Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1016224	02/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
St Bernards Physician Clinics, Inc	333 Red Wolf Blvd, Jonesboro, AR	

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
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through a review of quality control (QC) documentation for D-Dimer assays performed in November 2023, a review of patient test records in November 2023, and interviews with laboratory staff, it was determined the laboratory failed to perform two levels of quality control for D-Dimer assays each 8 hours of testing in 1 of 20 days reviewed. Survey findings include: A) A review of D-Dimer assay QC Reports for November 2023 revealed that quality control was documented once each day of testing in November 2023 and QC was performed at 08:22 a.m. on November 6, 2023.. B) A review of patient test records revealed that a D-Dimer assay was performed and reported on patient 100904 at 06:30 p.m. on November 6, 2023 which was greater than 8 hours since the QC was performed. C) During an interview at 03: 00 p.m. on 2/7/24, the employee #3 (as listed on the form CMS-209) stated that QC for D-Dimer determinations are only performed one time daily and confirmed that the laboratory failed to perform D-Dimer quality control each eight hours of patient testing.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

	This STANDARD is not met as evidenced by: Through review of the laboratory's "Quality Control Protocol" policy, quality control (QC) summary reports for the Medonic hematology analyzer, lack of documentation, and interview with laboratory staff members it was determined that the laboratory failed to document corrective action when QC results failed to meet the laboratory's criteria for acceptability. Findings follow: A) Review of the laboratory's "Quality Control Protocol" revealed, under the heading " Procedure for Corrective Action" paragraph f., "document all corrective action on the remedial action worksheet in the appropriate section". B) Review of the QC summary report for July 2023 revealed that hematology QC material (Lot # 2230231) was outside of acceptable range for red blood cell (RBC) count, hemoglobin (HGB) determination, and white blood cell counts (WBC), for six succesive runs between 7/12/23 at 07:05 a.m. until 7/13/23 at 07:17 a.m.. C) Upon request, the laboratory was unable to provide documentation of the corrective action required to bring the QC material into acceptable range. D) When asked in an interview on 2/7/24 at 02:07 p.m., if corrective action was documented for the unsuccessful QC determinations identified above, the laboratory staff member (# 3 on the CMS 209 form) replied " no, I can't get them to do it".