Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303212	09/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Huntsville Pediatric Associates	2004 Airport Road, Huntsville, AL	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) evaluations and an interview with Testing Personnel #1 (TP#1), the laboratory failed to ensure the accuracy of urine sediment examination, a non-regulated test, at least twice a year. The laboratory failed three of four PT surveys from October 2022 through May 2024 with no evidence of any other mechanism to verify the accuracy of the test. The findings include: 1. A record review revealed the laboratory utilized proficiency testing to verify the accuracy of urine sediment examination, however the laboratory failed the following PT surveys: A) 2022-MISC QA POC2; Urine Sediment-50 percent, B) 2023-MISC QA POC1; Urine Sediment-50 percent, C) 2024-MISC QA POC1; Urine Sediment-0 percent. 2. During an interview on 9/12/2024 at 1505 with TP#1, the laboratory provided investigation records and corrective action documentation on re-training of all TP for the failed PT performance however these were not effective in improving the laboratory's unsuccessful PT scores. TP#1 confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on a tour of the laboratory and an interview with Testing Personnel #1 (TP#1), the laboratory failed to ensure expired solutions were not utilized prior to patient testing. Microscopic examinations were performed using the same expired immersion oil solution from 2006 to the date of the current survey (9-12-2024). The findings include: 1. The laboratory tour with TP#1, revealed Resolve immersion oil solution Lot#37992 was used for microscopic examinations and had an expiration date of June 2006. The laboratory failed to provide another oil immersion solution that has an acceptable date at the time of the survey (9-12-2024). 2. During the laboratory tour on 9-12-2024 at approximately 8:38 AM, the Surveyor was presented with an immersion oil solution currently utilized for microscopic examinations that had exceeded expiration date. TP#1 confirmed these findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the Illumipro-10 incubator temperature logs, the Kwik Swab Device procedure, and an interview with Testing Personnel #1 (TP#1), the laboratory failed to document corrective action when the Illumipro-10 incubator temperatures were not within acceptable limits as specified on the Kwik Swab Device procedure. This was noted for 45 days out of 5 months reviewed in 2023 when Illumipro-10 incubator temperatures were outside the acceptable limits. The findings include: 1. A review of the incubator temperature logs for 2023 revealed the Illumipro-10 incubator temperatures were recorded higher than the laboratory's specified acceptable ranges with no evidence of corrective action documentation for the following months: a) January; 9 days of 30 days of patient testing, b) March; 12 days of 30 days of patient testing, c) April; 2 days of 30 days of patient testing, d) May; 1 day of 30 days of patient testing, e) June; 21 days of 29 days of patient testing. 2. A further review of the Kwik Swab Device procedure revealed, "g. Incubate the inoculated fluid media at 35-37 degrees Celsius..." 3. During the exit interview on 9-12-2024 at 1505, TP#1 confirmed the above findings.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

	This STANDARD is not met as evidenced by: Based on a review of the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) performance, PT Failure Corrective Action Worksheet, and an interview with Testing Personnel #1 (TP#1), the Technical Consultant (TC), who is also the Laboratory Director (LD), failed to implement appropriate in-service and re-training policies for personnel to ensure a passing score on PT. This was noted for three out of four unsuccessful PT events from 2022 through 2024. The findings include: 1. A review of the urine sediment PT performance records revealed the TC performed and documented the same corrective action for failing PT scores for the following events: a) 2022-MISC QA POC2: Urine Sediment score of 50% b) 2023-MISC QA POC1: Urine Sediment score of 50% c) 2024-MISC QA POC1: Urine Sediment score of 0% 2. A further review of the PT Failure Corrective Action Worksheet revealed the same corrective action regarding education on all three failing events. There was no evidence of another mechanism implemented to ensure passing results. 3. During the exit interview on 9/12/2024 at 1505, TP#1 discussed implementing personnel competency evaluation for urine sediment exam. TP#1 confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel evaluation records, and an interview with Testing Personnel #1 (TP#1), the Technical Consultant (TC), who is also the Laboratory Director (LD), failed to ensure training documentation was completed for all personnel listed on the CMS-209(Laboratory Personnel Report) prior to patient testing. This was noted for one out of six testing personnel performing moderate complexity testing. Findings include: 1. A review of the personnel evaluation records revealed no evidence of documentation of initial training prior to performing moderate complexity patient testing for TP#6. 2. During the exit interview on 9-12-2024 at 1505, TP#1 confirmed the above findings.