Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 26D1094558	**(X3) Date Survey Completed** 08/29/2022
Name of Provider or Supplier St Louis Medical Professionals	**Street Address, City, State** 8790 Watson Rd, Suite 100, Saint Louis, MO	

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**
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 the performance verification procedures for the Cell-dyn Emerald hematology analyzer and Beckman Coulter Access 2 chemistry analyzer, review of patient results and interview with the laboratory director (LD), the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Cell-dyn Emerald hematology analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, white blood cell (WBC) and differential prior to the beginning of patient testing in July 2021. 2. Review of patient results from July 2021 to date August 23, 2022 showed approximately 1784 complete blood count (CBC) patient results were reported. 3. Review of the performance specifications for the Beckman Coulter Access 2 chemistry analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: thyroid-stimulating hormone (TSH), total prostate-specific antigen (Total PSA), free thyroxine (free T4), testosterone, vitamin D, sex hormone binding globulin (SHBG) prior to the beginning of patient testing in August 2021. 4. Review of patient results from August 2021 to date August 23, 2022 showed

	150 TSH, 61 total PSA, 82 free T4, 15 testosterone, 53 vitamin D, and 10 SHBG patient results were reported. 5. Interview with the LD on August 23, 2022 at 10:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.