Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0700305	06/17/2021
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions for the HemoCue Glucose 201 Microcuvettes, a review of the laboratory's quality control records, a random review of patient test records from June 2021, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions and document the running of at least one level of quality control each day of patient testing for the HemoCue glucose meter. Findings include: 1. A review of the manufacturer's instructions for the HemoCue Glucose 201 Microcuvettes (Document number150702 150311) revealed the following: "The HemoCue Glucose 201 system must be verified on the days of testing using at least one level of commercially available controls. Follow local

	guidelines regarding quality control procedures. Only use controls recommended by HemoCue." 2. A review of the laboratory's quality control record revealed no documentation of the laboratory running at least one level of quality control material each day of patient testing on the HemoCue glucose meter. 3. A random review of patient test records from June 2021 revealed the following patient's samples were run on the HemoCue glucose meter with no documentation of at least one level of quality control material being run: Patient ID: 04141978 Patient ID: 09171946 4. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 6/16/21) on 6/17/21 at 10:40 a.m. in the break room, after review of the records, confirmed that the laboratory did not run quality control on the HemoCue glucose meter. This confirmed the above findings.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of the attestation statement, a review of the Beckman Coulter AcT diff 2 hematology analyzer, a review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records for 2019, 2020, and 2021 and staff interview, it was revealed the laboratory failed to have documentation of testing proficiency samples in the same manner it tested patient samples for 7 of 8 events in 2019, 2020, and 2021 for Hematology testing. Findings include: 1. A review of the AAB's attestation statement, signed by the laboratory's testing personnel for each proficiency testing event, revealed the following: "The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods. The undersigned analyst attests that samples were tested in the same manner as patient samples." 2. A review of the manufacturer's instructions for the Beckman Coulter AcT diff 2 hematology analyzer (PN 4237495B, June 2003) under the section titled "What Flags and Codes Mean" revealed the manufacturer provided actions to take when specific flags were identified on CBC results. For the flag of '*' the manufacturer stated: " '*'Possible sample handling problem. Possible dual RBC population. Possible interference with WBC count. Platelet distribution failure. Possible sample interference or instrument problem. See instructions for +++++, +, or -----." "---- Thoroughly mix and rerun the sample. If flag repeats then Zap the machine and do bleach bath. ++++ Zap and rerun samples. If flag is still present after the rerun Call tech support. XXXX Mix the sample with a wooden applicator and rerun. If repeats ZAP and do bleach bath. If continues call tech support. " 3. A review of the laboratory's AAB proficiency testing records for 2019 and 2020 revealed the following events/samples where the proficiency sample's results were flagged with a '*' by the analyzer and not repeated: a) 2019 Nonchemistry 1st Event Specimen 2: LY, MO, GR, LY#, MO#, GR# Specimen 4: LY, MO, GR, LY#, MO#, GR# b) 2019 Nonchemistry - 3rd Event Specimen 14: LY, MO, GR, LY#, MO#, GR# Specimen

	15: Plt, MPV c) 2020 Nonchemistry- 1st Event Specimen 1: LY, MO, GR, LY#, MO#, GR# Specimen 3: Plt, MPV Specimen 5: LY, MO, GR, LY#, MO#, GR# d) 2020 Nonchemistry - 2nd Event Specimen 9: LY, MO, GR, LY#, MO#, GR# Specimen 10: Plt, MPV e) 2020 Nonchemistry- 3rd Event Specimen 12: LY, MO, GR, LY#, MO#, GR# Specimen 13: Plt, MPV Specimen 14: LY, MO, GR, LY#, MO#, GR# Specimen 15: Plt, MPV f) 2021 Nonchemistry- 1st Event Specimen 2: LY, MO, GR, LY#, MO#, GR# Specimen 4: LY, MO, GR, LY#, MO#, GR# g) 2021 Nonchemistry - 2nd Event Specimen 6: LY, MO, GR, LY#, MO#, GR# Specimen 10: LY, MO, GR, LY#, MO#, GR# 4. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 6/16/21) on 6/17/21 at 11: 20 a. m. in the break room, after review of the records, confirmed the above findings. Key: GR = granulocytes MO = monocytes, eosinophils, basophils Ly = lymphocytes Plt = Platelet MPV = mean platelet volume
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and staff interview, it was revealed that the laboratory failed to make available a written procedure for the laboratory personnel to follow for complete blood count (CBC) testing on the Beckman AcT Diff 2 hematology analyzer. Findings include: 1. A review of the laboratory's policies revealed no documentation of a written procedure for CBC testing on the Beckman AcT Diff 2 hematology analyzer. 2. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 6/16/21) on 6/17/21 at 10: 30 a.m. in the laboratory revealed that the laboratory did not have a policy for hematology. This confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation, a review of the storage conditions for reagents stored in the laboratory's refrigerator, and staff interview it was revealed the laboratory failed to have documentation of monitoring the temperature in the laboratory's refrigerator where laboratory reagents were stored. Findings include: 1. During a tour of the facility on 6/17/21 at 10:20 a.m. the surveyor observed a small under counter refrigerator where the following laboratory reagents were stored: 16 boxes of

	HemoCue Glucose 201 Microcuvettes 1 box of Coulter 4C- ES Cell Control 1 box of HemoTrol Level 3 2. Further review of the laboratory reagents revealed the following storage conditions on the outside of the boxes: HemoCue Glucose 201 Microcuvettes 2 - 8 C Coulter 4C- ES Cell Control 2 - 8 C HemoTrol Level 3 2 -8 C 3. The laboratory was asked to provide documentation of monitoring the temperature of the refrigerator for compliance with the manufacturer's instructions. No documentation was provided. 4. An interview with testing person #2 (as indicated on the CMS 209 form, signed by the laboratory director on 6/16/21) on 6/17/21 at 10:40 a.m. in the break room revealed the facility did not monitor the refrigerator temperature. This confirmed the above findings.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and staff interview, it was revealed that the laboratory director failed to ensure that a quality assessment program was established and maintained to assure the quality of laboratory services provided. Findings include: 1. A review of the laboratory's policies revealed the laboratory director failed to have a written quality assessment policy for the laboratory. 2. The laboratory was asked to provide documentation of a quality assessment policy. No documentation was provided. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 6/16/21) on 6/17/21 at 11:30 a.m. in the break room revealed there was not a quality assessment policy. This confirmed the above findings.
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 review of the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to ensure that 1 of 2 testing personnel had documentation of training on the Beckman Coulter AcT Diff 2 hematology analyzer prior to performing patient testing (refer to D6066).

D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel records, and staff interview, it was revealed that 1 of 2 testing personnel failed to have documentation of training on the Beckman Coulter AcT Diff 2 hematology analyzer prior to performing patient testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 6/16/21) revealed the laboratory identified 2 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed that testing person #2 did not have documentation of training on the Beckman Coulter AcT Diff 2 hematology analyzer prior to performing patient testing. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 6/17/21 at 10:20 a.m. in the break room revealed the laboratory did not have documentation of the training for testing person #2. This confirmed the above findings.