

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0480653	(X3) Date Survey Completed 07/16/2018
Name of Provider or Supplier Scott J Zashin Md	Street Address, City, State 8230 Walnut Hill Lane, Ste 614, Dallas, TX	
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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, College of American Pathologists (CAP).
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 a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, College of American Pathologists (CAP), it was determined the laboratory failed to successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified</p>

	<p>under CLIA. The laboratory did not successfully participate in the specialty of hematology for the analytes Red Blood Cells (RBC) and Hematocrit (HCT).</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 a proficiency testing desk review of CMS form 155 and CAP records found that the laboratory failed to attain a score of at least 80% acceptable responses for each analyte in the subspecialty of hematology. Findings: 1. CAP 2015 - 1st event laboratory received the unsatisfactory score of 0 % for RBC. CAP 2015 - 1st event laboratory received the unsatisfactory score of 0 % for Hemoglobin. CAP 2015 - 1st event laboratory received the unsatisfactory score of 0 % for White Blood Cells. 2. CAP 2017 - 3rd event laboratory received the unsatisfactory score of 60 % for RBC. CAP 2017 - 3rd event laboratory received the unsatisfactory score of 60 % for HCT. 3. CAP 2018 - 2nd event laboratory received the unsatisfactory score of 60 % for RBC. CAP 2018 - 2nd event laboratory received the unsatisfactory score of 20 % for HCT.</p>
<p>D2122</p>	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CMS form 155 and CAP records found that the laboratory failed to attain an overall score of at least 80% for each testing event in the specialty of hematology. Finding: 1. CAP 2015 - 1st event laboratory received the unsatisfactory hematology event score of 46%.</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 desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Hematology. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings: 1. CAP 2017 - 3rd event laboratory received the unsatisfactory score of 60 % for RBC. CAP 2017 - 3rd event laboratory received the unsatisfactory score of 60 % for HCT. 2. CAP 2018 - 2nd event laboratory received the unsatisfactory score of 60 % for RBC. CAP 2018 - 2nd event laboratory received the unsatisfactory score of 20 % for HCT.</p>

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 desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016

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 a desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2130