

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D0997987	<b>(X3) Date Survey Completed</b> 08/22/2025
<b>Name of Provider or Supplier</b> M Francisco Gonzalez Md Facp	<b>Street Address, City, State</b> 3 Medical Court, Sumter, SC	
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 offsite Proficiency Test (PT) Desk survey was conducted at M Francisco Gonzalez MD FACP on August 22, 2025. The laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, at 42 CFR 493. The following is a list of CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016-42 CFR. 493.803 Condition: Successful participation [proficiency testing] D6000 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
<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 CONDITION is not met as evidenced by: Based on a proficiency testing desk review of Certification and Survey Provider</p>

	<p>Enhancement Report (CASPER)-0155D report and American Proficiency Institute (API) 2024 and 2025 records, the laboratory had not successfully participated in a proficiency testing program approved by (HHS), for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty Hematology for the analytes Red Blood Cells (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell Count (WBC), and Platelets (PLT) for 2 of 2 years (2024, 2025) . Refer to D2130, D2131.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 0155D report and graded proficiency reports from API 2024 (3rd Event) and 2025 (Events 1, 2) records, the laboratory failed to achieve a satisfactory performance (80% or better) for the same analyte in two consecutive testing events in the specialty and subspecialty of Hematology for the analytes RBC, HCT, HGB, WBC, and PLT for 2 of 2 years (2024, 2025). Findings included: 1. A review of the CAPSER 0155D report revealed the following scores for the specialty of Hematology with the following analytes: Hematology 2024 - 3rd Event the laboratory received an unsatisfactory score: RBC=0% HCT=0% HGB=0% WBC=0% PLT=0% Hematology 2025 - 1st Event the laboratory received an unsatisfactory score: RBC=0% HCT=0% HGB=0% WBC=0% PLT=0% 2. The scores were confirmed by review of the graded API results for the laboratory. Scores less than 80% for the analyte indicate failure or unsatisfactory performance. A failure of the analyte for two out of three testing events is scored as unsuccessful.</p>
<p><b>D2131</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 0155D report and API 2024, 2025 records, revealed that the laboratory failed to achieve satisfactory performance (80% or greater) for the overall specialty of Hematology in two of two consecutive testing events. Findings included: 1. A review of the laboratory's API PT evaluation for the 3rd event of 2024 and the 1st event of 2025 revealed that the laboratory has an overall score of 0% in the Speciality of Hematology. 2. A review of CASPER 0155D report confirmed the laboratory received the above results.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> 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</p>

with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on proficiency testing desk review of CASPER 0155D report and API 2024 and 2025 records, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D2130, D2131, D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on proficiency testing desk review of CASPER 0155D report and API Proficiency Testing 2024 and 2025 records, the laboratory director failed to ensure that the overall quality of the laboratory services were provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for 2 of 2 consecutive years (2024, 2025). Refer to D2130, D2131