Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0498557	05/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Baylor Scott & White Clinic-College Station	1700 University Drive, College Station, 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	Based on an announced validation survey performed on May 9, 2024, the laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's calibration verification records for the Abbott i-STAT 1 chemistry analyzer (serial number 338460) and confirmed in an interview with laboratory personnel, the laboratory failed to retain the performance documentation for one of four calibration verification performance studies reviewed from January 2022 to December 2023. The findings included: 1. A review of the laboratory's calibration verification records for the Abbott i-STAT 1 chemistry analyzer found the laboratory failed to retain the second calibration verification performed on the analyzer in 2022. The first calibration verification was performed in February 2022. Therefore, the second calibration verification should have been performed in August 2022. The next available records available for review were for two calibration verification studies done in 2023. 2. In an interview at 13:18 hours on May 8, 2024, in the conference room, the laboratory quality assurance representative confirmed the laboratory could not locate the second calibration verification performance for 2022.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance

	specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on surveyor observation, a review of the laboratory's policy titled 'Sysmex pocHi-100, the laboratory's instrument verification records for the Sysmex pocH-100i automated hematology analyzer, and confirmed in an interview of laboratory personnel, the laboratory failed to retain the records for its verification of patient normal ranges for the life of the test system but no less than two years for one of one Sysmex pocH-100i automated hematology analyzer currently in use. The findings included: 1. Based on surveyor observation made in the laboratory on May 8, 2024, at 9:25 hours, the surveyor observed one Sysmex pocHi automated hematology analyzer currently in operational use. 2. A review of the laboratory's policy titled "Sysmex pocHi-100" approved by the Laboratory Director on August 1, 2023, under 'Result Ranges' found the laboratory defined the following patient normal reference ranges: Birth to 1 month (male and female) 1 month & 1 day to 3 months (male and female) 3 months & day to 1 year (male and female) 1 year & 1 day to 2 years (male and female) 2 years & 1 day to 6 years (male and female) 6 years & 1 day to 10 years (male and female) 10 years &1 day to 12 years (male and female) 12 years & 1 day to adult (male and female) 3. Based on a review of the laboratory's instrument verification records for the Sysmex pocH-100i automated hematology analyzer found the laboratory failed to retain the verification of patient normal ranges as part of the verification study. 4. In an interview at 12:32 hours on May 8, 2024, in the conference room, the laboratory quality assurance representative confirmed the laboratory could not locate the patient normal reference range study performed on the Sysmex analyzer.