

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0892367	(X3) Date Survey Completed 11/26/2019
Name of Provider or Supplier Lebonheur Pediatrics, Llc	Street Address, City, State 3876 New Covington Pike, Memphis, 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: The laboratory failed to maintain satisfactory proficiency testing performance for the Bacteriology specialty in 2019 events two and three resulting in the first unsuccessful 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 consecutive testing events or two out of three consecutive testing events is</p>

unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and the laboratory's 2019 proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance for two consecutive PT events for the Bacteriology specialty, resulting in the first unsuccessful proficiency testing occurrence. The findings include: 1) Review of the CMS 155 report revealed the following unsatisfactory scores for Bacteriology: 2019 event two-20%, 2019 event three- 60%. 2) Review of the laboratory's 2019 microbiology event two PT summary report revealed sample numbers TH-07, TH-08, TH-09 and TH-10 scored as unacceptable for throat culture, resulting in an overall event score of 20% for bacteriology. 3) Review of the laboratory's 2019 microbiology event three PT summary report revealed sample numbers TH-14 and TH-15 scored as unacceptable resulting in an overall event score of 60% for bacteriology, and the first unsuccessful PT performance for the Bacteriology specialty.