Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0993008	12/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
North Whiteville Urgent Care	614 North J K Powell Blvd, Whiteville, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of 2020 Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, the absence of PT records, interview with Admin /Lab Manager 12/5/2023, and phone interview with PT provider representative 12/11 /2023, the laboratory failed to enroll in PT for 2021, 2022, and 2023. Findings: Review of PT records revealed the laboratory's last PT enrollment was for 2020. No records available to show PT enrollment for the speciality (Hematology) that the regulations require for enrollment for 2021, 2022, and 2023. During an interview at approximately 2:56 PM on 12/5/2023, the Admin/Lab Manager confirmed the last time the laboratory enrolled in PT was 2020. She confirmed there was no PT enrollment for 2021, 2022, and 2023. She stated the laboratory participated in an off-schedule event in 2021 and requested off schedule samples from American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) and College of American Pathologists (CAP) prior to the survey 12/5/2023. She stated the laboratory was not enrolled in PT with WSLH PT for 2024. During a phone interview at approximately 10:39 AM on 12/11/2023, WSLH PT representative confirmed the laboratory's last PT enrollment was in 2020. The representative verified the laboratory was not enrolled for 2021, 2022, 2023, and 2024.

D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of personnel records, and interview with the Admin/Lab Manager 12/5/2023, the laboratory director (LD) failed to ensure technical consultant (TC) duties were delegated to personnel meeting the qualification requirements for a TC. Findings: Review of the laboratory policies and procedures revealed a document titled "Laboratory Director/Delegation of Duties" that stated, "The laboratory director is responsible for the overall operation of the laboratory ... To assist in his duties, several of the responsibilities of the laboratory director may be delegated to the laboratory manager... The lab manager will review all proficiency testing results and summaries. All results will be signed and dated by the lab manager ... PT failures or problems will be investigated by the lab manager and a final resolution will be reported to the laboratory director." LD listed the Admin/Lab Managers name as designee of delegated duties. Review of personnel records revealed no documentation available to ensure Admin/Lab Manager met the qualifications to serve as TC. During interview at approximately 9:38 AM, 12/5/2023, Admin/Lab Manger stated she did not know if she is the TC or meets TC qualifications. This is a repeat deficiency previously cited at survey on 1/21/2020.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, and interview with the Admin /Lab Manager 12/5/2023, the laboratory director (LD) failed to ensure the laboratory was enrolled in proficiency testing (PT) for 2021, 2022, and 2023. Findings: Review of the laboratory policies and procedures revealed no PT enrollment for 2021, 2022, and 2023. See D2000. The laboratory did not follow policy for the document entitled "Proficiency Testing Program." This document states, "This office laboratory shall be enrolled in a COLA and HCFA approved proficiency testing program. Proficiency testing will be performed on each regulated analyte tested in the laboratory. The laboratory director or designee will evaluate the complexity of all new tests and will

	enroll them in proficiency testing if they are non-waived tests. Proficiency testing specimens should be treated according to the criteria set forth by the proficiency testing company and by HCFA..." During interview at approximately 2:56 PM, 12/5 /2023, Admin/Lab Manager stated she failed to ensure PT enrollment. She stated she forgot.