Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2169800	12/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bayless Pathmark, Inc	6777 Engle Road, Suite M (Room A), Middleburg Heights, OH	

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
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and an interview with Clinical Consultant (CC) #5, the laboratory failed to establish, perform and document a service protocol that ensured accurate and reliable microscope performance which was necessary for microscopic tissue biopsy grossing. All patient tissue biopsy grossing and slide preparation cases had the potential to be affected by this deficient practice from 08/26/2019 to the date of the initial inspection. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any mention of a microscope service policy and procedure. 2. Direct observation of the histopathology laboratory in Suite M (Room A) for the tissue biopsy grossing and processing on 12/05 /2019 at 12:30 PM found an Olympus BX51 microscope, serial number 000105, which was utilized to assess the acceptability of slide preparations and the intended stain activities prior to sending the tissue biopsy slides to another laboratory location to be interpreted and reported. Further observation revealed this microscope had not been serviced since 2016. 3. The Inspector requested the laboratory's microscope service policy and procedure and all microscope service documentation from CC#5. CC#5 confirmed that the laboratory did not establish a policy and procedure, perform and document any microscope service activities since 2016 and was unable to provide

	the requested documentation on the date of the inspection. The interview occurred on 12/05/2019 at 12:30 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 record review and an interview with Clinical Consultant (CC) #5, the laboratory failed to include on the final test report the name and address of the laboratory location where the patient tissue biopsy grossing procedures were performed. All patient tissue biopsy grossing procedures performed from 08/26/2019 to the date of the initial inspection were affected by this deficient practice. Findings Include: 1. Review of six out of six of the laboratory's corresponding test records and final test reports did not find the name and address of the laboratory location of where the patient tissue biopsy grossing procedures were performed. 2. CC#5 confirmed that the name and address of the laboratory location of where the patient tissue biopsy grossing procedures were performed was not indicated on the final test reports. The interview occurred on 12/05/2019 at 12:40 PM.