

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2089918	<b>(X3) Date Survey Completed</b>  10/05/2022
<b>Name of Provider or Supplier</b>  Southwest Pathology/P4 Diagnostix	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the specialty of Pathology at least twice annually during 2020 and 2021. Findings include: 1. No documentation was presented for review during the survey conducted on October 5, 2022 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading/diagnosis) of histopathology specimens at least twice annually during 2020 and 2021. 2. No documentation was presented for review during the survey conducted on October 5, 2022 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading/diagnosis) of cytology specimens at least twice annually during 2020 and 2021. 3. The facility personnel interviewed on 10/05/22 at approximately 11:03am confirmed that the laboratory failed to verify the accuracy of histopathology testing and cytology testing at least twice annually during 2020 and 2021. 4. The laboratory's approximate annual test volume under the specialty of Pathology is 19,864.</p>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT 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>

This STANDARD is not met as evidenced by:  
Based on review of established Quality Assessment policies and procedures for review and interview with the facility personnel, the laboratory failed to follow established policies and procedures related to accuracy verification for pathology testing performed by the laboratory. Findings include: 1. The laboratory performs the gross description and microscopic interpretation of patient specimens under the sub-specialties of Histopathology and Cytology, with an approximate annual test volume of 19,864. 2. The laboratory's established policy (Proficiency Testing QLT-16.0) reviewed during the survey states, "For tests for which CAP does not require PT (Proficiency Testing), the laboratory at least semi-annually exercises an alternative performance assessment system for determining the reliability of analytic testing... This alternative assessment should occur at least every six months for each test /analyte which does not have an external PT...Any discrepant result will be accessed, and a Non Conformity report will be generated." 3. During 2020 and 2021, the laboratory failed to follow the established policy indicated above to verify the accuracy at least every six months of Histopathology and Cytology test results reported by the laboratory. See D5217 for specific findings. 4. No documentation was presented for review during the survey to indicate the laboratory followed the established policy indicated above and completed a Non Conformity report for a discrepant result identified during the January 2022 accuracy verification process. The Jan. 2022 QA/QC log presented for review during the survey listed one discrepant result (SWS22-01061B). 5. The facility personnel interviewed during the survey on October 5, 2022 at approximately 12:17pm confirmed the laboratory failed to follow established policies specific to the frequency of accuracy verification processes and the actions to take in the event of a noted discrepancy.

**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 lack of (A) annual microscope maintenance documentation, (B) lack of centrifuge maintenance documentation and (C) lack of ThinPrep 2000 maintenance documentation for review and interview with the facility personnel, the laboratory failed to perform and document maintenance activities during 2020, 2021 and January through June of 2022. Findings include: A1. It is the practice of the laboratory to perform annual preventative maintenance of the microscopes used for patient testing in the specialty of Pathology. A2. No documentation was presented for review during the survey conducted on 10/05/2022 to indicate the laboratory performed annual preventative maintenance during 2020 and 2021 on the microscopes used for patient testing. A3. The facility personnel interviewed on 10/05/22 at 11:35am confirmed the laboratory failed to perform annual preventative maintenance on the microscopes used for patient testing. B1. No documentation was presented for review during the survey conducted on 10/05/2022 to indicate the laboratory performed maintenance activities

of the centrifuge from January 2020 through June 2022. B2. The Thermo Scientific Centrifuge is used for the processing of cytology specimens and the maintenance includes: Clean Chamber with disinfectant (daily); Clean Heads with disinfectant (daily); Clean exterior (as needed); and Calibrate instrument (annually). B3. The facility personnel interviewed on 10/05/22 at 11:40am confirmed the laboratory failed to perform and document maintenance activities indicated above on the centrifuge used in conjunction with patient testing. C1. No documentation was presented for review during the survey conducted on 10/05/2022 to indicate the laboratory performed maintenance activities of the ThinPrep 2000 Processor from January 2020 through June 2022. C2. The ThinPrep 2000 Processor is used for preparing cytology slides and the maintenance includes: Empty Waste bottle(daily/weekly); Clean Filter Cap(daily); Pneumatic Test (weekly); Cap Seal O-Ring Lube (weekly); Filter Seal O-Ring Lube (daily); Clean Cap Seal (daily); Door Cleaning (weekly); and general cleaning (monthly). C3. The facility personnel interviewed on 10/05/22 at 11:43am confirmed the laboratory failed to perform and document maintenance activities indicated above on the ThinPrep 2000 Processor used in conjunction with patient testing.

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to test staining materials each day of use for intended reactivity to ensure predictable staining characteristics in the sub-specialty of cytology. Findings include: 1. The laboratory performs testing in the specialty of Pathology, with an approximate annual test volume of 19,864. 2. The laboratory performs the Papanicolaou Stain on non-gynecologic specimens. 3. No documentation of the Papanicolaou Stain acceptability was presented for review for each day of patient testing that occurred prior to September 26, 2022. The number of patient specimens stained and tested using the Papanicolaou stain by the laboratory prior to 9/26/22 could not be determined at the time of the survey. 4. The facility personnel interviewed on 10/05/22 at 12:05pm confirmed that the laboratory failed to document the Papanicolaou stain acceptability as indicated above.

**D5633**

**CYTOLOGY**  
CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures and interview with the facility personnel, it was determined that the laboratory failed to establish written policies and

procedures to ensure that a maximum workload limit was established by the Technical Supervisor for five out of five Technical Supervisors who perform primary evaluation of cytology specimen slide evaluations. Findings include: 1. No documentation was presented for review during the survey to indicate the laboratory established written policies and procedures to ensure that a maximum workload limit was established by the Technical Supervisor for each Technical Supervisor who performs patient testing under the sub-specialty of Cytology. 2. The facility personnel interviewed on 10/05/22 at 11:50am confirmed that the laboratory did not have established policies and procedures related to workload limits for cytology testing personnel at the time of the survey.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 lack of Quality Control records for review, the laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5473 for findings.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on lack of training documentation for two out of two testing personnel who perform testing in the specialty of Pathology and interview with the facility personnel, the laboratory director failed to ensure that all testing personnel receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for two out of two testing personnel hired in January 2021 and April 2021, who perform the gross evaluation on patient specimens in the specialty of Pathology. 2. The facility personnel confirmed that the laboratory failed to have documentation of initial training for the testing personnel indicated above.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on lack of documentation of a semi-annual competency evaluation for two testing personnel and interview with the facility personnel, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for two out of two testing personnel who began grossing patient specimens in January 2021 and April 2021, respectively. 2. The facility personnel confirmed that the technical supervisor failed to document a semi-annual competency evaluation for the two testing personnel indicated above.