Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1000595	05/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Arts Inc	549 Queensland Circle, Ste 101, Corona, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory temperature records, and interview with the laboratory staff, it was determined that the laboratory failed to establish and follow written policies and procedures to assess employee and effectively verified the competence evaluations of the employees. The findings included: See D-5411
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 observation, and review of the laboratory's temperature records, and interview with the laboratory staff, it was determined that the laboratory failed to follow the manufacturer's instructions or the laboratory established procedures in a manner that provides the test results within the laboratory's stated performance specifications for each test system. The findings included: I a. The laboratory is a histology laboratory and used many equipment including, but not limited to the followings: tissue processors (T1 thru T7), embedding centers (E1,2), ovens (SO),

	slide drying, paraffin melting (PP), and refrigerators (R3,4) to stores reagents for H&E and special stains. b. Review of the laboratory temperature records, found incomplete and inconsistent temperature records among 5 weeks of the temperature records reviewed. c. There are two units in the temperature measurement units, Fahrenheit or Celsius. d. Review the "Daily Temperature Log" of Week of 10-2-17 to 10-6-17, the laboratory recorded the temperatures for a total of 12 equipments on Tuesday, Wednesday, and Thursday, but no records on Monday, Friday, Saturday and Sunday (incomplete). e. The laboratory established its acceptable temperature ranges for the equipments in Celsius unit. f. The temperature reader recorded in the table below is for the week of 10-2-17 to 10-6-17 out of the records for the duration between 10-2/2017 and 4-15-2008: . Equip Mon Tues Wed Thurs Fri Sat Sun R3 37 oC 38 33 oC R4 40 oC 42 44 oC g. The laboratory had established that an acceptable range for refrigerator was 4 oC +/- 3 oC (1 to 7 oC). h. The temperatures shown at 33, 37, 40, 42 and 44 with or without unit oC (inconsistent) were extremely high for a refrigerator conditions which was out of the acceptable range. i. Review of the temperature records from the week of 10-2-17 thru 4-15-2018, there were many incomplete and inconsistent data. j. The laboratory staff affirmed (5/1/2018 @ 11:50 AM) that the temperature records were inconsistent and incomplete to reflect the accurate data clearly. II. a. Observed a digital thermometer with 1 at Min, 11 at Max, and current temperature at 4. b. The laboratory set the acceptable temperature range between 1 to 7 oC. c. The refrigerator at some time passed had temperature reached to 11 oC which is out of the acceptable temperature range. d. Interview with the laboratory staff, the personnel does not familiarize the feature of the digital thermometer instructions. e. The laboratory took no actions neither to correct the problems nor to training the personnel how the digital thermometer operates.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and interview with the laboratory staff, it was determined that the laboratory failed to document all corrective actions taken, including actions taken when the temperature for proper storage of reagents and specimens. The findings included: D-5411
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and interview with the laboratory

	director, it was determined that the laboratory failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided. The findings included: See D-5209, D-5411 and D-5785