

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0986052	<b>(X3) Date Survey Completed</b> 03/11/2026
<b>Name of Provider or Supplier</b> Dr Elvin R Garcia Md Pa	<b>Street Address, City, State</b> 811 E Fern Ave Suite 1, 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>D5213</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2024 and 2025, and staff interview, the laboratory failed to have documentation of evaluating 8 of 8 results returned as 'not graded' by the proficiency testing agency. The findings included: 1. A review of the laboratory's American Proficiency Institutes proficiency testing records from 2024 and 2025 identified the following samples which were return at 'not graded' by the proficiency testing agency: a) 2024 Immunology Event 1 Anti-dsDNA Sample: ANA-01 Anti-RNP/Sm Sample: ANA-01 b) 2024 Immunology Event 2 Anti-dsDNA Sample: ANA-07 c) 2024 Immunology Event 3 Anti-dsDNA Sample: ANA-14 Anti-RNP/Sm Sample: ANA-12 d) 2025 Immunology Event 1 Anti-dsDNA Sample: ANA-02 Sample: ANA-04 e) 2025 Immunology Event 2 Anti-dsDNA Sample: ANA-06 2. The laboratory did not have documentation of evaluating the identified samples. 3. The technical consultant confirmed the findings in an interview after his review of the records on 03/11/2026 at 0940 hours in the break room.</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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</p>

applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's room temperature from January 2025 to February 2026, and staff interview, the laboratory failed to have documentation of corrective actions when room temperature was outside the laboratory's acceptable range on 12 of 316 test days. The findings included: 1. A review of the laboratory's room temperature records from January 2025 to February 2026 determine the laboratory had the following acceptable range: Room Temperature 72 - 77 F 2. Further review of the records identified the following 12 days where the documented temperature was outside the acceptable range: a) 2025 Date Temperature 01/02 78F 01/13 77.2F 02/20 71.1F 02/21 69.3F 02/24 69.8F 11/03 78.8F 11/20 77.8F 12/16 77.8F 12/22 79.1F b) 2026 Date Temperature 01/27 70.6F 02/11 77.1F 02/12 77.8F 3. The technical consultant confirmed the finding in an interview conducted on 03/11/2026 at 1120 hours in the break room.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's Sysmex XP-300 maintenance records from July 2024 to February 2026, and staff interview, the laboratory failed to have documentation of performing monthly maintenance for 9 of 20 months. The findings included: 1. A review of the laboratory's Sysmex XP-300 maintenance records from July 2024 to February 2026 determined the manufacturer required the following maintenance to be performed monthly: Clean RBC and WBC Transducer 2. Further review of the records determined the laboratory failed to have documentation of performing monthly maintenance for the following 9 months: July 2024 February 2025 March 2025 April 2025 June 2025 August 2025 September 2025 October 2025 February 2026 3. The technical consultant confirmed the findings in an interview conducted on 03/11/2026 at 1000 hours in the break room.

**D5785**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(3)

(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's temperature records for the Immunodot AutoImmune Panel from October 2025 and November 2025, review of patient test records from October 2025 and November 2025, and staff interview, the laboratory failed to have documentation of performing corrective actions when temperatures were outside the required range on 2 of 2 test days. The findings included: 1. A review

of the laboratory's temperature records for the Immunodot AutoImmune Panel from October 2025 and November 2025 determined the laboratory's required temperature range of 47.5 - 50.5F. 2. Further review of the temperature records identified the following days were the documented temperature was outside the acceptable range, however, patient testing was still performed without corrective actions being performed: a) October 31, 2025 Temperature: 53.2F b) November 18, 2026 Temperature: 53.2F 3. A review of patient test records from October 31, 2025 and November 2025 identified the following patient samples which were tested when the temperature was out of acceptable range: a) October 31, 2025 9 patients tested (see patient alias list) b) November 2025 10 patients tested (see patient alias list) 4. The technical consultant confirmed the findings in an interview conducted on 03/11/2026 at 1120 hours in the break room.