

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0244527	(X3) Date Survey Completed 05/10/2021
Name of Provider or Supplier Novant Health First Charlotte Physicians-Matthews	Street Address, City, State 1401 Matthews Township Parkwy, Suite 200, Matthews, NC	
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
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 review of CMS(Centers for Medicare and Medicaid Services) Casper report 155D, review of 2020 API(American Proficiency Institute) PT (proficiency testing) records and review of laboratory records 4/16/21, electronic communication with TC (technical consultant) on 4/19/21 and 4/20/21, and phone interview with the TC on 5 /10/21, the laboratory failed to notify the inspecting agency and the PT program when testing was suspended for serum HCG(human chorionic gonadotropin) and failed to participate with PT when testing resumed in 2020. Findings: Review of the CMS Casper report 155D and 2020 API PT records on 4/16/21 revealed the laboratory failed to participate and received a 0% score for serum HCG and an overall score of 0% for the Specialty of Endocrinology on the 2020 API Chemistry Core 3rd event. Review of laboratory records 4/16/21 revealed on the API Chemistry Core 3rd event's corrective action log, "Certified technologist not available-testing suspended". There was no documentation of the time-frames when testing was suspended or that the inspecting agency or the PT program was notified within the time frame for submitting PT results that patient testing was suspended. There was no further</p>

documentation that the laboratory participated with PT when serum HCG testing resumed in 2020. During email communication with the TC on 4/19/21, the TC confirmed serum HCG testing was suspended from August 2020 and resumed on October 12, 2020. She confirmed on 4/20/21 by email and at approximately 3:00 p.m. on 5/10/21 during phone interview that the laboratory did not participate with PT when the testing resumed in October 2020. During phone interview, she also confirmed the laboratory failed to notify the inspecting agency and the PT program when testing was suspended.

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 review of 2020 API(American Proficiency Institute) PT (proficiency testing) records and review of laboratory records 4/16/21, electronic communication with TC (technical consultant) on 4/19/21 and 4/20/21, and phone interview with the TC on 5/10/21, the laboratory failed to verify accuracy of the ACR(microalbumin/creatinine) testing at least twice annually. Findings: Review of 2020 API proficiency testing records on 4/16/21 revealed the laboratory verified accuracy of the ACR testing in April 2020 by participating in the API Chemistry Miscellaneous 1st event. Review of PT records also revealed the laboratory failed to participate and received a 0% score for Microalbumin/Creatinine on the 2020 API Chemistry Miscellaneous 2nd event. Review of laboratory records 4/16/21 revealed on the API Chemistry Miscellaneous 2nd event's corrective action log, "Certified technologist not available-testing suspended". There was no other documentation to indicate the time-frames of when testing was suspended. During email communication with the TC on 4/19/21, the TC confirmed ACR testing was suspended from August 2020 and resumed on October 12, 2020. She confirmed on 4/20/21 by email and at approximately 3:00 p.m. on 5/10/21 during phone interview that the laboratory did not verify accuracy of ACR testing when testing resumed in October 2020.