

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0699024	(X3) Date Survey Completed 02/23/2021
Name of Provider or Supplier Medical Center, Llp, The	Street Address, City, State 908 Hillcrest Pkwy, Dublin, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on February 23, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 review of the American Proficiency Institute, (API) proficiency testing (PT) provider, the laboratory failed to participate and score successfully in several events in 2019 and 2020, and failed to provide evidence that steps have been taken to correct the problem identified by the unsuccessful PT performance. Reference: D6019</p>

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API), Proficiency Testing (PT) documents for 2019, and 2020, the Laboratory Director (LD) failed to ensure that corrective action was performed on scores of less than 100%, Findings: 1. Review of the PT documents from API for the year 2019, Hematology, Urinalysis, Microscopy, Core Chemistry, Endocrinology, and Thyroid the laboratory failed to provide corrective action for the following analytes: First Event Of 2019, there was not a corrective action documented for a score of 0% in Hematology, Urinalysis, Microscopy, Core Chemistry, Endocrinology, and Thyroid. The laboratory failed to submit results for this event. Second Event of 2019, there was not a corrective action documented in Hematology for a score of 80% for Lymphocytes, in Core Chemistry a score of 80% for Myoglobin, 80% for Creatine Kinase, 60% for Calcium, and Thyroid with a score of 80% for T-3. Third Event of 2019, there was not a corrective action documented in Microscopy for a score of 0%, Core Chemistry a score of 0% for Glucose, and Thyroid a score of 80% for T3 and FT4. 2. Review of the PT documents from API for the year 2020, Hematology, Urinalysis, Microscopy, and Core Chemistry the laboratory failed to provide corrective action for the following analytes: First event of 2020, there was not a corrective action documented in Hematology for a score of 40% for Granulocytes, 80% for Monocyte, and Microscopy score of 50% in Urine Sediment. Second event of 2020, there was not a corrective action documented in Hematology for a score of 80% for Lymphocytes, in Core Chemistry score of 80% in Myoglobin, 80% in Creatine Kinase, 60% in Calcium, and 80% T-3. 3. Interview with the newly hired Technical Consultant, the LD, and the Medical Director, on February 23, 2021, at approximately 4:45, in the vacant office, on the front hall of the facility, confirmed that there was not ba corrective action documented for PT scores of less than 100%.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the Testing Personnel (TP) competency documents, and Employee Competency Policy, the Laboratory Director acting as the Technical Consultant, did not follow Policy and provide yearly competency checks for all employees. There was no competency documents for three out of three TP for the year 2019, and three out of 6 TP for the year 2020. Findings: 1. Review of the 2019 Competency Documents, there were documents for 2017 and 2018 for 3 out of 3 TP, but no annual competency

documents for the year 2019. 2. Review of the 2020 Competency Documents, there was 2 new hires, both having documents for their initial training, and their 6 month competency documents, but no annual documents for the 3 out of 2 TP with hire dates before 2018. 3. Interview with the Newly Hired Technical Consultant, the Laboratory Director and the Medical Director, on February 23, 2021, at approximately 4:15 pm, in the empty office, in the front of the facility, confirmed that the above aforementioned statements were true.