Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2041708	03/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Bleeding And Clotting Disorders Institute	427 W Northmoor Rd, Peoria, IL	

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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the general supervisor (GS); the laboratory failed to follow the laboratory's individual quality control plan (IQCP) for platelet function assays (PFA) for 5 of 5 patient test results reviewed. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the IQCP, "Siemens PFA-100, PFA Collagen/ADP and Collagen/EPI", which stated the following: "Type of Quality Control - Verification of new reagent lot using donor control performed in duplicate. (External QC) Frequency - With each shipment or new lot, or at any time to verify testing performance Criteria for Acceptability - Donor control result must fall into the normal reference range." 2. Review of quality control log for the PSA-100 found for 5 of 5 patient test results reviewed the laboratory failed to follow the IQCP for PFA testing by not performing the normal donor control in duplicate for the Collagen/ADP cartridges with each new lot or shipment. Patient Identifier Patient testing Date Quality Control Measures Taken P4 07-02-2018 None documented P5 11-27-2018 None documented P6 04-09-2019 Donor control Ran 1 time - 2-12-2019, lot 5596711 P15 10-29-2019 None documented P16 02-04-2020 None documented 3. On survey date 03-10-2020, at 3:20 pm, the GS confirmed the laboratory failed to perform the normal donor control in duplicate for the Collagen

	/ADP cartridges in 2018 through 2020 but confirmed the laboratory will occasionally check the Collagen/ADP cartridges with a normal control. 4. Review of the test volume worksheet found the laboratory performed 134 PFA tests in 2019 when the laboratory failed to perform the quality control measures as outlined in the IQCP for the Collagen/ADP test cartridges. 5. On survey date 03-10-2020, at 3:50 pm, the GS confirmed the above findings.