Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2091857	03/30/2023
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of 2021, 2022 and 2023 calibration records for Diazyme EZ Lite and Immulite 1000 analyzers and interview with general supervisor (GS) #1 on 3/29/23, the laboratory failed to retain at least 2 years of calibration records for testing performed on the Diazyme EZ Lite and Immulite 1000. Review of laboratory policy "General Policies and Procedures....Section 4...4.7 Record Retention..." revealed "Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities for at least 2 years.". 1. The laboratory failed to retain calibration records for the testing performed on the Diazyme EZ Lite analyzer since testing began in June of 2020. Findings: Review of laboratory policy "Diazyme DZ-Lite NT-proBNP Assay" revealed "2. Calibration procedure:...g. Review calibration results and store results electronically to Share Point.". Interview with GS #1 at approximately 1:45 p.m. confirmed calibration records for the Diazyme EZ Lite analyzer were not stored electronically to Share Point. He also confirmed the laboratory had not retained at least two years of calibration records for the testing performed on the Diazyme EZ Lite analyzer. 2. The laboratory failed to retain calibration records for the testing performed on the Immulite 1000 analyzer for at least 2 years. Findings: Review of Immulite 1000 calibration records, "adjustment reports", revealed the Immulite 1000 analyzer retained documentation of the last 2 or 3 three calibrations performed for each analyte. There was no documentation of calibrations, "adjustment reports" prior to the calibrations maintained on the analyzer, a period of approximately 2 years. Interview with GS #1 at approximately 1:45 p.m.

	confirmed the Immulite 1000 retained the last 2 or 3 calibrations performed for each analyte. He stated "adjustment reports" for any prior calibrations were not retained by the analyzer or printed and retained elsewhere. He also stated that calibrations were required for each analyte with each new lot change and at 4 week intervals for most analytes.
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 2020, 2021, and 2022 American Association of Bioanalysts (AAB) and 2020 and 2021 College of American Pathologists (CAP) proficiency testing records, and interview with GS #1 on 3/30/23, the laboratory failed to enroll in proficiency testing or establish a system to verify the accuracy of the adiponectin and sdLDL (small dense low density lipoprotein) testing at least twice a year. Review of the "Alternate Proficiency Assessment Methods" procedure revealed "Intended Use: To make certain that the laboratory has processes and procedures to effectively ensure that all analytes are covered by Proficiency Testing either through a formal program or an equivalent substitute at least twice a year at six months interval. ..." Review of the "General Policies and Procedures, Section 3 - Quality Systems" procedures revealed "... 3.3 Proficiency Testing ... Non-regulated analytes may be evaluated by an external assessment twice yearly. ..." Review of 2020, 2021, and 2022 AAB and 2020 and 2021 CAP proficiency testing records revealed: 1. The laboratory did not participate in proficiency testing for adiponectin in 2020, 2021, and 2022. 2. The laboratory did not participate in proficiency testing for sdLDL in 2020, 2021, and 2022. The laboratory participated in one verification event for sdLDL in 2021 on 3/15/21. During interview at approximately 2:05 p.m., GS #1 confirmed that the laboratory was not enrolled in proficiency testing for adiponectin and sdLDL in 2020, 2021, or 2022. He stated the laboratory has not performed any patient adiponectin tests yet.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory quality assurance policies and procedures, and deficiencies cited at time of survey 3/28/23 through 3/30/23, the laboratory director failed to ensure quality assessment policies and procedures were either established or maintained to identify failures found at time of survey. 1. The laboratory's QA policies and procedures failed to identify calibration records for the testing performed on the Diazyme EZ Lite and Immulite 1000 analyzers were not retained for at least 2 years. Findings: See D3031. 2. The laboratory's QA policies and procedures failed to identify the laboratory failed to enroll in proficiency testing or establish a system to verify the accuracy of the adiponectin and sdLDL (small dense low density

	lipoprotein) testing at least twice a year. Findings: See D5217. 3. The laboratory's QA policies and procedures failed to identify laboratory test reports failed to included the assay method of the PSA test and test results failed to include reference ranges for multiple tests performed. Findings: See D6098. Review of laboratory procedure "A5-LIS Verification Form" revealed "Patient final computer reports are checked for the following information...Reference ranges...". Review of laboratory procedure "A6-Chart Review" revealed "Quarterly Procedure: Randomly select five requisitions representing all areas of the laboratory. Obtain final result report corresponding to the requisitions. Reports must be checked for:...Reference Ranges...".
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of random patient test reports and interview with GS #1 on 3/29/23, the laboratory director failed to ensure test results included the identity of the prostate specific antigen (PSA) assay and failed to ensure test results included reference ranges for the testing performed. 1. The laboratory director failed to ensure PSA test results included the assay method. Findings: Review of laboratory procedure "Third Generation PSA" revealed "The results reported by the laboratory to the physician must include the identity of the assay used.". Review of random patient test reports revealed the following: a. "Patient ID #: 768...Test Date: 3/07/2023" revealed no assay method for the PSA test result. b. "Patient #: 776...Test Date: 3/20/2023" revealed no assay method for the PSA test result. 2. The laboratory director failed to ensure test results included reference ranges for the testing performed. Findings: Review of random patient test reports revealed the following examples; a. "Patient ID #: 768...Test Date: 3/07/2023" revealed no reference ranges for PSA, hemoglobin (HGB) and red blood cell count (RBC). b. "Patient ID #:270... Test Date:2/03/2023" revealed no reference ranges for HGB, RBC and Iron, Serum. c. "Patient #: 092204...Gender: Male...Run...on 9/29/2022...", revealed "Female Reference Range:...Ovulating...Post Menopausal...". The patient was male and the test report failed to include reference ranges for a male patient. The test report also failed to include reference ranges for Free Testosterone and Bioavailable Testosterone. d. "Patient #: 776...Test Date: 3/20/2023" revealed no reference ranges for HGB, RBC and PSA. The surveyor was unable to determine whether the patient was male or female. The reference range for the Testosterone was, "Female Reference Range:... Ovulating...Post Menopausal...". Interview with GS 3/29/23 at approximately 2:15 p. m. confirmed the test reports failed to include reference ranges for the testing performed and the PSA test result also failed to include the assay method.