Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0295178	04/20/2020
Name of Provider or Supplier	**Street Address, City, State**	
Eldridge E Mccormick Md Pa	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
D0000	An announced recertification survey was conducted on 04/16/20 to 04/20/20 at Eldridge McCormick MD PA. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 3:30 PM on 04/16/20. The laboratory failed to run 2 levels of control each day of patient testing for 2 (2018-2020) out of 2 years reviewed for Thyroid Stimulating Hormone (TSH), Free Thyroxine (Free T4), Vitamin D, Testosterone, and Prostate Specific Antigen (PSA), failed to have acceptable controls prior to reporting patient test results, failed to document room temperature and humidity for 2 (2018-2020) out of 2 years reviewed, and failed to develop a quality assurance plan that would identify and correct problems (D5400). Additionally, the Laboratory Director failed to ensure the laboratory was enrolled in proficiency testing, failed to ensure quality controls were ran prior to reporting patient test results, failed to ensure a quality assurance plan was established, and failed to ensure Testing Personnel were trained and competent (D6000). The following Conditions were not met: D2000 Enrollment and Testing of Samples 493.801 D5200 General Laboratory Systems 493.1230 D5400 Analytic System 493.1250 D6000 Moderate Complexity Laboratory Director 493.1403
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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.

	This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing and interview with Testing Person #A the laboratory was not enrolled in proficiency testing for Free Thyroxine (Free T4) in 2019. Findings Included: Review of API proficiency testing revealed that the laboratory had not been enrolled for Free T4 testing since 2018. Review of patient logs revealed that one patient was ran on 11/06 /19. Interview on 04/16/20 at 1:30 PM with Testing Person #A confirmed that the laboratory was not enrolled in proficiency testing for Free T4.
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 American Proficiency Institute (API) proficiency testing and interview with Testing Person #A the Laboratory Director failed to sign 4 (1st testing event 2020, 1st and 2nd testing event 2019, and 2nd testing event of 2018) out of 4 attestation statements. Findings Included: Review of API proficiency testing for 1st testing event 2020, 1st and 2nd testing event 2019, and 2nd testing event of 2018 revealed no Laboratory Director signature on the attestation pages. Interview on 04/16 /20 at 1:30 PM with Testing Person #A confirmed that the Laboratory Director did not sign the attestation statements.
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 record review and interview with the Laboratory Director, the Laboratory Director failed to perform competency evaluations on 2 (#A and #B) out of 2 Testing Personnel (See D5209).
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 record review and interview with the Laboratory Director, the Laboratory

	Director failed to perform competency evaluations on 2 (#A and #B) out of 2 Testing Personnel. This is a repeat deficiency from the 05/26/16 recertification survey. Findings Included: Review of the CMS 209, Laboratory Personnel Report signed by the Laboratory Director 4/16/20 revealed 2 Testing Personnel. Testing Personnel #A had worked in the laboratory since 2018 and Testing Personnel #B has been hired in 01/2020. Review of the "Evaluations and Competency Assessments for Testing Personnel" revealed that it must be done by the Laboratory Director (who is also the Technical Consultant) and "Two (2) Competency Assessments are required in the first year; one at 6 months and one at 12 months. Assessments are required annually thereafter." Record review revealed no competencies for Testing Person #A, and Testing Person #B had no initial training or initial competency. Person #B. Interview on 04/20/20 at 11:53 AM with the Laboratory Director confirmed the hire dates and that no competencies were conducted for either Testing Personnel. Review of the plan of correction signed by the Laboratory Director on 06/30/16 from the 05/26/16 recertification survey revealed that "What measures have been put into place to ensure competency evaluations are done for staff: A schedule for review has been posted on the calendar. The laboratory Director and Technical Consultant will be responsible for these annual evaluations."
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 American Proficiency Institute (API) proficiency testing and interview with Testing Person #A the laboratory failed to evaluate proficiency testing that received a "Not Graded" score for 2 (1st testing event in 2019 and 2nd testing event in 2018) out of 4 (1st testing event 2020, 1st and 2nd testing event 2019, and 2nd testing event of 2018) testing events. Findings Included: Review of API proficiency testing results for 1st testing event in 2019 revealed 3 out of 3 results "Not Graded" for Testosterone and 1 out of 3 results "Not Graded" for Vitamin D testing. Review of API proficiency testing results for 2nd testing event in 2018 revealed 3 out of 3 results "Not Graded" for Testosterone. There was no corrective action for any of the "Not Graded" testing results. Interview on 04/16/20 at 1:30 PM with Testing Person #A confirmed that the "Not Graded" testing results did not have any evaluations nor corrective actions.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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.

