Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314797	05/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lebonheur Pediatrics, Llc	806 Estate Place, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's quality control (QC) records, lack of records, and staff interview, the laboratory failed to retain statistical data parameters for complete blood count (CBC) QC performed on the Sysmex XP 300 instrument in 2023 and 2024 for twenty-one of twenty-one lots reviewed. The findings include: 1. Observation of the laboratory on 05/10/2024 at 9:45 am revealed the Sysmex XP 300 (Serial # A4122) instrument used for CBC patient testing. 2. A review of the laboratory's CBC QC records revealed no documentation of statistical parameters (mean or standard deviation) for twenty-one of twenty-one lot numbers reviewed as follows: 22770710, 22770711, 22770712 Expiration date 01/11/2023 23610710, 23610711, 23610712 Expiration date 04/05/2023 30800710, 30800711, 30800712 Expiration date 06/28/2023 31640710, 31640711, 31640712 Expiration date 09/20/2023 32480710, 32480711, 32480712 Expiration date 12/13/2023 33320710, 33320711, 33320712 Expiration date 03/06/2024 40510710, 40510711, 40510712 Expiration date 05/29/2024 3. An interview on 05/10/2024 at 12:30 pm with the interim technical consultant and laboratory lead confirmed that the laboratory failed to retain the statistical data for the Sysmex XP 300 CBC instrument in 2023 and 2024.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures

	that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of quality control (QC) records, and staff interviews, the laboratory failed to monitor the Sysmex XP 300 QC for accuracy and precision over time in 2023 and 2024. The findings include: 1. Observation of the laboratory on 05/10/2024 at 9:45 am revealed the Sysmex XP 300 instrument (Serial #A4122) used for CBC patient testing. 2. A review of the laboratory's 2023 and 2024 QC records revealed no evidence that the QC was monitored for accuracy and precision over time. 3. An interview on 05/10/2024 at 12:30 p.m. with the interim technical consultant and laboratory lead confirmed the survey findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's policy, calibration records, and staff interviews, the laboratory's quality assessment policy failed to include review of the Sysmex XP 300 complete blood count (CBC) instrument calibrations. The findings include: 1. Observation of the laboratory on 05/10/2024 at 9: 45 am revealed a Sysmex XP 300 (Serial #A4122) instrument used for CBC patient testing. 2. A review of the laboratory's quality assessment policy revealed that it did not include a review of Sysmex XP 300 instrument calibrations. 3. A review of the laboratory's calibration records revealed that two of three calibrations performed were not reviewed (02/27/2023 and 08/21/2023). 4. An interview on 05/10/2024 at 12:30 pm with the interim technical consultant and laboratory lead confirmed the laboratory did not review calibrations performed on the Sysmex XP 300 as part of the laboratory's quality assessment process in 2023.