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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 44D0311945 | (X3) Date Survey Completed 02/20/2018 |
| 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 |
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| 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: _____ ALWAYS REFER TO STANDARD TAG IN APPROPRIATE LAB SPECIALTY. BACTERIOLOGY: The laboratory failed to maintain satisfactory participation in two out of two events for bacteriology, resulting in the first unsuccessful Proficiency Testing (PT) occurrence for Bacteriology (Refer to D2028). _____</p> |
| D2028 | <p>BACTERIOLOGY CFR(s): 493.823(e)</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.

This STANDARD is not met as evidenced by:

_____ Based on a desk review of the CMA CASPER Report 0155D and the Laboratory's 2017 Proficiency Testing (PT) Evaluation Reports, determined the laboratory failed to maintain satisfactory performance for Bacteriology, events two and three of 2017, resulting in the first unsuccessful occurrence. The findings include: 1. Review of the CASPER Report 0155D revealed event two and three scores for Bacteriology as 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% which results in the first unsuccessful occurrence for Bacteriology.
