Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2013153	04/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cabral Internal Medicine	711 Fairgrove Church Road Se, Conover, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2016 and 2017 American Proficiency Institute (API) proficiency testing (PT) records 04/11/18, the laboratory director and testing personnel (TP#1) failed to sign attestation statements for all laboratory PT performed. Review of laboratory policy, "PROFICIENCY TESTING" revealed the following; "The Laboratory Director and all staff performing the testing should sign in the attestation spaces provided on the data sheet." Review of 2016 and 2017 API PT records revealed the laboratory participated in 10 of 12 API PT events. There were no attestation statements signed by the laboratory director or testing personnel for the 10 API PT events: 1. 2016 Chemistry Group 1 - 2nd Event 2. 2016 Chemistry Group 2 - 2nd Event 3. 2016 Hematology/Coagulation - 3rd Event 4. 2016 Chemistry Group 1 - 3rd Event 5. 2017 Hematology/Coagulation - 1st Event 6. 2017 Chemistry - Core - 1st Event 7. 2017 Chemistry - Miscellaneous - 1st Event 8. 2017 Hematology /Coagulation - 2nd Event 9. 2017 Chemistry - Core - 2nd Event 10. 2017 Hematology /Coagulation - 3rd Event
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the

	overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies, review of personnel records, review of 2016 and 2017 API PT records and review of laboratory quality assessment practices 04/11 /18, the laboratory failed to monitor, evaluate and correct problems within the general laboratory system. 1. Review of laboratory policy, "STAFF ORIENTATION, TRAINING AND COMPETENCY" and personnel competency records revealed the laboratory failed to follow competency policy and failed to monitor and evaluate the competency of testing personnel (see D5209). 2. Review of laboratory policy, "PROFICIENCY TESTING" and review of 2016 and 2017 API PT records revealed the laboratory failed to follow proficiency testing policy and failed to verify the accuracy of analytes that scored zero for nonparticipation in PT events (see D5215). 3. Review of 2016 and 2017 API PT records revealed the laboratory failed to verify the accuracy of 25-Hydroxy Vitamin D (25-OH Vitamin D) and Vitamin B-12 at least twice annually (see D5217). 4. Review of laboratory policy "QUALITY ASSESSMENT PLAN" revealed the laboratory failed to follow quality assessment policy and failed to monitor, evaluate and correct problems within the general laboratory system (see D5291).
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 laboratory policy and procedure manual, and review of personnel records 04/11/18, the laboratory failed to follow written policies to assess testing personnel competency. Review of laboratory policy, "STAFF ORIENTATION, TRAINING AND COMPETENCY" revealed the following statements under the section "ANNUAL ORIENTATION AND COMPETENCY OF LABORATORY STAFF.... As defined by CLIA, the following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing: 1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing 2. Monitoring the recording and reporting of test results 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records 4. Direct observations of performance of instrument maintenance and function checks 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples 6. Assessment of problem solving skills". Review of personnel records for competency revealed an "EMPLOYEE PERFORMANCE AND DEVELOPMENT APPRAISAL FORM" used as documentation for testing personnel competency. The form does not include the minimal regulatory requirements as stated in the laboratory's competency policy.
