

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0955426	<b>(X3) Date Survey Completed</b>  05/12/2021
<b>Name of Provider or Supplier</b>  Lebonheur Pediatrics Llc	<b>Street Address, City, State</b>  1255 S Germantown Rd, Germantown, TN	
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>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, the Centers for Medicare and Medicaid Services form 209 Laboratory Personnel Report (CLIA) (CMS-209) and interview with the technical consultant, the laboratory failed to test complete blood count (CBC) proficiency testing samples by routine testing personnel in 2019, 2020, and 2021. The finding include: 1. Review of the laboratory's CBC proficiency testing records revealed that testing personnel number five performed seven of seven CBC proficiency testing events (2019 events one, two, and three; 2020 events one, two, and three; 2021 event one). 2. Review of the form CMS-209 revealed seven personnel who perform patient testing for complete blood count. 3. Interview with the technical consultant on May 5, 2021 at 11:30 am confirmed that testing personnel number five performed seven of seven proficiency testing events for 2019, 2020, and 2021. The laboratory failed to test proficiency testing samples by the same personnel who perform patient testing for CBC in 2019, 2020, and 2021.</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units</p>

of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of final patient complete blood count (CBC) test reports and interview with the technical consultant, the patient CBC test reports failed to include units of measure for the white blood cell count, lymphocyte number, mononuclear cell number, granulocyte number, red blood cell count, and platelet count for 4 of 4 patient CBC reports reviewed in 2019, 2020, and 2021. The finding include: 1. Review of CBC final patient test reports revealed no units of measure for the white blood cell count, lymphocyte number, mononuclear cell number, granulocyte number, red blood cell count, and platelet count for patient number one dated 05.21.19, patient number two dated 03.07.20, patient number three dated 10.23.20, and patient number four dated 02.25.21. 2. Phone interview with the technical consultant on May 12, 2021 at 1pm confirmed the final patient test report for complete blood count did not include units of measure for white blood cell count, lymphocyte number, mononuclear cell number, granulocyte number, red blood cell count and platelet count in 2019, 2020, and 2021 for four of four patient CBC test reports reviewed.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of testing personnel number three competency assessment records and interview with the technical consultant, the technical consultant failed to ensure assessment of blind testing or external proficiency testing was included as part of the competency assessment for testing personnel number three in 2019 and 2020 for three of three competency assessments performed. The finding include: 1. Review of the competency assessment records for testing personnel number three revealed that blind testing or external proficiency testing was not included as part of the competency assessments performed on 02.14.2019, 09.05.2019, and 05.16.2020. 2. Interview with the technical consultant on May 12, 2021 at 1pm confirmed blind testing was not included as part of the competency assessment for testing personnel number three in 2019 and 2020 (three of three competency assessments performed).