Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314283	03/10/2025
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
D0000	During a recertification survey performed on 03/10/2025, the laboratory was found out of compliance with the following conditions: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
D2123	HEMATOLOGY CFR(s): 493.851(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) CASPER Report 0155D (CMS 155), the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, lack of records, and staff interview, the laboratory failed to participate in the 2024 Event One (one of three events reviewed) for the Complete Blood Count with White Blood Cell Differential (CBC w/Diff) analytes. The findings include: 1. A review of the CMS 155 report revealed the laboratory received a 0% score for the 2024 Event One. 2. A review of the laboratory's WSLH performance evaluation report for 2024 Event One revealed "Fail" in the status column with the comment "No results received" for the samples AT-1, AT-2, AT-3, AT-4, and AT-5 which resulted in a 0% score for the event. 3. An interview with the laboratory director, testing person one, and laboratory liaison on 03/10/2025 at 2:00

	pm confirmed that the laboratory failed to participate in the CBC w/Diff 2024 Event One and performed patient testing.
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 a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory personnel records, laboratory policy, lack of records, final patient test reports, and staff interviews, the laboratory failed to follow its policy for competency assessment for three of three new testing personnel (TP) that performed Complete Blood Count with White Blood Cell Differential (CBC w/Diff) patient testing in 2023 and 2024. The findings include: 1. A review of Form CMS-209 revealed five TP that performed CBC w/Diff patient testing. Three of the five were new since the last survey (TP three, four, and five). 2. A review of the laboratory personnel records revealed the following: TP three: The "Laboratory Competency Evaluation" form was completed on 01/05/2024, and the hire date was listed as 07/05/2023. TP four: The "Laboratory Competency Evaluation" form was completed on 08/06/2024, and the hire date was listed as 02/06/2024. TP five: The "Laboratory Competency Evaluation" form was completed on 08/26/2024, and the hire date was listed as 02/26/2024. 3. A review of the laboratory policy titled "Quality Assurance Plan" in the section "Personnel" revealed "New personnel shall undergo 2 week, 6 month, and annual, thereafter, reviews." and "Documentation of the reviews shall be available in the individual personnel jackets." 4. On the survey date (03/10/2025), the two-week review documentation was unavailable for TP three, four, or five. 5. A review of the final patient CBC w/Diff test reports revealed the following: TP three reported patient 141507 on 05/01/2024 at 12:05 pm. TP four reported patient 147120 on 08/14/2024 at 2:48 pm. TP five reported patient 146008 on 07/10/2024 at 10:59 am. 6. The laboratory director, TP one, and laboratory liaison confirmed the survey findings in an interview on 03/10/2025 at 2:00 pm. Word Key: CLIA- Clinical Laboratory Improvement Amendments
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, lack of documentation, and staff interviews, the laboratory failed to evaluate results that the WSLH PT agency did not grade for one of three events reviewed in 2024. The findings include: 1. A review of the

	laboratory's WSLH PT records revealed the following: 2024 Event Three: The performance evaluation report indicated "***" in the status column with a comment of "Not scored- Insufficient Peer Group" for the hematocrit (Hct) % analyte for samples AT-11, AT-12, AT-13, AT-14, and AT-15. The laboratory failed to provide documenation of a self-evaluation of the non-graded scores. 2. The laboratory director, testing person one, and laboratory liaison confirmed the survey findings in an interview on 03/10/2025 at 2:00 pm. Word Key %- percent
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) Casper Report 0155D (CMS 155), the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, the Department of Health and Human Services Centers for Medicare and Medicaid Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory personnel records, final patient test reports, and staff interviews, the laboratory director failed to ensure the laboratory participated in one of three PT events in 2024 (Refer to D6017), and failed to ensure three of five testing personnel (TP) had documentation of training and competency prior to patient Complete Blood Count with White Blood Cell Differential (CBC w/Diff) testing in 2023 and 2024 (Refer to D6029).
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program; This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) CASPER Report 0155D (CMS 155), the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) reports, and staff interviews, the laboratory director failed to ensure the PT results for 2024 Event One (one of three reviewed) were submitted to the PT agency before the event deadline (Refer to D2123). The findings include: 1. A review of the CMS 155 report revealed the laboratory received a 0% score for the 2024 Event One. 2. A review of the laboratory's WSLH performance evaluation report for 2024 Event One revealed "Fail" in the status column with the comment "No results received" for the samples AT-1, AT-2, AT-3, AT-4, and AT-5 which resulted in a 0% score for the event. 3. An interview with the laboratory director, testing person one, and laboratory liaison on 03/10/2025 at 2:00 pm confirmed that the laboratory director failed to ensure the laboratory participated in 2024 Event One and performed CBC w /Diff patient testing.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)