	This CONDITION is not met as evidenced by: Based on record review and interview with Testing Person #A the laboratory failed to run 2 levels of control each day of patient testing for 2 (2018-2020) out of 2 years reviewed for Thyroid Stimulating Hormone (TSH), Free Thyroxine (Free T4), Vitamin D, Testosterone, and Prostate Specific Antigen (PSA). This is a repeat deficiency from the 04/19/18 recertification survey (See D5445), failed to document room temperature and humidity for 2 (2018-2020) out of 2 years reviewed (See D5413), failed to have acceptable quality control prior to reporting patients (See D5481), and failed to develop a quality assurance plan that would identify and correct problems (See D5791).
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 record review and interview with Testing Person #A the laboratory failed to document the room temperature and humidity where testing was performed on the FREND NanoEnTek analyzer. Findings Included: Review of manufacturer's instructions for the FREND NanoEnTek analyzer that performs Thyroid Stimulating Hormone (TSH), Free Thyroxine (Free T4), Vitamin D, Testosterone, and Prostrate Specific Antigen (PSA) testing revealed that the operating conditions should be 20-30 degrees Celsius and humidity of 10-80%. Review of temperature logs since 05/2018 revealed no documentation of room temperature or humidity. Interview on 04/16/20 at 3:00 PM with Testing Person #A confirmed that the room temperature and humidity were not documented nor did they have an instrument to record the readings with.
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 record review and interview with Testing Person #A the laboratory failed to to have a complete IQCP (Individualized Quality Control Plan) and failed to run 2 levels of control each day of patient testing for 2 (2018-2020) out of 2 years reviewed

for Thyroid Stimulating Hormone (TSH), Free Thyroxine (Free T4), Vitamin D, Testosterone, and Prostate Specific Antigen (PSA). This is a repeat deficiency from the 04/19/18 recertification survey. Findings Included: 1. This deficiency is a repeat deficiency from the recertification survey ending on 04/19/18. An allegation of correction signed by the Laboratory Director on 06/01/18 revealed that "an individualized QC plan has been implemented (I.Q.C.P.) which will include risk ass [assessment], Q.C. plan and Q. assessment. All results will be documented in log manuel. Reviewed and sign by the Lab tech and Lab director." Review of the IQCP (last reviewed by the Lab Director on 05/31/18) revealed only a risk assessment. No quality control (QC) that indicated how often external controls should be ran or quality assurance (QA) to indicate how often QA would be performed to catch and correct errors could be found as part of the IQCP. 2. Review of the Manufacturers' Instructions (MI) under external quality control testing for TSH, Free T4, Testosterone and PSA state it is recommended that a minimum of two (2) levels of controls be run at least once per month or once for each new lot, whichever comes earlier. However, controls should be run with a minimum frequency, depending on number of tests run in the laboratory. Each laboratory should establish its own criteria based on the following parameters (1) Each new lot (2) Each new shipment (even if from the same lot previously received) (3) Each new operator (an individual who has not run the tests for at least two weeks) (4) Monthly, as a continued check on storage conditions. Review of the MI under external quality control testing for Vitamin D state, "It is recommended that a minimum of two (2) levels of controls be run once per day on days when assaying patient samples on the FREND Vitamin D Test. Or another QC [Quality Control] option may be adopted-Individualized Quality Control Plan (IQCP) is an all-inclusive approach to assuring the quality of the entire testing process. An IQCP includes practices, data and information that the laboratory already uses to ensure quality testing and meet CLIA, beyond testing a certain number of QC materials at a designated frequency. To ensure that these control procedures are equivalent to CLIA QC regulations and suitable for each laboratory." Review of the "CLIA Compliance Manual FREND" last revised 06/13/16 and reviewed by the Laboratory Director 12/27/17, states under external QC samples that QC frequency should be performed: on two levels of external QC monthly, with each new lot of reagents, with each new shipment of reagent, and when training new operators. 3. There was no external QC for TSH. A review of Patient Logs revealed patients were ran on 05/10/18, 05/14/18, 05/22/18, 05/31/18, and 06/04/18. The total volume of TSH testing was 10. There was no external QC for Free T4. A review of Patient Logs revealed patients were ran on 11/06/19, 05/10/18, 05/14/18, and 05/22/18. The total volume of Free T4 testing was 6. There was no external QC for Vitamin D. A review of Patient Logs revealed patients were ran on 04/16/20, 04/15/20, 04/08/20, 04/01/20, 03/25/20, 03/24/20, 03/18/20, 02/26/20, 02/19/20, 02/13/20, 02/12/20, 02/06/20, 02/05/20, 01/30/20, 01/22/20, 01/16/20, 12/23/19, 12/05/19, 11/27/19, 11/21/19, 11/20/19, 11/06/19, 10/28/19, 10/23/19, 10/22/19, 10/21/19, 10/09/19, 10/03/19, 09/30/19, 09/26/19, 09/19/19, 09/17/19, 09/12/19, 09/11/19, 09/09/19, 09/05/19, 08/22/19, 08/21/19, 08/08/19, 08/07/19, 07/22/19, 07/18/19, 07/17/19, 07/11/19, 07/02/19, 06/25/19, 06/18/19, 06/14/19, 06/13/19, 06/04/19, 05/30/19, 05/16/19, 05/08/19, 05/03/19, 05/02/19, 04/25/19, 04/23/19, 04/10/19, 04/11/19, 04/09/19, 03/27/19, 03/21/19, 03/20/19, 03/08/19, 03/07/19, 03/04/19, 02/14/19, 11/28/18, 11/20/18, 11/08/18, 10/30/18, 10/26/18, 10/16/18, 10/09/18, 09/27/18, 09/14/18, 09/13/18, 09/10/18, 09/06/18, 09/04/18, 08/31/18, 08/30/18, 08/28/18, 08/23/18, 08/22/18, 08/21/18, 08/16/18, 08/03/18, 08/02/18, 07/30/18, 07/27/18, 07/20/18, 07/17/18, 07/16/18, 07/12/18, 07/09/18, 06/29/18, 06/05/18, 06/04/18, 05/31/18, 05/22/18, 05/14/18, and 05/10/18. The total volume of Vitamin D testing was 149. There was external QC ran for Testosterone on 04/26/19, 11/06/18, 10/01/18, 09/06/18, and 08/01/18. Patients were ran on 08/14/19, 07/31/19,

