

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0933587	(X3) Date Survey Completed 07/02/2019
Name of Provider or Supplier Preventive Medicine Anti-Aging	Street Address, City, State 148 Cobb Parkway, Ringgold, GA	
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
D0000	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on July 2, 2019. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to ensure examination of the PT samples by testing personnel (TP) who routinely perform laboratory testing as required. Findings include: 1. American Proficiency Institute (API) PT document review and staff interview revealed the same TP/technical consultant (TC) performed 2018 Chemistry Core (Events two and three). 2. The API 2018 Core Chemistry (Event one) attestation statement was not available at the time of the survey. 3. An interview in the laboratory on 7/2/2019 with the TC at approximately 3:00 p.m. confirmed the aforementioned lack of TP rotation for PT testing.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) and the testing personnel (TP) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD and TP did not sign the 2018 Core Chemistry (first event).attestation statement. 2. An interview with the technical consultant in the laboratory on 7/2/2019 at approximately 3:00 p.m. confirmed the aforementioned PT attestation statement was not signed by the TP or LD.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of all PT records as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the following required documents were not available at the time of survey: Attestation statements -- 2018: Chemistry Core - Event One; 2019: Miscellaneous Chemistry - Event One; PT reports -- 2018: Chemistry Core -- Event Three. 2. An interview in the laboratory with the technical consultant on 7/2/2019 at approximately 3:00 p.m. confirmed the aforementioned missing PT documents.

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 procedure manual (SOP) review and staff interview, the lab failed to define imminently life-threatening test results, or panic or alert values for testing performed. Findings include: 1. Review of the SOP revealed the lab did not define imminently life-threatening test results, panic, or alert values for testing performed in hematology, chemistry, or endocrinology. 2. Interview with the technical consultant on 7/2/19 in the lab at approximately 12 Noon, confirmed the lab did not define the aforementioned values.

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 Pentra C-400 and AIA-900 validation document reviews and staff interview, the lab failed to demonstrate that the verification correlates with its in-house test performance. Findings include: 1. Review of the Pentra C-400 and AIA-900 validation documents revealed the lab did not perform correlation studies by testing "known" patient samples. 2. Interview with the technical consultant on 7/2/19 in the lab at approximately 12 Noon, confirmed the lab did not perform the aforementioned correlation studies.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on ABX Micros 60 and AIA-900 quality control (QC) document reviews and staff interview, the lab failed to monitor over time the accuracy and precision of test

	<p>performance. Findings include: 1. Review of ABX Micros 60 and AIA-900 QC documents revealed the lab was not printing and reviewing the Levy-Jennings (LJ) charts to monitor over time the accuracy and precision of test performance. 2. Interview with the technical consultant on 7/2/19 in the lab at 12:35 PM, confirmed the lab did not perform the aforementioned QC reviews.</p>
<p>D5781</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of ABX Micros 60 and AIA-900 quality control (QC) records and staff interview, the lab failed to document corrective actions when QC exceeded acceptable limits. Findings include: 1. Review of the aforementioned QC records revealed one (1) or more analytes were out of range without corrective actions documented. 2. Interview with the technical consultant on 7/2/19 in the lab at approximately 1240 PM, confirmed the corrective actions were not documented.</p>
<p>D6007</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</p> <p>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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p> <p>This STANDARD is not met as evidenced by: Based on ABX Micros 60, Pentra C-400, and AIA-900 validation document reviews and staff interview the lab director (LD) failed to review and approve the validation studies performed on each analyzer before patient testing was started. Findings include: 1. Review of validation documents performed on the ABX Micros 60, Pentra C-400, and AIA-900 including calibration, precision, accuracy, and linearity revealed the LD did not review or approve the data achieved during the installation process of each test system. 2. Interview with the technical consultant on 7/2/19 in the lab at approximately 12 Noon, confirmed the LD did not approve the validation documents.</p>
<p>D6015</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p>

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 proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure the laboratory was enrolled in an HHS approved PT program for the testing performed. Findings include: 1. American Proficiency Institute (API) PT document review revealed the laboratory was not enrolled in a PT program for hematology in 2018 for all three events. 2. An interview with the technical consultant in the laboratory on 7/2/2019 at approximately 1:45 p.m. confirmed the laboratory did not participate in Hematology PT in 2018.

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 proficiency test (PT)document review and staff interview, the laboratory director (LD) failed to review PT reports as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD did not review the PT reports for the following: 2018 -- Chemistry Core (Event one), Immunology (Event two); 2019 -- Miscellaneous Chemistry (Event one). 2. An interview with the technical consultant on 7/2/1019 in the laboratory at approximately 3:00 p.m. confirmed the lack of LD review of the aforementioned PT documents.

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:

	<p>Based on review of testing personnel (TP) training documents and staff interview, the lab director (LD) failed to ensure the TP receive the appropriate training for testing performed. Findings include: 1. Review of TP training documents revealed TP #4 (CMS 209 form) did not receive proper training by a qualified person on the ABX Micros 60 and Pentra C-400 analyzers. 2. Interview with the technical consultant on 7/2/19 in the lab at 10:15 AM, confirmed the LD did not ensure the TP receive the appropriate training for testing performed.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency documents and staff interview, the lab director (LD) failed to ensure the TP were competent to perform testing. Findings include: 1. Review of TP competency documents revealed TP #4 and TP #5 (CMS 209 form) did not receive competency evaluations semi-annually or annually in 2018. 2. Interview with the technical consultant (TC) on 7/2/19 in the lab at 10:15 AM, confirmed the LD did not ensure the TP/TC were competent to perform testing.</p>
<p>D6070</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1)</p> <p>Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on temperature and humidity (RH) document review and staff interview, the testing personal (TP) failed to document temperatures and RH each day of testing as required by the manufacturers. Findings include: 1. Review of temperature and humidity (RH) log sheets revealed the lack of documentation of the aforementioned values December 2017 till April 2018. 2. Interview with the technical consultant on 7/2/19 in the lab at 12:33 PM, confirmed the lab did not document the aforementioned values.</p>
<p>D6072</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument</p>

and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on maintenance log documents review and staff interview, the testing personal (TP) failed to document maintenance each day of testing as required by the ABX Micros 60 and Pentra C-400 manufacturers. Findings include: 1. Review of the ABX Micros 60 maintenance log sheets revealed the lack of documentation of the daily maintenance November -December 2017, January - March 2018, April 23 - 30, 2018. 2. Review of the Pentra C-400 maintenance log sheets revealed the lack of documentation of the daily, weekly, monthly, bi-monthly, or as needed maintenance February - November 2018, February 2019 - June 2019. 3. Interview with the technical consultant on 7/2/19 in the lab at 12:33 PM, confirmed the lab did not document the aforementioned maintenance.