Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0311228	07/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Knoxville Pediatric Associates, Pc	245 Joule Street, Alcoa, 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 07.02.2024, the laboratory was found to NOT be in compliance with the following conditions: D6033: 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant D6063: 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), College of American Pathologists (CAP) proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure that thirteen of sixteen testing personnel (TP) who routinely performed patient Complete Blood Count (CBC) testing also participated in proficiency testing in 2023. The findings include: 1. Observation of the laboratory on 07.02.2024 at 9:40 a.m. revealed a Sysmex XN-330 analyzer (serial number 14359) for patient CBC testing. 2. A review of the Form CMS-209 revealed sixteen testing personnel (TP1 through TP16) who perform moderately complex patient testing for CBC. 3. A review of the laboratory's CAP PT computer-generated attestation statements revealed that TP4, TP8, and TP16 were the only testing personnel who participated in hematology proficiency testing in 2023. 4. An interview with the Nurse Manager (TP16) on 07.02.2024 at 10:30 a.m. confirmed that TP1, TP2, TP3, TP5, TP6, TP7, TP9, TP10, TP11, TP12, TP13, TP14, and TP15 routinely performed patient CBC testing and did not participate in any PT events in 2023.

D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and staff interviews, the laboratory director and testing personnel failed to sign five of five PT attestation statements reviewed from 2023 and 2024. The findings include: 1. A review of proficiency testing records revealed that the laboratory director and testing personnel failed to sign the attestation statements for Hematology 2023 (events A, B, and C) and 2024 (events A and B). 2. An interview with TP4 and TP16 on 07.02.2024 at 10:15 a.m. confirmed that the laboratory director and testing personnel failed to sign five of five attestation statements reviewed from 2023 and 2024.
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 laboratory procedure manual and staff interview, the laboratory policy for testing personnel competency did not include requirements for initial training and demonstration of accuracy during training, the frequency of competency assessment to include interim during the first year of patient testing and annually thereafter, and reassessment of competency if test methodology or instrument changes. The findings include: 1. A review of the laboratory quality assessment procedure revealed the following statement regarding testing personnel competency assessment: "Our laboratory routinely evaluates performance of its staff." 2. An interview with the Nurse Manager (TP16) on 07.02.2024 at 2:00 p.m. confirmed the laboratory policy was not in compliance with the requirements in subpart M when it did not include a requirement for initial training, demonstration of accuracy during the first year of patient testing, annual competency assessment thereafter, and reassessment of competency when test methods or instrumentation changes.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on laboratory observation, review of the Clinical Laboratory Improvement Amendments Application for Certification (Form CMS-116), review of the

