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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 42D0997987 | (X3) Date Survey Completed 04/17/2023 |
| Name of Provider or Supplier M Francisco Gonzalez Md Facp | Street Address, City, State 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. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D0000 | The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director |
| 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 proficiency testing desk review of Centers for Medicare and Medicaid</p> |

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| | <p>Services (CMS) form 0155 and American Association of Bioanalysts (AAB) 2021 and 2022 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 of Hematology and for WBC Diff analyte. Refer to D2130 and D2131.</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 a proficiency testing desk review of CMS form 0155 and American Association of Bioanalysts (AAB) 2021 and 2022 records, revealed that the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in four of four consecutive testing events in the specialty of Hematology for WBC Diff analyte. Findings included: 1. Review of the CMS 0155 report revealed the following results: Hematology 2021 - 2nd Event the laboratory received an unsatisfactory score of 0% for the WBC Diff. Hematology 2021 - 3rd Event the laboratory received an unsatisfactory score of 40% for the WBC Diff. Hematology 2022 - 1st Event the laboratory received an unsatisfactory score of 60% for the WBC Diff. Hematology 2022 - 2nd Event the laboratory received an unsatisfactory score of 60% for the WBC Diff. 2. A proficiency desk review from American Association of Bioanalysts (AAB) 2021 and 2022 proficiency testing records confirmed the laboratory received the above results. Word Key: WBC Diff=White Blood Cell Differential</p> |
| <p>D2131</p> | <p>HEMATOLOGY CFR(s): 493.851(g)</p> <p>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 CMS form 0155 and American Association of Bioanalysts (AAB) 2021 and 2022 records, revealed that the laboratory failed to achieve satisfactory performance (80% or greater) for the overall specialty of Hematology in four of four consecutive testing events. Findings included: 1. Review of the CMS 0155 report revealed the following results: Hematology 2021 - 2nd Event the laboratory received an unsatisfactory score of 0% for Hematology. Hematology 2021 - 3rd Event the laboratory received an unsatisfactory score of 40% for Hematology. Hematology 2022 - 1st Event the laboratory received an unsatisfactory score of 60% for Hematology. Hematology 2022 - 2nd Event the laboratory received an unsatisfactory score of 60% for Hematology. 2. A proficiency desk review from American Association of Bioanalysts (AAB) 2021 and 2022 proficiency testing records confirmed the laboratory received the above results.</p> |
| <p>D6000</p> | <p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</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.

This CONDITION is not met as evidenced by:
Based on a proficiency testing desk review of CMS form 0155 and American Association of Bioanalysts (AAB) 2021 and 2022 records, 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 proficiency testing desk review of CMS form 0155 and American Association of Bioanalysts (AAB) 2021 and 2022 records, 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 an HHS approved proficiency testing program. Refer to D2130 and D2131.