Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2089918	01/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Pathology/P4 Diagnostix	6101 S Rural Rd, Ste 102, Tempe, AZ	

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
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's microscope maintenance policy and interview with the facility personnel, the laboratory failed to document the routine and preventative maintenance of the microscope used in patient testing under the sub-specialty of Histopathology. Findings include: 1. No microscope maintenance log for routine maintenance or evidence of preventative maintenance performed yearly was presented for the pathologist's microscope used in slide reading. 2. The facility personnel acknowledged that there was no documentation of microscope maintenance used for the professional component of testing under the sub-specialty of Histopathology
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to include on the test report the laboratory name and address where the testing was performed. Findings include: 1. Two test reports reviewed during the survey (SWS19-04823 and SWC19-00122) were missing the laboratory name and address where the testing was performed. 2. The reports failed to indicate that the grossing was performed at the address where the survey was conducted on January 13, 2020 and the professional component (the slide reading) was performed at the address indicated under CLIA #03D0526698 respectively 3. The facility personnel confirmed that the laboratory names and addresses were not indicated on the patient test reports referenced above.