Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0508889	01/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pecos County Memorial Hospital	511 North Main, Fort Stockton, 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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, American Proficiency Institute (API). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 successful participation in a proficiency testing program 493.1403 laboratories performing moderate complexity testing; laboratory director 493.807 (a) reinstatement after failure
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by:

	Based on a desk review of proficiency testing records it was determined the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of hematology for the analyte Cell ID or WBC Diff. Refer to D2130. ID = Identification WBC = White Blood Cells Diff = Differential
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: Based on a desk review of laboratory proficiency testing performance the laboratory failed to participate successfully in proficiency testing for the satisfactory performance in a specialty of hematology for analyte Cell ID or WBC DIff for two of three consecutive testing events and has not demonstrated sustained satisfactory performance on two consecutive proficiency events since the unsuccessful scores. Findings: 1. API 2016 - 2nd event laboratory received a score of 60% for Cell ID. 2. API 2017 - 1st event laboratory received a score of 67% for Cell ID. 3. API 2017 - 3rd event laboratory received a score of 0% for Cell ID. The laboratory must demonstrate sustained satisfactory performance (>80%) on two consecutive testing events for reinstatement.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CMS form 155 and American proficiency Institute API records found that the laboratory failed to attain a satisfactory score of at least 80% of acceptable responses for each analyte in the specialty of Hematology. Findings: 1. API 2016 - 2nd event laboratory received an unsatisfactory score of 60% for Cell ID or WBC Diff. 2. API 2017 - 1st event the laboratory received an unsatisfactory score of 67% for Cell ID or WBC Diff.
D2123	HEMATOLOGY

	CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a desk review of 2017 hematology proficiency testing PT results reported to CMS and records obtained from the PT provider, American proficiency Institute, the laboratory failed to participate in 3rd testing event of 2017 for hematology resulting in unsatisfactory performance. Findings: 1. API 2017 - 3rd event laboratory received an unsatisfactory score of 0% for Cell ID/WBC Diff. 2. API 2017 - 3rd event laboratory received an unsatisfactory score of 0% for RBC. 3. API 2017 - 3rd event laboratory received an unsatisfactory score of 0% for Hematocrit. 4. API 2017 - 3rd event laboratory received an unsatisfactory score of 0% for Hemoglobin. 5. API 2017 - 3rd event laboratory received an unsatisfactory score of 0% for WBC. 6. API 2017 - 3rd event laboratory received an unsatisfactory score of 0% for Platelets.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Hematology for all regulated analytes. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings: 1. API 2016 - 2nd event laboratory received an unsatisfactory score of 60% for Cell ID or WBC Diff. 2. API 2017 - 1st event the laboratory received an unsatisfactory score of 67% for Cell ID or WBC Diff. 3. API 2017 - 3rd event the laboratory received an unsatisfactory score of 0% for Cell ID or WBC Diff.
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 a desk review of laboratory proficiency testing performance it was revealed

	that the laboratory director failed to provide overall management and direction of the laboratory services. See D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2130