Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2112176	10/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Professional Pathology Laboratory, Llc	6517 N Armenia Ave, Tampa, FL	

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	An announced CLIA recertification survey was conducted at Private Autopsy Services LLC on 10/15/2019 The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation. review of material safety data sheets (MSDS), and interview with the Laboratory Manager, the laboratory failed to store flammable liquids in an approved flammable liquids storage area for 2 of 2 (60% and 80% Reagent Alcohol) flammable liquids. Findings Included: During the tour of the lab on 10/15/2019 at 11: 10 AM, observation revealed 3 large containers that were labeled 60% Alcohol and 80% Alcohol sitting out on a counter. The 60% alcohol and 80% alcohol reagents were made from 100% Reagent alcohol in the laboratory. Photographic evidence was obtained. Review of the MSDS for the 100% alcohol states "Store in an approved Flammable Liquids storage area." Interview on 10/15/19 at 11:50 AM with the Laboratory Manager confirmed that the 60% and 80% alcohol were kept on the counter and did not know that 60% and 80% alcohol should be stored in a flammable liquids storage area.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed

	following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the Laboratory Director failed to follow manufacturer's instructions for performing the Histopathology Bielschowsky's Stain Kit (Modified) from 01/2018 to 10/2019. Findings Included: 1. Review of the manufacturer's instructions for the Bielschowsky's Stain Kit (Modified) revealed the procedure stated: Place slide in warmed (by waterbath) Silver Nitrate Solution (20%) and incubate to 15 minutes at 40 degrees Celsius. 2. Review of the "Histology Temperature Sheet" showed that there no documentation of temperature of the water bath from 01/2018 to 10/2019. 3. Interview on 10/15/2019 at 1:00 PM with the Laboratory Director revealed he did not follow the manufacturer's instructions exactly for the Bielschowsky's Stain kit (Modified) for temperature and time requirement. He stated, he was going to write his own procedure.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the Laboratory Manager, the laboratory failed to label 3 carboys (large containers used for holding liquids) with the proper information on top of a counter in the Histopathology Laboratory. Findings Included: During a tour of the laboratory on 10/15/19 at 11:50 AM, 3 carboys that were labeled 60% alcohol, 80% alcohol, and 10% formalin were observed on the counter. The 80% alcohol carboy had a slip hazard label on the container. The carboys did not have the Lot# of the 100 % alcohol that the 60% and 80% alcohol solutions were prepared from. The containers did not have preparation dates or expiration dates. Also, the containers did not have a storage requirement documented on the container. Photographic evidence was obtained. Interview on 10/15/2019 at 11:50 AM with the Laboratory Manager confirmed that the containers were missing preparation and expiration dates and storage requirements.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Laboratory Manager, the

	laboratory failed to ensure the Schiff's solution for Histopathology Periodic Acid Schiff (PAS) stain was removed from use after the expiration date of 09/2017. Findings Included: Observation, during the tour of the laboratory on 10/15/19 at 11:55 AM, revealed a bottle of Schiff's solution (Lot#38019) with an expiration date of 09 /2017 and an opened date sticker of 09/14/16. Photographic evidence was obtained. A review of the "Special Stains Log" revealed PAS tests were performed from 01/2018 to 10/2019. Interview on 10/15/19 at 11:55 AM with the Laboratory Manager confirmed the Schiff's solution was expired and was unaware the solution had expired.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview with the Laboratory Manager the laboratory failed to ensure results of quality control for Histopathology special stains, Periodic Acid Schiff (PAS) stains, and Bielschowsky's stains were documented from 01/2018 to 10/2019. Findings included: Record review of the laboratory's logs revealed the Laboratory Director was not documenting the results of the quality controls for the PAS and Bielschowsky's Stain from 1/2018 to 10/2019. Interview on 10/15/2019 at 2:10 PM with the Laboratory Manager confirmed that the results of the special stain quality controls were not documented on a log or in a patient report from 1/2018 to 10/2019.