Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2065592	08/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Path Diagnostics	15785 Laguna Canyon Rd Ste 115, Irvine, 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
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory patient test result reports, the test ordering requisitions, and corresponding tissue slide labeling, and interview with the testing personnel, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the post analytic systems to verify and ensure accuracy, reliability and timely of the patient's final test result reports. The findings included: a. This laboratory received tissue samples in formalin and grossing onsite before sending to a histology laboratory to prepare for the tissue slides by Path Art, a histology laboratory in Corona. b. The testing person, a qualified pathologist, performs histopathology services and prints the final patient histopathology reports in a PDF format onsite. c. The laboratory testing personnel failed to follow written policy and procedures for an ongoing mechanism to verify and to ensure accuracy, reliability, and timely of the patient test result reports. d. Three out of 6 patients' histopathology reports were reviews at the time of 8/22/2022 @ 10:35 am, the errors were noticed as follows: DOS = date of service, ID = slide ID, DOS ID Name 8/11/2022 S22106 Huay (Corrected name = Huang) 7/26/2022 S20-1059 (Corrected ID = S221059) 7/22 /2022 S221035 (Corrected ID = S221058); Gender F (Corrected M) e. The testing personnel affirmed (8/22/2022 @ 10:35 am) that three out of 6 patient test reports were found inaccurate information.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory patient test result reports, the test ordering requisitions, and corresponding tissue slide labeling, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided to ensure accuracy, reliability and timely of the patient's final test result reports, and failed to follow its written quality assurance (QA) to identify failures and take appropriate remedial actions as they occur. The findings included: a. The laboratory director failed to follow written policy and procedures for an ongoing mechanism to verify, monitor, assess and, when indicated, correct problems identified in the post analytic systems to ensure accuracy, reliability, and timely of the patient test result reports, See D-5891.