Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1018413	04/16/2019
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with "off-site laboratory manager" 4/16/19, the laboratory failed to retain manufacturer's quality control and calibration assay sheets for chemistry and endocrinology testing for at least two years. Review of laboratory quality control and calibration records revealed the laboratory had retained only the current "in use" quality control and calibration assay sheets for chemistry and endocrinology testing. Interview with "off-site laboratory manager" at approximately 2:30 p.m. confirmed the laboratory had not retained the manufacturer's assay sheets for quality control and calibration reagents. He stated package inserts are not kept, they are thrown away once a new lot of quality control or calibration reagent is opened.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 manual, and review of manufacturer package inserts 4/16/19 the laboratory's quality control procedures failed to include the type and identity of the quality control (QC) reagents used for chemistry and endocrinology testing. Review of laboratory procedure "Quality Control and Calibrations Procedure" revealed "Procedure: Reagents, Controls, Calibrators, and Supplies...All quality control materials utilized are recommended by the instrument, system, and method manufacturers and/or have established assayed values for the methods being performed." The procedure fails to state the type and identity of QC reagents used for chemistry and endocrinology testing. Review of manufacturer package inserts for chemistry and endocrinology testing revealed the package inserts fail to state the type and identity of QC reagents. For example: The Ferritin reagent package insert, ST AIA-PACK FER, and the Thyroid Stimulating Hormone (TSH) reagent package insert, ST AIA-PACK TSH, both state "Quality Control Procedure... A. Commercially Available Controls...Commercially available controls shall be run at least once per day. It is recommended that at least two levels of controls...be used. Laboratory policy for this particular assay designates the following: Control material _____." The package inserts are left blank and do not state the type and identity of QC reagent.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 manufacturer's instructions, review of the laboratory's policies and procedures, observation, and interview with TP (testing personnel) 4/16/19, the laboratory failed to follow manufacturer's instructions for storage of the quality control material used on the Liasys 450 chemistry analyzer. The AMS Diagnostics MULTI CHEMISTRY CONTROL LEVEL 1 AND LEVEL 2 product inserts state "... STABILITY AND STORAGE ... 2. Reconstituted control is stable for up to seven days when stored at 2-8 degrees C except for Alkaline Phosphatase and Bilirubin which are stable for 2 days at 2-8 degrees C. ..." The laboratory's "Maintenance, Function and Test System Monitoring" policy states "... This laboratory will monitor the following conditions based on the recommendations of manufacturer's instructions and stated laboratory performance specifications for each test system. ... " The policy listed various items to be monitored, including "Handling and storage of reagents

	according to manufacturers recommendation". During a tour of the laboratory at approximately 2:55 p.m., surveyors observed one bottle of reconstituted Level 1 and one bottle of reconstituted Level 2 AMS Diagnostics MULTI CHEMISTRY CONTROL in the large refrigerator, available for use. Both bottles were labeled with open date 4/15/19 and expiration date 4/19/19. During interview at approximately 3: 00 p.m., TP #1 and TP #2 confirmed that the quality control material was used for bilirubin and alkaline phosphatase testing on the Liasys 450 chemistry analyzer. They stated the controls are usually reconstituted on Monday and used for the rest of the week (5 days). They stated they were unaware the reconstituted control material is only good for 2 days for bilirubin and alkaline phosphatase.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 temperature and humidity logs, observation, and staff interview 4/16/19, the laboratory failed to monitor and document the temperature of the small refrigerator used to store wash and diluent for the Tosoh AIA 900 analyzer. During a tour of the laboratory at approximately 2:55 p.m., surveyors observed supplies and reagents stored in two different refrigerators - a large, household-type refrigerator and a small, under-counter refrigerator. Random review of 2017 and 2018 temperature and humidity logs revealed the laboratory documented temperatures for only one refrigerator, "Fridge 1". There were no other refrigerator temperatures documented. During interview at approximately 4:30 p.m., the "off-site laboratory manager" confirmed that the laboratory had not monitored and documented the temperature of the small under-counter refrigerator used to store Tosoh wash and diluent.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 quality assurance records, review of laboratory verification records and interview with "off-site laboratory manager" 4/16/19, the laboratory failed to document the verification of accuracy for the Labtrak electronic

