Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2086253	06/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Unc Reach Enhanced Primary Care	401 E Whitaker Mill Rd, Raleigh, 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 laboratory records, lack of documentation and interviews with laboratory director (LD) and technical consultant (TC) 06/11/25, the laboratory failed to enroll in a proficiency testing (PT) program for the Complete Blood Cell Count with Differential (CBCD) performed on the PixCell HemoScreen analyzer since testing began in January of 2025. Findings: Review of laboratory records revealed no documentation of enrollment in a PT program for the CBCD performed on the PixCell HemoScreen analyzer. Interview with LD at approximately 10:00 a.m. confirmed CBCD testing began on the PixCell HemoScreen analyzer in January of 2025. Phone interview with TC at 2:30 p.m. confirmed the laboratory had not enrolled in a PT program for the CBCD testing.
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 review of TC personnel records, lack of documentation and interview with TC 06/11/25, the laboratory failed to establish a procedure for the competency assessment of the responsibilities delegated to the TC and failed to perform annual competency assessments of the TC. 1. The laboratory failed to establish a procedure for the competency assessment of the responsibilities delegated to the TC. Findings: Review of TC personnel records revealed a form entitled "Technical Consultant Documentation". The form lists the "Technical Consultant Responsibilities" and states "By signing, trainee indicates understanding of the Technical Consultant role, responsibilities and requirements.". The forms also states "By signing, the CLIA Laboratory Director is delegating the employee as a Technical Consultant with the roles and responsibilities indicated above.". The form delegates and lists the responsibilities of the TC but fails to include a procedure for the assessment of the TC's delegated responsibilities. Phone interview with TC at approximately 2:30 p.m. confirmed the facility does not have a separate policy or procedure for the assessment of the TC. They stated they thought the form was what could be used to demonstrate an annual TC competency. 2. The laboratory failed to ensure annual competency assessments of the TC were performed. Findings: Review of TC personnel records revealed form entitled "Technical Consultant Documentation". The form states "Technical Consultants must have documented evidence indicating education and experience qualifications, successful completion of annual competency assessment for point-of-care testing, as well as documented Technical Consultant (TC) training and annual TC competency thereafter.". There was no documentation of an annual TC competency assessment. Phone interview with TC at approximately 2:30 p.m. confirmed the facility does not have a separate policy or procedure for the assessment of the TC. They stated they thought the form was what would be needed to demonstrate an annual TC competency.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedure and interview with TC 06/11/25, the laboratory procedure for CBCD was incomplete and failed to include the protocol for the performance of calibration verification, to include the frequency of calibration verification and the type and levels of calibration materials to be utilized by the laboratory. Findings: Review of laboratory procedure"POC Ambulatory Whole Blood CBC Testing Using the PixCell HemoScreen" revealed on Page 23 "X. Calibration... The HemoScreen Analyzer is factory calibrated. No further calibration is required." The procedure fails to include the regulation requirement for the performance of a calibration verification every 6 months and also fails to include the type and levels of calibration materials to be utilized by the laboratory. Phone interview with TC at approximately 2:30 p.m. confirmed the procedure for the CBCD testing failed to include the protocol for the performance of a calibration verification. She stated that it was not due for a calibration verification yet and they were working on what type of calibration materials will be used.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of operator's manual, and interview with program manager 06/11/25, and review of patient testing log sent via email 06/13 /25, the laboratory failed to monitor and record the temperature of the room where the PixCell HemoScreen hematology analyzer, Cartridges and Samplers were stored and /or in use since testing began in January of 2025. Approximately 36 patients were tested since January of 2025. Findings: Review of laboratory procedure "POC Ambulatory Whole Blood CBC Testing Using the PixCell HemoScreen" revealed on pages 2 and 3 "...IV. Procedure - Necessary Items...A. Reagents and Supplies 1. PixCell HemoScreen Analyzer...store in a clean, dry area at room temperature... Ambient temperature range: 17-27C....Relative humidity range: 10-90% non-condensing...2. PixCell HemoScreen Cartridge...Store at room temperature (17-27C) unopened...3. PixCell HemoScreen Sampler...Store at room temperature (17-27C) unopened...". Review of operator's manual for the PixCell HemoScreen Analyzer revealed on page 22 "Cartridge Specifications...Storage Conditions: An ambient temperature range of +17C to +27C....Sampler Specifications...Storage Conditions: An ambient temperature range of +17C to +27C....Page 62...8.1 HemoScreen Analyzer...The HemoScreen Analyzer should be operated at the following temperature: An ambient temperature range of 17 C to 27 C. 8.2 HemoScreen Cartridge and Sampler...The environmental conditions for HemoScreen Cartridge and Sampler storage and operation are as follows: An ambient temperature range of 17 C to 27 C.". Interview with program manager at approximately 11:30 a.m. confirmed the laboratory failed to monitor and record the temperature of the room where the hematology analyzer, cartridges and samplers were stored and/or in use since testing began in January of 2025. Review of patient testing log revealed approximately 36 patients were tested since January of 2025.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(d) (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 surveyor observation and interview with interim clinic manager 06/11/25, the laboratory failed to ensure expired QC reagent; "MedTox Scan QC Test Devices", for drug screen testing was not available for use. Surveyor was unable to determine if the QC reagent was used after expiration. Findings: At approximately 2:00 p.m. surveyor observed in a blue folder a plastic zip-loc bag containing a silver zip-loc bag of "MedTox Scan QC Test Devices", positive and negative controls, Part number: 833075, Lot: 21, Expiration date: 2024-03-06. Interview with interim clinic manager at approximately 3:00 p.m. confirmed the MedTox Scan QC Test Devices were expired.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of verification of performance specification records, lack of documentation, interview with LD 06/11/25 and review of patient testing log sent via email 06/13/25, the laboratory failed to verify the performance specifications of the MedTox Scan drug screen analyzer prior to performing patient testing after it was moved to the facilities new location in October of 2023, approximately 141 patients were tested since October of 2023. Findings: Review of laboratory policy "Point of Care Quality Assurance Practices Policy" revealed "...B. Instrument Performance Verification...The performance of all instruments must be verified prior to initial use, after major maintenance or service and after relocation to ensure performance....If instruments or equipment are moved, appropriate function checks should be performed to ensure that the instruments were not adversely affected by the relocation process...". The procedure includes verifications procedures for various instruments, but does not include verification procedures for the MedTox Scan analyzer. Review of performance specification records for the MedTox Scan analyzer revealed a verification of performance was performed July 27, 2021. There was no documentation of a verification of performance performed after the analyzer was moved in October of 2023. Interview with LD at approximately 10:00 a.m. confirmed the analyzer was moved from the old location to their new location in October of 2023. He stated he went to pick it up and drove it to the new location. Review of excel worksheet patient testing log for the MedTox Scan analyzer revealed approximately 141 patients were tested since October of 2023.

D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with LD 6/11/25, the laboratory failed to ensure patient test reports included the correct facility name and the correct address to include the suite number in which the testing is performed. Findings: The facility became a multiple site in August of 2024, with separate testing performed in different suites at the same address and under different names. Review of patient test reports for each site revealed the test reports had the incorrect name for both facilities and also failed to include the suite numbers in which the testing is performed. Interview with LD at approximately 12:30 p.m. confirmed the test reports for each site failed to include the correct name of each facility and the address failed to include the suite number of each facility.