

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2144267	<b>(X3) Date Survey Completed</b>  11/14/2018
<b>Name of Provider or Supplier</b>  Elite Pathology Laboratory	<b>Street Address, City, State</b>  3744 W North Avenue # 2, Chicago, IL	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's manual, records, and an interview with the office staff; the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing Histopathology testing, affecting 3 out of 3 testing personnel (TP). Findings: 1. The CMS 209 lists 3 TP (TP-B2U, listed on line 1; TP-3A, listed on line 3; and TP-55K, listed on line 5) that perform Histopathology slide interpretations in the laboratory. 2. The personnel documents provided for 3 out of 3 TP were from South Loop GI laboratory. No documentation was presented as evidence that the competencies of the 3 TP were assessed at Elite Pathology Lab Inc. prior to reading slides for patients. 3. Review of the laboratory's manual revealed that it does not include an established competency policy or a step-by-step procedure to assess the TP performing the interpretation of Histopathology slides. 4. On an Initial survey conducted on 11/14/2018 at 11:30 AM, the office staff and the laboratory director confirmed the above findings.</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>

This STANDARD is not met as evidenced by:  
Based on the surveyor's review of the laboratory's manuals, logs, manufacturer's instructions, and an interview with the office staff ; the laboratory failed to perform and document the maintenance and function check protocols as defined by the manufacturer and with at least the frequency specified by the manufacturer, to ensure equipment, instrument, and test system performances are accurate and reliable. Findings: 1. On 11/14/2018 at 9:00 AM entering the laboratory, the surveyor observed one Microscope used for Histopathology slide interpretations. 2. The manufacturer's instructions for the maintenance of the microscope states the following: a). Inspect lamp socket every 6 months and every time you replace the lamp bulb; b). Periodically complete the maintenance "Check Items" chart (which is provided by the manufacturer); and c). A step-by-step procedure for cleaning the lenses and other glass components of the microscope. 3. The laboratory's "Microscope Maintenance" policy does not include any of the manufacturer's instructions listed in 'Findings #2'. 4. Review of the microscope log reveal that the hours of usage are not documented as required by the manufacturer. 5. On an Initial survey conducted on 11/14/2018 at 11: 35 PM the office staff and the laboratory director confirmed the above findings.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on the surveyor's review of laboratory's manuals, records, and an interview with the office staff the laboratory director (LD); the LD failed to provide overall management and direction in accordance with 493.1445 of this subpart. Findings: 1. The LD failed to 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 perform test procedures and report test results promptly and proficiently in the specialty of Histopathology. See D6103.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(13)

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.

This STANDARD is not met as evidenced by:  
Based on the surveyor's review of laboratory's manuals, records, and an interview with the office staff; the laboratory director (LD) failed to 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 perform test procedures and report test results promptly and proficiently, affecting 3 out of 3 testing personnel (TP). Findings: 1. The LD failed establish a competency policy and procedure for testing personnel (TP) performing Histopathology interpretations. See D5209. 2 The LD failed to assess it's TP for competence to interpret Histopathology slides, prior to testing patients. 3. The LD failed to establish a protocol or describe or defined a method that the laboratory will use to verify the accuracy of it's Histopathology slide interpretations for at least twice annually.