Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0691283	10/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
East Texas Hematology & Oncology Clinic Pa	1202 West Frank Avenue, Lufkin, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
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 review of laboratory policy, American Association of Bioanalyst (AAB) proficiency testing (PT) records from 2020 (events 1, 2, and 3) and 2021 (events 1, and 2), and confirmed in interview, the laboratory failed to analyze proficiency testing materials the same as patient samples for hematology for 5 of 5 testing events

	reviewed. Findings were: 1. Review of the laboratory PT Policy, signed and approved by the laboratory director 7/23/2019, section 4. Testing section a. states "PT samples will be tested in the same manner as patient samples." 2. Review of AAB proficiency testing records from 2020 (events 1, 2, and 3) and 2021 (events 1, and 2) revealed the laboratory ran the CBC's in duplicate prior to the end of the testing window for 5 of 5 testing events. Nonchemistry Event 1 2020: Hematology Sample 2 Tested by TP3 on 2 /14/2020 at 11:30 AM Tested by TP6 on 2/14/2020 at 11:53 AM Hematology Sample 5 Tested by TP 3 on 2/14/2020 at 11:37 AM Tested by TP1 on 2/14/2020 at 11:56 AM Nonchemistry Event 2 2020: Hematology Sample 7 Tested by TP6 on 5/15/2020 at 12:23 PM Tested by TP1 on 5/15/2020 at 12:37 PM Hematology Sample 9 Tested by TP6 on 5/15/2020 at 12:29 PM Tested by TP3 on 5/15/2020 at 12:45 PM Nonchemistry 2020 Event 3: Hematology Sample 13 Tested by TP1 on 9/24/2020 at 04:09 PM Tested by TP3 on 9/25/2020 at 09:51 AM Hematology Sample 14 Tested by TP1 on 9/24/2020 at 04:12 PM Tested by TP6 on 9/25/2020 at 10:49 AM Nonchemistry 2021 Event 1: Hematology Sample 1 Tested by TP5 on 2/12/2021 at 11: 20 AM Tested by TP2 on 2/12/2021 at 12:08 PM Hematology Sample 2 Tested by TP5 on 2/12/2021 at 11:21 AM Tested by TP1 on 2/12/2021 at 12:00 PM Hematology Sample 4 Tested by TP5 on 2/12/20021 at 11:23 AM Tested by TP6 on 2/12/2021 at 11:15 AM Nonchemistry 2021 Event 2: Hematology Sample 7 Tested by TP1 on5/21 /2021 at 12:03 PM Tested by TP6 on 5/21/2021 at 12:31 PM Hematology Sample 8 Tested by TP1 on 5/21/2021 at 12:03 PM Tested by TP5 on 5/21/2021 at 12:11 PM Hematology Sample 9 Tested by TP1 on 5/21/2021 at 12:04 PM Tested by TP2 on 5 /21/2021 at 12:17 PM Hematology Sample 10 Tested by TP1 on 5/21/2021 at 12:05 PM Tested by TP3 on 5/21/2021 at 12:54 PM Tested by TP4 on 5/21/2021 at 12:36 PM 3. An interview with TP1 on 10/26/2020 at 1401 hours in the conference room confirmed that they do not run patient specimens in duplicate by different testing personnel prior to reporting patient results.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based upon a review of proficiency testing (PT) instructions, PT records for program years 2019, 2020, 2021, and staff interview, the laboratory failed to ensure that the attestation statements were signed by the laboratory director for seven of eight events reviewed. The findings included: 1. Review of the proficiency test instructions from the American Association of Bioanalysts (AAB) proficiency testing (PT) program states; "In addition to the analysts' signature, one of the following must sign once for all analytes reported on this form. Director, or Technical Consultant. Or Technical Supervisor." 2. Review of proficiency test records from the American Association of Bioanalysts (AAB) PT program revealed that the laboratory director or designee failed to sign attestation statements in two of three testing events for the year 2019, three of three testing events in 2020, and two of two testing events for 2021. a. 2019 Hematology With Diff Testing event 2 and 3 failed to have a signature of the laboratory director or designee. b. 2020 Hematology With Diff Testing event 1, 2, and 3 failed to have a signature of the laboratory director or designee. c. 2021 Hematology

