

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 02D2054623	<b>(X3) Date Survey Completed</b> 04/15/2021
<b>Name of Provider or Supplier</b> Health North Family Medicine Llc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory is in substantial compliance with the CMS Interim Final Rule (CMS-3401-IFC) on Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE) effective August 25, 2020. No deficiencies were cited.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on proficient testing record review and Technical Consultant interview during a routine survey, the laboratory failed to successfully participate in proficiency testing (PT) for the analytes Free Thyroxin (T4), Free T3, and Thyroid Stimulating Hormone (TSH). Refer to D2107.</p>

**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 proficiency testing (PT) record review and technical consultant interview, the laboratory failed to achieve success performance for Free T3 (THY), Free Thyroxin (T4), and Thyroid Stimulating Hormone (TSH) in 2 out of 3 testing events. Findings: Analyte/Event/Score THY 2019 not enrolled in PT, no alternate verification of accuracy documented THY 2020-2 = 0% T4 2019-3 = 0% T4 2020-2 = 0% TSH 2019-3 = 0% TSH 2020-2 = 0%

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review of and Technical Consultant interview, the laboratory failed to twice annually verify the accuracy of Vitamin D in 2019; Estradiol in 2020; and PSA and Testosterone in 2019 and 2020. Findings: 1. The laboratory did not have records verifying the accuracy of Vitamin D twice annually in 2019. and Estradiol, PSA, and Testosterone in 2019 and 2020. 2. The laboratory performs approximately 60 Vitamin D tests, 85 Estradiol tests, 75 PSA tests, and 150 Testosterone tests annually. 3. The Technical Consultant confirmed these findings on 4/15/2021 at 3:00 pm.