

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2054623	(X3) Date Survey Completed 03/15/2024
Name of Provider or Supplier Health North Family Medicine Llc	Street Address, City, State 35911 Kenai Spur Hwy, Suite 6, Soldotna, 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 an off-site desk review of the laboratory's 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) records and a phone interview with the testing person, it was determined the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the analyte Free Thyroxin and the subspecialty Endocrinology in two (2) out of three (3) Endocrinology testing events resulting in unsuccessful PT performance. Refer to D2107 and D2108.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of the laboratory's 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) records and a phone interview with the testing person, it was determined the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the analyte Free Thyroxin in two (2) out of three (3) Endocrinology testing events resulting in unsuccessful PT performance. Findings include: 1. Desk review of the laboratory's 2023 and 2024 API PT records revealed Free Thyroxine scores of less than eighty percent for the following Endocrinology events: a. 2023 API Chemistry Core 3rd event: 0% b. 2024 API Chemistry Core 1st event: 40% 2. In a phone interview with the testing person on 3/20/2024 at 2:10 PM, it was confirmed that the laboratory was unsuccessful in the PT events listed above.

D2108

ENDOCRINOLOGY

CFR(s): 493.843(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of the laboratory's 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) records and a phone interview with the testing person, it was determined the laboratory failed to attain a score of at least eighty (80) percent of overall testing event score for the subspecialty Endocrinology in two (2) out of three (3) Endocrinology testing events resulting in unsuccessful PT performance. Findings include: 1. Desk review of the laboratory's 2023 and 2024 API PT records revealed Endocrinology scores of less than eighty percent for the following events: a. 2023 API Chemistry Core 3rd event: 50% b. 2024 API Chemistry Core 1st event: 70% 2. In a phone interview with the testing person on 3/20/2024 at 2:10 PM, it was confirmed that the laboratory was unsuccessful in the PT events listed above.