	With Diff Testing event 1, and 2 failed to have a signature of the laboratory director or designee. 3. Interview with Testing Personnel 1 on October 26, 2021 at 14:00 hours in the conference room confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor observation made on 10/26/2021 at 1400 hours in the laboratory, review of the manufacturer's instructions for the Sysmex XN 430L hematology analyzer, review of patient test records, and confirmed in interview with facility personnel, the laboratory failed to provide documentation of following the manufacturer's instructions to verify patient test results with flags or alerts for 19 of 20 patient results reviewed. The findings include: 1. A review of the manufacturer's instructions for the Sysmex XN-L series hematology analyzer (Code No.BW212660, June 2017) Chapter 5 "IP Messages" (page 5-1 to 5-2) stated the following: "The system judges flags for analysis data based on comprehensive survey of numerical data, distributions and scattergrams, and provides easily-to-understand messages indicating the results. These messages are referred to as "IP (Interpretive Program) messages" ...A positive or Error judgment indicates the possibility of an abnormality. 'Positive judgement is classified into the 3 types shown below. [Diff. Abnormal]: Indicated an abnormal blood cell differentiation value. [Morph. Abnormal]: Indicates an abnormal cell morphology. [Count Abnormal]: Indicates an abnormal blood cell count. The suggested action for these flags was: "If a Positive or Error judgment occurs, check the data and repeat the analysis, or examine carefully in accordance with the protocol of your laboratory." 2. A review of the purpose statement in laboratory policy titled "Flag Policy" (approved and signed by the laboratory director 1 /11/2021) states: 'The purpose of the flag policy is to provide information on how flags from the Horiba ABX Micros 60 are managed.' 3. When asked for a flag policy for the Sysmex XN 430L hematology analyzer, testing personnel 1(TP1) stated on 10 /26/2021 at 1450 hours 'they do not have one' and that they 'will occasionally rerun specimens to see if the flag clears, but no other steps are taken.'. 4. A review of 20 patient test results from October 26, 2021 revealed the following 19 patient had results with Positive IP flags or alerts that had no documentation of being verified before results were released to the clinician. 110262111166 - Morph. 110262111172 - Morph. 110262111127 - Morph. 110262111129 - Diff. 110262111130 - Count 110262111131 - Morph. Count 110262111159 - Diff. Count 110262111165 - Count 110262111171 - Diff. 110262111135 - Diff. Morph. Count 110262111139 - Count 110262111140 - Diff 110262111143 - Morph. Count 110262111144 - Diff. 110262111145 - Diff. 110262111147 - Morph. 110262111157 - Diff. Morph. 110262111149 - Diff. Morph. 110262111155 - Morph. Count 5. An interview with the TP1 on 10/26/2021 at 1535 hours in the conference room -after her review of the records- confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies for the Sysmex XN 430L hematology analyzer (serial number 11421), review of patient test records and staff interview, the laboratory failed to have documentation of verifying patient normal ranges for 2 of 2 patient normal ranges used for testing CBCs (complete blood count). The findings included: 1. A review of the laboratory's verification studies revealed the laboratory failed to have documentation of verifying patient normal ranges. 2.Review of final patient results found the following two normal ranges were in use. Female: WBC 3.5 - 10 Lymphocytes % 19.3 - 51.7 Lymphocytes absolute 1.2 -3.2 Monos % 4 - 10 Monos absolute 0.3 - 0.8 Eo % 0.7 - 5.8 Eo absolute 0.04 - 0.36 Baso % 0.1 -1.2 Baso absolute 0.01 - 0.08 Ig % 0 - 0 Ig absolute 0 - 0 RBC 3.8 - 5.8 HGB 11 - 16.5 HCT 35 - 50 MCV 80 - 97 MCH 26.5 - 33.5 MCHC 31.5 - 35 RDW 36.4 - 46.3 Platelets 150 - 450 MPV 6.5 - 11 Male: WBC 4 - 12 Lymphocytes % 21.8 - 53.1 Lymphocytes absolute 1.2 - 3.2 Monos % 4 - 10 Monos 0.3 - 0.8 Eo % 0.8 - 7.0 Eo absolute 0.04 - 0.54 Baso % 0.1 -1.2 Baso absolute 0.01 - 0.08 Ig % 0 - 0 Ig absolute 0 - 0 RBC 4 - 6.2 HGB 12 -17 HCT 35 - 55 MCV 80 - 100 MCH 26.5 - 33.5 MCHC 31.5 - 35 RDW 35.1 - 43.9 Platelets 150 - 450 MPV 6.5 - 11 3. Review of patient records revealed the listed CBC ranges were in use for females and males. 4. Review of the annual test volume listed on the CMS-116 form 10/26/2021 lists their 'Total Estimated Annual Test Volume' for the Specialty 'hematology' as 70,410. 5. The laboratory was asked to provide documentation of verifying the patient normal ranges currently in use. No documentation was provided. 6. An interview with the technical consultant on 10/26/2021 at 14:30 hours in the laboratory confirmed that it was unclear where the ranges came from. Key: % - percent Eo - eosinophils Baso - basophils Ig - immature granulocytes RBC - red blood cell WBC - white blood cell HGB - hemoglobin HCT - hematocrit MCV - mean cell volume MCHC - mean corpuscular hemoglobin concentration RDW - red cell distribution width MPV - mean platelet volume
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 instrument verification records for the Sysmex XN 430L

	hematology analyzer, instrument manufacturer installation instructions, laboratory personnel records, and confirmed in interview of facility personnel, the laboratory failed to ensure that four of four testing personnel had documentation of training prior to testing patients when it installed a new hematology analyzer in January 2021. The findings included: 1. Review of instrument verification records for the Sysmex XN 430L hematology analyzer found the laboratory installed the instrument in January 2021. 2. Review of the manufacturer's installation instructions (Verification Document Number: 1251-LSS) section 4: 'Training Checklists and Competencies states: "Proper training of the laboratory personnel is critical to the success of implementing any new process or analyzer ..." 3. Review of the annual test volume listed on the CMS-116 form submitted 10/26/2021 lists their 'Total Estimated Annual Test Volume' for the Specialty 'hematology' as 70,410. 4. Interview with TP1 on 10/26 /2021 at 1345 hours in the conference room confirmed there was no documentation of training on the new analyzer for review. They stated, 'We got trained, but we didn't fill anything out for documentation.'.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Laboratory Personnel Report (CMS Form 209) signed by the laboratory director on 10/262021, personnel records, and staff interview, the laboratory failed to provide education credentials required to perform moderate complexity testing for one of seven testing personnel (refer to D6065). Key: CMS - Centers for Medicare and Medicaid Services
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records, and confirmed in interview of facility personnel, the laboratory failed to ensure that three of six testing personnel (TP) had the appropriate education requirements to perform moderate complexity testing. The findings included: 1. A review of personnel records at the time of the survey revealed that 3 of 6 testing personnel (TP4, TP5, TP6) did not have educational documentation

	available for proof of qualification. 2. An interview with TP1 in the conference room at 09:00 hours on 10/26/2021 confirmed the above findings. They stated they have been short staffed and thought they (TP4, TP5, TP6) would be able to provide their transcripts, but the documentation had yet to be provided. TP4, and TP5, were removed from testing, and TP6's last day would be 10/31/2021.