Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0718169	10/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lebonheur Pediatrics Llc	51 North Dunlap Suite 310, 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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of patient number two complete blood count (CBC) test report, the laboratory's quality control (QC) limits for the CBC instrument and the manufacturer package insert limits, the quality control review report and patient data logs, monthly quality assessments for June and July 2018, and interview with the technical consultant, the laboratory's quality assessment process was ineffective when it failed to detect and correct problems with quality control limits for lot numbers 069600 and 089600 in 2018 with approximately 119 patients reported during lot number use. The findings include: 1. Review of patient number two test report revealed CBC patient testing reported on June 7, 2018. 2. Review of the laboratory's QC limits and the manufacturer package insert revealed the following: Lot number 069600: Red Cell Distribution Width (RDW)- laboratory QC limit in use = 5.6 - 23.6%, manufacturer limit = 12.1 - 17.1% Lot number 089600: RDW-Laboratory QC limit in use = 13.1-15.1%, Manufacturer limit = 12.1 - 16.1% Hematocrit - laboratory limit in use = 12.7 - 86.7%; manufacturer limit = 45.7 to 53.7% 3. Review of the quality control review report for lot numbers 069600 and 089600 and the patient data logs revealed the affected lot numbers were in use May 7, 2018 through July 30, 2018 with approximately 119 patients reported during this period. 4. Review of the June and July 2018 quality assurance reports revealed review of the affected lot numbers by the technical consultant with no corrective action documented for the use of incorrect quality control limits. 5. Interview with the technical consultant on October 25, 2018

	at 2:00 pm confirmed the laboratory uses the manufacturer's quality control limits, incorrect quality control limits were in use from May 7, 2018 to July 30, 2018 for RDW for lot 069600, RDW and Hematocrit for lot 089600, with approximately 119 patient CBCs reported. There was no corrective action documented for the incorrect quality control limits. The laboratory's quality assessment process was ineffective when it failed to detect and correct incorrect quality control limits in 2018.