Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2161157	07/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Select Laboratories - Marion County, Fl Llc	11115 Sw 93rd Court Road Unit 100, Ocala, 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 CLIA recertification survey was conducted at Select Laboratories-Marion County FL LLC on 07/09/2025 - 07/15/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6168 493.1487 Condition: Testing Personnel
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers 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, the Laboratory reported Patient test results when quality control (QC) was not in the normal range for Parathyroid Hormone (PTH) on 12/28/2023 and Alanine Aminotransferase (ALT) on 07/22/2024. Findings Included: 1. The QC was reviewed for 12/2023, 07/2024, and 03/2025 for all analytes tested. 2. Review of PTH QC revealed level 1 lower than the normal range with 1 Patient tested and reported. 3. Review of ALT controls revealed level 2 and level 3 both lower than the normal range with 8 Patients tested and reported. 4. Interview on 07/10/2025 at 2:00 PM the Technical Supervisor confirmed the unacceptable QC with Patients reported.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test

	performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to have Patient reports that had an accurate date for testing and accurate reference Laboratory listed for send outs for 1 of 1 Patient record reviewed. Findings Included: 1. Review of Patient laboratory report from 12/08/2023 revealed that the Hematology, Chemistry, and the send out testing was all completed on 01/04/2025. 1a. Review of the Hematology and Chemistry analyzers revealed that the testing was performed 12/28/2023. 2. Review of the send out testing (Creatinine, Random Urine) revealed that it was performed by a sister laboratory in South Carolina and was performed by a reference laboratory in Virginia. 2a. Review of the send out results for Creatinine, Random Urine revealed that it was performed by the reference laboratory in Virginia. 3. Interview on 07/10 /2025 at 4:00 PM the Technical Supervisor confirmed that the testing date and location of send outs were incorrect.
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 record review and interview, the Laboratory had 1 (# B) out of 2 (#A and #B) Testing Personnel (TP) that did not qualify to perform High Complexity testing (See D6170).
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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training

	may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory had 1 (# B) out of 2 (#A and #B) Testing Personnel (TP) that did not qualify to perform High Complexity testing. Findings Included: 1. Review of the FORM CMS-209 signed and dated by the Laboratory Director 07/07/2025 revealed there were 2 TP who performed High Complexity Testing. 2. Review of TP#B employee file revealed they were hired on 10/2024. He had a transcript from a Medical Clinical Laboratory Technician Program and a High School diploma. 3. Interview with the school on 07/09/2025 at 3:41 PM confirmed that the school did not issue an associates degree, but issues "career certificates". 4. Interview on 07/09/2025 at 4:00 PM TP#B confirmed that he did not have any other college classes, only his high school diploma and career certificate and that he performed High complexity Hematology and Chemistry testing in the Laboratory.