Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1010541	01/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Silsbee Family Medicine, Pa	280 Hwy 418 East, Silsbee, 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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, laboratory policy, and confirmed in interview, the laboratory failed to test PT samples the same number of times that it routinely tests patient samples for infectious mononucleosis for one of two Immunology/Immunohematology PT events reviewed in 2022. The findings include: 1. Review of the 2022 Immunology/Immunohematology proficiency testing records for events one had a sticky note attached to the result page with the following information: Mono - 3/29/22 1 + 1 + 2 - 2 - 3 + 3 + 4 - 4 - 5 - 5 - 2. Review of the laboratory policy titled "proficiency testing program" Section "Procedure" had the following statement: "No special (multiple) analysis should be performed on the survey material." Surveyor queried testing person (TP) 1 if repeat testing, as indicated by the sticky note, was how routine patients were tested. TP 1 indicated that the laboratory did not repeat mono testing on patients. 3. In an interview on 1/19/2023 at 11:15 hours, in the laboratory, TP 1 confirmed that the laboratory had not tested PT samples in the same manner as it tested patients.
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 laboratory policy, review of proficiency testing (PT) records, and confirmed in interview, the laboratory failed to follow its own policy for the documentation of review of results for PT evaluation reports for two of four PT performance reviews reviewed in 2022. The findings include: 1. Review of the laboratory policy "Assignment of Responsibility of Laboratory Duties" had the following statement: "Laboratory Director must review, sign, and date all proficiency test results." 2. Review of PT "Performance Review and Corrective Action" records for 2022 had the following two PT results with no signature for the documentation of review: 2022 Immunology / Immunohematology - 2nd Event 2022 Hematology / Coagulation - 2nd Event 3. In an interview on 1/19/2023 at 11:15 hours, in the laboratory, testing person (TP) 1 confirmed that the laboratory director had not documented a review of proficiency testing results for the second event in 2022.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, patient test records, laboratory policy, and confirmed in interview, the laboratory failed to document corrective action for seven of seven instances where quality control for the DREW3 hematology analyzer was outside of performance specifications in April of 2022. The findings include: 1. Review of laboratory DREW3 hematology analyzer QC records for April 2022 had the following seven QC failures without documentation of corrective action taken to get QC into performance specifications. 4/11/2022: High Level Control, Lot EX0422H, had the following out-of-range controls at 08:21 hours with no documentation of corrective action taken. Analyte - Value - (Expected Value) WBC - 2.3 - (18.8 - 23.2) LYM% - 50.6 - (9.0 - 19.0) MID% - 12.1 - (0.5 - 6.5) GRAN% - 37.3 - (75.5 - 89.5) LYM# - 1.2 - (1.9 - 3.9) GRA# - 0.9 - (15.8 - 18.8) RBC - 2.24 - (5.33 - 6.01) HGB - 5.9 - (17.1 - 19.9) HCT - 17.7 - (51.1 - 56.7) MCV - 79.0 - (90.0 - 100.0) MCH - 26.3 - (29.8 - 35.4) PLT - 77 - (435 - 575) A review of patient test records had the following three patients tested since the last acceptable QC on 4/8 /2022: Patient ID 00015 00016 00018 4/19/2022: High Level Control, Lot EX0422H, had the following out-of-range controls at 08:07 hours with no documentation of corrective action taken. Analyte - Value - (Expected Value) WBC - 2.4 - (18.8 - 23.2) LYM% - 52.2 - (9.0 - 19.0) GRAN% - 11.5 - (75.5 - 89.5) LYM# - 36.3 - (1.9 - 3.9) MID# - 1.2 - (0.1 - 1.5) GRA# - 0.9 - (15.8 - 18.8) RBC - 2.26 - (5.33 - 601) HGB - 6.1 - (17.1 - 19.9) HCT - 18.0 - (51.1 - 56.7) MCV - 79.8 - (29.8 - 35.4) MCH - 27.0 - (29.8 - 35.4) PLT - 77.0 - (435 - 575) A review of patient test records had the following five patients tested since the last acceptable QC on 4/18/2022: Patient ID 00005 00008 00009 00010 00011 4/20/2023: Low Level Control, Lot EX0422L, had the following out-of-range controls at 08:37 hours with no documentation of corrective action taken. Analyte - Value - (Expected Value) WBC - 8.0 - (1.7 - 2.7)

