

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2118978	(X3) Date Survey Completed 11/17/2020
Name of Provider or Supplier Wyoming Valley Pathology Assoc	Street Address, City, State 300 Laird Street Sutie A2, Wilkes Barre, PA	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 review of the laboratory procedure manuals and interview with testing personnel (TP) #5, the laboratory failed to establish a complete competency assessment policy to assess 3 of 4 clinical consultants (CC) and 1 of 2 technical supervisors (TS) for competency in 2018, 2019 and 2020. Findings include: 1. On the Laboratory personnel report (CLIA) Form CMS - 209, Personnel #3 and #4 are listed as a CC and personnel #2 is listed as a CC and TS. 2. On the day of survey, 11/17/2020, the laboratory could not provide a complete competency assessment policy to assess consultants and supervisors for competency. 3. Personnel #2 performed the directors peer reviews in 2018, 2019 and 2020. 4. The laboratory could not provide competency assessments performed for 3 of 4 CC and 1 of 2 TS in 2018, 2019 and 2020. 5. TP #5 confirmed the findings above on 11/17/2020 around 10:00 am.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS 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: Based on observation of service stickers on the Fisher brand thermometers and</p>

interview with testing personnel (TP) # 5, the laboratory failed to perform service maintenance for 2 of 2 Fisher brand refrigerator thermometers and 1 of 1 Fisher scientific hygro room temperature thermometer in 2018 and 2019. Findings include: 1. On the day of survey, 11/17/2020, observation of the laboratory revealed, 2 of 2 Fisher brand refrigerator thermometers were due for maintenance on 06/19/2019. 2. Observation of 1 of 1 Fisher scientific hygro room temperature thermometer revealed, the thermometer did not state a maintenance date and the laboratory could not provide documentation of maintenance checks performed in 2018 and 2019. 3. The laboratory could not provide a maintenance policy for the maintenance of the refrigerator and room temperature thermometers. 4. The refrigerator stored stains and reagents used for the examination of histopathology slides. 5. TP #5 confirmed the findings above on 11/17/2020 around 10:15 am.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the Hematoxylin and eosin (H&E) quality control (QC) records and interview with the testing personnel (TP) #5, the laboratory failed to document daily immunohistochemical (IHC) and specials stains QC for histopathology slides examined from 06/26/2018 to the day of survey. Findings include: 1. On the day of survey, 11/17/2020, review of the H&E QC records revealed, daily IHC and specials stains QC were not documented for histopathology slides examined from 06/26/2018 to 11/17/2020. 2. In 2018 - 122 specials stains and 947 IHC stains were used for histopathology slides examinations. 3. In 2019 - 2,569 specials stains and 218 IHC stains were used for histopathology slides examinations. 4. In 2020 (01/01/2020 to 11/17/2020) - 1,537 specials stains and 188 IHC stains were used for histopathology slides examinations. 5. TP#5 confirmed the findings above on 11/17/2020 around 9:45 am.