

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1100604	<b>(X3) Date Survey Completed</b>  08/14/2024
<b>Name of Provider or Supplier</b>  Lebonheur Pediatrics Llc	<b>Street Address, City, State</b>  511 Market Blvd, Suite 105, Collierville, 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>D6055</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of final patient test reports, personnel records, and staff interviews, the technical consultant failed to perform competency assessments for testing personnel prior to complete blood count (CBC) patient testing on the new instrument in May 2024. The findings include: 1. Observation of the laboratory on 08/14/2024 at 9:35 am revealed the Sysmex XP300 (Serial # C6790) instrument used for CBC patient testing (new since the last survey). 2. A review of final patient test reports revealed that patient ECW2170474, reported on 05/02/2024 at 3:20 pm, was the first patient reported from the Sysmex XP300 CBC instrument. 3. A review of the laboratory's personnel records revealed that competency assessments were not performed prior to patient testing on the new Sysmex XP300 for testing persons one, two, and three (three of four). 4. An interview with the technical consultant on 08/14/2024 at 12:00 pm confirmed the competency assessments for three of four testing persons were not performed prior to patient testing on the new Sysmex XP300 CBC instrument.</p>