	LYM% - 29.0 - (41.5 - 55.5) GRAN% - 63.3 - (33.0 - 45.0) LYM# - 2.3 - (0.9 - 1.3) MID# - 0.6 - (0.1 - 0.5) GRA# - 5.1 - (0.7 - 1.1) RBC - 4.32 - (1.97 - 2.47) HGB - 13.2 - (5.4 - 6.6) HCT - 38.0 - (16.0 - 20.0) MCV - 88.0 - (76.0 - 86.0) MCH - 30.6 - (24.6 - 29.4) PLT - 216 - (44 - 104) A review of patient test records had the following three patients tested since the last acceptable QC on 4/19/2022: Patient ID 00004 00005 00006 4/26/2023 Normal Level Control, Lot EX0422N, had the following out-of-range controls at 07:43 hours with no documentation of corrective action taken. Analyte - Value - (Expected Value) PLT - 191 - (205 - 305) High Level Control, Lot EX0422H, had the following out-of-range controls at 07:46, hours with no documentation of corrective action taken. Analyte - Value - (Expected Value) LYM% - 19.6 - (9.0 - 19.0) LYM# - 4.5 - (1.9 - 3.9) High Level Control, Lot EX0422H, had the following out-of-range controls at 07:48, hours with no documentation of corrective action taken. LYM% - 19.6 - (9.0 - 19.0) LYM# - 4.5 - (1.9 - 3.9) A review of patient test records had 22 patients tested since the last acceptable QC on 4/25/2022 to include the five sample patients: Patient ID 00008 00011 00014 00017 00020 4/27 /2023 High Level Control, Lot EX0422H, had the following out-of-range controls at 08:04, hours with no documentation of corrective action taken. Analyte - Value - (Expected Value) PLT - 576 - (435 - 575) A review of patient test records had 17 patients tested since the last acceptable QC on 4/26/2022 to include the five sample patients: Patient ID 00009 00010 00012 00031 00032 2. Review of the laboratory policy titled "Quality Control Policy", subsection "Unacceptable Results/Failed Controls" had the following statement: "If control levels are out of range troubleshooting must be initiated/documented." Surveyor queried for the documentation of corrective action for the above QC failures, and none was provided. 3. In an interview on 1/19/2023 at 12:15 hours, in the laboratory, testing person (TP) 1 confirmed that there was no corrective action documentation for the stated quality control failures for the DREW3 hematology analyzer. Key: WBC - White blood cell LYM% - percent lymphocytes GRAN% - percent granulocytes MID% - percent mid cells LYM# - absolute lymphocyte MID# - absolute mid cells GRA# - absolute granulocytes RBC - red blood cells HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin PLT - platelet
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of laboratory policy and confirmed in interview the laboratory failed to maintain its quality assurance (QA) program for the review of laboratory preanalytic and analytic processes for 2022. The findings include: 1. Review of the laboratory Quality Assurance Manual has the following areas with the frequency of monitoring for preanalytical and analytical processes in the laboratory. A. Preanalytical: 1. Laboratory Policy and Procedure Manual Frequency of Monitoring: Annual 2. Patient Specimen Log(s) Frequency of Monitoring: Quarterly 3. Written Orders for Test Frequency of Monitoring: Annual B. Analytical 1. Test Requisition /Report Frequency of Monitoring: Annual 2. Quality Control Frequency of Monitoring: Monthly Surveyor queried for the 2022 documentation of the monitoring

	of the above processes, and none was provided. 2. In an interview on 1/19/2023 at 13: 20, in the conference room, testing person (TP) 2 stated that the laboratory had QA activities had been documented for 2022.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of proficiency test records, a review of laboratory policy, and confirmed in an interview, the Laboratory Director failed to ensure all proficiency testing reports received were reviewed for two of four events reviewed in 2022. Refer to D5401.
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 laboratory documents, laboratory policy, and confirmed in interview, the laboratory director failed to ensure that the laboratory quality assessment (QA) program was maintained to assure the quality of laboratory services in 2022. Refer to D5891.