

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0286049	(X3) Date Survey Completed 07/14/2020
Name of Provider or Supplier Ross D Nochimson Md Pa	Street Address, City, State 4994 N University Dr, Lauderhill, FL	
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
D0000	A recertification survey conducted on 07/14/2020 found that Ross D Nochimson MD PA clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2100	<p>ENDOCRINOLOGY CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on record review of Proficiency Testing and staff interviews, the laboratory failed to participate in 1 (1st event 2020) out of 6 events reviewed (3rd event 2028, 3 events 2019 and 2 events 2020) for Endocrinology specialty resulting in a 0% score and for the tests of Free Thyroxine (FTY) and Thyroid Stimulating hormone (TSH). Findings include: Records reviewed of American Proficiency Institute (API) PT, revealed that the laboratory failed to perform the 1st Event of 2020 for Endocrinology Specialty for the tests FTY and TSH resulting in a score of 0 %. During an interview on 7/14/2020 at 1:30 PM, the Laboratory Director confirmed that the laboratory failed to participate in the PT event of above-reference.</p>
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on records review and interviews with the laboratory director (LD), the laboratory failed to fully document the competency assessment for 1 out of 1 testing personnel (TP) for 2 out of 2 years reviewed (2019 and 2020) Findings include: Review of CMS form 209, Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 07/14/2020 revealed that there was 1 TP. -Review of Test Menu revealed that the laboratory perform test for TSH, FTY, Testosterone, vitamin D and PSA using the Nano FrenD System and allergens tests using the Hitachi CLA-1. -Review of TP competency assessment for the years 2019 and 2020, revealed that the evaluation failed to assess the competency on the tests of reference. During an interview on 07/14/2020 with Laboratory Director at 1:00 pm confirmed that the competency for the TP failed to evaluate the competency for each test that the TP performed.

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 records review and staff interviews, the laboratory failed to follow manufacturer instructions (MI) to perform Verification of Linearity and Precision for the FrenD System from NanoEntek for the new analyzer received on 2/10/2020. The laboratory perform the FTY, TSH, Vitamin D, PSA and Testosterone tests with this analyzer. Findings include: -Review of the MI instructions for the FrenD System analyzer revealed that when a new analyzer is put into use, it is required to perform a linearity verification. - Review of Controls print out revealed that the laboratory used analyzer with serial number (S/N)F10U140804-017 at least from 2018 to 2/09/2020. The laboratory started using a new analyzer with S/N F10U190703-110 from 2/10/2020 to 7/13/2020. -No documentation of Verification of Linearity and Precision for the new analyzer was found. -The following tests were performed: FTY, TSH, Vitamin D, PSA and testosterone. The lab tested 198 patients with the new analyzer from 2/10/2020 to 7/13/2020. During an interview on 7/14/2020 at 1:30 PM, with the laboratory director confirmed that the laboratory failed to perform the verification of linearity and precision for the new analyzer that the laboratory started to use since 2/10/2020.