

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0889444	(X3) Date Survey Completed 05/17/2023
Name of Provider or Supplier North Park Medical Group	Street Address, City, State 8363 Meadow Road, 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 (Centers for Medicare and Medicaid Services) national database and verified with the proficiency testing company, Medical Laboratory Evaluation (MLE). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 Successful participation in a proficiency testing program 493.1403 Laboratory Director, Moderate Complexity
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:</p>

	<p>Based on a desk review of proficiency testing records obtained from the Casper database and verified with the proficiency testing company, Medical Laboratory Evaluation (MLE), it was determined 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 did not successfully participate in the analytes of ABO and D (Rho) Typing (refer to D2153 and D2162).</p>
<p>D2153</p>	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a)</p> <p>Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test 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 Center for Medicare and Medicaid Services (CMS) form 0155 report and Medical Laboratory Evaluation proficiency testing records, found that the laboratory failed to attain a score of at least 100% acceptable responses for ABO Group and D (RHO) typing. Findings Included: 1. Review of the CMS 0155 report revealed the following results for the analytes, ABO Group and D (RHO) typing: a. MLE 2022 (event 3) - laboratory received an unsatisfactory score of 0% for ABO. b. MLE 2023 (event 1) - laboratory received an unsatisfactory score of 0% for ABO. c. MLE 2022 (event 3) - laboratory received an unsatisfactory score of 0% D (RHO). d. MLE 2023 (event 1) - laboratory received an unsatisfactory score of 0% for D (RHO). 2. Review of Medical Laboratory Evaluation proficiency testing records, obtained from the proficiency testing company, confirmed the above findings.</p>
<p>D2162</p>	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in 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 desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (100% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of immunohematology for ABO Group. Two out of three unsatisfactory scores results in unsuccessful PT performance. 1. Review of the CMS 0155 report revealed the following results for the analytes, ABO Group and D (RHO) typing: a. MLE 2022 (event 3) - laboratory received an unsatisfactory score of 0% for ABO. b. MLE 2023 (event 1) - laboratory received an unsatisfactory score of 0% for ABO. c. MLE 2022 (event 3) - laboratory received an unsatisfactory score of 0% D (RHO). d. MLE 2023 (event 1) - laboratory received an unsatisfactory score of 0% for D (RHO). 2. Review of Medical Laboratory Evaluation proficiency testing records, obtained from the proficiency testing company, confirmed the above findings.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

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 proficiency testing records, it was determined the Laboratory Director failed to ensure proficiency testing was tested as required. The laboratory failed to achieve satisfactory performance (100% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of immunohematology for ABO Group. Two out of three unsatisfactory scores results in unsuccessful PT performance. (Refer to D2153 and 2162).