

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0230376	<b>(X3) Date Survey Completed</b> 11/06/2020
<b>Name of Provider or Supplier</b> Pediatric Center, Pc	<b>Street Address, City, State</b> 901 Enterprise Pkwy - Suite 200, Hampton, VA	
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>	An unannounced, off-site CLIA proficiency testing desk review was conducted for Pediatric Center, PC on November 6, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulations: D2016 - 42 CFR. 493.803 Condition: Successful Participation. Specific deficiencies cited are as follows.
<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 an off-site desk review of the laboratory's 2019 and 2020 American Proficiency Institute proficiency testing (PT) records and an interview, the laboratory</p>

	<p>failed to attain a score of at least eighty percent of acceptable responses for urine colony count in two (2) of three testing events reviewed and 2 consecutive throat culture testing events reviewed resulting in unsuccessful Bacteriology PT performance. See D2028.</p>
<p><b>D2020</b></p>	<p><b>BACTERIOLOGY</b> 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 a desk review of the laboratory's proficiency testing (PT) records and an interview, the laboratory failed to attain a score of at least eighty (80) percent (%) of acceptable responses for throat culture in one (1) out of three (3) Bacteriology testing events reviewed for calendar year 2019. Findings include: 1. Review of the laboratory's American Proficiency Institute PT records (2019 Events 1-3) revealed throat culture scores of less than 80% for the following Bacteriology event: API 2019 1st Event - Throat Culture = 20% (challenges TH -01, TH-03, TH-04, TH-05 scored as unacceptable). 2. In an interview with the lead nurse on 11/6/20 at approximately 10 AM, the above findings were confirmed.</p>
<p><b>D2028</b></p>	<p><b>BACTERIOLOGY</b> 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 a desk review of the laboratory's 2019 and 2020 proficiency testing (PT) records (a total of six events) and an interview, the laboratory failed to attain a score of at least eighty (80) percent (%) of acceptable responses for urine colony count in two (2) of three (3) testing events reviewed and 2 consecutive throat culture testing events reviewed resulting in unsuccessful Bacteriology PT performance. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT records (2019 Events 1-3, 2020 Events 1-3) revealed urine colony count scores of less than 80% for the following Bacteriology events: API 2019 3rd Event - Urine Colony Count = 50% (challenge UR -11 scored as unacceptable); API 2020 2nd Event - Urine Colony Count = 50% (challenge UR-7 scored as unacceptable); resulting in unsuccessful PT performance. 2. Review of the laboratory's API PT records (2019 Events 1-3, 2020 Events 1-3) revealed throat culture scores of less than 80% for the following consecutive Bacteriology events: API 2020 2nd Event - Throat Culture = 60% (challenges TH-06 and TH-07 scored as unacceptable); API 2020 3rd Event - Throat Culture = 60% (challenges TH-13 and TH-14 scored as unacceptable); resulting in unsuccessful PT performance. 3. In an interview with the lead nurse on 11/6/20 at approximately 10 AM, the above findings were confirmed.</p>