Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2066674	07/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Freeman Physician Group Of Pittsburg	1201 East Centennial, Pittsburg, KS	

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
D3017	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products. This STANDARD is not met as evidenced by: Based on documentation of transfusion services provided on site, the lack of a transfusion service agreement, and interview, the laboratory failed to have a transfusion service agreement reviewed and approved by the responsible parties that govern the procurement, transfer, and availability of blood and blood products. Findings: 1. The surveyor noted that a blood bank refrigerator was in the lab. The surveyor asked the general supervisor (GS) if blood and/or blood products were transfused at this site. The GS confirmed that blood and blood products were transfused, but no immunohematology testing was performed at this site. 2. Request was made to see the transfusion services agreement with the blood product service provider. The document provided was a procedure from another CLIA laboratory (lab B) which provided immunohematology services, blood and blood products to this site. The lab B document did not list any information as to an agreement with this laboratory for immunohematology services. 3. Interview with the GS on 7/18/22 at 3: 15 p.m. confirmed, the laboratory failed to have a transfusion service agreement reviewed and approved by the responsible parties that govern the procurement, transfer, and availability of blood and blood products.
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 performance verification documentation for the Sysmex XN1000 hematology analyzer, non-waived test lists, and interview, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population prior to performing patient testing. Findings: 1. Review of the verification documentation of the Sysmex XN1000 hematology analyzer, S/N N81132, for the analytes: White Blood Cell Differential, Red Blood Cell Count, Hemoglobin, Hematocrit, White Blood Cell Count, and Platelet testing showed no verification of normal values at time of survey. Document listed patient testing began in 1/17/22. 2. Review of the KS-CLIA-PS02 non-waived test lists showed the XN1000 annual test volume was 17,423 patient test results. 3. Interview with the GS on 7/18/22 at 2:10 p.m. confirmed, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population prior to performing patient testing.