Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0058283	05/24/2018
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	During a recertification survey completed on 05/24/2018 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 4931403 Laboratory Director, moderate complexity
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on the review of patient test records, application records, quality control records and interview with the laboratory director, the laboratory failed to perform and document quality control for gram stains each week of use August - December 2017 for 29 (P1-P29) of 29 (P1-P29) patients reviewed. This failed practice could result in the laboratory's failure to identify staining failures related to poor technique or deterioration of the stains. Findings are: A. During interview on 5/24/18 at 11:06 am, the laboratory director stated that there was no quality control performed for gram stains prior to January 2018. He further stated that there were no quality control slides available when he started working for the laboratory in August 2017. The laboratory director identified the problem and started performing quality control in January 2018. B. Review of the 2018 gram stain quality control records confirmed that the laboratory starting performing quality control on 01/03/18. C. Review of the laboratory's "Laboratory Productions" reports for State Fiscal Year 2018 (July 2017-April 2018) revealed that the laboratory performed at total of 131 gram stains July 2017-December 2017. Review of the August and September patient logs confirmed testing for 19 patients (P1-P19) in August 2017 and 10 patients (P20-P29) in December 2017. D. In September 2016, the laboratory submitted an application on 09 /14/16 to change from a high complexity laboratory (bacterial identification tuning a manual culture method) to a moderate complexity laboratory and to change the

	laboratory director. Review of the application revealed no reference to the continued performance of gram stains in the laboratory. The application was signed by the previous laboratory director on 09/13/16. E. In August 2017, the laboratory submitted an application to change the laboratory director. Review of the application revealed no reference to the continued performance of gram stains in the laboratory. The application was signed by the current laboratory director on 08/01/17.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the review of patient test records, application records, quality control records, proficiency records from the Centers for Medicare & Medicaid (CMS) database and the proficiency agency, and interview with the laboratory director, the laboratory director failed to provide overall management and direction of the laboratory. Findings are: A. The laboratory director failed to ensure the laboratory was enrolled in proficiency testing for gram stains for the years 2016-2017. See D6015 B. The laboratory director failed to ensure a quality control plan was established and followed for gram stain quality control. See D6020
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the review of patient test records, application records, proficiency records from the Centers for Medicare & Medicaid (CMS) database and the proficiency agency, and interview with the laboratory director, the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for gram stains for the years 2016-2017. Findings are: A. On 5/24/18 at 11:06 am, the laboratory director stated that the laboratory was not enrolled in proficiency testing for gram stains when he started working in the laboratory in August 2017. He also stated that he had identified the problem and enrolled for 2018. B. Review of the 2016-2017 proficiency test scores from the CMS confirmed that no results for bacteriology were reported to CMS for the 3rd event of 2016 and all three events of 2017. C. Review of the 2016-2018 proficiency test records from the College of American Pathologists (CAP) confirmed the laboratory had not enrolled or participated in proficiency testing for gram stains since the first event of 2016. D. Review of the laboratory's "Laboratory Productions" reports for State Fiscal Year 2018 (July 2017-April 2018) revealed that the laboratory performed at total of 131 gram stains July 2017-December 2017. Review of the August and September patient logs confirmed testing for 19 patients (P1-P19) in

	August 2017 and 10 patients (P20-P29) in December 2017. E. In September 2016, the laboratory submitted an application on 09/14/16 to change from a high complexity laboratory (bacterial identification tuning a manual culture method) to a moderate complexity laboratory and to change the laboratory director. Review of the application revealed no reference to the continued performance of gram stains in the laboratory. The application was signed by the previous laboratory director on 09/13/16. F. In August 2017, the laboratory submitted an application to change the laboratory director. Review of the application revealed no reference to the continued performance of gram stains in the laboratory. The application was signed by the current laboratory director on 08/01/17.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of patient test records (P1-P29), application records, quality control records and interview with the laboratory director, the laboratory director failed to ensure a quality control plan was established and followed for gram stain quality control. Findings are: The laboratory failed to perform and document quality control for gram stains each week of use August - December 2017 for 29 (P1-P29) of 29 (P1-P29) patients reviewed. See D5503