	medical record (EMR) data system. Review of laboratory quality assurance records indicate a new EMR data system, Labtrak, was installed and began operation on 3/7 /18. It also indicates that data transfer verification was completed on 3/8/18. Review of laboratory data transfer verification records revealed no documentation for the verification of accuracy of the Labtrak EMR data system. Interview with "off-site laboratory manager" at approximately 2:30 p.m. confirmed there was no documentation of the data transfer verification for the Labtrak EMR. He stated it may have been placed in a box somewhere when the facility was remodeled.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions, review of 2017 and 2018 monthly quality assessment records, and interview with staff 4/16/19, the laboratory failed to perform and document instrument maintenance as required. Findings: A. Medonic M-Series hematology analyzer The CDS/Medonic M-Series Maintenance Quick Reference Guide specifies the performance of maintenance procedures on a daily, monthly, and six-month basis. The Quick Reference Guide also includes instructions for performing a "clot prevention procedure" at least once a month or every 1000 samples processed. Random review of 2017 and 2018 monthly quality assessment records revealed the only Medonic hematology maintenance records available were for monthly cleaning and clot prevention performed 11/9/18. There were no other hematology maintenance records available for review. B. Tosoh A1A 900 chemistry analyzer The Tosoh A1A 900 operator's manual specifies the performance of maintenance procedures on a daily, weekly, monthly and quarterly basis. Review of laboratory records revealed the laboratory had no documentation for the performance of the required maintenance procedures. C. Liasys 450 chemistry analyzer The Liasys 450 operator's manual specifies the performance of maintenance procedures on a daily, bi-weekly, monthly, quarterly, bi-annually, and an every 2000 hours basis. Review of laboratory records revealed the laboratory had no documentation for the performance of the required maintenance procedures. During interview at approximately 12:20 p.m., the "off-site laboratory manager" stated maintenance was performed because the laboratory's analyzers would not operate if maintenance was not performed. He confirmed maintenance was not documented.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following

	occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of manufacturer package inserts, review of calibration verification records and interview with "off-site laboratory manager" 4/16/19, the laboratory failed to perform three point calibration verifications of Ferritin (FERR) and Prostate Specific Antigen (PSA) every 6 months as required. Review of laboratory procedure "Calibration and Verification Policy" revealed "Calibrations are performed for each analyzer testing system according manufacturer's instructions and /or CLIA requirements...Calibrations are performed using the manufacturers test system instructions, recommended calibration materials and frequency." Review of manufacturer package inserts, (test system instructions) revealed the laboratory performs a two point calibration for the analytes FERR and PSA as required by manufacturer. Review of calibration verification records revealed no documentation the laboratory had performed a three point calibration for FERR and PSA since time of last survey 6/30/17, a period of approximately 23 months. Interview with "off-site laboratory manager" at approximately 12:30 p.m. confirmed the laboratory had no documentation that three point calibration verifications had been performed for FERR and PSA testing.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 temperature and humidity logs, review of the laboratory's policies and procedures, and interview with staff 4/16/19, the laboratory failed to ensure corrective action was taken and documented for humidity readings outside the acceptable limits. Random review of 2017 and 2018 temperature and humidity logs revealed there was no documentation of corrective action on days when humidity was below acceptable limits. Examples: 1. January 2018 - 4 of 22 humidity readings were below acceptable limits with no corrective action documented; 2. March 2018 - 12 of 21 humidity readings were below acceptable limits with no

