Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0700305	06/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Livingston Clinic	219 Eastwood Ave, Livingston, TX	

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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: . Based on review of American Association of Bioanalysts (AAB) hematology proficiency testing documentation for the first event of 2018, confirmed by staff interview, the laboratory failed to score at least 80 percent of acceptable responses for the analytes erythrocytes and hematocrit using the Coulter AcT diff 2 analyzer. Findings: 1. AAB proficiency testing documents for hematology in the first quarter 2018 showed the following unsatisfactory scores: a. Erythrocytes-60% b. Hematocrit-0% 2. In an interview at the site on 06-19-2018, testing person 1 (CMS form 209) stated that she had examined the scores when they arrived and was aware of the unsatisfactory results. A review of instrument printouts for the testing event showed no clerical errors. .
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	This STANDARD is not met as evidenced by: . Based on review of American Association of Bioanalysts (AAB) hematology proficiency testing results for the first event of 2018, confirmed by staff interview, the laboratory failed to take corrective action for unacceptable scores in hematology. Findings: 1. AAB proficiency testing scores for the first quarter 2018 were reviewed. Scores for hematology testing, using the Coulter AcT diff 2 analyzer, showed unacceptable scores as follows: a. Sample 4-Erythrocytes-reported: 5.23 expected range: 5.35-6.03 b. Sample 5-Erythrocytes-reported: 2.16 expected range: 2.18-2.46 c. Sample 1-Hematocrit-reported: 48.1 expected range: 48.7-55.0 d. Sample 2-Hematocrit-reported: 35.6 expected range: 36.3-40.9 e. Sample 3-Hematocrit-reported: 16.1 expected range: 16.3-18.3 f. Sample 4-Hematocrit-reported: 46.3 expected range: 48.5-54.7 g. Sample 5-Hematocrit-reported: 15.7 expected range: 16.3-18.4 (erythrocytes are reported as millions per microliter; hematocrit as percentage of total volume) 2. Documentation for the first quarter 2018 did not include remedial action for the unacceptable scores. 3. In an interview at the site on 06-19-2018, testing person 1 (CMS form 209) stated that no such action had been taken. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on surveyor observation, review of laboratory procedures and quality control documentation for the Coulter AcT Diff 2 hematology analyzer for 2016 and 2017, confirmed by staff interview, the laboratory failed to establish a procedure to monitor control results over time. Findings: 1. During review of hematology quality control documentation for 2017, a cumulative record of control results was requested. None could be provided. In an interview at the site on 06-19-2018, testing person 1 stated she did not know whether the analyzer was capable of producing a list of results for a particular control lot or date range. 2. Review of the operator's manual for the Coulter AcT Diff 2 hematology analyzer revealed that the instrument could produce a listing of control results as well as Levy-Jennings plots for the current control lot. 3. In an interview at the site on 06-19-2018, testing persons 1 and 2 both stated they had not been trained in the procedure for producing and printing cumulative reports of quality control results. The laboratory was, therefore, unable to monitor changes in test system performance over time. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on surveyor observation, review of hematology quality control documentation for 2016 and 2017 and staff interview, the laboratory director failed to ensure that laboratory testing personnel received appropriate training in the operation of the Coulter AcT Diff 2 hematology analyzer. Findings: 1. During review of hematology quality control documentation for 2017, a cumulative record of control results was requested. None could be provided. 2. In an interview at the site on 06-19-2018, testing persons 1 and 2 both stated they had not been trained in the procedure for producing and printing cumulative reports of quality control results.