

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2161157	(X3) Date Survey Completed 12/21/2020
Name of Provider or Supplier Select Laboratories - Marion County, FL Llc	Street Address, City, State 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 recertification survey was conducted on 12/21/20 at Select Laboratories - Marion County, a clinical laboratory in Ocala, Florida. Select Laboratories - Marion County is NOT in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. .
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with staff, the laboratory did not maintain complete proficiency testing records when remedial actions were performed for unsatisfactory test results for one of two chemistry testing events reviewed in 2019. Findings include: On 12/21/20, the laboratory AAB (American Association of Bioanalysts) proficiency testing records were reviewed. During the review, it was determined that the laboratory had received unsatisfactory test scores. The records provided by the laboratory did not identify the cause of the error or describe the steps that the laboratory performed in order to ensure that the error did not reoccur. 2019, Testing event #3 PSA (Prostate-specific antigen)-50% The interview with the Technical Supervisor on 12/21/20 on or about 11:35am revealed there was an investigation performed but was unable to locate the documentation. .</p>
D2105	ENDOCRINOLOGY

CFR(s): 493.843(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on record review and interview with staff, the laboratory did not maintain complete proficiency testing records when remedial actions were performed for unsatisfactory test results for one of two endocrinology testing events reviewed in 2020. Findings include: On 12/21/20, the laboratory AAB (American Association of Bioanalysts) proficiency testing records were reviewed. During the review, it was determined that the laboratory had received unsatisfactory test scores. The records provided by the laboratory did not identify the cause of the error or describe the steps that the laboratory performed in order to ensure that the error did not reoccur. 2020, Testing event #1 TT3 (Total Triiodothyronine)-60% The interview with the Technical Supervisor on 12/21/20 on or about 12:40pm revealed there was an investigation performed but was unable to locate the documentation.