

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0933273	<b>(X3) Date Survey Completed</b>  09/23/2022
<b>Name of Provider or Supplier</b>  Medical Associates Of Brownsville Pa	<b>Street Address, City, State</b>  425 E Los Ebanos Blvd Ste 100, Brownsville, 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 September 23, 2022, 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 CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute proficiency testing records, the laboratory failed to successfully participate in</p>

	<p>two of three testing events for the analyte ANA (Anti-nuclear antibodies) in 2021 and 2022, resulting in unsuccessful performance. Refer to D2084.</p>
<p><b>D2084</b></p>	<p><b>GENERAL IMMUNOLOGY</b> CFR(s): 493.837(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test 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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) Comparative Evaluations, the laboratory failed to achieve satisfactory performance for the analyte ANA (Anti-nuclear antibodies) in two of three testing events in 2021 and 2022. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) Comparative Evaluations, the laboratory received the following unsuccessful performance for the analyte ANA (Anti-nuclear antibodies) in the specialty of General Immunology in two of three events: 2021 API (event 3) ANA (analyte #0095) 60% 2022 API (event 2) ANA (analyte #0095) 40% Failure to achieve satisfactory performance for the same analyte in two of three testing events is unsuccessful performance.</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 with 493.1407 of this subpart.</p> <p>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 American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for the analyte ANA (Anti-nuclear antibodies) in the specialty of General Immunology. Refer to D6016.</p>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>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;</p>

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 American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for analyte ANA (Anti-nuclear antibodies) in the specialty of General Immunology. Refer to D2084.