

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0912802	<b>(X3) Date Survey Completed</b>  01/31/2018
<b>Name of Provider or Supplier</b>  J A Villarreal Md Pa	<b>Street Address, City, State</b>  13725 Northwest Blvd #110, Corpus Christi, 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>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>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory environmental records, and confirmed in interview of facility personnel, the laboratory failed to define an acceptable temperature range for the laboratory. The findings were: 1. Direct observation made in the laboratory during the initial tour of the laboratory on 01/31 /2018 revealed that the laboratory and patient exam rooms had an off-site temperature control system and the laboratory's defined temperature range was "72-72 degrees Fahrenheit." 2. Review of the laboratory's environmental records from July 2017,</p>

September 2017, and January 2018 (4 out of 59 days reviewed) revealed the following days when the temperature was documented outside of the laboratory's defined acceptable range of "72 - 72 degrees Fahrenheit." July 26, 2017 73 degrees Fahrenheit July 27, 2017 74 degrees Fahrenheit July 28, 2017 73 degrees Fahrenheit September 5, 2017 73 degrees Fahrenheit 3. The laboratory was asked to provide documentation of defining an acceptable room temperature range based on the manufacturer's instructions for each of the kits and supplies it utilizes in the laboratory and stores in patient exam rooms. No documentation was provided. 4. An interview with testing personnel one as listed on the Form CMS-116 on 01/31/2018 at 1130 hours at the nurse's station confirmed the findings.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:  
Based on direct observations and confirmed in interview, the laboratory failed to ensure that expired supplies were not available for patient testing. Findings included:  
1. Observations made on 01/31/2018 found 2 expired UTM-RT (universal transport medium room temperature) vials (lot 2REK00, expiration date: 2017/09). 2. In an interview of testing personnel one as listed on the Form CMS-116 on 01/31/2018 at 1130 hours at the nurse's station confirmed the findings. She confirmed the items were expired.