

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2260031	<b>(X3) Date Survey Completed</b>  02/10/2023
<b>Name of Provider or Supplier</b>  Dr. Efren B. De La Rosa Dpm Da	<b>Street Address, City, State</b>  114 W. Castellano Drive, El Paso, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780. 493. 801 Condition: Enrollment and testing of samples 493. 1441 Condition: Laboratories Performing High Complexity Testing; Laboratory Director; 493. 1453 Condition: Laboratories Performing High Complexity Testing; Clinical Consultant.
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based upon review of the Laboratory Quality assessment Plan (signed 06/22/2022) proficiency testing records and interview of facility personnel, the laboratory failed to enroll in a Bacteriology proficiency testing program for the calendar year 2023. The findings included: 1. Review of the Laboratory Quality Assessment Plan(signed 06/22 /2022) found on page 3 Under the heading Proficiency Testing (PT)Policy: "The laboratory maintains annual enrollment in PT for the following types of tests: (check those that apply): regulated analytes performed by non-waived methods, unregulated analytes performed by non-waived methods [and] waived tests." 2. Review of proficiency testing records found no evidence of the laboratory participating in a proficiency testing program in 2023 for Bacteriology. 3. During interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted</p>

February 8, at 9:35 AM, she confirmed the laboratory had not enrolled in a Bacteriology proficiency testing program for 2023.

**D6076**

**LABORATORY DIRECTOR**

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based upon review of the CMS report 209 Laboratory Personnel Report, review of personnel records and interview of facility personnel, the laboratory failed to have a director that met the minimum education requirements for High Complexity testing in Bacteriology. (See D 6078)

**D6078**

**LABORATORY DIRECTOR QUALIFICATIONS**

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:  
Based on review of the CMS Report 209 Laboratory Personnel Report, personnel files and interview of facility personnel the individual identified as the laboratory director failed to meet the minimum education requirements for high complexity testing in Bacteriology. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory identified one individual as the laboratory director. 2. Review of the personnel files for the individual identified as the laboratory director found no documentation of education available for review. 3. During interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted July 8, 2023 at 9:35 AM, she stated that the laboratory director was a PhD and confirmed there were no records were available to review.

**D6134**

**CLINICAL CONSULTANT**  
CFR(s): 493.1453

The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.

This CONDITION is not met as evidenced by:  
Review of the CMS Report 209 Laboratory Personnel Report, personnel files and interview of facility personnel found the individual identified as the clinical consultant for the laboratory failed to meet the minimum education requirements for a laboratory performing high complexity testing in Bacteriology. (See D 6135)

**D6135**

**CLINICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1455

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:  
Based on review of the CMS Report 209 Laboratory Personnel Report, personnel files and interview of facility personnel the individual identified as the clinical consultant failed to meet the minimum education requirements for the laboratory performing high complexity testing in Bacteriology . The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory identified one individual as the clinical consultant. 2. Review of the personnel files for the individual identified as the clinical consultant found no documentation of education available for review. 3. During interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted February 8, 2023 at 9:35 AM, she stated that the clinical consultant was a PhD and confirmed there were no records available to review.