	laboratory's policy and procedure manual, and staff interview, the laboratory failed to establish written procedures for complete blood count (CBC) testing or urine cultures performed to detect bacterial growth, with an average of 18,031 tests performed annually. The findings include: 1. Observation of the laboratory on 07.02.2024 at 9:40 a.m. revealed a Sysmex XN-330 analyzer (serial number 14359) used for patient CBC testing. Also observed were Aidian Urucult media used for performing urine cultures. 2. A review of the laboratory's Form CMS-116 revealed the laboratory performed approximately 18,031 hematology and bacteriology tests annually. 3. A review of the laboratory's policy and procedure manual revealed no written procedures for performing CBC patient testing on the Sysmex XN-330 analyzer or procedures for performing urine cultures using Aidian Uricult media. 4. An interview with the Nurse Manager (TP16) on 07.02.2024 at 2:00 p.m. confirmed the above survey findings.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on a review of Form CMS-209, review of personnel records, lack of documentation, and staff interview, the laboratory director failed to ensure that the person performing technical consultant duties in 2023 through the survey date (07.02.2024) had the appropriate education to qualify as a technical consultant (TC) (Refer to D6033 and D6035). The findings include: 1. A review of the Form CMS-209 form revealed 24 testing personnel (TP) who perform moderately complex patient testing and one TC. 2. A review of the personnel records revealed annual personnel competency assessments for 2023 through survey date (07.02.2024) for TP1 through TP13 revealed the initials of TP16 as the evaluator, a person not listed as a TC on Form CMS-209. 3. There was no evidence in the personnel records that TP16 met the minimum regulatory requirements to qualify as a technical consultant at CFR 493.1411(b)(4)(ii). 4. An interview with the Nurse Manager (TP16) on 07.02.2024 at 2:00 p.m. confirmed the above survey findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(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: CITATION NUMBER ONE: Based on a review of Form CMS-209, laboratory personnel records, and staff interview, the laboratory director failed to ensure that one of three new testing personnel had documentation of the highest level of education for performing moderately complex testing (Refer to D6063 and D6065). The findings include: 1. A review of Form CMS-209 revealed three new testing personnel (TP) listed as performing moderately complex testing since the last survey date. 2. A review of TP records revealed that one (TP15) of the three did not have documentation of the highest level of education. 3. An interview with the Nurse Manager (TP16) on 07.02.2024 at 2:00 p.m. confirmed there was no documentation of the highest level of education for one of three new testing personnel who perform moderately complex testing. CITATION NUMBER TWO: Based on a review of Form CMS-209, laboratory personnel records, and staff interview, the laboratory director failed to ensure three of three new testing personnel (TP) had initial training and demonstrated accuracy prior to performing moderately complex patient testing in 2023. The findings include: 1. A review of the CMS-209 revealed that TP14, TP15, and TP16 (new since the last survey date) were listed as performing moderately complex testing. 2. A review of testing personnel records revealed the following: - TP14 with initial training on 11.29.2023, no laboratory director review/approval. - TP15 and TP16: There was no documentation of initial training/demonstration of accuracy. 3 An interview with TP16 on 07.02.2024 at 2:00 p.m. confirmed the above survey findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY 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 testing personnel competency assessments and personnel education verification records, the person performing testing personnel competency assessments was not qualified to perform the duties (Refer to D6035), and the technical consultant of record did not perform annual competency assessments for seven of 24 testing personnel (Refer to D6054).
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 possess qualifications that are equivalent to those required for such certification; 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 one year of laboratory training or experience, or both in non-waived 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) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of testing personnel competency assessments, personnel education verification, and staff interview, the person performing technical consultant (TC) duties in 2023 through the survey date (07.02.2024) did not have the required education to perform the duties. The findings include: 1. A review of testing personnel (TP) competency assessments revealed that TP16's initials were in the "initials" boxes on the annual personnel assessment forms completed in 2023 through the survey date for TP1 through TP13. 2. A review of the highest level of education documentation revealed that TP16 did not have the required education to perform the TC duties as defined in the regulations. 3. An interview with TP16 on 07.02.2024 at 2:00 p.m. confirmed the above survey findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of Form CMS-209, review of personnel records, and staff interview, the technical consultant failed to perform annual competency assessments for seven of seven providers who read urine cultures in 2023 and 2024 and failed to perform annual competency assessments for 13 of 13 testing personnel who perform complete blood count (CBC) patient testing in 2023 through the survey date (07.02.2024). The findings include: 1. Observation of the laboratory on 07.02.2024 at 9:40 a.m. revealed the moderately complex Sysmex XN-330 hematology analyzer (serial number 14359) for complete blood count (CBC) patient testing and an incubator used for performing urine cultures for detection of bacterial growth in urine samples obtained from pediatric patients. 2. A review of the

	Form CMS-209 form revealed 24 testing personnel who perform moderately complex patient testing. 3. A review of the personnel records revealed the following; -No documentation of annual testing personnel (TP) competency assessments for providers who read urine cultures (TP18, TP19, TP20, TP21, TP22, TP23, and TP24). - The qualified TC of record did not perform annual competency assessments for 2023 and 2024 for TP1 through TP13, which perform CBC patient testing. 4. An interview with the Nurse Manager (TP16) on 07.02.2024 at 2:00 p.m. confirmed the above survey findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, personnel qualifications, and staff interview, testing person number fifteen (TP15) did not meet the regulatory education requirements for moderately complex testing personnel (Refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the Form CMS-209, lack of documentation, and staff interview, testing personnel number 15 (TP15) did not qualify to perform moderately complex patient testing due to a lack of documentation of the highest level of education (one of three new testing personnel since the last survey). The findings include: 1. A review of the Form CMS-209 form revealed TP15 listed as performing moderately complex patient testing. 2. A review of testing personnel records revealed no documentation of the highest level of education for TP15. 3. An interview with the Nurse Manager (TP16) on 07.02.2024 at 2:00 p.m. confirmed the above survey findings.