Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2118978	06/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wyoming Valley Pathology Assoc	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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with the laboratory director (LD), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess Laboratories corrective Assessment in 2017 to the date of survey. Findings include: 1. On the day of survey, review of the laboratory's manuals, revealed that the laboratory failed to have a written policy to assess the quality of its laboratory systems in 2017 and 2018 (January 1st, 2018 to June 26th, 2018). 2. The LD confirmed the findings above on 06 /26/2018 around 9:30 am.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of refrigerator temperature logs and interview with Laboratory Director (LD) and Testing Personnel (TP) #5, the laboratory failed to document the corrective actions for refrigerator temperature outside of acceptable range (2 to 8

	degrees Celsius) from October 25th, 2017 to June 26th, 2018. Findings include: 1. The histopathology refrigerator houses the, Roche Ventana tissue-based diagnostic antibodies that are used with the VENTANA BenchMark Special Stains instrument. 2. The Immunoperoxidase stains package inserts state under the storage section, "Upon receipt and not in use, store at 2- 8 degree Celsius. 3. On the day of survey, review of Hisotpathology laboratory refrigerator temperature logs, revealed: a). 34 of 63 days of patient testing, refrigerator temperature were outside of acceptable range in 2017 (October 25th, 2017 to December 31st, 2017). b). 96 of 122 days of patient testing, refrigerator temperature were outside of acceptable range in 2018 (January 1st, 2018 to June 26th, 2018). 4. From October 25th, 2017 to December 31st, 2017, 69 special stains were processed. 5. From January 1st, 2018 to June 26th, 2018, 91 special stains were processed. 6. LD and TP#5 confirmed the finding above on 06/26/2018 around 10:00 am.
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 personnel record review and interview with the Laboratory Director (LD), the technical supervisor failed to evaluate the competency of all testing personnel from 2017 to the date of survey. Findings Include: 1. On the day of survey, 06/26 /2018, The laboratory could not provide the follow documentation for Testing personnel (TP) #6: a). 6 month competency assessment (TP#6 started date was May of 2017), should have been performed by November 2017 but was not documented. b) First year competency assessment, should have been performed by May 2018, but was not documented. 2. The LD confirmed the finding above on 06/26/2018 around 9:00 am.