Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2091857	10/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Select Reference Laboratories, Llc	1100 Revolution Mill Drive, Greensboro, 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
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 the laboratory's policies and procedures, review of 2017 and 2018 AAB (American Association of Bioanalysts) proficiency testing records, and interview with GS (general supervisor) #2 on 10/25/18, the laboratory failed to enroll in proficiency testing or establish a system to verify the accuracy of the free PSA (prostate specific antigen) and SHBG (sex hormone binding globulin) at least twice per year. The laboratory's "General Policies and Procedures" manual states on page 19-20 "... 3.3 Proficiency Testing ... The laboratory will enroll and successfully participate in a proficiency testing program that includes each specialty and subspecialty where proficiency testing is required ... For analytes that do not require proficiency testing or analytes that are not regulated, the laboratory will verify the accuracy of the test procedure twice annually through external assessment programs or split sample comparisons with another laboratory's instrument/method. ..." Review of 2017 and 2018 AAB proficiency testing records revealed the laboratory was not enrolled in proficiency testing for free PSA and SHBG. During interview at approximately 2:20 p.m., GS #2 confirmed that the laboratory was not enrolled in proficiency testing and had not established a system to verify the accuracy of the free PSA and SHBG testing at least twice a year.
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 review of laboratory procedure manual, review of manufacturer's instructions, review of patient test reports, review of performance verification records and interview with general supervisors (GS #1 and #2) on 10/24/18 and 10/25/18, the laboratory's procedure manual was not complete and current for the testing performed. The laboratory performs Third (3rd) Generation Prostate Specific Antigen (PSA), Sex Hormone Binding Globulin (SHBG), Estradiol (E2), Testosterone (T), Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH) and Free Prostate Specific Antigen (FPSA) testing on the Siemens Immulite 1000 analyzer. 1. Review of laboratory procedure manual and manufacturer's package inserts revealed the laboratory's quality control procedures failed to include the type of quality control material used for each analyte, the frequency of quality control, what criteria is used to determine if quality control results are acceptable, and the corrective action to take when quality control results are not acceptable. Example: The laboratory's "Follicle Stimulating Hormone (FSH)" procedure stated "Quality Control Material...Use controls or sample pools with at least two levels (low and high) of FSH. Commercially available quality control materials." Review of manufacturer's instructions for FSH revealed "Quality Control Samples: Follow government regulations or accreditation requirements for quality control frequency. Use control or sample pools with at least two levels (low and high) of FSH." 2. Review of laboratory procedure manual and manufacturer's package inserts revealed the laboratory's calibration procedures failed to include the criteria used to determine if calibration was acceptable, and the corrective action to take when calibration was not acceptable. 3. Review of laboratory procedure manual revealed the laboratory performs a two point calibration at various intervals for all analytes tested on the Siemens Immulite 1000 analyzer. The laboratory procedure manual failed to include a calibration verification procedure for all analytes tested on the analyzer. 4. Review of laboratory procedure manual, patient test reports and performance verification records revealed laboratory procedures failed to include reference intervals (normal values) that were consistent with patient test reports and performance verification records. Example: The laboratory's "Total Testosterone" procedure included a chart for females, ovulating and post-menopausal, and a chart for males, ages 20-49 years and greater than 50 years. For a male greater than 50 years, the chart indicates a reference range of 129-767 ng/dl. Review of a random patient test report for a male greater than 50 years (#MANE400172990) revealed a reference range of 300.0 - 890.0 ng/dl. Performance verification records for total testosterone included a reference range of

	72.0 - 853.0 ng/dl. 5. Review of laboratory procedure manual revealed the procedure manual did not include a procedure for entering patient test results in the patient record. 6. Review of laboratory procedure manual revealed the procedure manual did not include a procedure for reporting critical values. Example: The laboratory's "Estradiol" procedure stated "Reporting....Add your laboratory-specific protocol for reporting results here...Critical Values.....Add your laboratory-specific critical values here." 7. Review of laboratory procedure manual revealed the procedure manual did not include a procedure for the course of action to take if a test system becomes inoperable. Interview with GS #1 and GS #2 10/25/18 at approximately 11:30 a.m. confirmed the laboratory's procedure manual was not complete and current for the testing performed. They stated that they were performing testing for Third (3rd) Generation Prostate Specific Antigen (PSA) only and were in the process of developing test procedures for all other analytes when they decided to perform testing temporarily for their sister facility located in another state on September 13, 14, 17 and 18, 2018.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with general supervisors (GS #2 and #3) on 10/24 /18, the laboratory failed to discard materials that had exceeded their expiration dates and were available for use. Findings. 1. At 5:00 p.m., the surveyor observed 2 bottles of Siemens Immulite Probe Cleaning Kits on the analyzer. One bottle was open and in use, and the other bottle had not been opened. Both bottles were Lot number 46520087A, with the Expiration Date 2018-10-10. During interview with GS #2 and GS #3 at 5:10 p.m., it was determined that approximately 88 patients were tested during the period between 10/10/18 and 10/25/18. 2. At 5:20 p.m., the surveyor observed 3 unopened boxes of Quantimetrix Lipoprint LDL Subfractions Kits, Lot Number 96980A, with the Expiration Date 2017-12 on the bottom shelf in the laboratory. During interview with GS #2 and GS #3 at 5:30 p.m., the surveyor was told that these items were not being used and that they should have been discarded.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of laboratory validation records, laboratory procedures and random patient test reports 10/24/18 and 10/25/18, the laboratory failed to ensure reference intervals (normal ranges) were accurate on patient test reports and failed to accurately identify the test method used for Total Testosterone testing on patient test reports. 1. Review of random patient test report revealed the laboratory failed to ensure reference intervals were accurate on patient test reports. For example: Review of patient test

