

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0215484	<b>(X3) Date Survey Completed</b>  02/22/2024
<b>Name of Provider or Supplier</b>  Crofton Family Practice	<b>Street Address, City, State</b>  1684 Village Green, Crofton, MD	
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>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to ensure that the individual testing or examining the samples and the laboratory director (LD) signed the PT attestation statements, attesting that PT specimens were run in the same manner as patient samples. Findings: 1. A review of chemistry PT records from 2023 showed that in one of three events, the attestation statements were not signed by the LD or the testing person (TP) who performed the PT. The attestation statement for one of three PT events was missing (Chemistry M1, 2023). 2. During an interview on 02/22/2024 at 1: 15 PM, the TC confirmed that the attestation statements were not signed by the LD or the TP.</p>
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of PT records for 2023 showed that a signed</p>

attestation statement was not available at the time of the survey for the 1st chemistry PT event of 2023 (Chemistry M1, 2023). 2. During an interview on 02/22/2024 at 1:15 PM, the TC confirmed that the laboratory did not maintain all PT documents for a minimum of two years from the date of the PT testing event.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of 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 proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory director (LD) did not ensure that all PT reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. A review of chemistry PT records from 2023 showed that PT results were not reviewed and signed by the LD for three out of three events in 2023. 2. During an interview on 02/22/2024 at 1:15 PM, the TC confirmed that chemistry PT results were not reviewed and signed.