Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314283	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Memphis & Shelby County Pediatric Group	1444 East Shelby Dr, Suite 317, 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, lack of procedure, patient test reports and interview with the laboratory director, the laboratory failed to have a procedure to follow for corrective 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 01/03 /24 at 9:00 am revealed the Beckman Coulter AcT Diff (system ID # 57517593) on the counter in use for performing patient testing for 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. 4. 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. There was no procedure to follow for

	actions to take when CBC results were flagged. 4. A review of patient test reports from the Beckman Coulter AcT Diff instrument revealed that four of four patients with flagged results did not have corrective action taken. Date: 08/04/22, patient 000137130 - RBC, Hct, MCV, MCH, MCHC, RDW, PLT and MPV results flagged with X with no action or corrective actions performed. Date:02/28/23, patient 000106311- Diff results flagged with "3" with no actions taken. Date: 08/24/23, patient 000127695 - Diff results flagged with "*" with no actions taken Date: 12/05 /23, patient 000125201 - Diff results and RDW flagged with "*" with no actions taken. All four patient results were reported in the patient electronic medical record. 5. Interview with the laboratory director on 01/03/24 at 2:30 pm confirmed the laboratory did not have a procedure to follow 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 MCH=Mean Corpuscular Hemoglobin MCHC=Mean Corpuscular Hemoglobin Concentration
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer control package insert, and interview with the lab director, the laboratory failed to label controls with open date and corrected expiration date (three of three controls in use). The findings include: 1. Observation of the controls in use for the Beckman Coulter AcT Diff CBC instrument on 01/03/24 at 9 am revealed the controls were not labeled with an open date or corrected expiration date (Lots 068700, 078700, 088700). 2. Review of the manufacturer package insert revealed the controls are good for 35 days after opening for a maximum of 20 samplings within the 35 days. 3. Interview with the lab director on 01/03/24 at 9 am confirmed the laboratory failed to label controls with open and corrected expiration date for the current controls in use on the date of the survey.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by:

	Based on review of final patient test reports and interview with the lab director, the laboratory failed to ensure final patient test results for Complete Blood Count with automated white blood cell differential (CBC w/Diff) were accurately transcribed from the instrument printout to the electronic medical record (EMR) for one of four patients reviewed. The findings include: 1. Review of CBC w/Diff results for patient 000125201 performed on 12/05/23 revealed the following: The results for Monocyte %, Granulocyte %, Red Blood Cell, and Hemoglobin were not reported correctly in the electronic medical record (EMR) as follows: Monocyte %-Printout = 5.0, EMR = 5.01, Granulocyte %-Printout=79.7, EMR=12.4, Red Blood Cell- Printout=5.01, EMR=38.6, Hemoglogin-Printout=12.4, EMR=77. 2. Interview with the lab director on 01/04/24 at 2:30 pm confirmed the laboratory failed to ensure the CBC w/Diff results were accurately entered into the patient EMR for patient 000125201 performed on 12/05/23.
D5805	TEST REPORT CFR(s): 493.1291(c) 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 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 patient complete blood count with automated white blood cell differential (CBC w/ diff) results in the electronic medical record, and interview with the lab director, the final patient test report failed to include units of measure for 11 of 16 analytes reported from the CBC w/diff for four of four patients reviewed from 2022 and 2023. The findings include: 1. Review of four patient CBC results entered into the electronic medical record revealed the units of measure were not included for the following analytes: WBC, RBC, MCV, MCH, MCHC, RDW, PLT, MPV, LY#, MO#, GR#. Patient identification numbers and dates of service as follows: 000137130 - 08/04/22, 000106311 - 02/28/23, 000127695 - 08/24/23, and 000125201 - 12/05/23. 2. Interview with the lab director on 01/03/24 at 2:30 pm confirmed the final patient test reports did not include the units of measure for four of four patients reviewed. Word Key: MCV=Mean Corpuscular Volume MCH=Mean Corpuscular Hemoglobin MCHC=Mean Corpuscular Hemoglobin Concentration RDW=Red Cell Distribution Width PLT=Platelet Count MPV=Mean Platelet Volume LY#=Lymphocyte Absolute Count MO#=Monocyte Absolute Count GR#=Granulocyte Absolute Count