Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D1069733	**(X3) Date Survey Completed** 01/05/2021
Name of Provider or Supplier Saint Francis Physician Network, Llc	**Street Address, City, State** 8025 Us Hwy 64 Ste 101, Memphis, TN	
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**
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for the red blood cell and hematocrit analytes in 2020 event one, 2020 event two and 2020 event three, resulting in the second unsuccessful PT occurrence for the red blood cell and hematocrit analytes. (Refer to D2130)
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive

	events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Center for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's 2020 proficiency testing (PT) evaluation reports, the laboratory failed to maintain satisfactory performance in three out of three PT events for the red blood cell (RBC) and hematocrit (HCT) analytes, resulting in the second unsuccessful occurrence for the RBC and HCT analytes. The findings include: 1) Review of the CMS 155 revealed the following unsatisfactory scores for the RBC and HCT analytes: 2020 Event one: RBC=0%; HCT=0% 2020 Event two: RBC=40%; HCT=60% 2020 Event three: RBC=40%; HCT=60% 2) Review of the laboratory's 2020 event one PT evaluation report revealed the following: RBC=0% for "Failure to Participate" HCT=0% for "Failure to Participate" 3) Review of the laboratory's 2020 event two PT evaluation report revealed the following: Sample numbers HEM-08, HEM-09 and HEM-10 scored as unacceptable for the RBC analyte, resulting in an overall score of 40% for the RBC analyte. Sample numbers HEM-08 and HEM-10 scored as unacceptable for the HCT analyte, resulting in an overall score of 60% for the HCT analyte. 4) Review of the laboratory's 2020 event three PT evaluation report revealed the following: Sample numbers HEM-12, HEM-14, and HEM-15 scored as unacceptable for the RBC analyte, resulting in an overall score of 40% for the RBC analyte and the second unsuccessful occurrence for the RBC analyte. Sample numbers HEM-14 and HEM-15 scored as unacceptable for the HCT analyte, resulting in an overall score score of 60% for the HCT analyte and the second unsuccessful occurrence for the HCT analyte.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The laboratory director failed to maintain compliance with successful red blood cell and hematocrit analytes proficiency testing performance and failed to follow the approved allegation of compliance (AOC) for the red blood cell and hematocrit analytes, resulting in the second unsuccessful PT occurrence for the red blood cell and hematocrit analytes. (Refer to D6004)
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	This STANDARD is not met as evidenced by: Based on a desk review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155), the laboratory's 2020 proficiency testing (PT) evaluation reports and the laboratory's Allegation of Compliance (AOC), the laboratory director failed to follow the approved September 14, 2020 AOC for the red blood cell (RBC) and hematocrit (HCT) analytes, resulting in the second unsuccessful PT occurrence for the RBC and HCT analytes. The findings include: 1) Review of the CMS 155 report and the laboratory's PT evaluation reports for 2020 event one, 2020 event two, and 2020 event three revealed the following scores for the RBC and HCT analytes: 2020 event one: RBC=0%; HCT=0% 2020 event two: RBC=40%; HCT=60% 2020 event three: RBC=40%; HCT=60% 2) Review of the laboratory's AOC dated September 14, 2020, in reference to a previous failure to maintain compliance with successful PT, signed by the laboratory director on September 21, 2020 revealed the laboratory would perform retraining of personnel on mixing of PT sample and implement a PT tracking log to ensure timely submission.