

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2111663	<b>(X3) Date Survey Completed</b> 07/26/2018
<b>Name of Provider or Supplier</b> Wellmont Medical Associates Inc	<b>Street Address, City, State</b> 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>
<b>D0000</b>	An announced CLIA Recertification survey was conducted at the Wellmont Medical Associates on July 25 and 26, 2018 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:
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: A. Based on the initial tour of the laboratory, review of the manufacturer's verification protocol, policy manual, patient test logs and interviews, the laboratory failed to follow the written procedure in performing initial verification procedures for the automated Estimated Sedimentation Rate (ESR) Excyte Mini test system on February 6, 2017 prior to reporting one-thousand nine-hundred and ninety-six (1996) from February 6, 2017 to the date of survey on July 26, 2018. Findings include: 1. The initial tour of the laboratory on July 25, 2018 revealed that the laboratory was performing ESR tests using the automated ESR Excyte Mini test system. 2. Review of the manufacturer's recommended verification protocol for the automated ESR Excyte Mini test system revealed the following statements: "The laboratory must compare the accuracy and precision of the test results it obtains using a test system to the manufacturer's accuracy claims. This should be done by testing commercially available quality control materials with known values. If test results for these samples</p>

fall within the manufacturer's published acceptable limits and are reproducible, a laboratory has demonstrated accuracy and precision of the test system." 3. Review of the general laboratory quality systems policy revealed the following statements: " 6. Performance Specifications- Before a new nonwaived quantitative test is added or a different test system is put into use, we will ensure that our laboratory verifies the performance specifications by the following methods: - We will run at least two levels of controls at least 10 times each to show accuracy and precision. - Our clinical consultant will evaluate our patient demographics to determine if the manufacturer's reference intervals are applicable. The laboratory director and/or the technical consultant will review all above data prior to the release of any patient results. All data will be stored with other instrument installation records." 4. The inspector requested to review the initial verification procedures performed for the new test system on or prior to testing patients on February 6, 2017. The documentation was not available for review. Review of the patient test logs revealed that 1996 patients were assayed and resulted from February 6, 2017 up to the date of survey on July 26, 2018. 5. An interview with the technical consultant and testing personnel on July 26, 2018 at approximately 1:00 PM confirmed that the laboratory failed to perform the initial verification procedures for the automated ESR Excyte Mini test system prior to resulting patients. B. Based on the tour of the laboratory, review of the policy manual, patient test logs and interviews, the laboratory failed to follow the written procedure for performing initial verification procedures for the Meridian ImmunoCard Mycoplasma EIA test system prior to resulting one-hundred and fourteen (114) patients from February 23, 2018 up to the date of survey on July 26, 2018. Findings include: 1. The initial tour of the laboratory on July 25, 2018 revealed that the laboratory was performing patient testing using the Meridian ImmunoCard Mycoplasma EIA test system. 2. Review of the general laboratory quality systems policy revealed the following statements: " 6. Performance Specifications- "Before a new nonwaived test or test system is used, we will run external negative and positive controls to establish that we can achieve results established by the manufacturer. The laboratory director and/or the technical consultant will review all above data prior to the release of any patient results. All data will be stored with other instrument installation records." 3. The inspector requested to review the initial verification procedures performed for the new test system prior to testing patients on February 23, 2017. The documentation was not available for review. Review of the patient test logs revealed 114 patients were resulted from February 23, 2017 up to the date of survey on July 26, 2018. 4. An interview with the technical consultant and testing personnel on July 26, 2018 at approximately 1:00 PM confirmed that the laboratory failed to perform the initial verification procedures for the Meridian ImmunoCard Mycoplasma EIA test system prior to resulting patients.

**D6023**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:  
Based on the tour of the laboratory, review of the policy manual, patient test logs and

interviews, the laboratory director failed to ensure that written procedure for performing initial verification procedures for the automated Estimated Sedimentation Rate (ESR) Excyte Mini and Meridian ImmunoCard Mycoplasma EIA test systems was followed prior to testing and reporting patients in February 2017 (Cross Reference D5421). Findings include: 1. The initial tour of the laboratory on July 25, 2018 revealed that the laboratory was performing the automated Estimated Sedimentation Rate (ESR) Excyte Mini and the Meridian ImmunoCard Mycoplasma EIA test systems. 2. Review of the general laboratory quality systems policy (signed by lab director on March 16, 2016 and on April 17, 2017) revealed the following statements: " 6. Performance Specifications- Before a new nonwaived quantitative test is added or a different test system is put into use, we will ensure that our laboratory verifies the performance specifications by the following methods: - We will run at least two levels of controls at least 10 times each to show accuracy and precision. - Our clinical consultant will evaluate our patient demographics to determine if the manufacturer's reference intervals are applicable. Before a new nonwaived test or test system is used, we will run external negative and positive controls to establish that we can achieve results established by the manufacturer. The laboratory director and/or the technical consultant will review all above data prior to the release of any patient results. All data will be stored with other instrument installation records." 3. The inspector requested to review the initial verification performance documentation of each system listed. The documentation was not available for review. 4. An interview with the technical consultant and testing personnel on July 26, 2018 at approximately 1:00 PM confirmed that the laboratory director failed to ensure that the initial verification procedures were followed for the two (2) test system specified above prior to resulting patients.