

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 50D2041210	<b>(X3) Date Survey Completed</b> 05/30/2023
<b>Name of Provider or Supplier</b> Sanw Pathology	<b>Street Address, City, State</b> 34612 6th Ave S Ste 110, Federal Way, WA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, and an interview with the laboratory Histotechnician on 05/29/2023, the laboratory failed to establish a quality assessment (QA) plan for performing an ongoing quality assessment to monitor, assess, and, when indicated, correct problems identified during receipt, processing and timely submission of histopathology patient tissue samples. Finding includes: 1. Review of the laboratory policies and procedures revealed a lack of a QA plan being established to monitor, track, and report specimen acceptability, tissue grossing processing, and slide preparation issues. 2. The laboratory Histotechnician confirmed by an interview on 05/29/2023, at 11:00 AM, the lack of a policy or procedure for conducting a QA for the testing performed. 3. The laboratory reports performing 2000 Histopathology tissue samples annually.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of maintenance records, the manufacturer's instructions, and an interview with the Histotechnician on 05/29/2023. the laboratory failed to perform and document maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer for the Miles Scientific Tissue-Tek VIP tissue processor and slide stainer. Findings include: 1. Review of the laboratories policy and procedures manual did not include the daily maintenance as stated in the manufacturer's manual for the Miles Scientific Tissue-Tek V.I.P. tissue processor. Daily: 2-1-2 After each cycle, clean the retort, prior to initiating the cleaning cycle 2-1-3 Reservoirs, dispose of the water in the water reservoir and fill to proper level 2-1-4 Exterior Surfaces, Clean 2-1-5 Spill Trays Remove, clean and remove paraffin accumulations. 2-1-6 Remove the inle/outlet filter, clean thoroughly with cloth moistened with xylene before reinstalling 2. The laboratory failed to document the maintenance as directed by the manufacturer for the survey years reviewed, 2021, 2022, and 2023. 3. The Histotechnician confirmed by interview on 05/29/2023, the lack of documenting the daily maintenance as specified by the manufacturer. 4. The laboratory reports performing 2000 tissue slides annually.

**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 a record review of the laboratory's analyzer function checks, and an interview with the Histotechnician, on 05/29/2023, the laboratory failed to establish a maintenance protocol to ensure the Miles Scientific Tissue-Tek Vaccume Infiltration Processor (V.I.P.), auto-processor/stainer, the Premiere paraffin dispenser, and the laboratory microscope had annual function checks for performance and safety. Findings include: 1. Review of the Miles Scientific Tissue-Tek V.I.P auto-tissue processor and stainer, the Premiere Paraffin dispenser XH-4002, and the laboratory microscope, revealed no function check as having been performed. Request for records of the function checks revealed a lack of documented performance of annual functions checks for all three instruments. 2. The laboratory Histotechnician confirmed by an interview on 05/30/2023, the lack of documented functions checks for the equipment listed. 3. The laboratory reports performing 2000 patient tissue Histopathology samples annually.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on the request for documentation for competency assessments for the Histotechnician (TP -1) performing tissue grossing, blocking and staining of histopathology tissue slides, the lack of documentation of competency assessments, and interview with the laboratory TP-1 on May 29, 2023, the laboratory Technical Supervisor failed to assess the competency of the laboratory TP-1 for specimen handling and evaluation for acceptability of tissue specimens for processing and testing. Findings include: 1. Request for review of competency records for the TP-1 revealed a lack of documentation of competency assessments being performed for the years 2021, 2022 and 2023. 2. The TP-1 confirmed by interview on 05/29/2023, at 11:00 am the lack of competency assessments being performed for 2021, 2022 and 2023.. 3. The laboratory reports performing 2000 Histopathology patient tissue samples annually.