Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1076170	03/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Amc Laboratory	1600 West 21st Street Suite B, Clovis, 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 proficiency desk review on 02/21/2019, the laboratory was found out of compliance with the following condition: 42 CFR part 493.803 Successful Participation
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 the review of 2017-2018 proficiency records and results reported to the CMS (Centers for Medicare & Medicaid Services) proficiency testing database, the laboratory failed to successfully participate in proficiency testing for Hematocrit (HCT) and Creatinine Kinase (CK). Findings are: A. Desk review on 02/21/19 of CASPER report 155D, Individual Laboratory Profile, revealed the laboratory received

	failing scores for: 1. HCT - 3rd event of 2017 (testing period began 10/17/17 and results were due 11/01/17) and the 1st event of 2018 (02/20/18 - 03/15/18). 3rd event 2017 = 60% 1st event 2018 = 0% See D2121, D2128, D2130 2. Creatinine Kinase - 2nd (testing period began 04/24/18 and the results were due 05/10/18) and 3rd events (08/28/18- 09/24/18) of 2018. 2nd event 2018 = 0%. 3rd event 2018 = 0%. See D2089, D2094 B. The laboratory failed to submit CK test results for the 2nd event of 2018. See D2089
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 the review of 2018 proficiency records and results reported to the CMS (Centers for Medicare & Medicaid Services) proficiency testing database, the laboratory failed to obtain a score of 80 % for 2 consecutive test events. Findings are: Desk review on 02/21/19 of CASPER report 155D, Individual Laboratory Profile, revealed the laboratory received failing scores for: Creatinine Kinase - 2nd (testing period began 04/24/18 and the results were due 05/10/18) and 3rd events (08/28/18- 09 /24/18) of 2018. 2nd event 2018 = 0%. 3rd event 2018 = 0%.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(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 the review of 2018 proficiency records and results reported to the CMS (Centers for Medicare & Medicaid Services) proficiency testing database, the laboratory failed to submit Creatinine Kinase results for the 2nd event of 2018. Findings are: A. Desk review on 02/21/19 of CASPER report 155D, Individual Laboratory Profile, revealed the laboratory received failing scores for: Creatinine Kinase - 2nd (testing period began 04/24/18 and the results were due 05/10/18) and 3rd events (08/28/18- 09/24/18) of 2018. 2nd event 2018 = 0%. 3rd event 2018 = 0%. B. Desk review on 03/19/19 of online proficiency reports from American Association of Bioanalysts revealed the laboratory failed to submit test results for the 2nd event of 2018. The 3rd event score indicated the laboratory discontinued testing.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e)

	(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on the review of 2018 proficiency records and results reported to the CMS (Centers for Medicare & Medicaid Services) proficiency testing database, the laboratory failed to obtain a score of 80 % for 2 consecutive test events and must obtain training and/or technical assistance. Findings are: Desk review on 02/21/19 of CASPER report 155D, Individual Laboratory Profile, revealed the laboratory received failing scores for: Creatinine Kinase - 2nd (testing period began 04/24/18 and the results were due 05/10/18) and 3rd events (08/28/18- 09/24/18) of 2018. 2nd event 2018 = 0%. 3rd event 2018 = 0%.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of 2018 proficiency records and results reported to the CMS (Centers for Medicare & Medicaid Services) proficiency testing database, the laboratory failed to obtain a score of 80 % for 2 consecutive test events resulting in unsuccessful participation in proficiency testing for Creatinine Kinase. Findings are: Desk review on 02/21/19 of CASPER report 155D, Individual Laboratory Profile, revealed the laboratory received failing scores for: Creatinine Kinase - 2nd (testing period began 04/24/18 and the results were due 05/10/18) and 3rd events (08/28/18- 09 /24/18) of 2018. 2nd event 2018 = 0%. 3rd event 2018 = 0%.
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 the review of 2017-2018 proficiency records and results reported to the CMS (Centers for Medicare & Medicaid Services) proficiency testing database, the laboratory failed to obtain a score of 80 % for 2 consecutive test events. Findings are: A. Desk review on 02/21/19 of CASPER report 155D, Individual Laboratory Profile, revealed the laboratory received failing scores for: Hematocrit - 3rd event of 2017 (testing period began 10/17/17 and results were due 11/01/17) and the 1st event of 2018 (02/20/18 - 03/15/18). 3rd event 2017 = 60% 1st event 2018 = 0% B. During a desk review on 03/11/19 of the online proficiency test reports from the American

	Association of Bioanalysts (AAB) confirmed the HCT scores reported to CMS on 11 /13/18.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on the review of 2017-2018 proficiency records and results reported to the CMS (Centers for Medicare & Medicaid Services) proficiency testing database, the laboratory must obtain training and technical assistance for the Hematocrit proficiency testing failures in 2017-2018. Findings are: A. Desk review on 02/21/18 of CASPER report 155D Individual Laboratory Profile, revealed the laboratory received failing scores for the 3rd event of 2017 and the 1st event of 2018. Hematocrit - 3rd event of 2017 (testing period began 10/17/17 and results were due 11/01/17) and the 1st event of 2018 (02/20/18 - 03/15/18). 3rd event 2017 (10/17/17 - 11/01/17) = 60% 1st event 2018 (02/20/18 - 03/15/18) = 0% B. Review of the reports from the American Association of Bioanalysts (AAB) confirmed the scores reported to CMS on 11/12/18.
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 the review of 2017-2018 proficiency records and results reported to the CMS (Centers for Medicare & Medicaid Services) proficiency testing database, the laboratory failed 2 consecutive test events for Hematocrit (HCT) proficiency testing failures in 2017-2018 resulting in unsuccessful participation in proficiency testing. Findings are: A. Desk review on 02/21/18 of CASPER report 155D, Individual Laboratory Profile, revealed the laboratory received failing scores for the 3rd event of 2017 and the 1st event of 2018. Hematocrit - 3rd event of 2017 (testing period began 10/17/17 and results were due 11/01/17) and the 1st event of 2018 (02/20/18 - 03/15 /18). 3rd event 2017 = 60% 1st event 2018 = 0% B. Review of the reports from the American Association (AAB) confirmed the scores reported to CMS on 11/12/18.