Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0058283	12/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Aggie Health And Wellness / Nmsu	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	Based upon the onsite recertification survey conducted on 12/09/2022, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 42 CFR Part 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions, patient test records and logs, CMS (Centers for Medicare & Medicaid Services) form 116, Annual Test Volume Spreadsheet and interview with the laboratory director, the laboratory failed to establish performance specifications studies for the modified, non-FDA cleared, LW Scientific refractometer prior to testing and resulting 43 of 48 patient samples from July 20, 2022 to November 15, 2022. Findings included: 1. During a tour of the laboratory on 12/09/2022 at 10:00am, a new ATC refractometer, by LW Scientific, serial # 2114020014 was observed on the counter of the laboratory. 2. The manufacturer's package insert for the ATC refractometer from LW Scientific stated, "For veterinary and educational use only." The laboratory failed to perform

	performance specification studies to include accuracy, precision, analytical sensitivity, reportable range and reference intervals for the modified test system which was used to test human samples. 3. Review of patient test records and test logs revealed a total of 48 patients had a urine specific gravity verified by the ATC refractometer. Of the 48 patient specific gravities verified by the ATC refractometer, 43 specific gravities were reported. The 43 patients reported from the ATC refractometer: Date of test Medical Record # SG result 7/20/2022 121467 1.005 7/27/2022 99044 1.022 8/02 /2022 119920 1.012 8/05/2022 102825 1.022 8/09/2022 117974 1.026 8/09/2022 120414 1.018 8/11/2022 119417 1.026 8/16/2022 92309 1.030 8/23/2022 125825 1.016 8/24/2022 125834 1.012 8/24/2022 116609 1.020 8/26/2022 125837 1.016 8/30 /2022 116696 1.028 9/01/2022 125961 1.018 9/02/2022 115637 1.009 9/07/2022 125990 1.026 9/08/2022 125500 1.024 9/13/2022 126014 1.020 9/13/2022 125526 1.022 9/14/2022 126048 1.008 9/14/2022 120969 1.020 9/16/2022 125360 1.018 9/26 /2022 119653 1.015 9/26/2022 122861 1.030 9/26/2022 126234 1.010 9/30/2022 126249 1.025 10/07/2022 124244 1.012 10/07/2022 102527 1.008 10/07/2022 125968 1.030 10/12/2022 125976 1.018 10/18/2022 126379 1.018 10/18/2022 126390 1.014 10/20/2022 126414 1.020 10/20/2022 124138 1.024 10/24/2022 126439 1.018 10/31 /2022 126390 1.026 11/02/2022 126557 1.014 11/08/2022 124134 1.030 11/08/2022 119328 1.020 11/09/20222 126534 1.023 11/11/2022 126629 1.020 11/15/2022 126686 1.030 11/15/2022 124244 1.010 4. Review of the CMS (Centers for Medicare & Medicaid Services) form 116, and the Annual Test Volume Spreadsheet confirmed that that the facility was performing specific gravities using a manual refractometer and reported an annual test volume of 252 for 2021. 5. During an interview on 12/09 /2022 at 10:30 am, the laboratory director stated that he only uses the manual refractometer to confirm weak urines when performing urine HCG (Human Chorionic Gonadotropin) pregnancy tests and he confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Urinalysis Patient/QC log, and staff interview, the laboratory failed to establish the number and frequency of performing quality controls to ensure accuracy and precision and to detect immediate errors for the ATC refractometer from LW Scientific, prior to reporting 43 specific gravities from July 21,2022 to Dec 12, 2022. Findings included: 1. Review of the laboratory policy /procedure titled "Urinalysis Procedures Urine Specific Gravity, Procedure #; UA. 0001.00.03", dated June 1, 2013, and reviewed by laboratory director on 10-07-22 revealed; Under section 6.3 labeled Control Frequency: "Analyze Distilled water, 5% NaCl solution, and Level 1 and 2 Dipper controls daily or when a new lot is opened." Under section 10.0 labeled Procedural Notes: "Refractometer Specific Gravity will be

	used in place of Urine Dipstick specific gravity. If Refractometer is broken or if unavailable the Urine dipstick method can be substituted." The laboratory failed to update the Urine Specific Gravity procedure to include the implementation of a new refractometer and to follow the written protocol in regard to the frequency of performing quality control (QC). 2. Review of the Urinalysis Patient/QC log from July 21, 2022 to Dec 12, 2022 shows that quality control was performed once a week. 3. During interview on 12/09/2023 at 8:30 am, the Laboratory Director stated that the refractometer was placed in use in July 2022 and that quality control was performed once a week on Mondays using water (H2O) as a blank and 5% saline.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the review of personnel credentials, CMS (Centers for Medicare & Medicaid Services) Laboratory Personnel Report form 209, facility and laboratory policies, patient urine/HCG logs, patient final reports, manufacturer's instructions for use, the Laboratory Director failed to provide overall direction and management of the laboratory. Findings included: The laboratory director failed to ensure that the facility employed a director who meets the qualifications requirements to manage and direct a laboratory performing high complexity testing. Refer to D6078
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory

	director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on the review of personnel records (college transcripts) and the CMS (Centers for Medicare & Medicaid Services) Laboratory Personnel Report form 209, list of non-waived testing performed at the laboratory, the Laboratory failed to ensure he met the qualification requirements to manage and direct a laboratory performing high complexity testing. Findings included: 1. Review of personnel credentials (college transcripts) revealed the Laboratory Director had a Bachelor of Science degree and did not meet the qualification requirements to function as the laboratory director of a high complexity laboratory. 2. Review of the CMS (Centers for Medicare & Medicaid Services) Laboratory Personnel Report form 209 revealed one laboratory director who also functions as a testing person. 3. Review of the "non-waived" testing systems performed at the laboratory revealed that the laboratory modified the manufacturer's instructions for a non-FDA cleared, LW Scientific refractometer, making it a high complexity test system.