

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2161157	<b>(X3) Date Survey Completed</b>  07/16/2019
<b>Name of Provider or Supplier</b>  Select Laboratories - Marion County, Fl Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Initial survey conducted on 07/16/2019 found Condition at D-6063 out of compliance.
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, and staff interview, the facility failed to ensure the glass jars used for the Wrights Stain procedure were labeled with the identity of the stain, preparation, and expiration date. Finding include: 1. During the tour of the laboratory on 7/16/19 at 12:50 pm, one jar with no label was observed on the counter in the hematology testing area with liquid inside. The interview with the testing person on 7/16/19 at 12:50 pm confirmed the jar was used for making blood smears using the Wrights Stain procedure.</p>
<b>D6063</b>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview it was determined that the staff member who</p>

performed the establishment of performance verification on the ACL 2000, IR 1200, and IR 500 does not possess a current license issued by the state of Florida to be compliance by state law. (Refer to D6064)

**D6064**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:  
Based on record review and interview it was determined that the staff member who performed the establishment of performance verification on the ACL 2000, IR 1200, and IR 500 does not possess a current license issued by the state of Florida to be compliance by state law. Findings include: The review of instrument validation documentation showed the staff member who performed the validation studies for the ACL 2000, IR 1200, and IR 500 is not licensed in State of Florida as a clinical laboratory technologist or clinical laboratory technician. Since patient testing began in May 2019, 2 patients have been tested on the ACL 2000 for coagulation studies, 96 patients on the IR 1200 for Chemistry, and 0 patients tested on the IR 500 for Toxicology. During an interview with the general supervisor on 7/16/19 at 11:30am, it was confirmed the staff member is not licensed in State of Florida as clinical laboratory technologist or clinical laboratory technician.