Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0694261	07/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Salinas Pathology Services Medical Grp Inc	450 E Romie Ln, Salinas, CA	

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
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of CAP (College of American Pathologists) "PAP PT Individual Evaluation" for 2016 and ASCP (American Society for Clinical Pathology) "Individual Participant Test Scores" for 2017 and 2018, the lack of laboratory documents, and interview with the Laboratory Director (Technical Supervisor/Testing Person), it was determined that the Laboratory Director failed to ensure that all proficiency testing reports were reviewed to identify problems requiring corrective action. Findings included: a. Gynecologic proficiency testing reports revealed that Testing Person-4 (Cytotechnologist) downgraded High grade lesions as follows: Year Reported Reference / Discrepancy ---------- 2016 LSIL HSIL and above 2017 LSIL HG/Cancer 2018 LSIL HG/Cancer LSIL: Low grade squamous intraepithelial lesion (mildly abnormal) HSIL: High grade squamous intraepithelial lesion (moderate or severe dysplasia) HG/Cancer: High grade cancer b. The Laboratory failed to provide documents assessing the consistent discrepancies in proficiency testing and the impact to patients results. c. The Laboratory Director (Technical Supervisor/Testing Person) affirmed (7/15/19 at 3pm) the aforementioned lack of documents. d. The reliability and quality of results reported as LSIL could not be assured. The laboratory's annual statistics for reporting LSIL were as follows: 2017: 8 cases 2018: 19 cases
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v)

	The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and documents for annual competency assessment, the lack of laboratory documentations, and interview with the Technical Supervisor (Laboratory Director), it was determined that competency evaluations failed to include performance in external proficiency testing. Findings included: a. Individual proficiency testing reports for Testing Person-4 (Cytotechnologist) revealed consistent discrepancies in reporting High grade lesions as Low grade in 2016, 2017, and 2018. b. The documents for annual competency assessment failed to include the proficiency testing performances. c. The Technical Supervisor (Laboratory Director) affirmed (7/15/19 at 3pm) there were no other documents for annual competency assessments; and thus the failure to include the individual's performance on external proficiency testing. d. The reliability and quality of results reported by Testing Person-4 could not be assured when performances on external proficiency testing were not addressed in the annual competency assessments.