

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0541553	(X3) Date Survey Completed 03/29/2019
Name of Provider or Supplier Leo E Orr Md	Street Address, City, State 1245 Wilshire Blvd Ste 801, Los Angeles, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2016	<p>SUCCESSFUL PARTICIPATION 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 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.</p> <p>This CONDITION is not met as evidenced by: Based on reviews of the AccuTest, and the American Association of Bioanalysts (AAB) proficiency testing records, and interview with the testing personnel, it was determined that the laboratory failed to successfully participate in a PT program approved by the CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events in the specialty of Hematology constituting subsequent unsuccessful PT performance. (See D2130).</p>

<p>D2121</p>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the second quarter (Q2-2017) of the AccuTest proficiency testing records, random patient test results, and interview with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Red Blood Cell (RBC) count analyte. The findings included: a. Cycle 02- 2017, AccuTest proficiency testing program reported an unsatisfactory score of 20% for RBC analyte b. For eight (8) out of eight (8) random patient test results reviewed covering period from 5/19/2017 to 3/5/2018, the laboratory analyzed and reported RBC count approximately during the time the laboratory received the failed proficiency testing score. c. The testing personnel confirmed (3/29/2019, 1330) that the laboratory received the above unsatisfactory proficiency testing score.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the AccuTest and the American Association of Bioanalysts (AAB) proficiency testing records, and interview with the testing personnel (3/29 /2019, 1330), it was determined that the laboratory failed to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive PT events for the analyte Hematocrit (HCT), resulting in subsequent unsuccessful performance. The findings included: a. The laboratory failed to maintain successful performance with the PT program by failing to obtain a score of 80% of acceptable performance in two out of three consecutive PT performances for HCT analyte, as follows: Analyte: Score: Event/Year: HCT 60% Q1-2017 HCT 20% Q2-2017 HCT 40% Q1-2018 b. Failure to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT resulted in a subsequent unsuccessful performance for the analyte, HCT.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity testing: The laboratory Director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6016).</p>

D6016**LABORATORY DIRECTOR RESPONSIBILITIES**

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

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on reviews of the AccuTest, and the American Association of Bioanalysts (AAB) proficiency testing records, and interview with the testing personnel, it was determined that the laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under subpart H of this part. The findings included: For the analyte HCT, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events, resulting in subsequent unsuccessful PT performance. (See D 2016 and D 2130).