Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0680113	11/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bay West Endocrinology Associates	6535 N Charles St 400 North, Baltimore, MD	

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
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 review of proficiency testing (PT) data and interview with the laboratory manager, the laboratory did not maintain all copies of PT records that was obtained during the testing of PT samples. Findings: 1. The laboratory did not maintain a copy of all raw data, worksheets, and instrument print outs that was obtained for PT during the 2018 and 2019 year. 2. The laboratory manager stated that they were keeping everything at one time and just stopped.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be

	maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) data, interview with the laboratory manger, and testing person, the laboratory did not perform corrective action procedures for failed PT results. Findings: 1. The laboratory failed the American Proficiency Institute 2019 2nd event Creatine 70%. 2. The laboratory did not perform an investigation utilizing the laboratory PT investigation tool. 3. The testing person and the manager stated that they were unsure an investigation needed to be done.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the laboratory manager, the laboratory did not maintain corrective action procedures to ensure the quality of laboratory services. Findings: 1. The laboratory did not maintain a problem log to document quality control errors, specimen and instrument problems. 2. The corrective action procedure states that when an error is discovered an investigation must be performed. 3. The laboratory manager stated that all problems in the lab were corrected but were not documented.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the laboratory supervisor, the technical consultant (TC) failed to perform technical and scientific oversight of the laboratory. Findings: 1. The TC failed to provide technical notes for quality assurance (QA) review by the laboratory director and staff when she was on site and nor was a copy of the TC schedule available that included all contact information. 2. The TC failed to review quality control (QC) during the year 2019 to ensure that testing meet the laboratory's criteria of acceptability. 3. The laboratory written QA procedure states that QC will be faxed or emailed to the TC for monthly review and a report is generated for the lab director every three months. 4. The TC failed to review all instrument maintenance logs. 5. The laboratory written QA procedure states that the TC will review all maintenance procedures. 6. The TC failed to perform the six month random patient correlation between the electronic medical record and the analyzer results as written in the QA procedure. 7. The TC failed to perform the instrument correlation twice per year where samples will be sent to a

	reference lab as written in the QA procedure. 8. The TC failed to perform the correlation of the manual lab report against the EMR twice a year as written in the QA procedure.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of training and competency records and interview with the laboratory manager, the technical consultant (TC) failed to perform direct observations of laboratory staff. Finding: 1. The TC failed to perform direct observations of staff performing patient testing during the year 2019. 2. The laboratory manager confirmed that direct observations were not performed during the year 2019 when training and competency procedures were performed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of training and competency records and interview with the laboratory manager, the technical consultant (TC) failed to perform training and competency procedures for all testing personnel during the year 2018. Findings: 1. The TC failed to perform training and competency procedures during the year 2018 for personnel performing patient testing. 2. The laboratory manager confirmed that training and competency procedures were not performed during the year 2018 for personnel performing patient testing.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of training and competency records and interview with the laboratory manager, the technical consultant (TC) failed to perform training for all testing personnel when new technology was introduced in the lab. Findings: 1. The laboratory started using a new laboratory information system (LIS) during the year 2018. 2. All testing personnel were not trained on the new LIS by the TC. 3. The laboratory

	manager stated that she was trained but she did not train all testing personnel on the new LIS.