Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0963636	03/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Specialists Of Marion County	325 South Cedar Ave Ste 1, South Pittsburg, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the manufacturer instructions for use (IFU), lack of documentation, and staff interview, the laboratory failed to follow the manufacturer's instructions for performing quality control (QC) on the McKesson Consult Diagnostics 120 Urine Analyzer for 12 of 12 months reviewed from March 2024 to March 2025. The findings include: 1. An observation of the laboratory on 03 /04/2025 at 8:45 a.m. revealed that it used a McKesson Consult Diagnostics 120 Urine Analyzer (ID: 197G10041F2) and McKesson Consult Diagnostics 10SG Urine Reagent Strips for patient testing. 2. A review of the McKesson Consult Diagnostics IFUs revealed the following QC requirements: - The user manual for the McKesson Consult Diagnostics 120 Urine Analyzer states to test "known positive and negative" controls when the laboratory opens a new canister of strips for testing, a new operator uses the analyzer, when test results seem inaccurate, and after performing maintenance or service on the analyzer. - The package insert for the McKesson Consult Diagnostics 10SG Urine Reagent Strips states to test positive and negative quality controls with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips. Additionally, it states QC is needed when an opened container of test strips are stored for more than 30 days "to ensure reagent storage integrity", to train new users, confirm test performance, and "when patients' clinical conditions or symptoms do not match the results obtained on the test strips." 3. No documentation of quality control testing for the McKesson Consult Diagnostics 120

	Urine Analyzer or 10SG reagent strips was available for review. 4. An interview with testing person two on 03/04/2025 at 9:15 a.m. confirmed the laboratory had not performed urinalysis QC from March 2024 to March 2025.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of patient test reports, quality control (QC) records, and staff interviews, the laboratory failed to ensure that the Complete Blood Count (CBC) QC was within acceptable limits before reporting patient CBC results for two of five days reviewed in 2024 and 2025. The findings include: 1. Observation of the laboratory on 03/04/2025 at 8:45 a.m. revealed a Beckman Coulter DXH-520 hematology instrument (ID: 83961757) for performing patient CBC testing. 2. A random review of patient test reports revealed the laboratory performed CBC testing on 08/01/2024 (Patient: 11594), 10/16/2024 (Patient: 10378), 01/03/2025 (Patient: 14744), and 01/30/2025 (Patient: 13799). 3. A review of 2024 and 2025 QC records revealed the following unacceptable DxH 500 Series QC results: - On 10/16/2024, the Abnormal Low Level (Lot: 352416411) flagged the WBC, RBC, and LY# analytes out of range at 8:25 a.m. There was no successful run of the abnormal low level QC on 10/16/2024. - On 01/03/2025, the Abnormal Low Level (Lot: 352416711) flagged the WBC and LY# analytes out of range at 8:29 a.m., 8:35 a.m., 8:36 a.m., and 9:01 a.m. There was no successful run of the abnormal low level QC on 01/03/2025. 4. An interview with TP2 on 03/04/2025 at 1:30 p.m. confirmed the laboratory performed and reported patient CBCs on 10/16/2024 and 01/03/2025 without QC being within acceptable limits. Key: WBC = White Blood Cell count, LY# = Absolute lymphocyte count, RBC= Red Blood Cell count
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of daily quality control (QC) records, lack of documentation, and staff interviews, the laboratory failed to document corrective actions for unacceptable QC of their hematology analyzer for 24 of 60 patient testing days reviewed in 2024 and 2025. The findings include: 1. A random review of the laboratory's complete blood count (CBC) QC data for the Beckman Coulter DXH-520 hematology instrument (ID: 83961757) revealed the following: - The laboratory performed QC 19 days in January 2025 using three levels (Low, Normal, High) of DxH 500 Series QC (Lots: 352416711, 712, and 713) material. The analyzer recorded unacceptable QC

