

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0938565	<b>(X3) Date Survey Completed</b> 06/16/2021
<b>Name of Provider or Supplier</b> South Texas Regional Laboratories Inc	<b>Street Address, City, State</b> 1975 N Veterans Blvd, Suite 5-A, Eagle Pass, TX	
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>	Based on a proficiency testing desk review survey performed on June 16, 2021, the laboratory was found to be out of compliance based on the following <b>CONDITION LEVEL DEFICIENCIES</b> : D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
<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 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 <b>CONDITION</b> is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and College of American Pathologists (CAP) proficiency testing records, the facility failed to achieve</p>

	<p>successful performance in two out of three consecutive testing events for the analyte White Blood Cell (WBC) Differential, Red Blood Cells (RBC), and Hematocrit (HCT) resulting in unsuccessful performance (refer to D2121 and D2130).</p>
<b>D2121</b>	<p><b>HEMATOLOGY</b> 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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists evaluation report, the facility failed to attain a score of at least 80 percent for the analyte White Blood Cell (WBC) Differential, Red Blood Cells (RBC), and Hematocrit (HCT) in two out of three consecutive testing events in 2020 and 2021. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists (CAP) evaluation reports, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for the analyte WBC Differential, Red Blood Cells (RBC), and Hematocrit (HCT) in the specialty of Hematology in two out of three consecutive testing events: WBC failures 2020 CAP 3rd event 60% 2021 CAP 1st event 0% RBC failures 2020 CAP 2nd event 60% 2021 CAP 1st event 0% HCT failures 2020 CAP 2nd event 60% 2021 CAP 1st event 0%</p>
<b>D2122</b>	<p><b>HEMATOLOGY</b> 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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists evaluation report, the facility failed to participate in the 1st event of 2021 resulting in a score of 0% for the overall hematology testing event score. The findings included: 1. CAP 2021 - 1st event reported a hematology testing event score of 0%. 2. Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.</p>
<b>D2123</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two</p>

proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists evaluation report, the laboratory failed to participate in event 1 of 2021 for the specialty of hematology. An unacceptable score of zero, results in unsuccessful performance. The findings included: 1. CAP reported "failure to participate" in event 1 of 2021 resulting in a score of 0% for all analytes in the specialty of hematology. White Blood Cell differential 0% RBC score 0% Hematocrit score 0% Hemoglobin score 0% White Blood Cells score 0% Platelets score 0% 2. Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

**D2130**

**HEMATOLOGY**

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists (CAP) evaluation reports, the facility failed achieve satisfactory performance for the analyte White Blood Cells (WBC) Differential, Red Blood Cells (RBC), and Hematocrit (HCT) in two out of three consecutive testing events in 2020 and 2021. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists (CAP) evaluation reports, the laboratory received the following unsuccessful performance for the analyte White Blood Cells (WBC) Diff, Red Blood Cells (RBC), and Hematocrit (HCT) in the specialty of Hematology in two out of three consecutive testing events. WBC failures 2020 CAP 3rd event 60% 2021 CAP 1st event 0% RBC failures 2020 CAP 2nd event 60% 2021 CAP 1st event 0% HCT failures 2020 CAP 2nd event 60% 2021 CAP 1st event 0%. Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

**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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and College of American Pathologists (CAP) proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for analyte Platelet count in the specialty of Hematology (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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and College of American Pathologists (CAP) proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for analytes White Blood Cell (WBC) Differential, Red Blood Cells (RBC), and Hematocrit (HCT) in the specialty of Hematology (refer to D2016).