Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 02D1036810	**(X3) Date Survey Completed** 07/20/2022
Name of Provider or Supplier Nick Sarrimanolis Md Llc	**Street Address, City, State** 1867 Airport Way Suite 145b, Fairbanks, AK	
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: Based on a review of the laboratory's 2022 American Proficiency Institute (API) evaluation of proficiency testing (PT) records and an interview with the testing person on July 20, 2022, it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for 25-OH Vitamin D in two (2) out of three (3) testing events resulting in unsuccessful PT performance. See 2099
D2099	ENDOCRINOLOGY CFR(s): 493.843(b)

	Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory's 2022 American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the testing person on July 20, 2022 it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for 25-OH Vitamin D in two (2) out of three (3) testing events. Findings include: 1. Review of the laboratory's 2022 API PT records revealed 25-OH Vitamin D scores of less than eighty percent for the following Chemistry events: API Chemistry Core 2022 1st event -score of 50%, API Chemistry Core 2022 2nd event -score of 50% 2. There was no documentation or evidence of result review or remedial action taken for the unsatisfactory Vitamin D PT results. 3. The laboratory reports performing 550 25-OH Vitamin D tests annually. 4. The testing person confirmed these findings by interview on July 20, 2022 at 3:00 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's package insert, patient test reports, and interview with the testing person, the laboratory failed to include follow the manufacturer's instructions for reporting the Total Prostate Specific Antigen (PSA) using the Siemens Dimension EXL analyzer. Findings: 1. The Siemens package insert for PSA, issue date 2019-07-29 states, 'The results reported by the laboratory to the physician must include the identity of the PSA assay used.' 2. A review of a test result report on patient #2087 revealed the PSA result did not include the identity of the Siemens Dimension EXL PSA assay. 3. The laboratory reports performing 475 PSA tests annually. 4. The testing person confirmed these findings by interview on July 20, 2022 at 3:00 pm.