	results on 01/03, 01/06, 01/08, 01/09, 01/13, 01/15, 01/21, 01/28, and 01/29. - The laboratory performed QC 23 days in October 2024 using three levels (Low, Normal, High) of DxH 500 Series QC (Lots: 352416411, 412, and 413) material. The analyzer recorded unacceptable QC results on 10/7, 10/11, 10/16, 10/18, 10/25, 10/21, 10/28, and 10/30. - The laboratory performed QC 18 days in September 2024 using three levels (Low, Normal, High) of DxH 500 Series QC (Lots: 352416311, 312, and 313) material. The analyzer recorded unacceptable QC results on 09/03, 09/09, 09/10, 09 /11, 09/13, 09/16, 09/20, and 09/24. 2. No documentation of corrective actions or troubleshooting for unacceptable QC was available for 09/03, 09/09, 09/10, 09/11, 09 /13, 09/16, 09/20, 09/24, 10/7, 10/11, 10/16, 10/18, 10/25, 10/21, 10/28, and 10/30 in 2024; and 01/03, 01/06, 01/08, 01/09, 01/15, 01/21, 01/28, and 01/29 in 2025. 3. An interview with TP2 on 03/04/2025 at 1:30 p.m. confirmed that the laboratory did not routinely document corrective actions when daily controls were outside acceptable limits.
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. This STANDARD is not met as evidenced by: Based on a review of laboratory policies, interlaboratory quality assurance (QA) records, lack of documentation, and staff interviews, the laboratory failed to establish an effective procedure for reviewing the overall accuracy and precision of its hematology test system or follow its policy for QA records review and documentation in 2024 and 2025 (12 months reviewed). The findings include: 1. A review of the laboratory's "Quality Assurance Plan" revealed that all quality assurance records are dated and initialed by the staff performing the review and the laboratory director. 2. A review of the laboratory's 2024 and 2025 Beckman Coulter interlaboratory quality assurance program reports for four sets (3 levels each) of quality control (3524162, 3524163, 3524164, and 3524167) revealed the following: - The report defines the coefficient of variation compared to the peer (CVI) as a measurement of precision and the standard deviation index (SDI) as a measurement of accuracy. The report instructions state, "When a note to review SDI data is generated, one must assess the clinical significance between the participant and the pool means." - Lot 362416212 (level 2) showed a flagged SDI of 2.27 for the white blood count analyte (WBC). - Lot 352416711 (level 1) showed a flagged CVI of 2.62, and lot 362416712 (level 2) showed a flagged CVI of 2.16 for the mean corpuscular volume analyte (MCV). Lot 372416713 (level 3) showed a flagged CVI of 2.52 for the white blood count analyte (WBC). 3. There was no documented review of the interlaboratory QA program reports by staff or the director. There was no evidence that the laboratory used the interlaboratory QA reports to identify potential issues with the test system's accuracy and precision. 4. An interview with TP2 on 03/04/2025 at 1:30 p.m. confirmed that the laboratory did not identify flags on the Beckman Coulter interlaboratory QA program reports, nor were reviews of these reports documented.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established

	and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on the laboratory's Quality Assurance Plan, Quality Assurance Checklist, records review, and staff interviews, the laboratory director failed to ensure that the laboratory maintained an effective quality control (QC) and quality assessment program in 2024 and 2025 and that it identifies failures in quality as they occur. The findings include: 1. A review of the laboratory's Quality Assurance Plan revealed the following statement: - "Our laboratory uses this quality assurance program to improve the laboratory services we provide to our physicians and patients. We will perform a quality review annually and review the results with the laboratory director." 2. A checklist attached to the Quality Assurance Plan titled "Patient Quality Assurance Monitor" had the following items marked as acceptable under the section titled "Quality Control Policy": - "All necessary remedial action was performed and documented." - "All quality control/ calibrators were performed and were within acceptable limits before patient results were reported." - "Quality control results were examined for possible problems" The checklist had the following items marked as acceptable under the section titled "Personnel Policies": - "Personnel evaluations were performed as necessary" The laboratory did not record any comments in the checklist's section stating, "If any of the above were not complied with, explain the problem and how it was resolved." 3. A review of laboratory records revealed the following: - The laboratory had not performed and documented all remedial actions for QC errors (Refer to D5783 and D5791). - All QC was not within acceptable limits before the laboratory reported patient results (Refer to D5481). - The laboratory did not effectively examine QC results for possible problems (Refer to D5481, D5783, and D5791). - The laboratory did not conduct all necessary testing personnel competencies (Refer to D6053). 4. An interview with TP2 on 03/04/2025 at 1:30 p.m. confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), testing personnel (TP) records, lack of documentation, and staff interviews, the technical consultant failed to evaluate the competency for one of three testing personnel (TP) at least twice within their first year of testing. The findings include: 1. A review of the FORM CMS-209 revealed three persons (TP1, TP2, and TP3) who performed moderate complexity hematology testing. TP3 was a new testing person listed on the FORM CMS-209 since the laboratory's last survey. 2. A review of the laboratory's testing personnel records revealed TP3 began in March 2024. 3. The laboratory did not have evidence of two completed competency assessments for TP3 at the time of the survey (03/04/2025). 4. An interview with TP2 on 03/04/2025 at 1:30 p.m. confirmed that the laboratory did not complete the minimum two competency assessments during TP3's first year of testing.