

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0963978	(X3) Date Survey Completed 08/16/2018
Name of Provider or Supplier Village Surgicenter	Street Address, City, State 5473 Village Common Drive, Erie, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory clinical manager on the date of the survey, (08/16/2018) the laboratory did not follow the the written procedure for Frozen Section procedure for reporting out of range temperatures the month of July 2018. Findings include: 1. The Frozen Section procedure Equipment Note A requires out of range cryostat temperatures to be reported to Warren General Hospital Pathology Department. 2. The July 2018 cryostat temperature log revealed 4 of 21 temperatures were out of range (-18 C to -25 C), 07/10/2018 (-26 C), 07/13/2018 (-26 C), 07/24/2018 (-26 C), and 07/31/2018 (-26 C).. 3. During the survey (08/16/2018), the laboratory clinical manager confirmed the above findings.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and interview with the laboratory clinical manager, at the time of the survey (09:30 08/16/2018), the laboratory failed to ensure that all in</p>

use supplies, had not exceeded their expiration date for 5 of 26 bottles observed. Findings include: 1. The following histopathology reagents had no expiration date and or no opening date , 1 bottle of each: Hematoxylin, Eosin, 3% Acetic acid, Lithium Carbonate + 70% Alcohol, and 70% Alcohol. was found in the laboratory, during the survey. 2. During the survey (08/16/2018), the laboratory clinical manager confirmed the above findings.