

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1018588	(X3) Date Survey Completed 12/20/2021
Name of Provider or Supplier All Childrens Pediatric Clinic	Street Address, City, State 626 North Texas Blvd, Weslaco, 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	Based on a proficiency testing desk review survey performed on December 20, 2021, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: 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: Based on 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 failed to achieve successful</p>

	<p>performance in two of three testing events for the analyte Group A Strep (molecular), resulting in unsuccessful performance in the specialty of Bacteriology (refer to D2020, D2021, and D2028).</p>
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory 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 American Proficiency Institute (API) proficiency testing records, the laboratory failed to attain an overall score of at least 80% for the specialty of Bacteriology. The findings included: 1. API 2021 - 1st event laboratory received an unsatisfactory score of 70% for Bacteriology. 2. API 2021 - 2nd event laboratory received an unsatisfactory score of 0% for Bacteriology.</p>
D2021	<p>BACTERIOLOGY CFR(s): 493.823(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</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 American Proficiency Institute (API) proficiency testing records, the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program resulting in a score of zero (0%). The findings included: 1. The laboratory failed to return the proficiency testing results for the 2nd testing event of 2021 within the time frame specified by the program for Bacteriology. 2. This failure to return the results within the specified time frame resulted in a score of 0% and unsatisfactory performance for the specialty of Bacteriology.</p>
D2028	<p>BACTERIOLOGY CFR(s): 493.823(e)</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 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 failed to achieve satisfactory performance (80% or greater) for two consecutive testing events resulting in unsuccessful PT performance. The findings included: 1. API 2021 - 1st event the laboratory received an unsatisfactory score of 70% for Bacteriology. 2. API 2021 - 2nd event the laboratory received an unsatisfactory score of 0% for Bacteriology.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR 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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute proficiency testing records, the laboratory director failed to provide overall management and direction of the laboratory services. The findings included: 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 a HHS approved proficiency testing program for Bacteriology (refer to D6016).</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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> <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 Bacteriology (refer to D2020, D2021, D2028).</p>