

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1038599	(X3) Date Survey Completed 07/11/2019
Name of Provider or Supplier Crosspoint Medical Clinic	Street Address, City, State 2505 W Trenton, Edinburg, TX	
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
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to ensure a stable electrical source is maintained in the laboratory for the refrigerator. The findings were: 1. Surveyor observation made on June 10, 2019 at 10:10 hours revealed that the facility stored CLINIQA quality control materials used for Vitamin D, PSA, and TSH testing. The quality control materials were stored in the laboratory refrigerator. 2. Surveyor observation made on June 10, 2019 at 10:28 hours revealed the facility experienced a complete power outage. The electrical power was off from 10:28 hours to 10:33 hours, for a total of five minutes. 3. Interview with the laboratory director on June 10, 2019 at 10:30 hours during the power outage, when asked how frequently this occurs, he stated, "No more than once a year." 4. Interview with the technical consultant on June 10, 2019 at 10:30 hours after the power outage, when asked if the facility has a power outage contingency policy, she stated, "No." She went on to say that the facility needs a min/max thermometer for the refrigerator. Key: PSA - prostate specific antigen TSH - thyroid stimulating hormone</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

This STANDARD is not met as evidenced by:

NEW STANDARD DEFICIENCY: Based on surveyor observation, review of manufacturer's instructions,, and confirmed in interview the laboratory failed to ensure expired items were not available for use in preparation of quality control materials for 1 of 1 box of reagent grade water. The findings were 1. Surveyor observation on June 10, 2019 at 10:15 hours in the laboratory revealed the following 1 of 1 boxes of EKI High Purity Reagent Grade water was expired. The box was opened with an open date of 05-30-2019. As of July 10, 2019, the date of the unannounced follow-up visit revealed the reagent had been opened for 41 days. 2. Review of the manufacturer's instruction located on the package labeling stated, "To prevent microbial contamination, use entire contents within 30 days." The container was in use 11 days after its revised expiration date. 3. An interview with the primary testing person on June 10, 2019 at 10:15 hours confirmed the findings. She confirmed that she had not revised the expiration date after opening the box.