

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0295178	(X3) Date Survey Completed 04/19/2018
Name of Provider or Supplier Eldridge E Mccormick Md Pa	Street Address, City, State 410 43rd St W Suite I, Bradenton, FL	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on American Proficiency Institute (API) record review and interview with the Medical Technologist, the laboratory failed to enroll in proficiency testing for 1 year (2017). Findings included: During the API proficiency testing record review, it was found that the laboratory failed to enroll in API proficiency testing for the Prostate Specific Antigen analyte for the testing year of 2017. During an interview on 04/19/18 at 10:45 a.m., the Medical Technologist confirmed that the laboratory failed to enroll in API proficiency testing for the Prostate Specific Antigen analyte for the testing year of 2017.</p>
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 American Proficiency Institute (API) record review and interview with the Medical Technologist, the laboratory failed to include all Testing Personnel (1 out 2) in performing proficiency testing for Endocrinology, Free Thyroxine (Free T4), and Thyroid Stimulating Hormone (TSH) for one year (1st Event, 2nd Event, and 3rd Event for 2017 and 1st Event for 2018). Findings included: During API proficiency testing record review it was discovered that Testing Personnel #2 had not performed proficiency testing for Endocrinology, Free T4, and TSH for the 1st, 2nd or 3rd Event for 2017 and 1st Event for 2018. During an interview on 04/19/18 at 11:30 a.m., the Medical Technologist confirmed that the Medical Technologist was the only personnel that performed proficiency testing for Endocrinology, Free T4, and TSH for the 1st, 2nd, and 3rd Event for 2017 and 1st Event for 2018</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: During American Proficiency Institute (API) record review and interview with the Medical Technologist, the laboratory failed to evaluate the API proficiency testing results for the Endocrinology, Free Thyroxine(Free T4), and Thyroid Stimulating Hormone for the 1st, 2nd, and 3rd Event for the 2017. Findings included: During the API proficiency testing record review for Endocrinology, Free T4 and TSH (1st, 2nd, and 3rd Event for 2017), it was revealed that there was no documentation of the review of the API proficiency testing records by the Laboratory Director. During an interview on 04/19/18 at 11:00 a.m., the Medical Technologist confirmed the Laboratory Director was not documenting the review of the API proficiency testing results for Endocrinology, Free T4, and TSH (1st, 2nd, and 3rd Event)</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of Chemistry procedure manual, review of quality control and maintenance , and interview with the Medical Technologist, the laboratory failed to follow manufacturer's instructions (see D5411), have Chemistry procedure approved, signed, and dated by Laboratory Director (see D5407), and perform external quality control procedures at least once per day (see D5445).</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based upon Chemistry procedure manual review and interview with the Medical Technologist, the laboratory failed to have the Vitamin D procedure initially approved, signed and dated by the Laboratory Director. Findings included: During the Chemistry procedure manual review it was discovered that the Vitamin D procedure was missing from the procedure manual. The laboratory only had a Quick Operation Manual for Vitamin D that was not initially approved, signed, and dated by the Laboratory Director. During an interview on 04/19/18 at 10:00 a.m., the Medical Technologist stated that the manufacturer had not provided a Vitamin D procedure only the Quick Operation Manual.

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 manufacturer's instructions, maintenance records, and interview with the Medical technologist, the laboratory failed to print the Daily System Check for the Chemistry analyzer. Findings included: During chemistry procedure manual review it was found that the laboratory should print the Daily System Check every day of testing. During the maintenance record review it was observed that the following days the Daily System Check was not printed: 12/04/2017, 12/05/2017, 12/07/2017, 12/11/2017, 12/14/2017, 12/18/2017, 12/19/2017, 12/21/2017, 12/26/2017, 02/05/2018, 02/08/2018, 02/12/2018, 02/12/2018, 02/13/2018, 02/19/2018, 02/20/2018, 02/22/2018, 02/26/2018, 02/27/2018, 03/01/2018, 03/12/2018, 03/13/2018, 03/15/2018, 03/20/2018, 03/21/2018, 03/22/2018, 03/27/2018, 04/02/2018, 04/03/2018, 04/05/2018, 04/09/2018, 04/10/2018, and 04/12/2018. During an interview on 04/19/18 at 12:00 p.m., the Medical Technologist confirmed that the Daily System Check for the Chemistry analyzer was not being printed every day of testing

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on manufacturer's instructions and manual, Chemistry quality control records for (December 2017, February, March, and April 2018) and interview with the Medical Technologist, the laboratory failed to perform control procedures to develop an Individualized Quality Control Plan which includes Risk Assessment, Quality Control Plan, and Quality Assessment. Findings included: During review of the Chemistry manual provided by the manufacturer it was found that the manufacturer, stated that external controls should be tested monthly or with new lot of reagents. The Manufacturer manual did not state an Individualized Quality Control Plan needed to be put in place but provided documents to design an Individualized Quality Control Plan. During review of Chemistry quality control records it was observed that the laboratory had not performed external quality testing once per day of testing on the following days: 12/4/2017, 12/5/2017, 12/7/2017, 12/11/2017, 12/12/2017, 12/14/2017, 12/18/2017, 12/19/2017, 12/21/2017, 12/26/2017, 02/01/2018, 02/05/2018, 02/06/2018, 02/07/2018, 02/08/2018, 02/09/2018, 02/12/2018-02/15/2018, 02/19/2018 - 02/22/2018, 02/26/2018-02/28/2018, 03/01/2018, 03/02/2018, 03/05/2018, 03/06/2018, 03/12/2018, 03/13/2018, 03/15/2018, 03/19/2018, 03/20/2018, 03/22/2018, 03/26/2018, 03/27/2018, 04/02/2018, 04/03/2018, 04/05/2018, 04/09/2018, 04/10/2018, 04/12/2018, 04/14/2018, 04/15/2018, and 04/18/2018. During an interview on 04/19/18 at 1:00 p.m., the Medical Technologist confirmed that external quality control was not being tested once per day and an Individualized Quality Control Plan had not been developed for the laboratory.

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 Chemistry procedure manual and interview with the Medical Technologist, the Laboratory Director failed to establish and follow a quality assurance program. Findings included: During review of the Chemistry procedure manual, it was found that the laboratory did not have a Quality Assurance procedure. During an interview on 04/19/18 at 12:30 p.m., the Medical Technologist confirmed the laboratory did not have a Quality Assurance procedure.