

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0691430	(X3) Date Survey Completed 11/17/2021
Name of Provider or Supplier Sharp Rees Stealy Clinics Laboratory	Street Address, City, State 525 3rd Ave, Chula Vista, CA	
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
D2099	<p>ENDOCRINOLOGY CFR(s): 493.843(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from the CMS 96 Report, laboratory proficiency reporting from CAP (College of American Pathologists), and an interview with the laboratory technical specialist (TS) on 11/17/2021 between 8:30 a.m. and 10:30 a.m., it was determined that there were two unacceptable (below 80 %) proficiency testing (PT) results for Endocrinology. Findings include: 1. On 11/17/2021, an inspection was conducted between 8:30 a.m. and 10:30 a.m. 2. A follow up visit was completed on 11/30/21. 3. During a review of the laboratory documentation from CAP (agency providing the proficiency specimens), it was noted at approximately 9:30 a.m. that there were two unacceptable PT results for Endocrinology. The laboratory utilizes the ACCESS instrument for toxicology and endocrinology testing. 4. The findings were as follows: Cycle 1 2020 Endocrinology Category Analyte: Thyroxine, Free (0/5 unacceptable) No results were submitted based on the corrective action documentation. Analyte: TSH (0/5 unacceptable) No results were submitted based on the corrective action documentation. 5. The TS affirmed the unacceptable results listed above.</p>
D2110	<p>TOXICOLOGY CFR(s): 493.845(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p>

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from the CMS 96 Report, laboratory proficiency reporting from CAP (College of American Pathologists), and an interview with the laboratory technical specialist (TS) on 11/17/2021 between 8:30 a.m. and 10:30 a.m., it was determined that there was an unacceptable (below 80 %) proficiency testing (PT) result for Toxicology. Findings include: 1. On 11/17/2021, an inspection was conducted between 8:30 a.m. and 10:30 a.m. 2. A follow up visit was completed on 11/30/21. 3. During a review of the laboratory documentation from CAP (agency providing the proficiency specimens), it was noted at approximately 9 a.m. that there was unacceptable PT results for Toxicology. The laboratory utilizes the ACCESS instrument for toxicology testing. 4. The findings were as follows: Cycle 1 2019 Toxicology Category Analyte: Theophylline (0/5 unacceptable) No results were submitted based on the corrective action documentation. 5. The TS affirmed the unacceptable results listed above.