

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0307305	<b>(X3) Date Survey Completed</b>  10/15/2019
<b>Name of Provider or Supplier</b>  Willard M West Md	<b>Street Address, City, State</b>  1425 W Baddour Pkwy, Lebanon, TN	
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>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 153 &amp; 155 (CMS 153 &amp; 155) and the Medical Laboratory Evaluations (MLE) evaluation reports, the laboratory failed to enroll in the specialty Hematology Complete Blood Count (CBC) for all analytes: red blood cells (RBC), white blood cells (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), and automated WBC differential (WBC diff) for the year 2017.</p>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified</p>

in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:  
Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 153 & 155 (CMS 153 &155) and the Medical Laboratory Evaluations (MLE) evaluation reports, the laboratory failed to maintain satisfactory performance in the specialty Hematology Complete Blood Count (CBC) for all analytes: red blood cells (RBC), white blood cells (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), and automated WBC differential (WBC diff) for the 1st and 2nd events of 2018 and 2019 (4 of 5 events unsuccessful) resulting in the second unsuccessful performance occurrence. (Refer to D2131).

**D2131**

**HEMATOLOGY**  
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 153 & 155 (CMS 153 &155) and the Medical Laboratory Evaluations (MLE) evaluation reports, the laboratory failed to maintain satisfactory performance in the specialty Hematology Complete Blood Count (CBC) for all analytes: red blood cells (RBC), white blood cells (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), and automated WBC differential (WBC diff) resulting in the second unsuccessful occurrence. The findings include: 1. Review of the CMS CASPER report 153 & 155 revealed a score of 0% in the specialty Hematology Complete Blood Count (CBC) for all analytes: red blood cells (RBC), white blood cells (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), and automated WBC differential (WBC diff) for the 1st and 2nd events of 2018 and 2019 (4 of 5 events unsuccessful). 2. Review of MLE evaluation reports revealed a score of 0% in the specialty Hematology Complete Blood Count (CBC) for all analytes: red blood cells (RBC), white blood cells (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), and automated WBC differential (WBC diff) for the 1st and 2nd events of 2018 and 2019 (4 of 5 events unsuccessful).

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on a review of the laboratory's unsatisfactory performance of proficiency testing (PT) second unsuccessful performance, the laboratory failed to maintain satisfactory performance in the specialty Hematology Complete Blood Count (CBC) for all analytes: red blood cells (RBC), white blood cells (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), and automated WBC differential (WBC diff) for the 1st and 2nd events of 2018 and 2019 (4 of 5 events unsuccessful) resulting in the second unsuccessful performance occurrence. (See D6004)

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory's unsatisfactory performance of proficiency testing (PT) second unsuccessful performance, the laboratory failed to maintain satisfactory performance in the specialty Hematology Complete Blood Count (CBC) for all analytes: red blood cells (RBC), white blood cells (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), and automated WBC differential (WBC diff) for the 1st and 2nd events of 2018 and 2019 (4 of 5 events unsuccessful) resulting in the second unsuccessful performance occurrence. Findings include: 1. Review of the CMS CASPER report 153 & 155 revealed a score of 0% in the specialty Hematology Complete Blood Count (CBC) for all analytes: red blood cells (RBC), white blood cells (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), and automated WBC differential (WBC diff) for the 1st and 2nd events of 2018 and 2019 (4 of 5 events unsuccessful). 2. During a review of an email correspondence from the PT agency (MLE) official on August 8, 2019, at 1:44:50pm, revealed the laboratory failed a score of 0% in the specialty Hematology Complete Blood Count (CBC) for all analytes: red blood cells (RBC), white blood cells (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), and automated WBC differential (WBC diff) for the 1st and 2nd events of 2018 and 2019 (4 of 5 events unsuccessful).