	(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on a review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, a lack of documentation, and staff interviews, the laboratory director failed to ensure that the PT corrective action plan was followed for the Complete Blood Count with White Blood Cell Differential (CBC w/Diff) PT results that were unacceptable for 2024 Event Three (one of three reviewed). The findings include: 1. A review of the laboratory's WSLH PT records revealed the following: The 2024 Event Three Performance Evaluation Report, reviewed by the laboratory director on 11/16/2024, had "Fail" in the Status column for Sample AT-15 for the White Blood Cell Count, Red Blood Cell Count, and Hemoglobin analytes. No corrective action was documented for the unacceptable scores. 3. The laboratory director, testing person one, and laboratory liaison confirmed the survey findings in an interview on 03/10/2025 at 2:00 p.m.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory personnel records, final patient test reports, and staff interviews, the laboratory director failed to ensure three of five testing personnel (TP) that performed Complete Blood Count with White Blood Cell Differential (CBC w/Diff) patient testing had documentation of training or demonstrated accuracy prior to patient testing in 2023 and 2024. The findings include: 1. A review of Form CMS-209 revealed five TP that performed patient testing for CBC w/Diff. 2. A review of the laboratory personnel records revealed the following: TP three: The laboratory director did not sign the "Medical Assistant Laboratory Check-Off" training form dated 07/24/2023. TP four: The laboratory director did not sign the training form labeled "Medical Assistant Training---Check Off List" dated 02/20/2024. TP five: Training documentation was not available. 3. A review of the final patient CBC w/Diff test reports revealed the following: TP three reported patient 141507 on 05/01/2024 at 12: 05 pm. TP four reported patient 147120 on 08/14/2024 at 2:48 pm. TP five reported patient 146008 on 07/10/2024 at 10:59 am. 4. The laboratory director, TP one, and laboratory liaison confirmed the survey findings in an interview on 03/10/2025 at 2:00 pm. Word Key: CLIA- Clinical Laboratory Improvement Amendments
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory personnel records, and staff interviews, competency assessments for three of five testing personnel (TP) were performed by an individual that did not meet the minimum educational and experience requirements for performing technical consultant duties (Refer to D6035). Word Key: CLIA-Clinical Laboratory Improvement Amendments
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

	This STANDARD is not met as evidenced by: Based on a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory personnel records, lack of documentation, final patient test reports, and staff interviews, three of five testing personnel (TP) competency assessments performed in 2024 were not performed by an individual that qualified as a technical consultant. The findings include: 1. A review of Form CMS-209 revealed five TP and one laboratory director who also served as the laboratory technical consultant. 2. A review of the laboratory personnel records revealed that TP one signed the competency assessments for TP three (completed on 01/05/2024), TP four (completed on 08/06/2024), and TP five (completed on 08/26/2024). 3. The laboratory failed to provide educational documentation that qualified TP one to perform technical consultant duties. 4. A review of the final patient CBC test reports revealed the following: TP three reported patient 141507 on 05/01/2024 at 12:05 pm. TP four reported patient 147120 on 08/14/2024 at 2:48 pm. TP five reported patient 146008 on 07/10/2024 at 10:59 am. 5. The laboratory director, TP one, and laboratory liaison confirmed the survey findings in an interview 03/10/2025 at 2:00 pm. Word Key: CLIA- Clinical Laboratory Improvement Amendments