

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0058283	(X3) Date Survey Completed 05/15/2024
Name of Provider or Supplier Aggie Health And Wellness / Nmsu	Street Address, City, State 3080 Breland, Las Cruces, NM	
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
D0000	An onsite recertification survey conducted on May 15, 2024, at Aggie Health and Wellness / NMSU found the laboratory to be in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, laboratory policy, hematology patient normal range study, and staff interview, the laboratory's hematology policy failed to provide reference ranges consistent with the reference ranges determined by the laboratory for 15 of 15 analytes in 2024. Findings included: 1. A review of the</p>

laboratory's test menu revealed the following analytes are reported by the Sysmex XN-330 analyzer: White Blood Cells (WBC) Red Blood Cells (RBC) Hemoglobin (Hgb) Hematocrit (Hct) Mean Corpuscular Volume (MCV) Mean Corpuscular hemoglobin (MCH) Mean Corpuscular Hemoglobin Concentration (MCHC) Red Cell Distribution Width (RDW-CV) Platelets Neutrophils Lymphocytes Monocytes Eosinophils Basophils Immature Granulocytes 2. Review of the laboratory policy titled "XN-330 Automated Hematology Analyzer .1000.01.00" stated the following patient normal hematology ranges: WBC: 3.8 - 10.8 RBC: Female 3.80 - 5.10 Male 4.20 - 5.80 Hgb: Female 11.7 - 15.5 Male 13.2 - 17.1 Hct: Female 35.0 - 45.0 Male 38.5 - 50.0 MCV: Female 80 - 100 Male 80 - 100 MCH: 27.0 - 33.0 MCHC: 32.0 - 36.0 Platelets: 140 - 400 RDW-CV: 11.0 - 15.0 Neutrophils: 50.0 - 70.0 (%) Lymphocytes: 20.0 - 40.0 (%) Monocytes: 0.0 - 12.0 (%) Eosinophils: 0.0 - 6.0 (%) Basophils: 0.0 - 1.0 (%) Immature Granulocytes: 0.0 - 5.0 (%) 3. Review of the laboratory's hematology normal range study titled "Reference Intervals for Clinical and Lab Medicine" (signed on 10/06/2022 by Technical Consultant 2 as listed on the CMS form 209) stated the following ranges: WBC: Female 3.98 - 10.04 ($10^3/uL$) Male 4.23 - 9.07 ($10^3/uL$) RBC: Female 3.93 - 5.22 ($10^6/uL$) Male 4.63 - 6.08 ($10^6/uL$) Hgb: Female 12.0 - 16.0 (gm/dL) Male 13.0 - 17.0 (gm/dL) Hct: Female 36.0 - 48.0 (%) Male 39.0 - 51.0 (%) MCV: Female 79.4 - 94.8 (fL) Male 79.4 - 94.8 (fL) MCH: Female 25.6 - 32.2 (pg) Male 25.7 - 32.2 (pg) MCHC: Female 32.2 - 35.5 (g/dL) Male 32.3 - 36.5 (g/dL) Platelets: Female 182 - 369 ($10^3/uL$) Male 163 - 337 ($10^3/uL$) RDW-CV: Female 11.0 - 15.0 (%) Male 11.0 - 15.0 (%) Neutrophils: Female 34.0 - 71.1 (%) Male 34.0 - 67.9 (%) Lymphocytes: Female 19.3 - 51.7 (%) Male 21.8 - 53.1 (%) Monocytes: Female 4.7 - 12.5 (%) Male 5.3 - 12.2 (%) Eosinophils: Female 0.7 - 5.8 (%) Male 0.8 - 7.0 (%) Basophils: Female 0.1 - 1.2 (%) Male 0.2 - 1.2 (%) Immature Granulocytes: Female 0 - 5 (%) Male 0 - 5 (%) The laboratory's hematology policy failed to provide reference ranges that are in use by the laboratory as determined from the laboratory's patient normal range study. 4. During an interview on 05/15/2024 at 9:00 am, after review of the above results, the laboratory director confirmed the findings. Word key: uL = microliters gm/dL = grams per deciliter % = percent fL = femtoliters pg = picograms