Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0956041	02/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
North Knoxville Pediatrics	1400 Dutch Valley Drive, Knoxville, 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
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 review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), review of 2021 and 2022 Complete Blood Count (CBC) American Proficiency Institute (API) Proficiency Testing (PT) attestation sheets and upon interview with the lead testing person, the laboratory failed to ensure proficiency testing was performed by testing personnel (TP) who routinely perform patient testing for 2021 and 2022. The findings include: 1. Review of the form CMS 209 revealed four testing personnel who perform patient testing for CBC. 2. Review of 2021 and 2022 API proficiency testing attestation records for CBC testing revealed testing persons 1, 2 and 4 listed on the CMS-209 showed participation in testing PT samples. 3. Review of 2021 and 2022 API proficiency testing attestation records for CBC testing revealed testing person 3 listed on the CMS-209 failed to participate in testing PT samples in 2021 and 2022. 4. Interview with the lead testing person on 02.13.2023 at approximately 10:40am confirmed testing person 3 listed on the CMS-209 failed to participate in CBC proficiency testing in 2021 and 2022.
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 lead testing person, the laboratory director failed to review and approve the validation documents for the Sysmex XP-300 complete blood count (CBC) instrument that was completed in 2021. The findings include: 1. Observation of the laboratory on 02.13.2023 at approximately 10:40 a.m. revealed the Sysmex XP-300 CBC instrument (Serial #B9733) on the counter in use for patient testing. 2. Review of validation studies performed on the Sysmex XP-300 CBC instrument (Serial #B9733) revealed the studies had not been reviewed or approved by the laboratory director. 3. Interview with the lead testing person on 02.13.2023 at approximately 12:10 p.m. confirmed the lab director had not reviewed or approved the validation studies performed in March 2021 for the Sysmex XP-300 CBC instrument.