

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D1080070	<b>(X3) Date Survey Completed</b> 03/09/2021
<b>Name of Provider or Supplier</b> Novant Health Hillsdale Medical Associates	<b>Street Address, City, State</b> 121 Medical Drive, Advance, NC	
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>D5779</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on off-site review of laboratory proficiency testing (PT) policy, review of 2 of 6, 2019 and 2020 American Proficiency Institute (API) proficiency testing (PT) Hematology/Coagulation (Hem/Coag) event records, and review of laboratory "Corrective Action Log"s 3/9/21, the laboratory failed to follow established corrective action policies to ensure all laboratory staff have reviewed unsuccessful PT results and the corrective action. Findings: Review of PT policy "Proficiency and Split Sample Testing" revealed "13. Any result graded as Unacceptable, ...or labeled with any code will be investigated and documented, which includes a self-grade for any proficiency not submitted by the required due date....15. All laboratory staff, including the Laboratory Director, will review the above investigation, signing the Performance Review Summary included with the results and scoring of the proficiency as well as any corrective action required within 30 days of receipt." Review of 2019 API Hem /Coag 2nd PT event revealed the laboratory scored 0% for all analytes due to a "failure to participate". Review of the performance summary for the PT event revealed no signatures to indicate laboratory staff review of the "investigation". Review of the laboratory's "Corrective Action Log" for the PT event revealed signatures of the laboratory director (LD) and technical consultant (TC), but failed to include the signature of all staff, including testing personal (TP) #2 who was responsible for the "failure to participate." Review of 2020 API Hem/Coag 2nd PT event revealed the laboratory scored 0% for Vaginal Wet Preparation (KOH) due to an "Unacceptable" result on sample #VKP-02. Review of performance summary for the PT event revealed no signatures to indicate laboratory staff review of the</p>

"investigation". Review of laboratory's "Corrective Action Log" for the PT event revealed signatures of the LD and TC, but failed to include the signature of all staff, including TP #2 who performed the PT for sample #VKP-02.