Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2091857	01/16/2025
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
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 review of the laboratory's policies and procedures, review of personnel records, and interview with staff 1/14/25, the laboratory failed to follow written policies for evaluating the competency of personnel. Findings: Review of the laboratory's "General Policies and Procedures" revealed "SECTION 1 - PERSONNEL ... 1.2 Competency Assessment... Documented competency assessments will be performed on all persons that perform patient testing and/or report patient test results. At a minimum, this includes technical and clinical consultants, technical supervisors, general supervisors and testing personnel. The Technical Supervisor/Laboratory Director is responsible for performing and documenting competency assessments. ..." Review of personnel records revealed missing and incomplete competency evaluation documentation. Examples: 1. Review of personnel records revealed no documentation of 2023 and 2024 TP (testing personnel) competency evaluations for GS (general supervisor) #2 for testing performed on the IR 500 and IR 1200 chemistry analyzers. During interview at approximately 2:10 p.m., GS #2 confirmed she performs testing on these analyzers. 2. Review of personnel records revealed 2023 TS (technical supervisor), GS, and TP competency evaluations for TS #1 were not signed to indicate who performed the evaluations. In addition, there were no 2024 competency evaluations for TS #1 available for review. During interview at approximately 11:10 a.m., TS #1 and TS #3 confirmed that TS #1's 2023 competency evaluations were not signed, and they stated they were unable to locate any of her 2024 competency evaluations. 3. Review of personnel records revealed no documentation of semiannual or annual TP competency evaluations for TS #2 for testing performed on the

	Thunderbolt in 2024. During interview at approximately 1:15 p.m., GS #1 stated there was no semiannual or annual Thunderbolt competency evaluation for TS #2 performed in 2024.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 tour of laboratory and interview with staff on 1/14/25 and 1/15/25, the laboratory failed to discard expired reagents. Findings: During a tour of the laboratory at approximately 3:15 p.m. on 1/14/25, the surveyor observed two bottles of expired Immulite TES Adjustor (Lot 134, expiration date 12/7/24), in the laboratory's American Biotech refrigerator, available for use. The bottles were in a closed container with previously tested proficiency samples, located on the right side of the refrigerator, on the second shelf from the top. There were no identifying marks on the storage container. During an interview at approximately 3:25 p.m., GS #1 stated that supplies are reviewed for expiration dates on a regular basis. He was unsure why the reagents and proficiency samples were left in the container. He stated that TS #2 might have further information, but TS #2 was unavailabe at that time. During an interview at approximately 9:00 a.m. on 1/15/25, TS #2 stated the Adjustor had been removed from its orginal kit and set aside for an unspecified purpose. She stated the expired Adjustor could not be used on patients since the Immulite analyzer would not allow it to be loaded.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment Chart/Computer Monitoring Form, review of patient test reports and corresponding analyzer printouts, and interview with the General Supervisor (GS #1) on 1/14/25, and interview with GS #1 on 1/16/25, the laboratory failed to follow their procedure to assess data, identify problems, and take corrective action as required. Findings: Review of the Quality Assessment Chart/Computer Monitoring Form revealed instructions for review of reports. The QA monitor instructs, "Reports must be checked for....." eight elements including, "Reference Ranges." The QA monitor also instructs, "If there are test results missing from the report or the results are not accurrate, investigate and submit a corrected report to the client." Review of patient test reports and corresponding analyzer printouts for each test system revealed reference range discrepancies between patient test reports and analyzer printouts and missing reference ranges on analyzer printouts with no corrective action documented. Examples: 1. Review of patient hematology test reports and corresponding analyzer printouts revealed inaccurate reference ranges for the hematology test system. The final test report for Accession

	#40790 included an RBC (red blood cell count) reference range of 4.10 - 5.10 while the analyzer printout indicated an RBC reference range of 4.50 - 5.90. This accession number was reviewed on the 1/14/25 Quality Assessment Chart/Computer Monitoring Form which had been graded with a score of 100% with no applicable corrective action. 2. Review of patient chemistry test reports and corresponding analyzer printouts revealed incorrect and missing reference ranges on analyzer printouts for the IR 1200 chemistry test system. Accession #30981 Complete Metabolic Panel test report indicated a TP (Total Protein) reference range of 6.0 - 8.5 g/dl (grams per deciliter) and GLU (Glucose) reference range of 70 - 110 mg/dl (milligrams per deciliter), while the IR 1200 analyzer printout contained a TP reference range of 60 - 83 g/dl and a GLU reference range of 3.89 - 6.11 mg/dl. The final report also revealed reference ranges for BUN (Blood Urea Nitrogen) and Creat (Creatinine) while the IR 1200 analyzer printout had no reference ranges for BUN and Creat. 3. Review of patient immunoassay test reports and corresponding analyzer printouts revealed discrepancies for the Thyroid Function Panel on Accession #30921. The test report indicated Free T3 (triiodothyronine) reference range of 1.5 - 4.1 pg/mL (picograms per milliliter). The immunoassay analyzer printout indicated a normal Free T3 range of 1.0 - 40.0 with no other range listed. Accession #30981 and Accession #30921 were reviewed on the 5/4/2023 Quality Assessment Chart/Computer Monitoring Form which had been graded with a score of 100% with no applicable corrective action. During an interview at approximately 3:30 p.m. on 1/14/25, GS #1 confirmed that 5 patient requisitions are randomly chosen for annual chart review. He stated that discrepancies are fixed and corrected reports are sent. During a second interview at approximately 2:55 p.m. on 1/16/25, GS #1 stated that findings are documented on the CMP-129 Form and results have been all good.