

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0983714	<b>(X3) Date Survey Completed</b>  01/24/2018
<b>Name of Provider or Supplier</b>  Luis A Rodriguez Md Pa	<b>Street Address, City, State</b>  1400 E Ridge Rd Suite 8, Mcallen, 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>	<p>The laboratory was found to be out of compliance based on the following  <b>CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition:</b>                      Laboratory Director; moderate complexity 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.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>                      CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by:                      Based on review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure testing personnel had the appropriate education and training to perform moderate complexity testing. The findings were: 1. The laboratory director failed to ensure 1 of 6 testing personnel had documentation of</p>

education (refer to D6065). 2. The laboratory director failed to ensure 3 of 6 testing personnel had documentation of training (refer to D6066).

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments. The findings were: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing competency assessments on testing testing personnel. Testing personnel number 1 (as listed on Form CMS 209) was identified as the "Evaluator" on the assessments which were then signed off by the technical consultant. Testing personnel number 1 did not meet the qualifications of a technical consultant. The competency assessments performed by testing personnel number 1 were: Testing personnel number 2 - performed 3/2017 Testing personnel number 2 - performed 4/2017 Testing personnel number 2 - performed 8/2017 Testing personnel number 3 - performed 10/2017 Testing personnel number 3 - performed 12/2017 Testing personnel number 4 - performed 6/2016 Testing personnel number 4 - performed 10/2016 Testing personnel number 4 - performed 3/2017 Testing personnel number 4 - performed 8/2017 Testing personnel number 4 - performed 2/2016 Testing personnel number 5 - performed 6/2016 Testing personnel number 6 - performed 4 /2016 2. The laboratory was asked to provide documentation of the technical consultant evaluating the competency of the testing personnel. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 01/24/2018 at 1030 hours in the office revealed she was delegated the responsibility to perform the competency assessments. She stated she was unaware she did not meet the qualification to perform this technical consultant's responsibility. This confirmed the findings.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's competency assessments performed in 2016 and 2017, and staff interview, it was revealed the technical consultant failed to include the review of previously analyzed specimens or proficiency testing samples as part of the laboratory's competency assessments. The findings were: 1. A review of the laboratory's competency assessments performed in 2016 and 2017 revealed the technical consultant failed to include the review of previously analyzed specimens or proficiency testing samples as part of the competency assessments. 2. The laboratory was asked to provide documentation of including the missing component as part of

the competency assessment. No documentation was provided. 3. An interview with testing personnel number 1 on 01/24/2018 at 1030 hours in the office - after her review of the records- confirmed the findings.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to had documentation of the technical consultant performing semiannual competency assessments on testing personnel number 5 within the first year of testing patient samples. The findings were: 1. A review of the laboratory's personnel records for testing personnel number 5 (as listed on Form CMS 209) revealed they were documented as being fully trained and ready to start patient testing on March 25, 2015. Thus two competency assessments were to be performed before March 25, 2016. 2. Further review of the personnel records for testing personnel number 5 revealed the laboratory had documentation of 1 competency assessment being performed on testing personnel number 5 with the first year of testing. It was documented as being performed on 02/04/2016. The next documentation of a competency assessment being performed was on 06/18/2016. 3. The laboratory was asked to provide documentation of a second competency assessment being performed within the first year to testing personnel performing testing. No documentation was provided. 4. An interview with testing personnel number 1 on 01/24/2018 at 1030 hours in the office - after her review of the records- confirmed the findings.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

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.

This CONDITION is not met as evidenced by:  
Based on review of the laboratory's records and staff interview, it was revealed the laboratory failed to ensure testing personnel met the qualifications to performed testing. The findings were: 1. The laboratory failed to have documentation of education for 1 of 6 testing personnel (refer to D6065). 2. The laboratory failed to have documentation of training for 3 of 6 testing personnel (refer to D6066).

**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 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 1 of 6 testing personnel. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 01/24/2018) revealed the laboratory identified 6 testing personnel who performed moderately complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify 1 of 6 testing personnel. The laboratory personnel missing documentation of education was (as listed on Form CMS 209): Testing personnel number 5 The file for testing personnel number 5 contained a certification as a medical assistant, but did not contain, at a minimum, a high school diploma or GED. 3. The laboratory was asked to provide documentation of education to qualify testing personnel number 5. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 01/24/2018 revealed she thought the office manager may have a copy of the education records from testing personnel number 5, however she was not at the office during the survey. This 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 3 of 6 testing personnel who performed moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 01/24/2018) revealed the laboratory identified 6 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to had documentation of training for 3 of 6 testing personnel who performed testing. They were (as listed on Form CMS 209): Testing personnel number 2 Testing personnel number 3 Testing personnel number 5 3. The laboratory was asked to provide documentation of training for the identified personnel. No documentation was provided. 4. An interview with testing personnel number 1 on 01/24/2018 at 1030 hours in the office revealed the laboratory did not have documents which covered training for testing personnel. She stated the laboratory had switched to using a new form for training, however, this form was actually a competency assessment form. This confirmed the findings.