Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0963978	(X3) Date Survey Completed 08/10/2020
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of review of peer review records and interview with the registered nurse (RN) manager and the administrator, the laboratory failed to ensure verification of accuracy for frozen section examinations were performed at least twice annually in 2018 and 2019. Findings Include: 1. On the day of survey, 08/10/2020, the RN manager and the administrator could not provide twice annual verification of accuracy for frozen section examinations performed in 2018, 2019. 2. The RN manager and the administrator confirmed the finding above on 08/10/2020 around 01:30 pm.
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 registered nurse (RN) manager and the administrator, the laboratory failed to establish a quality assessment (QA) policy to assess ongoing mechanism to monitor the laboratory's systems from 2018 to the day of survey. Findings Include: 1. On the day of survey, 08/10/2020, the RN manager and the administrator could not provide a QA

	policy to assess the quality of its laboratory systems from 08/16/2018 to 08/10/2020. 2. The RN manager and the administrator confirmed the finding above on 08/10/2020 around 2:45 pm.
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 slide staining records and interview with the registered nurse (RN) manager and the administrator, the laboratory failed to document hematoxylin and eosin (H&E) stain slide quality control (QC) performed on frozen sections examinations in house from 08/16/2018 to the day of survey. Findings Include: 1. On the day of survey, 08/10/2020, review of the frozen sections examinations staining records revealed, the H&E stain QC's were not performed and documented by the reading physician onsite. 2. 6 frozen sections examinations were analyzed from 08/16/2018 to 12/31/2018. 3. 5 frozen sections examinations were analyzed from 01/01/2019 to 12/31/2019. 4. 1 frozen sections examinations were analyzed from 01/01/2020 to 08/10/2020. 5. The RN nurse manager and the administrator confirmed the findings above on 08/10/2020 around 03:00 pm.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the review of patient test reports and interview with the registered nurse (RN) manager and the administrator, the laboratory failed to include on test reports (3 of 3 reviewed) the location where frozen section slides were analyzed from 08/16/2018 to the date of survey. Finding Include: 1. On the day of survey, 08/10/2020, a review of frozen section test reports (3 of 3 reviewed) revealed, test reports failed to include an address where slides were analyzed from 08/16/2018 to 08/10/2020. 2. 6 frozen sections examinations were analyzed from 08/16/2018 to 12/31/2018. 3. 5 frozen sections examinations were analyzed from 01/01/2019 to 12/31/2019. 4. 1 frozen sections examinations were analyzed from 01/01/2020 to 08/10/2020. 5. The RN nurse manager and the administrator confirmed the findings above on 08/10/2020 around 02:35 pm.