

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0721322	(X3) Date Survey Completed 08/02/2018
Name of Provider or Supplier Pediatric Choice Clinic, Dayton	Street Address, City, State 149 Walnut Grove Church Road, Dayton, TN	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: ===== Based on review of laboratory's IQCP (Individualized Quality Control Plan) for taxo discs and SSA media for performing strep screen throat cultures, lack of weekly Quality Control (QC) documentation and interview with the Laboratory Manager, determined the laboratory failed to follow their IQCP for performing weekly QC for 2017 and 2018. The findings include: 1. Review of IQCP for taxo discs and SSA media states to perform weekly quality controls with known organisms. 2. Lack of weekly QC documentation for taxo discs and lack of QC documentation for SSA media for 2017 and 2018. 3. Interview at approximately 12:30 p.m. August 2, 2018 with the Laboratory Manager confirmed the laboratory was performing taxo disc and SSA media QC with each new lot number, but the QC for the SSA media was not documented for the 2 year period. =====</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

===== Based on review of 2 SSA strep screen culture reports for July 2018, package insert for performing strep screen cultures and interview with the laboratory manager, determined the laboratory failed to follow manufacturer's instructions for incubation time. The findings include: 1. Review of 2 SSA strep screen culture reports for 7/19/18 and 7/26/18 were documented as being read at 96 hours (4 days). 2. Package insert for performing strep screen throat cultures states to read cultures no longer than 48 hours. 3. Interview at approximately 12:00 p.m. August 2, 2018 with the laboratory manager confirmed that SSA throat cultures planted on Thursdays were not read until the following Monday (4 days or 96 hours) due to office not open on weekends, which fails to follow manufacturer's instructions for incubation time.

=====