Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314283	03/17/2022
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
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 review of laboratory records, patient test reports, and staff interview, the laboratory failed to retain complete blood count (CBC) analytic records including quality control (09/04/2020 to 10/27/2020 and 09/01/2021 to 02/28/2022), calibrator assay sheets (three of four), and quality control assay sheets (nine of twenty-one) for two years in 2020, 2021, and 2022 with patient testing reported. Approximately 343 patients were reported during the gaps in quality control records. The findings include: 1. Review of laboratory CBC analytic records revealed the following: The laboratory did not retain QC records for two years for dates ranging from 09/04/2020 to 10/27/20 and 09/01/2021 to 02/28/2022. The laboratory did not retain calibrator assay sheets for three of four calibrations reviewed (08/13/2020, 02/04/2021, 08/30 /2021). The laboratory did not retain quality control assay sheets for nine of twenty-one lots (068800, 078800, 088800, 069600, 079600, 089600, 068900,078900, and 089600). 2. Review of patient CBC reports revealed patient 000140826 reported on November 1, 2021 and patient 000142092 reported on February 1, 2022 on dates when QC records were not available. Further investigation revealed approximately 43 patients were reported during the QC retention gap from 09/04/2020 to 10/27/2020 and approximately 300 patients were reported during the QC retention gap from 09/01 /2021 to 02/28/2022 for a total of 343 patients. 3. Interview with the laboratory director on 03/17/2022 at approximately 3:30 p.m. confirmed the laboratory failed to retain all CBC analytic records for two years in 2021 and 2022. The laboratory

	director stated that the QC printouts are discarded at the end of each month. There were no other records available for the dates in question. He also confirmed other records including calibrator and quality control assay sheets were not retained.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: The laboratory failed to have an effective quality assessment process (Refer to D5293) and failed to ensure appropriate quality control ranges were used (Refer to D5439).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and the checklist used for performing testing personnel competency assessment, and interview with the laboratory director, the laboratory failed to have a procedure to include all six criteria for assessing testing personnel competency in 2022. The findings include: 1) Review of the laboratory procedure manual revealed the laboratory did not have a policy /procedure for assessing testing personnel competency. The checklist being used to assess competency did not include all six criteria as required by the regulations. The six criteria required for assessing testing personnel competency include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Interview on 03/17/2022 at 3:30 p.m. with the laboratory director confirmed the laboratory did not have a policy/procedure for assessing testing personnel competency and the checklist being used did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).
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 observation of the laboratory, review of laboratory complete blood count (CBC) quality control (QC) records, and interview with the laboratory director, the laboratory failed to have an effective quality assessment process in place to prevent the use of incorrect quality control limits and lot numbers, and lack of retention of analytic records including quality control, control assay sheets and calibrator assay sheets. The findings include: 1. Observation of the laboratory on 03/17/2022 at approximately 9 a.m. revealed the Beckman Coulter AcT Diff CBC instrument in use for patient testing (Serial # BB50055). 2. Review of the laboratory's current quality control revealed the following: Lot numbers in the instrument setting = 068900, 078900, 088900 with an expiration date of 08/30/2021. Lot number in use was 069300, 079300, and 089300 with an expiration date of 03/28/2022. Incorrect quality control limits were in use for the current lot numbers. 3. Review of historic QC records revealed gaps in retention of quality control from 09/04/2020 to 10/27/2020 and 09/01/2021 to 02/28/2022 and lack of retention of calibrator and control assay sheets. (three of four calibrator assay sheets and nine of twenty-one control assay sheets). 4. Interview with the laboratory director on 03/17/2022 at approximately 3:30 p.m. revealed the following statements: Quality Assessment is performed monthly. The daily QC printouts are discarded at the end of the month. Testing personnel are suppose to be printing the cumulative QC reports for review purposes, but no reports were available from 09/04/2020 to 10/27/2020 and 09/01/2021 to current date. No corrective action had been performed for the use of incorrect quality control limits, incorrect lot numbers, and missing QC records. The laboratory failed to have an effective quality assessment process in place to detect and correct errors with analytic CBC records and record retention.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 complete blood count quality control limits, and staff interviews, the laboratory failed to verify the quality control limits in use for complete blood count (CBC) performed on the AcT CBC instrument in 2021. The findings include: 1. Observation of the laboratory on 03/17/2022 at approximately 9 a.m. revealed the Beckman Coulter AcT Diff CBC instrument on the counter in use for patient testing (serial #BB50055). 2. Review of quality control limits in use for the current lot numbers (069300, 079300, 089300) when compared to

	the manufacturer control assay sheet revealed the ranges in use did not match the manufacturer control limits for the Beckman Coulter AcT Diff. 3. Interview with testing personnel number one on 03/17/2022 at approximately 9 a.m. revealed the following statement: Control limits for new lot numbers are entered into the instrument each time a new lot is put into use. The control limits entered are taken from the control assay sheet and the lab enters the limits for the Beckman Coulter AcT Diff 2 instrument. 4. Interview with the laboratory director on 03/17/2022 at approximately 3:30 p.m. confirmed the laboratory failed to use the correct manufacturer quality control limits for the current lot when it used the limits for the AcT Diff 2 instrument instead of the AcT Diff instrument. The laboratory failed to verify correct quality control limits when changing lot numbers. The current lot numbers were put into use on 12/20/2021.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory records and interview with the lab director, the laboratory director failed to review and approve the validation documents for the Beckman Coulter AcT Diff complete blood count (CBC) instrument that was completed in 2019. The findings include: 1. Observation of the laboratory on 03/17/2022 at approximately 9 a.m. revealed the Beckman Coulter AcT Diff CBC instrument (Serial #BB50055) on the counter in use for patient testing. 2. Review of validation studies performed on the Beckman Coulter AcT Diff CBC instrument (serial number BB50055) revealed the studies had not been reviewed or approved by the laboratory director. 3. Interview with the lab director on 03/17/2022 at approximately 3:30 p.m. confirmed he had not review or approved the validation studies performed in January 2019 for the Beckman Coulter AcT Diff CBC instrument.