

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2132023	(X3) Date Survey Completed 03/30/2022
Name of Provider or Supplier The Emergency Clinic At The Pearl	Street Address, City, State 2015 Broadway Street, Suite B, San Antonio, 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
D0000	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D6063	<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 review of the laboratory's submitted CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 2 of 13 testing personnel (refer to D6065).</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the</p>

laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 2 of 13 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 13 personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of education to qualify 2 of the 13 testing personnel. They were (as listed on Form CMS 209): Testing personnel number 5 Testing personnel number 13 3. The laboratory was asked to provide documentation of education for the identified personnel. No documentation was provided. 4. An interview with the technical consultant on 03/30/2022 at 1145 hours in the break room confirmed the findings.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of training for 4 of 13 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 13 testing personnel. 2. A review of the laboratory's personnel files revealed the laboratory failed to have documentation of training for 4 of 13 testing personnel. Employees missing documentation of training were: a) Testing personnel number 7 BioFire b) Testing personnel number 10 BioFire c) Testing personnel number 11 BioFire Sysmex MetLac 12 Cardiac Ddimer d) Testing personnel number 12 BioFire Sysmex MetLac 12 Cardiac Ddimer 3. The laboratory was asked to provide documentation of training. No documentation was provided. 4. An interview with the technical consultant on 03/30/3031 at 1300 hours - after her review of the records- confirmed the findings.