Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0338518	05/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Bayless Pathmark, Inc	19250 E Bagley Road, #101, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review, direct observation and an interview with the Technical Supervisor (TS), the laboratory failed to label each of the secondary containers of reagents, solutions and stains with the lot numbers (pertinent information required for proper use) and expiration dates of their contents which were utilized for the processing of high complexity tissue biopsy frozen section testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect nine out of nine patient tissue biopsy frozen section procedures performed between 06/27 /2023 through 05/14/2024. Findings Include: 1. Review of the laboratory's "Bayless Pathmark, Inc. Procedure Manual" approved by the new Laboratory Director via signature and date on 06/27/2023 and provided for inspection review did not find any instructions of the laboratory's labeling policies and procedures for secondary containers of reagents, solutions and stains. 2. Direct observation of the Histopathology manual slide staining station on 05/14/2024 at 3:26 PM found each of the secondary containers of reagents, solutions and stains labeled only with their contents and without any indication of the lot numbers and expiration dates. 3. The Inspector requested the laboratory's policy and procedure for labeling secondary containers of reagents, solutions and stains from the TS. The TS confirmed the laboratory did not establish a policy and procedure for labeling secondary containers of reagents, solutions and stains, the laboratory did not label secondary containers of

	reagents, solutions and stains as required by CLIA regulation and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 05/14/2024 at 3:26 PM.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on record review, direct observation and an interview with the Technical Supervisor (TS), the laboratory failed to ensure reagents, solutions and stains, utilized for the processing of high complexity tissue biopsy frozen section testing procedures performed in the subspecialty of Histopathology, were not used when they had exceeded their expiration dates. This deficient practice had the potential to affect nine out of nine tissue biopsy frozen section testing procedures performed between 06/27 /2023 through 05/14/2024. Findings Include: 1. Review of the laboratory's "Bayless Pathmark, Inc. Procedure Manual" approved by the new Laboratory Director via signature and date on 06/27/2023 and provided for inspection review did not find any instructions to not utilize reagents, solutions and stains when they had exceeded their expiration dates. 2. Review of the laboratory's 2023 and 2024 "Reagent Log QC" log revealed the documentation did not include the date that the specific reagents, solutions and stains were opened and utilized for patient frozen section testing procedures performed. 3. Direct observation of the Histopathology laboratory area on 05/14/2024 at 3:26 PM found the following list of expired reagents, solutions and stains which continued to be utilized for the staining of high complexity tissue biopsy frozen section testing procedures performed: Reagent Lot Expiration Solution Number Date Stain Tissue Inking Dyes Black 11073 08/2023 Blue 11074 08/2023 Green 11075 08/2023 Red 11076 08/2023 Yellow 11077 08/2023 Orange 108677E 06 /2023 Clear Rite 3 548491T 07/2022 Xylene Substitute Mountant 441468 02/2020 112218 11/2023 4. The TS confirmed the above listed reagents, solutions and stains were expired and continued to be utilized for patient frozen section testing procedures when they had exceeded their expiration dates. The interview occurred on 05/14/2024 at 3:26 PM.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure that one out of five testing personnel (TP) had demonstrated they could perform all tissue biopsy and frozen section testing procedures reliably to provide and report accurate results prior to performing patient

	testing in the subspecialty of Histopathology. This deficient practice had the potential to affect all patient tissue biopsy and frozen section testing procedures performed by one (TP#4) out of five TP from starting to test independently in this laboratory on 11 /15/2023 through 05/14/2024. Findings Include: 1. Review of the laboratory's Form CMS-209, signed and dated by the Laboratory Director on 05/14/2024, revealed five individuals listed and credentialed as TP to conduct high complexity patient tissue biopsy and frozen section testing procedures. 2. Review of the laboratory's "Accuracy Verification Process Evaluation Assessment" policy and procedure, approved by the Laboratory Director on 06/27/2023 and provided on the date of the inspection, found the following instructions: "This accuracy verification is done after initial training, after six months, and annually thereafter for each pathologist." 3. Review of the laboratory's 2023 and 2024 competency assessment documentation did not find any initial demonstration of competence documentation prior to independent patient tissue biopsy and frozen section testing procedures for TP#4. 4. The Inspector requested the laboratory's 2023 initial demonstration of competence documentation for TP#4 from the TS. The TS confirmed that the laboratory did not conduct and document initial demonstration of competence for TP#4 prior to independent patient tissue biopsy and frozen section testing procedures performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 5/14/2024 at 1: 45 PM.