

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0311945	(X3) Date Survey Completed 06/19/2018
Name of Provider or Supplier Children's Clinic Pllc	Street Address, City, State 221 W Tyrone Rd, Oak Ridge, 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
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: _____ Bacteriology: The laboratory failed to maintain satisfactory participation in three out of three events for Bacteriology, resulting in the Second Unsuccessful Proficiency Testing (PT) Occurrence. (Refer to D2028) _____</p>
D2028	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

_____ Based on a desk review of the CMS CASPER Report 0155D and the Laboratory's 2017 and 2018 Proficiency Testing (PT) Evaluation Reports, determined the laboratory failed to maintain satisfactory performance for Bacteriology, events two and three of 2017 and event one of 2018, resulting in the Second Unsuccessful Occurrence for Bacteriology. The findings include: 1. Review of the CASPER Report 0155D revealed events two and three of 2017 scores for Bacteriology as 77% and event one of 2018 score at 77%. 2. Review of the Laboratory's 2017 event two PT report revealed sample numbers TC-06 and TC-08 had unacceptable grades for Throat Culture results, resulting in a score of 75%. 3. Review of the Laboratory's 2017 event three PT report revealed sample numbers UC-12 and UC-13 had unacceptable grades for Urine Culture results, resulting in a score of 75% and the First Unsuccessful PT Occurrence for Bacteriology. 4. Review of the Laboratory's 2018 event one PT report revealed sample numbers UC-03 and UC-05 had unacceptable grades for Urine Culture results, resulting in a score of 75% and the Second Unsuccessful PT Occurrence for Bacteriology.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:

_____ The Laboratory Director failed to provide direction for successful Proficiency Testing (PT) Participation in Three of Three Events for Bacteriology in 2017 and 2018 resulting in the SECOND Unsuccessful PT Occurrence (Reference D6004). _____

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

_____ Based on review of the CMS 0155D Report and the PT Program Evaluation Report of the Unsatisfactory Scores for

Bacteriology for three of three events for 2017 and 2018, determined the Laboratory Director failed to provide effective direction over Proficiency Testing for Bacteriology in 2017 and 2018, resulting in the SECOND UNSUCCESSFUL Proficiency Testing performance. The findings include: 1. A review of the CMS Report 0155D for Bacteriology 2017 revealed event two as Unsatisfactory with a score of 77%; event three as Unsatisfactory with a score of 77% and event one of 2018 as Unsatisfactory with a score of 77%, resulting in the SECOND UNSUCCESSFUL Occurrence for Bacteriology. 2. A review of the PT Evaluation Report for 2017 revealed event two as Unsatisfactory with a score of 78%, event three as Unsatisfactory with a score of 78% and event one of 2018 as Unsatisfactory with a score of 78%, resulting in the SECOND UNSUCCESSFUL Occurrence for Bacteriology which determined the Laboratory Director failed to provide effective direction over Proficiency Testing for Bacteriology in 2017 and 2018 resulting in the SECOND UNSUCCESSFUL Proficiency Testing performance.