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 2016 and 2017 API PT records and review of laboratory policy 04 /11/18, the laboratory failed to evaluate zero scores for nonparticipation in PT events and failed to verify the accuracy of the analytes that scored zero for nonparticipation. Review of 2016 and 2017 API PT records revealed the following PT events had zero scores for nonparticipation. There was no documentation of an evaluation of the zero scores for nonparticipation. There was no documentation the laboratory had assessed the accuracy of the analytes that scored zero for nonparticipation. 1. 2016 Chemistry Group 2 - 3rd Event 2. 2017 Chemistry - Miscellaneous - 1st Event 3. 2017 Chemistry - Core - 3rd Event Review of laboratory policy, "PROFICIENCY TESTING" revealed "Alternative Assessment Procedures", which the laboratory failed to use to verify the accuracy of the analytes that scored zero for nonparticipation.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of Tosoh A1A-900 system validation records and review of 2016 and 2017 API PT records 4/11/18, the laboratory failed to verify the accuracy of 25-Hydroxy Vitamin D (25-OH Vitamin D) and Vitamin B-12 at least twice annually. Findings: 1. Review of Tosoh A1A-900 system validation records revealed the laboratory started patient testing for 25-OH Vitamin D in May 2016. Review of 2016 and 2017 API PT records revealed the laboratory failed to enroll in PT for 25-OH Vitamin D until the 2017 2nd Chemistry - Miscellaneous test event, approximately 12 months after the initiation of patient testing. There was no documentation to indicate the laboratory performed any other activity to verify the accuracy of its 25-OH Vitamin D testing at least twice from May 2016 - May 2017. 2. Review of Tosoh A1A-900 system validation records revealed the laboratory started patient testing for Vitamin B-12 in May 2016. Review of 2016 and 2017 API PT records revealed the laboratory enrolled in PT for Vitamin B-12, but failed to obtain acceptable PT scores for 3 consecutive test events: a. On the 2016 Chemistry Group 2 - 2nd event, the laboratory provided incorrect responses for both samples and received a score of 0%; b. On the 2016 Chemistry Group 2 - 3rd event, the laboratory failed to participate and received a score of 0%; c. On the 2017 Chemistry - Miscellaneous - 1st event, the laboratory failed to participate and received a score of 0%. There was no documentation to indicate the laboratory performed any other activity to verify the accuracy of its Vitamin B-12 testing at least twice from May 2016 - May 2017.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of quality assessment records, review of 2016 and 2017 API PT records, and review of personnel records 04/11/18, the laboratory failed to follow written policies and procedures to monitor, assess, and correct problems within the general laboratory system. Review of laboratory policies revealed the laboratory had established a quality assessment program to monitor, assess and correct problems within the general laboratory systems. Review of laboratory policy, "QUALITY ASSESSMENT PLAN" revealed the following; "Quality Indicators for this facility have been defined as, ...a. Personnel qualifications, training and performance evaluation.....f. Evaluation of Proficiency Testing and Split Sample Testing.....Each quality indicator is reviewed according to the annual calendar established, and documented on a quality assessment report form....Included will be ...a summary and analysis of the findings....corrective action to be taken..." Review of quality assessment records revealed no documentation indicating the laboratory followed the policies to monitor, assess and correct problems within the general laboratory system. Findings: 1. Review of 2016 and 2017 API PT records revealed the laboratory failed to identify that attestation statements were not signed, failed to review and evaluate zero scores for nonparticipation in PT events, and failed to verify the accuracy of 25-OH Vitamin D and Vitamin B-12 (see D2009, D5215, and D5217). 2. Review of personnel records and laboratory policies revealed the laboratory failed to follow policy to assess testing personnel competency (see D5209).
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 manufacturer's operating manual, review of hematology calibration records, and interview with testing personnel (TP#1), the laboratory failed to perform and document calibration of the Horiba Micros 60 hematology analyzer every 6 months as required. The laboratory began testing on the Horiba Micros 60 hematology analyzer in May 2016. Review of manufacturer's operating manual for the Horiba Micros 60 analyzer revealed instructions for how to perform a calibration, but failed to include the frequency of calibration. Review of hematology calibration records for the Horiba Micros 60 analyzer revealed the laboratory performed an initial calibration in May of 2016. There was no documentation that a calibration was performed since initial calibration in May 2016, a period of approximately 22 months in which no calibration was performed. During interview at approximately 1:00 p.m., TP#1 confirmed the Horiba Micros 60 analyzer had not been calibrated since May 2016, and stated " the service rep said it would not require additional calibration."
