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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>49D2111663 | <b>(X3) Date Survey Completed</b><br>08/30/2022 |
| <b>Name of Provider or Supplier</b><br>Wellmont Medical Associates Inc   | <b>Street Address, City, State</b><br>671 Hwy 58 East, Norton, VA      |   |
| 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>  |
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| <b>D0000</b>              | An announced CLIA Recertification survey was conducted at the Wellmont Medical Associates DBA Ballad Health Medical Associates on 08/30/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.   |
| <b>D2009</b>              | <p>TESTING OF PROFICIENCY TESTING SAMPLES<br/>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:<br/>Based on the review of proficiency testing (PT) records, lack of documentation, and interview with the lab manager and technical consultant, the lab director failed to review and sign one of two attestation statements in 2022. Findings include: 1. Review of the American Proficiency Institute (API) PT records revealed the lack of documentation of the lab director review and signature on the 2022 Chemistry second event attestation statement. 2. An exit interview with the laboratory manager and technical consultant on 08/30/22 at approximately 1500 confirmed the above findings.</p> |
| <b>D5217</b>              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>CFR(s): 493.1236(c)(1)</p> <p>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.</p>  |

This STANDARD is not met as evidenced by:

Based on the review of proficiency testing (PT) records, lack of documentation and interviews, the lab failed to verify the accuracy of the folate and vitamin B12 analytes twice a year in 2021. Findings include: 1. The laboratory utilizes American Proficiency Institute (API) PT for verification of accuracy of the folate and vitamin B12 analytes, categorized as a non-regulated analyte. 2. API provides three events per calendar year for the folate and vitamin B12 analytes. Review of API PT results revealed the laboratory received the following scores: 2021 Routine Chemistry Event 1- unsatisfactory score of 60% for folate and vitamin B12, 2021 Routine Chemistry Event 2- 100% for folate and vitamin B12, and 2021 Routine Chemistry Event 3- unsatisfactory score of 60% for folate and vitamin B12. On 08/30/22 at approximately 11:15 AM, the surveyor requested the laboratory manager and technical consultant (TC) provide documentation of an alternative method(s) for verification of accuracy twice a year for the above-specified analyte in 2021. The documentation was not available for review. 3. An exit interview with the laboratory manager and technical consultant on 08/30/22 at approximately 1500 confirmed the above findings.