	07/22/19, and 07/17/19. The total volume of Testosterone testing was 4. There was external QC ran for PSA on 04/29/19. Patients were ran on 04/16/20, 04/15/20, 04/09 /20, 04/01/20, 03/25/20, 03/18/20, 03/11/20, 02/26/20, 02/20/20, 02/19/20, 02/12/20, 02/06/20, 02/05/20, 01/30/20, 01/22/20, 11/27/19, 11/13/19, 11/08/19, 10/28/19, 10/24 /19, 10/23/19, 10/22/19, 10/21/19, 10/16/19, 10/09/19, 10/03/19, 09/30/19, 09/11/19, 09/09/19, 08/22/19, 08/21/19, 08/13/19, 08/08/19, 08/07/19, 07/31/19, 07/22/19, 07/18 /19, 07/17/19, 07/02/19, 06/25/19, 06/13/19, 06/04/19, 05/30/19, 05/16/19, 05/08/19, 04/17/19, 04/11/19, 04/10/19, 04/04/19, 03/28/19, 03/27/19, 03/21/19, 03/20/19, 03/15 /19, 03/07/19, 02/26/19, 02/21/19, 11/28/18, 11/27/18, 11/19/18, 11/08/18, 11/06/18, 10/26/18, 06/04/18, 05/31/18, and 05/22/18. The total volume of PSA testing was 77. 4. Interview on 04/16/20 at 2:30 PM with Testing Person #A confirmed that there was no other QC to review and that external QC was not ran everyday of patient testing.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #A the laboratory reported patients out without having acceptable controls each day of patient testing for 2 (2018-2020) out of 2 years reviewed for Thyroid Stimulating Hormone (TSH), Free Thyroxine (Free T4), Vitamin D, Testosterone, and Prostate Specific Antigen (PSA). This is a repeat deficiency from the 05/26/16 recertification survey. Findings Included: 1. This deficiency is a repeat deficiency from the recertification survey ending on 05/26/16. An allegation of correction signed by the Laboratory Director on 06/30/16 revealed that "The measure that have been out into effect to prevent failure to have at least two acceptable levels of quality control each day of patient testing: The Laboratory Director and Technical Consultant and testing staff will continue to monitor the Quality Control values through daily, weekly and monthly reviews. The Quality control process will be monitored through the periodic reviews of the analytic process through the Quality Assessment process." Review of the IQCP (Individual Quality Control Plan), last reviewed by the Lab Director on 05/31/18, revealed only a risk assessment. No quality control (QC) that indicated how often external controls should be ran or quality assurance (QA) to indicate how often QA would be performed to catch and correct errors could be found as part of the IQCP. 2. Review of the Manufacturers' Instructions (MI) under external quality control testing for TSH, Free T4, Testosterone and PSA state it is recommended that a minimum of two (2) levels of controls be run at least once per month or once for each new lot, whichever comes earlier. However, controls should be run with a minimum frequency, depending on number of tests run in the laboratory. Each laboratory should establish its own criteria based on the following parameters (1) Each new lot (2) Each new shipment (even if from the same lot previously received) (3) Each new operator (an individual who has not run the tests for at least two weeks) (4) Monthly, as a continued check on storage conditions. Review of the MI under external quality control testing for Vitamin D state, "It is recommended that a minimum of two (2) levels of controls be run once per day on days when assaying patient samples on the FREND Vitamin D Test. Or another QC [Quality Control] option may be adopted-Individualized Quality Control Plan (IQCP) is an all-inclusive approach to assuring the quality of the entire testing process. An IQCP includes practices, data and