	corrective action documented. The laboratory's "Maintenance, Function and Test System Monitoring" policy states "... The following conditions will be monitored and documented on the 'Daily Temp & Maintenance Log' each day that laboratory testing is performed. Any temperature or humidity level that is out of range will be remedied immediately. ..." During interview at approximately 1:20 p.m., the "off-site laboratory manager" stated that corrective action should be documented on the "Corrective Action Log". He stated that the laboratory's electronic corrective action logs were lost during the computer update, and he confirmed there was no documentation of corrective action for the out-of-range humidity readings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records 4/16/19, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure the establishment and maintenance of an effective quality control program (see D6020). 2. The laboratory director failed to ensure patient test results were reported only when test systems were functioning properly (see D6025). 3. The laboratory director failed to ensure that PSA (prostate specific antigen) test reports included the identity of the assay used (see D6026). 4. The laboratory director failed to ensure that prior to testing patient specimens, all testing personnel received appropriate training for the testing performed (see D6029). 5. The laboratory director failed to ensure that competency evaluations included assessment of all tests performed (see D6046).
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of policies and procedures, observation, and interview with staff 4/16 /19, the laboratory director failed to ensure the establishment and maintenance of an effective quality control program to assure the quality of testing performed on the Liasys 450 and Tosoh AIA 900 analyzers. Findings: 1. The laboratory failed to retain quality control assay sheets for at least two years (see D3031). 2. The laboratory's quality control procedures did not include the identity of the quality control material used on the Liasys 450 and Tosoh AIA 900 (see D5403). 3. The laboratory failed to follow manufacturer's instructions for use of the AMS Diagnostics MULTI CHEMISTRY CONTROL LEVEL 1 and LEVEL 2 for Alkaline Phosphatase and Bilirubin testing (see D5411).

D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of laboratory records, observation, and staff interview 4/16/19, the laboratory director failed to ensure patient test results were reported only when the test systems were functioning properly. Findings: 1. The laboratory failed to monitor and document the temperature of the small refrigerator used to store wash and diluent for the Tosoh AIA 900 analyzer (see D5413). 2. The laboratory failed to perform and document instrument maintenance as required for the Medonic M-series hematology analyzer, the Tosoh AIA 900 chemistry analyzer, and the Liasys 450 chemistry analyzer (see D5429). 3. The laboratory failed to perform calibration verification as required for the Ferritin and PSA tests (see D5439). The laboratory performs approximately 36,878 hematology tests per year and approximately 140,083 chemistry and endocrinology tests per year.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, review of patient test report, and interview with "off-site laboratory manager 4/16/19, the laboratory director failed to ensure the assay identity for Prostate Specific Antigen (PSA) testing was included in the patient test report. Review of package insert for PSA reagent, ST AIA-PACK PA, revealed "The concentration of PSA in a given specimen may vary with devices from different manufacturers. Values obtained with different assay methods cannot be used interchangeably...It is mandatory that results reported by the laboratory to the physician include the identity of the assay used." Review of random patient test report, sample #119901, revealed the test report failed to include the identity of the assay used for the PSA testing performed. Interview with "off-site laboratory manager" at approximately 2:30 p.m. confirmed the assay identity for PSA testing was not included in patient test reports.
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 personnel records and interview with staff on 4/16/19, the Laboratory Director failed to ensure training for 1 of 2 testing personnel (TP #2) for all required testing. Findings: Review of personnel records for TP #2 revealed training was completed in October and November 2018. Training documentation did not include Potassium Hydroxide (KOH)/Wet Prep and Urine microscopic testing. During interview at approximately 10:15am, the "off-site laboratory manager" confirmed that TP #2 performs KOH/Wet prep and Urine microscopic testing on patients.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with staff on 4/16/19, the Technical Consultant (Laboratory Director) failed to ensure that competency evaluations for 2 of 2 TP (testing personnel) included all required testing. Findings: Review of personnel records for TP #1 revealed competency evaluations were performed in February and August 2018. The competency evaluations did not include assessment of KOH(potassium hydroxide)/Wet prep and urine microscopic testing. Review of personnel records for TP #2 revealed a competency evaluation was performed in March 2019. The competency evaluation did not include assessment of KOH/Wet prep testing. During interview at approximately 10:15 a.m., the "off-site laboratory manager" confirmed that both TP #1 and TP #2 perform KOH/Wet prep and Urine microscopic testing on patients.