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 policies and procedures, review of 2016, 2017 and 2018 laboratory records, review of 2016, 2017 and 2018 API PT records and interview with TP #1 04/11/18, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure the laboratory was enrolled in a PT program for the first PT event of 2018 (see D6015). 2. The laboratory director failed to ensure that PT results were returned within established time frames (see D6017). 3. The laboratory director failed to ensure that all PT reports were reviewed and evaluated (see D6018). 4. The laboratory director failed to ensure that a corrective action plan was followed for unacceptable and not graded PT scores (see D6019). 5. The laboratory director failed to ensure the laboratory quality assessment program was implemented and maintained (see D6021). 6. The laboratory director failed to ensure acceptable levels of analytical performance for each test system (see D6023).
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 2018 API PT Order Confirmation, review of laboratory test menu 04/11/18, and e-mail correspondence with API technical personnel 05/03 /18, the laboratory director failed to ensure the laboratory was enrolled in a PT

	program for the first PT events of 2018 in the specialties of Chemistry and Hematology. Review of 2018 API PT Order Confirmation revealed the laboratory failed to enroll in a PT program until 03/27/18. E-mail correspondence with API technical personnel confirmed the laboratory did not enroll in PT until 03/27/18 and confirmed, due to late enrollment, the laboratory did not participate in the first PT events of 2018 for the specialities of Chemistry and Hematology. E-mail correspondence with API technical personnel and review of laboratory test menu revealed the laboratory failed to participate in the first PT event of 2018 for the following regulated analytes: 1. In the speciality of Chemistry, a. Albumin b. Alamine aminotransferase c. Cholesterol, HDL d. Glucose e. Triglycerides g. Carbon Dioxide h. Alkaline Phosphatase i. Bilirubin, Total j. Cholesterol, Total k. LDL Cholesterol (Calculated) l. Urea Nitrogen/BUN m. Potassium n. Calcium, Total o. Creatinine p. Total Protein q. Uric Acid r. Chloride s. Thyroid Stimulating Hormone t. Free Thyroxine u. Carbon Dioxide (CO2) 2. In the speciality of Hematology: a. Erythrocyte Count (RBC) b. Hematocrit c. Hemoglobin d. Whole Blood Differential e. Leukocyte Count (WBC) f. Platelet Count
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of 2016 and 2017 API PT records 04/11/18 and e-mail correspondence with API technical personnel 05/13/18, the laboratory director failed to ensure that PT testing results were returned within timeframes established by the PT program. Review of 2016 and 2017 API PT records revealed the laboratory scored 0% for failure to participate in the following 2 API PT events: 1. 2016 Chemistry Group 2 - 3rd Event 2. 2017 Chemistry Core - 3rd Event E-mail correspondence with API technical personnel confirmed the laboratory was enrolled for the 2 API PT events, but failed to submit results within the timeframes established, resulting in scores of 0% for failure to participate.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2016 and 2017 API PT records 04/11

	/18, the laboratory director failed to ensure that all PT reports were reviewed and evaluated. Review of laboratory policy "PROFICIENCY TESTING" revealed the following statement under the section; "ASSESSMENT OF THE PROFICIENCY TESTING REPORT", ..."Initially, both the testing personnel and the Laboratory Supervisor should review the PT scores, and if all are satisfactory, the forms are signed and dated.....The Laboratory Director also must sign the forms as reviewed, and reports are filed in the Proficiency Testing Manual". Review of 2016 and 2017 API PT records revealed the laboratory participated in 10 of 12 PT events. The laboratory director failed to 7 of the 10 events to indicate their review and evaluation: 1. 2016 Chemistry Group 1 - 2nd Event 2. 2016 Chemistry Group 2 - 2nd Event 3. 2016 Chemistry Group 1 - 3rd Event 4. 2016 Chemistry Group 2 - 3rd Event 5. 2017 Chemistry - Core - 2nd Event 6 . 2017 Chemistry - Core - 3rd Event 7. 2017 Hematology/Coagulation - 3rd Event Review of 2016 and 2017 API PT records revealed TP#1 had not signed all 10 PT events that she, as the only testing personnel, participated in to indicate their review and evaluation.