Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0872587	11/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Novant Health Forsyth Pediatrics Kernersville	240 Broad Street, Kernersville, NC	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2020, 2021, and 2022 API (American Proficiency Institute) proficiency testing records and interview with the TC (technical consultant) 11/15/22, the laboratory failed to review and evaluate all proficiency testing results. Findings: 1. The laboratory failed to evaluate the following ungraded results: a. 2020 hematology 3rd event - ungraded urine sediment identification sample US-06; b. 2021 hematology 3rd event - ungraded wet prep/KOH (potassium hydroxide) sample VKP-03. 2. The laboratory failed to evaluate a 50% score for urine colony count on the 2020 microbiology 2nd event. 3. The laboratory failed to review and evaluate results for the 2021 hematology 2nd event. Results for the 2021 hematology 2nd event were not available in the laboratory's proficiency testing records at the time of the survey. During interview at approximately 9:35 a.m., the TC confirmed that there was no documentation of evaluation for the ungraded, unacceptable, and missing results.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of 2020, 2021, and 2022 media quality control records and interview with the TC (technical consultant) 11/15/22, the laboratory failed to document visual inspection of each new lot number of Uricult media for 6 of 9 lot numbers used during 2020, 2021, and 2022. Review of 2020, 2021, and 2022 Uricult quality control records revealed the laboratory utilized a "MEDIA CHECK-IN LOG" and documented visual inspection for 3 of 9 lot numbers of Uricult media received. There was no documentation of visual inspection for the other 6 lot numbers of Uricult media used by the laboratory during 2020, 2021, and 2022. During interview at approximately 12: 30 p.m., the TC confirmed the laboratory had not documented visual inspection of each new lot number of Uricult media. She stated they thought it was acceptable to save the manufacturer's documentation of quality control for each lot number and they did not realize documentation of the visual inspection was required.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan and review of 2020, 2021, and 2022 quality assessment monitors 11/15/22, the laboratory director failed to ensure the quality assessment program was maintained to assure the quality of the laboratory services offered. Findings: The laboratory's "Quality Assessment Plan" consists of monitors to be completed on a quarterly basis and a year-end annual assessment. The "Quality Assessment Plan" states "... V. PROCESSES / PROGRAM COMPONENTS Quality Assessment Activities ... 4. Testing personnel, the Laboratory Director, Technical Consultant and Clinic Administrator shall review and sign the completed monitors. ..." Review of 2020, 2021, and 2022 quality assessment monitors revealed many of the monitors for 2020 and 2021 had not been signed by all personnel required to review them. Examples: 1. 2020 - 1st and 2nd quarter monitors and year-end annual assessment signed by the testing personnel who completed the monitors, but not signed by the laboratory director, the technical consultant, or the clinic administrator. 2. 2021 - 1st quarter monitor signed by the testing personnel who completed the monitor, but not by the laboratory director, the technical consultant, or the clinic administrator. 2nd, 3rd, and 4th quarter monitors signed by the testing personnel who completed the monitor and the technical consultant, but not by the laboratory director or the clinic administrator.