Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1018413	03/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Unc Family Medicine At Blue Ridge	2605 Blue Ridge Road, Suite 300, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of 2020 and 2021 American Proficiency Institute (API) proficiency testing (PT) Microscopy/Urine Sediment records and interview with testing personnel (TP) 3/14/23, the laboratory failed to review the PT data summaries for 2 of 2 "not graded" PT results. Findings: Review of 2020 and 2021 API PT Microscopy/Urine Sediment records revealed the following samples had performance results of "not graded" and no documentation a review of PT data summaries. 1. 2020 API Hematology/Coagulation - 3rd event - Microscopy/Urine Sediment - Sample US-06. 2. 2021 API Hematology/Coagulation - 3rd event - Microscopy/Urine Sediment - Sample VKP-03. Interview with TP #2 at approximately 1:30 p.m. confirmed there was no documentation of a review of the "not graded" PT results. She stated she began employment in October of 2022 so was not aware of the problem. She also stated she would ensure 'not graded' PT results would be reviewed in the future.
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 policy, review of 2020. 2021, 2022 and 2023 API PT records and interview with TP #2 3/14/23, the laboratory director (LD) failed to ensure the laboratory was enrolled in PT for the Complete Blood Cell Count (CBC) testing performed for 3 of the 10 PT events reviewed; the 1st event of 2020, the 1st event of 2022 and the 1st event of 2023. Findings: Review of laboratory policy "Proficiency Testing Policy" revealed "Policy: In compliance with CLIA accreditation policies, this lab will run quarterly proficiency testing on all regulated laboratory tests.". Review of 2020, 2021, 2022 and 2023 API PT records revealed no documentation the laboratory was enrolled in PT for the CBC testing performed for the 1st event of 2020, the 1st event of 2022 and the 1st event of 2023. Interview with TP #2 at approximately 12:00 p.m. confirmed the laboratory had no documentation of CBC PT enrollment for the 1st event of 2020, the 1st event of 2022 and the 1st event of 2023. She stated she did not begin employment until October of 2022 but it appears they missed the first events because the forgot to enroll for those years. She also stated she was unaware of the need to enroll in PT for 2023 because notifications were being sent to emails that were no longer in use. TP #2 did enroll in CBC PT for 2023 at time of survey.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of testing personnel (TP) files and records and interview with TP #2 3/14/23, the laboratory director (LD) failed to ensure TP #2 had documented training for the urine sediment and wet prep testing performed. Findings: Review of laboratory policy "Personnel Competency Assessment" revealed "Purpose:...they have the appropriate training and comprehension to perform testing procedures...Procedure:...Each laboratory testing personnel will have a file maintained in the lab with the following information:... Training Checklist: One form for each test the tech is performing.". Review of TP #2 personnel files and records revealed no documentation of training for the urine sediment and wet prep testing. Interview with TP #2 at approximately 12:00 p.m. confirmed there was no documentation of her training for the urine sediment and wet prep testing performed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)

	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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of laboratory policy and review of 2020, 2021, 2022 and 2023 TP competency assessment records 3/14/23, the LD failed to ensure TP# 1 had annual competency assessments for 4 of 4 years reviewed. Findings: Review of laboratory policy "Personnel Competency Assessment" revealed "...Procedure: Evaluation will be performed at 6 mths after the techs start date and 1 year after the start date. Evaluation will be performed annually from then on.". Review of TP #1 2020, 2021, 2022 and 2023 competency assessment records revealed no documentation of annual competency assessments for 4 of 4 years reviewed.