

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2166916	(X3) Date Survey Completed 10/06/2022
Name of Provider or Supplier Southeast Pathology Consultants	Street Address, City, State 1815 Back Creek Drive, Charlotte, NC	
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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) Casper report 155D, the absence of records, and interview with the Cytology general supervisor (GS) 10/6/22, the laboratory failed to retain all proficiency testing records for at least two years. Findings: Review of CMS Casper report 155D revealed the laboratory participated in proficiency testing with American Proficiency Institute (API) for the 1st and 3rd Microbiology events of 2020. Review of CMS Casper report 155D revealed the laboratory failed to participate in the 2020 Microbiology 2nd event. The Cytology GS was able to print the submitted results for the API 2020 Microbiology 1st event and the graded results for the API 2020 Microbiology 3rd event during the survey. There were no other 2020 proficiency testing records available for review. During interview at approximately 10:35 a.m., the Cytology GS stated he was unable to locate any of the 2020 API records.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures and review of personnel records 10/4/22 - 10/6/22 and interview with the laboratory director 10/5/22, the laboratory director failed to ensure policies and procedures were established for monitoring the competency of the 2 histology testing personnel (TP #1 and TP #2) who perform grossing. Findings: Review of the laboratory's policies and procedures revealed the laboratory did not have a detailed, specific policy for histopathology competency evaluations. Review of personnel records revealed the competency evaluations for grossing were performed by personnel who did not meet the requirements to serve as technical supervisor or general supervisor in the specialty of histopathology. For example, TP #2's 2021 grossing competency evaluation was performed by TP #1. TP #1 has a bachelor's degree in biological sciences. For 2022, the Cytology general supervisor (GS) performed the grossing competency for TP #1 and TP #2. During interview at approximately 3:30 p.m., the laboratory director stated the Cytology GS supervises TP #1 and TP #2, so that's why he performed the 2022 evaluations.