Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1064292	10/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Select Laboratories- Sc Llc	1051 Bill Buyck Blvd, Manning, SC	

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 onsite recertification survey was conducted at Select Laboratories-SC, LLC on October 23rd, 2024, by South Carolina Department of Public Health's (SCDPH), Bureau of Nursing Home and Medical Services. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the standards of the CLIA program. The following STANDARD LEVEL DEFICIENCES were found to be out of compliance:
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: During an onsite recertification survey on 10/23/2024, based on procedure review, and staff interview, the laboratory failed to have a current client instructions manual with written information specified for specimen handling (e.g. collection, preservation, storage, transport, testing schedule times and how to obtain additional assistance for unusual circumstances). Findings include: 1) The surveyor reviewed client manual titled "Directory of Services", April 2017. The test menu was out of date. Lack current requirements to ensure client(s) have written instructions containing information on specimen handling. 2) During an interview with Vice President (VP), Compliance Officer (CO), general supervisor (GS) in the conference room on 10/23/2024@4:30 pm, the above findings were confirmed.
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 direct observation, review of records, manufacturer's instructions, and interview with TS, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings included: 1) During a 2nd tour of the laboratory on 10/23 /2024 at 4:13 pm, the surveyor observed the storage of the following items in the blood draw room: a. 1 pack of Becton Dickinson (BD) vacutainer K2E, Lavender Blood Collection Tubes, Lot#4166471, expiration (exp.) 10/31/2025 b. 1 pack of BD vacutainer SST, Serum Blood Collection Tubes, Lot#4236796, exp.07/31/2025. c. 1 pack of BD vacutainer SST, Serum Blood Collection Tubes, Lot#4194257, exp.06/30 /2026 d. 1 pack of BD vacutainer Sodium Citrate, Blue Collection Tubes, Lot#4073696, exp. 12/31/2024 e. 13 tubes, BD vacutainer Plain Red, Serum Blood Collection Tubes, Lot#3194576, exp. 07/31/2025 f. 3 each, Qiagen, Lot#575015683 g. 2 each, Qiagen, Lot#57802430 Review of manufacturer's label instructions reveal collection kits and supplies were to be stored between 4 to 25 degrees Celsius (a-g and o-t). The warehouse storage room contained the following items: h. Aptima Urine collection kit for males and females' urine specimens. 1 kit (50 swabs), Lot#898300V, exp. 03/31/2026 i. Aptima Multi-test Swab, specimen collection, 2 kits (50 swabs per kit), Lot#88924V j. Aptima Multi-test Swab, specimen collection, 2 kits (50 swabs per kit), Lot#89305V k. 10 boxes , Plylo Plus+, manufactured by ARJ Medical , Inc. Oldsmar, FL 34677 l. 5 boxes (50 tubes in each), QuantiFeron TB Gold Plus (QFT-Plus) Review of manufacturer's label instructions reveal kits temperature requirements are 15 to 30 degrees Celsius (h-l). m. 2 each, Urethral swabs, ref# 99-08C14-VCF, Lot #248516, exp. 01/05/2025 Diagnostic Hybrids, Inc. n. 7 each, Nasopharyngeal swabs, ref# 99-08015-VCF,Lot#247310, exp. 12/27/2024, Diagnostic Hybrids, Inc. Review of manufacturer's label instructions reveal kit temperature requirements are 2 to 25 degrees Celsius (m,n). o. 4 packs (100 per pack) BD vacutainer K2E, Lavender Blood Collection Tubes, Lot#4198187, exp. 11/30/2025. p. 4 packs BD vacutainer, SST Tiger Serum Blood Collection Tubes, Lot#4135886, exp. 04/30/2025 q. 6 packs BD vacutainer, Plain Red Blood Collection Tubes, Lot#4194257, exp. 06/30/2024 r. 2 cases (1,000 per case) BD vacutainer Lavender Blood Collection Tubes s. 9 packs(100 per pack) + 1 case (1,000) BD vacutainer, SST Tiger Serum Blood Collection Tubes, t. 2 packs (100 per pack) + 2 cases (1,000) BD vacutainer, Blue Top Blood Collection Tubes, Lot# 4073696, exp. 12/31/2024 2) The surveyor observed no temperature monitoring devices in the blood draw room, or laboratory storage area. 3) Review of environmental temperature logs for chemistry reveals the laboratory failed to define temperature criteria/range for proper storage of reagents and specimens. 4) The laboratory failed to ensure materials had been stored as required. 5) In an interview on 10/23/2024 at 4:30 pm with VP, CO, and GS in the conference room, the above findings were confirmed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation and staff interviews, the laboratory failed to define functional check protocol that ensures equipment performance that is necessary for accurate and reliable test results and test result reporting. Findings include: 1) During an onsite recertificate visit on 10/23/2024 at 11:00am, the surveyor directly observed that no function checks were performed on microscopes. The following microscopes were in the laboratory at Select Laboratories: a. Microscope in UA, tag HCA Biomedical Services 007280, no service/maintenance tag. b. Olympus BX41, Calib Photoelectric Tech, Service Tag date 02/15/2022. c. Olympus BX40, No service /maintenance tag. 2) In an interview on 10/23/2024 at 4:30 pm in the conference room with TS the above findings were confirmed.