	report, #MANE0500023285, a male patient age 35 years, revealed a reference range (interval) of 300.0 - 890.0 ng/dl for Total Testosterone (T). Review of validation record "Assay Summary" for T revealed a reference interval of 72.00-853.00 ng/dL. Review of laboratory procedure "Total Testosterone" revealed a chart for females, ovulating and post-menopausal and a chart for males, ages 20-49 years and greater than 50 years. For a male age 20-49 years the chart indicates a reference interval of 160-726 ng/dl. Review of patient test report, #MANE0500023285, a male patient age 35 years, revealed a reference range (interval) of 10.0-57.0 nmol/L for Sex Hormone Binding Globulin (SHBG). Review of validation record "Assay Summary" for SHBG revealed no reference interval. Review of laboratory procedure "Sex Hormone Binding Globulin" revealed a chart for males and females, the chart indicates a reference interval of 13-71 nmol/L. 2. Review of random patient test report revealed the laboratory failed to accurately identify the method used to perform Total Testosterone testing on patient test reports. Review of patient test report, #MANE0500023285, revealed the statement "On February 11, 2016 Methodology for Total Testosterone changed from Siemens Immulite 2000 to Siemens Centaur XP." The laboratory performs Total Testosterone testing on the Siemens Immulite 1000 analyzer.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of laboratory performance verification documentation, "Assay Summary" records and patient test reports 10/24/2018, the laboratory director failed to ensure verification procedures were performed and were adequate to determine all performance specifications for the testing performed on the Siemens Immulite 1000 analyzer. Findings: A. The laboratory began testing Third (3rd) Generation Prostate Specific Antigen (PSA) on the Siemens Immulite 1000 analyzer in October of 2017. Review of performance verification records revealed the laboratory director failed to review and approve the accuracy, reportable range, and reference intervals (normal values) of the 3rd Generation PSA prior to the initiation of patient testing. Performance verification records were approved by the laboratory director 9/30/18, approximately 11 months after patient testing began. Review of performance verification records revealed laboratory personnel had performed a precision study for 3rd Generation PSA. The precision study failed to demonstrate what acceptable limit of deviation was established to determine acceptability and the laboratory director failed to review and approve the precision study. B. On September 13, 14, 17 and 18, 2018, the laboratory received specimens from their sister facility in another state. The sister facility was closed due to weather conditions and they were unable to test the specimens. During this period the laboratory began testing for Sex Hormone Binding Globulin (SHBG), Estradiol (E2), Testosterone (T), Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH) and Free Prostate Specific Antigen (FPSA) on the Siemens Immulite 1000 analyzer. 1. Review of performance verification documentation, "Assay Summary" records and patient test reports revealed the laboratory failed to establish reference intervals (normal values) for SHBG, E2, T, FSH, LH and FPSA. In addition, there was no documentation the laboratory director had approved the reference intervals (normal values) reported on the patient test

	report. For example: a. The "Assay Summary" for E2 shows reference intervals (normal values) of 0.00 - 400.00 pg/mL. Review of patient test report, MANE400040554, shows a reference range (normal value) of 0 - 57 pg/mL and includes a table of ranges for females. b. The "Assay Summary" for T shows reference intervals (normal values) of 72.00 - 853.00 ng/dL. Review of patient test report, MANE400172990, shows a reference range (normal value) of 300.0 - 890.0 ng/dL. c. The "Assay Summary" for FSH shows reference intervals (normal values) of 0.7 - 11.1 IU/L. Review of patient test report, MANE05000023285, shows reference ranges (normal values) on a chart, in which postmenopausal FSH has a range of 21.7 - 153 IU /L. 2. Review of performance verification documentation revealed the laboratory had performed precision studies for SHBG, E2, T, FSH, LH and FPSA. The studies were completed over a period of two days by the service representative only and did not include testing personnel. The precision studies failed to include operator variance. 3. Review of performance verification documentation and "Assay Summary" records revealed the laboratory failed to establish the analytical (reportable) range for SHBG.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records 10/24/18 and 10/25/18 and the deficiency cited at D6171, the laboratory failed to verify that 1 of 7 testing personnel (TP #5) met the qualification requirements to perform high complexity testing.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2) (ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)

(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures and review of personnel records 10/24/18 and 10/25/18, and interview with staff 10/25/18, the laboratory failed to ensure 1 of 7 testing personnel (TP #5) met the education requirements to be qualified to perform high complexity testing. The laboratory's "General Policies and Procedures" manual states on page 4 "... 1.1 Qualification and Responsibilities All personnel working in the laboratory will meet the qualification requirements set forth in 42CFR 493 Subpart M of the Clinical Laboratory Improvement Amendments. The laboratory will maintain personnel records on all individuals. ..." Review of personnel records for TP #5 revealed a Bachelor of Science degree in Health Science and an unofficial transcript dated 12/13/2017 which did not include a graduation date or a major. During interview 10/25/18 at approximately 3:30 p.m., the laboratory's compliance representative stated that TP #5 had previously worked at another laboratory for approximately three years performing high complexity toxicology testing, so they did not realize she did not meet the education requirements for high complexity testing.