

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0665433	(X3) Date Survey Completed 11/16/2021
Name of Provider or Supplier Pardo Forstot Baca & Alboukrek Pa	Street Address, City, State 1050 Nw 15 St Ste 212a, Boca Raton, 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	A recertification survey conducted on 11/16/2021 found that PARDO FORSTOT BACA & ALBOUKREK PA clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following condition was cited: -D6063- Laboratory Testing Personnel.
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> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to stop using complete blood controls (CBC) after the expiration date. Findings include: -Review of the CDS Next Generation Hematology controls for Cell Dyn 1800 analyzer product insert revealed that, controls are stable after opening 14 days if stored at 2-8 Celsius Degrees (C) . -During the laboratory tour on 11/16/2021 at 10:00 AM, the surveyor observed that the laboratory had in use 3 CBC controls with an open date 10/18/2021 but no new expiration date registered. Photographic evidence collected. -As per package instruction the controls expired on 10/30/2021. The laboratory tested 168 patients from 11/01/2021 to 11/12/2021. During an interview on 11/16/2021 at 12:30 PM, the Testing Personnel A, confirmed that controls in use were not label with the new expiration date and the laboratory tested 168 patients with the expired controls.</p>
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.</p>

1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on record review and testing personnel interview, the laboratory failed to verify the education of 1 out of 2 Testing Personnel. Refers to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(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 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 record review and Testing Personnel (TP) A interview, the laboratory failed to verify the education of 1 (TP B) out of 2 testing personnel (A, B). Findings include:
-Review of employee files revealed that the diploma of TP B it is a foreign degree, the laboratory failed to request the evaluation of the equivalence to a United States Diploma. During an interview on 11/16/2021 at 12:30 PM with TP A, she confirmed that the laboratory failed to verify the Diploma of TP B to confirm that fulfilled the minimum education requirement.