	information that the laboratory already uses to ensure quality testing and meet CLIA, beyond testing a certain number of QC materials at a designated frequency. To ensure that these control procedures are equivalent to CLIA QC regulations and suitable for each laboratory." Review of the "CLIA Compliance Manual FREND" last revised 06 /13/16 and reviewed by the Laboratory Director 12/27/17, states under external QC samples that QC frequency should be performed: on two levels of external QC monthly, with each new lot of reagents, with each new shipment of reagent, and when training new operators. 3. There was no external QC for TSH. A review of Patient Logs revealed patients were ran on 05/10/18, 05/14/18, 05/22/18, 05/31/18, and 06/04 /18. The total volume of TSH testing was 10. There was no external QC for Free T4. A review of Patient Logs revealed patients were ran on 11/06/19, 05/10/18, 05/14/18, and 05/22/18. The total volume of Free T4 testing was 6. There was no external QC for Vitamin D. A review of Patient Logs revealed patients were ran on 04/16/20, 04/15 /20, 04/08/20, 04/01/20, 03/25/20, 03/24/20, 03/18/20, 02/26/20, 02/19/20, 02/13/20, 02/12/20, 02/06/20, 02/05/20, 01/30/20, 01/22/20, 01/16/20, 12/23/19, 12/05/19, 11/27 /19, 11/21/19, 11/20/19, 11/06/19, 10/28/19, 10/23/19, 10/22/19, 10/21/19, 10/09/19, 10/03/19, 09/30/19, 09/26/19, 09/19/19, 09/17/19, 09/12/19, 09/11/19, 09/09/19, 09/05 /19, 08/22/19, 08/21/19, 08/08/19, 08/07/19, 07/22/19, 07/18/19, 07/17/19, 07/11/19, 07/02/19, 06/25/19, 06/18/19, 06/14/19, 06/13/19, 06/04/19, 05/30/19, 05/16/19, 05/08 /19, 05/03/19, 05/02/19, 04/25/19, 04/23/19, 04/10/19, 04/11/19, 04/09/19, 03/27/19, 03/21/19, 03/20/19, 03/08/19, 03/07/19, 03/04/19, 02/14/19, 11/28/18, 11/20/18, 11/08 /18, 10/30/18, 10/26/18, 10/16/18, 10/09/18, 09/27/18, 09/14/18, 09/13/18, 09/10/18, 09/06/18, 09/04/18, 08/31/18, 08/30/18, 08/28/18, 08/23/18, 08/22/18, 08/21/18, 08/16 /18, 08/03/18, 08/02/18, 07/30/18, 07/27/18, 07/20/18, 07/17/18, 07/16/18, 07/12/18, 07/09/18, 06/29/18, 06/05/18, 06/04/18, 05/31/18, 05/22/18, 05/14/18, and 05/10/18. The total volume of Vitamin D testing was 149. There was external QC ran for Testosterone on 04/26/19, 11/06/18, 10/01/18, 09/06/18, and 08/01/18. Patients were ran on 08/14/19, 07/31/19, 07/22/19, and 07/17/19. The total volume of Testosterone testing was 4. There was external QC ran for PSA on 04/29/19. Patients were ran on 04/16/20, 04/15/20, 04/09/20, 04/01/20, 03/25/20, 03/18/20, 03/11/20, 02/26/20, 02/20 /20, 02/19/20, 02/12/20, 02/06/20, 02/05/20, 01/30/20, 01/22/20, 11/27/19, 11/13/19, 11/08/19, 10/28/19, 10/24/19, 10/23/19, 10/22/19, 10/21/19, 10/16/19, 10/09/19, 10/03 /19, 09/30/19, 09/11/19, 09/09/19, 08/22/19, 08/21/19, 08/13/19, 08/08/19, 08/07/19, 07/31/19, 07/22/19, 07/18/19, 07/17/19, 07/02/19, 06/25/19, 06/13/19, 06/04/19, 05/30 /19, 05/16/19, 05/08/19, 04/17/19, 04/11/19, 04/10/19, 04/04/19, 03/28/19, 03/27/19, 03/21/19, 03/20/19, 03/15/19, 03/07/19, 02/26/19, 02/21/19, 11/28/18, 11/27/18, 11/19 /18, 11/08/18, 11/06/18, 10/26/18, 06/04/18, 05/31/18, and 05/22/18. The total volume of PSA testing was 77. 4. Interview on 04/16/20 at 2:30 PM with Testing Person #A confirmed that there was no other QC to review and that external QC was not ran everyday of patient testing.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of quality assurance (QA) documentation and interview with Testing Person #A the laboratory failed to establish and follow a QA plan that identifies and

