

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0925165	<b>(X3) Date Survey Completed</b>  03/16/2021
<b>Name of Provider or Supplier</b>  Novant Health Southern Piedmont Primary Care	<b>Street Address, City, State</b>  1995 Wellness Boulevard Building B, Suite 110, Monroe, 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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2018, 2019, 2020, and 2021 QC(quality control) records and the absence of documentation 3/16/21, the laboratory failed to retain all required QC records for the Triage Meter Cardiac Panel and D-Dimer testing performed. Findings: Review of the Triage Meter Cardiac Panel and D-Dimer QC records 3/16/21 revealed the laboratory failed to retain copies of the Triage Total 5 control assay sheets with the quality control material acceptable ranges for the following lot numbers: 1. Level 1 lot # C3450, expiration date 6/13/19; 2. Level 1 lot # C3498, expiration date 9/14/19; 3. Level 1 lot # C3452, expiration date 11/17/19; 4. Level 1 lot # C3454, expiration date 1/7/20; 5. Level 1 lot # C3532, expiration date 1/27/20; 6. Level 1 lot # C3534, expiration date 2/10/20; 7. Level 1 lot # C3535, expiration date 2/24/20; 8. Level 1 lot # C3536, expiration date 3/13/20; 9. Level 1 lot # C3537, expiration date 3/22/20; 10. Level 2 lot # C3492, expiration date 7/25/19; 11. Level 2 lot # C3494, expiration date 9/5/19; 12. Level 2 lot # C3460, expiration date 11/15/19; 13. Level 2 lot # C3463, expiration date 1/5/20; 14. Level 2 lot # C3555, expiration date 1/19/20; 15. Level 2 lot # C3558, expiration date 2/9/20; 16. Level 2 lot # C3559, expiration date 2/22/20; 17. Level 2 lot # C3562, expiration date 3/30/20.</p>
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures and review of 2018, 2019, and 2020 API(American Proficiency Institute) PT (proficiency testing) records 3/16/21, the laboratory director failed to ensure that all PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: Review of the laboratory's Proficiency Testing policy 3/16/21 revealed under D. Results of Proficiency Tests, "2...b. Survey and corrective action forms will be signed by the lab Director or designee.....4.....The results of the evaluation and corrective actions are documented and reviewed by the responsible laboratory director. " Review of 2018, 2019, and 2020 API PT records revealed PT reports were not reviewed by appropriate staff for the following: 1. 2018 API Hematology 3rd event: Unacceptable response for Vaginal Wet prep KOH (potassium hydroxide)- Sample VKP-03- was not reviewed or evaluated for the unacceptable response. 2. 2019 API Hematology 1st event: Ungraded responses for Urine Sediment-Sample US-2 and Vaginal Wet prep KOH- sample VKP-01- was not reviewed or evaluated for the ungraded responses. 3. 2019 API Immunology 2nd event: Graded report was not reviewed.