. with the technical consultant confirmed the QA plan was not followed and no PT corrective action was performed and documented.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the May 19, 2017 to August 25, 2017 and December 2017 CBC quality control (QC) records, the 2017 patient data logs, the QA monthly review records, and interview with testing personnel number one, the laboratory director failed to ensure the QC program was maintained in 2017. The findings include: 1) Review of the May 19, 2017 to August 25, 2017 CBC QC records revealed the acceptable normal QC limits were incorrectly entered into the CBC instrument. December 22, 2017 two levels of QC were not acceptable for the platelet count. 2) Review of the 2017 patient data log revealed patient testing was performed May 19, to August 25, 2017 and December 22, 2017. 3) Review of the monthly QA review records revealed the technical consultant signed review (no date of review) with the statement, "All parameters were in normal control according to the pool." 2) Interview on May 18, 2018 at 11:00 am with testing personnel number one confirmed the normal QC acceptable limits were entered incorrectly into the CBC instrument, the December 22, 2017 platelet count did not have two levels of QC acceptability. The technical consultant signed review of the QA with no corrective actions performed and documented.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the competency assessment records for the laboratory testing

	personnel and interview with testing personnel number one, the Technical Consultant failed to document review for five testing personnel performing Hematology CBC testing in 2017 and 2018. The findings include: 1. Based on review of the competency assessment records for testing personnel one, two, three, four and five revealed the technical consultant failed to have a documented review for 2017 and 2018. 2. Interview with testing personnel number one on May 18, 2018 at 9:30 a.m. confirmed the Technical Consultant failed to document a review of the 2017 and 2018 competency assessments for five testing personnel performing CBC patient testing.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the testing personnel records and interview with testing personnel number one, the Technical Consultant failed to perform and document a semi-annual competency evaluation for the CBC in 2016 and 2017. The findings include: 1. Review of the testing personnel records revealed no semi-annual competency performed and documented for the following: testing personnel: number two initial training date September 2017; number three initial training date 5.32.16; number four initial training date 5.23.16, and number five initial training date 5.20.16. 2. Interview on May 18, 2018 at 9:45 am with testing personnel number one confirmed that no semi-annual competency evaluation for the CBC was documented performed and documented for testing personnel numbers two, three, four and five.