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2016 and 2017 API PT records 04/11 /18, the laboratory director failed to ensure that a corrective action plan was followed for unacceptable and not graded PT scores. Review of laboratory policy, "PROFICIENCY TESTING" revealed the following under section "ASSESSMENT OF THE PROFICIENCY TESTING REPORT ...Evaluate all ungraded responses and perform a self-evaluation to verify the accuracy of analytes that are not graded..... Document any corrective action for unacceptable responses..." Review of 2016 and 2017 API PT "Proficiency Testing Performance Evaluation Records" revealed the following APT PT events had unacceptable or not graded PT scores in which the laboratory failed to evaluate and failed to document corrective action: 1. API 2016 Chemistry Group 2 - 2nd Event, the laboratory received a score of "Unacceptable" for Alamine Aminotransferase (ALT); sample CH-06, a score of "Unacceptable" for Vitamin B-12; sample IA-03, and a score of "Unacceptable" for Vitamin B-12; sample IA-04. 2. API 2017 Chemistry - Core - 1st Event, the laboratory received a score of "Not Graded" for Low-density Lipoprotein (LDL) Cholesterol; sample CH-01, a score of "Not Graded" for Triglycerides; sample CH-01 and a score of "Not Graded" for Free Thyroxine; sample CH-01. 3. API 2017 Chemistry - Core - 2nd Event, the laboratory received a score of "Unacceptable" for Aspartate Aminotransferase (AST); sample CH-07.
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 laboratory quality assessment policies, review of quality assessment records and interview with TP#1 04/11/18, the laboratory director failed to ensure the laboratory quality assessment program was implemented and maintained to assure the quality of laboratory services provided. Review of laboratory quality assessment policy "QUALITY ASSESSMENT PLAN" revealed the laboratory had established "Quality Indicators", for example: personnel training and performance, evaluation of proficiency testing, procedure manual review, verification of calibration, quality control and maintenance. The quality assessment plan also included "QA Forms", for example; "Calendar checklist", "Monthly Checklist-Analytic" and "Proficiency Testing Checklist". There was no documentation to indicate the laboratory had implemented or performed any of the quality assessment programs that were established. During interview at approximately 1:00 p.m., TP #1 confirmed the laboratory had not implemented or maintained the laboratory's quality assessment program.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of Horibas Micros 60 calibration records, and review of 2016 and 2017 API PT records 04/11/18, the laboratory failed to ensure the maintenance of acceptable levels of analytical performance for the Horibas Micros 60 hematology analyzer, the 25-OH Vitamin D analyte and the Vitamin B-12 analyte. Review of Horibas Micros 60 calibration records revealed the analyzer has not been calibrated every 6 months as required (see D5439). Review of 2016 and 2017 API PT records revealed the analytes 25-OH Vitamin D and Vitamin B-12 had not been verified for accuracy at least twice annually (see D5217).
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of laboratory personnel records 04/11/18 and the deficiency cited at

	D6065, the laboratory failed to verify that 1 of 1 testing personnel (TP#1) met the minimum education requirements for performing moderate complexity testing. Review of personnel records revealed no education credentials on file for TP #1. During interview at approximately 11:00 a.m., TP #1 confirmed she did not have her education credentials on file.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview with testing personnel (TP) 04/11 /18, the laboratory failed to verify that 1 of 1 testing personnel (TP#1) met the minimum education requirements for performing moderate complexity testing. To be qualified to perform moderate complexity testing, personnel must have a minimum of a high school diploma or a high school graduation equivalency diploma (GED). Review of personnel records revealed no education credentials on file for TP #1. During interview at approximately 11:00 a.m., TP #1 confirmed she did not have her education credentials on file.