Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D2029285	**(X3) Date Survey Completed** 06/05/2025
Name of Provider or Supplier Delta Medical Group Of Pathologists Inc	**Street Address, City, State** 975 S Fairmont Ave, Lodi, 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**
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the lack of laboratory's written policies and procedures and an interview with the laboratory director (LD); it was determined that the laboratory failed to have an established policy and procedure that met 493.1274. The findings include: 1. The surveyors' review of the policies and procedures showed that the laboratory lacked protocols for criteria for patient testing, retrieval of final reports and slides, and the criteria for unsatisfactory cytology specimens. 2. The LD affirmed on June 5, 2025, at approximately 11:20 a.m. that the laboratory lacked written policies and procedures of all those mentioned in statement #1. 3. Based on the testing volume declaration submitted at the time of survey, the laboratory processed and reported approximately 11,939 Pathology samples annually for which the laboratory lacked written policies and procedures for the criteria for patient testing, retrieval of final reports and slides, and the criteria for unsatisfactory cytology specimens.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were

	available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on the surveyors' review of the laboratory's policy/procedure, statistics reports and an interview with the laboratory director (LD); it was determined that the laboratory failed to have an annual statistics documentation for the number of cases to include in this section. The findings include: 1. The laboratory failed to provide a written policy and procedure for an annual statistical evaluation to show the discrepant gynecologic cytology cases. 2. The LD affirmed by interview on June 5, 2025, at approximately 11:20 a.m. of the findings mentioned in statement #1. 3. According to the laboratory testing declaration submitted at the time of survey, the laboratory tested and reported 1,293 Cytology samples annually for which annual statistics for discrepancies were not evaluated.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy/procedure, survey findings and an interview on June 5, 2025, the laboratory director is herein cited for failure to ensure that an approved, signed, and dated, procedure manual that accurately reflects current laboratory practices is available for all personnel. See D5401.