| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0506359 | 11/06/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ruben De Los Santos Md Pa | 1955 East Main Street, Eagle Pass, TX | |

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 |
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| **D0000** | The laboratory was found NOT to be in compliance with the CLIA regulations found at 42 C.F.R. 493 CLIA requirements for laboratories as a result of an announced recertification survey performed on 11/06/2025. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's American Association of Bioanalysts/Medical Laboratory Evaluation (AAB/MLE) proficiency testing records from 2024 and 2025, and staff interview, the laboratory failed to have documentation the laboratory director signing 4 of 5 attestation statements and testing personnel signing 5 of 5 attestation statements. The findings included: 1. A review of the laboratory's AAB/MLE proficiency testing records from 2024 (M1, M2 and M3) and 2025 (M2 and M3) determined the laboratory failed to have documentation of the following signatures: a) laboratory director 2024 M1 2024 M2 2024 M3 2025 M2 b) testing personnel 2024 M1 2024 M2 2024 M3 2025 M2 2025 M3 2. The technical consultant confirmed the findings in an interview conducted on 11/06/2025 at 0940 hours in the office. |
| **D2010** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(2)<br><br>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's American Association of Bioanalysts/Medical Laboratory Evaluation (AAB/MLE) proficiency testing records from 2024 and 2025, and staff interview, the laboratory failed to test proficiency testing samples the same number of times it tested patient samples for 2 of 5 events. The findings included: 1. A review of the laboratory's AAB/MLE proficiency testing records from 2024 (M1, M2 and M3) and 2025 (M2 and M3) determined the laboratory testing proficiency testing samples multiple times for 2 of 5 events. They were: a) 2025 M2 Sample: HD-6 tested: 5/21/2025 10:19 tested: 5/21/2025 10:35 Sample: HD-7 tested: 5/21/2025 10:21 tested: 5/21/2025 10:37 Sample: HD-8 tested: 5/21/2025 10:23 tested: 5/21/2025 10:38 Sample: HD-9 tested: 5/21/2025 10:25 tested: 5/21/2025 10:40 Sample: HD-10 tested: 5/21/2025 10:28 tested: 5/21/2025 10:41 b) 2025 M3 Sample: HD-11 tested: 9/12/2025 14:18 tested: 9/12/2025 14:27 Sample: HD-12 tested: 9/12/2025 14:20 tested: 9/12/2025 14:28 Sample: HD-13 tested: 9/12/2025 14:22 tested: 9/12/2025 14:30 Sample: HD-14 tested: 9/12/2025 14:24 tested: 9/12/2025 14:31 Sample: HD-15 tested: 9/12/2025 14:25 tested: 9/12/2025 14:32 2. The technical consultant confirmed the findings in an interview conducted on 11/06/2025 at 0940 hours in the office. He stated he tested the proficiency testing samples twice just to verify the results. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the patient reports, review of the laboratory's verification studies performed on the Beckman Coulter DX520 hematology analyzer in February 2025, and staff interview, the laboratory failed to have documentation of verifying 1 of 1 sets of patient normal ranges. The findings included: 1. A review of patient reports determined the laboratory utilized the following patient normal ranges for samples tested on the Beckman Coulter DX520 hematology analyzer: WBC 3.77 - 11.03 LY% 18.51 - 48.98 MO% 4.72 - 11.35 NE% 41.35 - 72.27 EO% 0.71 - 6.09 BA% 0.05 - 0.47 LY# 1.16 - 3.78 MO# 0.28 - 0.83 NE# 2.03 - 7.67 EO# 0.04 - 0.42 BA# 0.00 - 0.03 RBC 3.83 - 5.06 HGB 11.59 - 15.11 HCT 34.6 - 44.1 MCV 80.0 - 98.0 MCH 26.6 - 33.5 MCHC 32.9 - 35.4 RDW 12.6 - 15.6 RDWSD 38.9 - 50.6 PLT 169.1 - 368.3 MPV 7.45 - 10.84 2. A review of the laboratory's verification studies performed on the Beckman Coulter DX520 hematology analyzer in February 2025 determined the laboratory failed to have documentation of verifying the stated normal ranges. 3. The technical consultant confirmed the findings in an interview conducted on 11/06/2025 at 1015 hours in the office. KEY WBC white blood cell LY% lymphocyte percent MO% monocyte percent NE% neutrophil percent EO% eosinophil percent BA% basophil percent LY# lymphocyte count MO# monocyte count NE# neutrophil count EO# eosinophil count BA# basophil count RBC red blood cell HGB hemoglobin HCT hematocrit MCV mean corpuscular volume MCH mean corpuscular |

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| | hemoglobin MCHC mean corpuscular hemoglobin concentration RDW red cell distribution width PLT platelet MPV mean platelet volume |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's hematology quality control records from March 2025 to November 2025, and staff interview, the laboratory failed to have documentation of verifying 9 of 9 lots of quality control material prior to placing them into use. The findings included: 1. A review of the laboratory's hematology quality control records from March 2025 to November 2025 determined the laboratory placed 9 lots of control into use. They were: Lot: 25168 Lot: 25169 Lot: 25171 Lot: 25172 Lot: 25173 Lot: 25174 Lot: 25175 Lot: 25176 Lot: 25177 2. Further review of the laboratory's quality control records determined the laboratory failed to have documentation of verifying the identified lots prior to use. 3. The technical consultant confirmed the findings in an interview conducted on 11/06/2025 at 1035 hours in the office. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient test reports from October 2025 and staff interview, the laboratory failed to include the facility's address on patient test reports. The findings included: 1. A review of patient test reports from October 2025 determined the laboratory failed to include the facility's address on the reports. 2. The technical consultant confirmed the findings in an interview conducted on 11/06/2025 at 1030 hours in the office. |
| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421 |

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| | 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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation to qualify 1 of 1 testing personnel (refer to D6065). |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation to qualify 1 of 1 testing personnel. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 1 testing personnel. 2. A review of the laboratory's personnel records determined the laboratory did not have documentation of education to qualify testing personnel number one to perform moderate complexity testing. 3. The technical consultant confirmed the findings in an interview conducted on 11/06/2025 at 0915 hours in the office. |