Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0547058	11/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Protzel Pathology Laboratory	9735 Wilshire Blvd Ste 241, Beverly Hills, 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
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on observation and interviews with Office Manager and Intake and Reporting Specialist the laboratory failed to ensure cytology specimen slides and laboratory records from 2018 through the date of the survey in 2022 were maintained and stored in a secure area. Findings include: 1. On November 14, 2022 at 9:30 AM, the Office Manager was observed arriving at the facility carrying a cardboard box with cytology specimen slides and patient records. a. During an interview on November 14, 2022 at 9:45 AM, the Office Manager stated that all known cytology specimen slides and corresponding patient records had been kept at the Laboratory Director/Technical Supervisor's place of residence since the initial survey in April 2022. Specimen slides and patient records include: -Cytology specimen slides from 2018, 2019, 2020, 2021 and 2022; -Copies of final cytology test reports for cytology cases from 2018, 2019, 2020, 2021 and 2022; -Copies of corresponding test requisitions. b. The Office Manager confirmed that there was no record in the facility of what had been removed to the Laboratory Director/Technical Supervisor's residence. 2. On November 14, 2022 at 2:15 PM, the Survey Team observed specimen slides and patient records not maintained. Slide folders, plastic containers and mail envelopes were not organized and were scattered in piles on shelves and counters. As the identification of slides and records could not occur while enclosed in their containers and envelopes, a random selection of a few revealed: a. Some envelopes had been stored unopened so contents were not retrieved and properly stored. One sealed envelope was opened in the presence of Intake and Reporting Specialist and included a specimen paraffin block and corresponding patient records that were returned to the facility on an unknown date. b. Some slide folders and containers, which were opened in presence of Intake

	and Reporting Specialist, included specimen slides dating back to 2017. c. Intake and Reporting Specialist and Secretary/Office Assistant stated it was Couriers job to file and it hadn't been done in some time. d. Intake and Reporting Specialist and Office Manager were unable to tell the Survey Team how many cytology slides or cytology cell blocks were in the piles on the shelves. e. Intake and Reporting Specialist confirmed the only cytology specimens that were located and identified with certainty and maintained for retrievability by staff were the cytology specimens that were randomly identified by the Survey Team during the initial visit on April 6, 2022 and the three specimens received since that date.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 lack of a written cytology policy and procedure manual and interviews a written procedures manual for all cytology tests and examinations performed by the laboratory was not available to laboratory personnel. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy and procedure manual for all cytology tests and examinations performed by the laboratory. 2. During an interview on November 14, 2022 at 10:05 AM the Office Manager provided a manual that was brought into the laboratory during the survey. a. The Office Manager stated that the manual "was the old one" and "had been retrieved from the private residence of the Laboratory Director/Technical Supervisor." b. When asked if any of the newly implemented and approved policies and procedures were in the old manual, the Office Manager replied, "I don't think so, it's not updated with anything current, but it is now all online." c. The Survey Team requested that the current online policy and procedures manual be retrieved. The Office Manager replied, "I do not know how to do that. We don't use the computer here and I have no way to retrieve anything until the Intake and Reporting Specialist arrives with his computer." 3. During an interview on November 14, 2022 at 10:35 AM the Survey Team requested of the Intake and Reporting Specialist to retrieve the current policy and procedures manual. The Intake and Reporting Specialist stated that the laboratory's allegation of compliance responses could be retrieved but there was not a policy and procedures manual. 4. During an interview on November 15, 2022 at 9:00 AM the Intake and Reporting Specialist confirmed that the laboratory failed to have a written cytology policy and procedures manual. The Intake and Reporting Specialist stated that the difference between the allegation of compliance responses and a policy and procedure manual was not known but was now understood and it could be developed.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical

	consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's allegation of compliance documents received on 5/5/2022, 6/7/2022 and 7/5/2022, interviews with the Office Manager and Intake and Reporting Specialist and lack of a policy and procedure manual the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations. Cross refer to D3011, D3013, D5201 and D5401 Findings include: 1. The Laboratory Director failed to be responsible for ensuring the necessary precautions for safety from physical, chemical and biohazardous materials. See D3011 2. The Laboratory Director failed to be responsible for the maintenance, retrievability and storage of cytology specimen slides in a secure area. See D3013 3. The Laboratory Director failed to be responsible for ensuring the confidentiality of patient information. See D5201 4. The Laboratory Director failed to be responsible for ensuring a written policy and procedures manual for all cytology tests and examinations performed by the laboratory was accessible and available onsite to all laboratory personnel. See D5401
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on the lack of a policy and procedure manual and interviews the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Cross refer to D5401 1. The Laboratory Director failed to ensure an approved procedures manual was available to all personnel.