

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0338518	(X3) Date Survey Completed 02/09/2021
Name of Provider or Supplier Bayless Pathmark, Inc	Street Address, City, State 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
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Manager (PM), the Technical Supervisor (TS) failed to evaluate and document the 12 month competency assessment during the first year for one out of two testing personnel (TP) that conducted high complexity tissue biopsy slide interpretation testing procedures in the specialty of Histopathology. All patient slide interpretations conducted by TP#3 from 06/22/2020 to 02/09/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209, provided for the virtual inspection, revealed two out of four individuals newly listed as TP, since the last CLIA inspection on 05/09/2018, to perform high complexity tissue biopsy slide interpretation testing procedures. 2. Review of the laboratory's "Quality Assurance and Competency Assessment Program" policy and procedure found "The components of the review include assessment of the gross description, diagnosis, timeliness, transcription/final report, appearance and coding. Any issues identified will be documented on the daily QC/QA review, discussed with the monitored personnel and documented with report revisions generated as necessary. 3. Review of the laboratory's competency assessment documentation for TP#3, provided for the virtual inspection, found "Annual Competency Review" records for initial training and demonstration dated 10/02/2019, six month assessment dated 06/22/2020, however did not find a 12 month tissue biopsy slide interpretation competency assessment conducted in 2020 (TP#3 began patient tissue biopsy slide interpretation testing procedures in 10/2019). 4. The Surveyor requested the laboratory's 12 month tissue</p>

biopsy slide interpretation testing competency assessment documentation for TP#3 from the PM. The PM confirmed the TS did not conduct and document a 12 month competency assessment for tissue biopsy slide interpretation testing procedures for TP#3 in 2020 and was unable to provide the requested documentation on the date of the virtual inspection. The email interview occurred on 02/09/2021 at 12:05 PM.