Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0920583	12/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lebonheur Pediatrics Llc	871 Ridgeway Loop Rd Ste 200, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the operator's manual, the laboratory procedure, patient test reports and interview with the technical consultant, the laboratory procedure failed to include actions to take for flagged Complete Blood Count with automated white blood cell differential (CBC w/diff) results, resulting in results that were not verified prior to reporting the CBC results to the provider. The findings include: 1. Observation of the laboratory on 12/18/23 at 8:05 am revealed the Beckman Coulter AcT Diff (serial number AZ02002) on the counter in use for performing patient testing for Complete Blood Count with automated white blood cell

differential (CBC w/Diff). 2. Review of the Beckman Coulter AcT Diff operator's manual revealed the following: If any flags appears, review the results according to your laboratory's protocol. ----- (dashes) Total voteout. Suggested Action: 1. Thoroughly mix and rerun the sample. 2. If the voteout repeats, zap apertures. 3. Thoroughly mix and rerun the sample. 4. If voteout repeats, run a previously run sample with known values. 5. If voteout repeats, clean the baths according to Clean the Baths. 6. Thoroughly mix and rerun the sample. 7. If the voteout repeats, call your Beckman Coulter Representative. +++++ (pluses). Suggested Action: 1. Ensure that the bath shield is in place. 2. Make a dilution to determine the parameter result. For WBC and Hgb, if it occurs on multiple samples, verify correct delivery of lyse. For MCV, verify results by alternative method, such as blood film review or spun Hct. XXXXX Aperture Alert. A problem was detected during counting that could compromise the integrity of the results. Suggested Action: 1. Remove the stopper and gently mix the sample with a wooden applicator stick to check for fibrin strands or clots. If found, collect and run a new sample. If not found, thoroughly mix and rerun the sample. 2. If the Aperture Alert repeats, run a previously run sample with know values. 3. If the Aperture Alert repeats, zap apertures. 5. If the Aperature Alert repeats, clean the baths according to the clean the Baths procedure in this chapter. 6. Thoroughly mix and rerun the sample. 7. If the Aperture Alert repeats, use an alternative method. 8. If the Aperture Alert repeats, call your Beckman coulter Representative. ..... (dots) Incomplete calculation. Result cannot be calculated. System does not have enough information to compute a result. Suggested Actions: See instructions for voteout (-----). If for Hgb, error was detected during Hgb measurement. The Hgb Blank and/or Hgb Read results do not correlate. Suggested actions: 1. Thoroughly mix and rerun the sample. 2. If Hgb ..... repeats, call your Beckman coulter Representative. If on all samples: 1. Verify that Hgb lamp is illuminated. If not, call your Beckman Coulter Representative. If it is illuminated, run startup to set Hgb lamp voltage. 2. If problem persists, call your Beckman Coulter Representative. If for Diff parameters: Suggested Actions: If for WBC: 1. Confirm results. 2. Do manual differential. If for WBC voteout: See instructions for voteout (-----). If for results cannot be calculated: 1. Verify sample handling. 2. If the sample has been refrigerated, warm to room temperature then thoroughly mix and rerun sample. 3. Wait 10 to 15 minutes, then thoroughly mix and rerun the sample. 4. If sample is more than 5 hours old, collect a fresh sample or perform manual differential. If RBC voteout, see instructions for voteout (-----), If for RBC, Hgb, or MCV over operating range (+++++) see instructions for over operating range. If Hgb incomplete-see instruction for Hgb. If platelet voteout-see instruction for voteout (-----), If for Plt over operating range-see instructions for over operating range. If for MPV, associated with platelet voteout-see instructions for voteout (-----), If for plt over operating range-see instruction for over operating range (+++++). + (plus) Overrange results. Indicates result is greater than linear range but less than operating range. Suggested Action: Verify results according to your laboratory's protocol. If any parameter is outside linearity limits, cycle diluent blank before proceeding with subsequent samples. 1,2,3,4,M. Cause: Differential parameters failed the internal regional size distributional criteria at on e specific region or multiple regions. Suggested actions: Verify the results according to your laboratory's protocol. X- Review results. X flag indicates that one of the multiple Aperture Alert criteria was not met. Suggested action: 1. Thoroughly mix and rerun the sample. 2. If flag does not repeat, report result. 3. If flag repeats, clean the aperture. If after cleaning, problem persists, contact your Beckman Coulter Representative. * *occurs on parameters influenced by +++++, +, -----. Depending on parameter flagged, Possible causes listed are: Possible dual RBC population, Possible sample handling problem, Possible interference with WBC count, Sweepflow error, possible sample interference or instrument problem. See

	instructions for +++++, +, or -----. 3. Review of the laboratory procedure titled "Procedure for CBC Analysis" revealed no procedures or actions to take for flagged CBC results. 4. A review of patient test reports from the Beckman Coulter AcT Diff instrument from 12.06.23 to 12.15.23 revealed that four of six patients with flagged results did not have corrective action taken. Date: 12/07/23, patient 001838049- Diff results flagged with "*" and "M" with no actions taken. Date: 12/11/23, patient 000656483- Diff results flagged with "3" with no actions taken. Date: 12/11/23, patient 002155173 - Diff results flagged with "M" with no actions taken Date: 12/15 /23, patient 002153417 - Diff results flagged with '3" with no actions taken. 5. Interview with the technical consultant on 12/18/23 at 12:25 pm confirmed the laboratory 's CBC procedure did not include instructions or actions to take if results are flagged by the CBC instrument, resulting in patients reported without verifying the test results. Word Key: Diff=White blood cell differential WBC=White Blood Cell RBC=Red Blood Cell MCV=Mean Corpuscular Volume Hgb=Hemoglobin MPV=Mean Platelet Volume Hct=Hematocrit Plt=Platelet
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (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 quality assurance plan, the laboratory's quality control data, and interview with the technical consultant, the laboratory's quality assessment process was ineffective in correcting problems with shifts in quality control (QC) for two of five months of QC reviewed. The findings include: 1. Observation of the laboratory on 12/18/23 at 8:05 am revealed the Beckman Coulter AcT Diff (serial number AZ02002) on the counter in use for performing patient testing for Complete Blood Count with automated white blood cell differential (CBC w/Diff). 2. Review of the laboratory Quality Assurance Plan revealed one of the goals for the Quality Assurance Program as: 2. "Identify problems in our laboratory and apply corrective action." 3. Review of the laboratory's cumulative quality control data revealed the following: Lot numbers 068500, 078500, and 088500 in use during October and November 2023. Level two (Normal) (lot 078500) was repeated multiple times on multiple dates to bring the control into range, shifts were noted on the Levy-Jennings graphs. Level three (Abnormal) (lot 088500) with shifts noted on the Levy-Jennings graphs. The Levy-Jennings were printed and reviewed by the technical consultant with no documented corrective action or investigation into the cause for the shift in Red Blood Cell (RBC) values. 4. Interview with the technical consultant on 12/18/23 at 12:25 pm confirmed the laboratory's quality assessment process was ineffective when it did not identify and correct the problems with shifts in quality control data for data reviewed from October and November 2023.