	corrects problems in analytic systems for 2 (2018-2020) out of 2 years reviewed. Findings Included: Review of laboratory documentation revealed that there was no QA documentation. Interview on 04/16/20 at 3:00 PM with Testing Person #A confirmed that there was no QA documentation nor any policy or procedure.
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 record review and staff interview the Laboratory Director failed to ensure the laboratory was enrolled in proficiency testing (See D6015), failed to ensure quality controls were ran prior to reporting patients (See D6020), failed to ensure a quality assurance plan was established (See D6021), and failed to ensure Testing Personnel were trained and competent (See D6030).
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 American Proficiency Institute (API) proficiency testing and interview with Testing Person #A the Laboratory Director failed to ensure the laboratory was enrolled in proficiency testing for Free Thyroxine (Free T4) in 2019. Findings Included: See D2000.
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 record review and interview with the Laboratory Director and Testing Person #A the Laboratory Director failed to run 2 levels of control each day of patient testing for 2 (2018-2020) out of 2 years reviewed for Thyroid Stimulating Hormone (TSH), Free Thyroxine (Free T4), Vitamin D, Testosterone, and Prostate Specific

	Antigen (PSA). Findings Included: See D5445. Interview on 04/20/20 at 11:53 AM with the Laboratory Director revealed that he was not sure about the external control for the FREND instrument.
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 lack of quality assurance (QA) documentation and interview with the Laboratory Director and Testing Person #A the Laboratory Director failed to establish and follow a QA plan that identifies and corrects problems in analytic systems for 2 (2018-2020) out of 2 years reviewed. This is a repeat deficiency from the 04/19/18 recertification survey. Findings Included: Review of laboratory documentation revealed that there was no QA documentation. Interview on 04/16/20 at 3:00 PM with Testing Person #A confirmed that there was no QA documentation nor any policy or procedure. Interview on 04/20/20 at 11:53 AM with the Laboratory Director confirmed that he did not have any QA documentation. Review of the recertification survey from 04/19/18 revealed that this was a repeat deficiency. The Allegation of Correction (signed off by the Laboratory Director on 06/01/18) revealed that they would have a QA plan and "each tech will review and sign off, also the Lab director."
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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; This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the Laboratory Director failed to perform competency evaluations on 2 (#A and #B) out of 2 Testing Personnel. Findings Included: Review of the CMS 209, Laboratory Personnel Report signed by the Laboratory Director 4/16/20 revealed 2 Testing Personnel. Testing Personnel #A had worked in the laboratory since 2018 and Testing Personnel #B has been hired in 01/2020. Review of the "Evaluations and Competency Assessments for Testing Personnel" revealed that it must be done by the Laboratory Director (who is also the Technical Consultant) and "Two (2) Competency Assessments are required in

	the first year; one at 6 months and one at 12 months. Assessments are required annually thereafter." Record review revealed no competencies for Testing Person #A and Testing Person #B had no initial training or initial competency. Person #B. Interview on 04/20/20 at 11:53 AM with the Laboratory Director confirmed the hire dates and that no competencies were conducted for either Testing Personnel.