Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0684946	10/26/2020
Name of Provider or Supplier	**Street Address, City, State**	
H L Blumenthal Md	3619 Park East Suite 209, Beachwood, 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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and the office staff, the laboratory failed to test and document hematoxylin and eosin (H&E) stain quality control (QC) procedures for the intended stain reactivity to ensure predictable staining characteristics each day of use. All patient tissue biopsy slide interpretations performed on the days when the intended stain reactivity QC was not performed and documented had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Policy and Procedures for Histopathology 2018", provided on the date of the inspection, approved and signed by the Laboratory Director on 06/02/2018, did not find any instructions to assess the actual intended reactivity of the H&E stain, however found the following statements: "Review and Interpretation of Slides Have available the Histopathology Slide Quality Stain Control Form. H&E stain quality control is determined by the depth of color of the stain and contrast. Laboratory Director will interpret the H&E stain quality, check the result in appropriate columns and initial it." "Quality Control/Quality Assessment Procedures Prior to reading slides Laboratory Director interprets the H&E stain quality of the control slide, checks the result in appropriate columns on the 'Histopathology Quality Stain Control' form, dates and initials it." 2. Review of two out of three of the laboratory's 2020 patient tissue biopsy reports and the H&E stain QC records did not find any H&E stain QC performed and documented on 07/25/2020 and 10/09/2020 when patient tissue biopsy slide interpretations were performed and reported. 3. The

	Inspector requested the laboratory's H&E stain policy and procedure that included the intended H&E stain reactivity and the 2020 QC records for each day of patient tissue biopsy interpretations from the Laboratory Director and the office staff. The Laboratory Director and the office staff confirmed the laboratory did not include established criteria for the intended stain reactivity of the H&E stain in their policies and procedures and did not perform and document the actual observed H&E staining characteristics each day of patient tissue biopsy slide testing. The interviews occurred on 10/26/2020 at 4:30 PM.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and the office staff, the Laboratory Director failed to ensure that the intended reactivity of the H&E stain quality control (QC) program was maintained to identify the QC failures on 07 /25/2020 and 10/09/2020 prior to patient tissue biopsy slide interpretations. The lack of maintaining a QC program failed to assure the quality of patient tissue biopsy slide interpretations performed in the specialty of Histopathology. All patient tissue biopsy slide interpretations performed on the days when the intended stain reactivity QC was not performed and documented had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to test and document hematoxylin and eosin (H&E) stain quality control (QC) procedures for the intended stain reactivity to ensure predictable staining characteristics each day of use. All patient tissue biopsy slide interpretations performed on the days when the intended stain reactivity QC was not performed and documented had the potential to be affected by this deficient practice. (Refer to D5473)
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and office staff, the Laboratory Director failed to ensure that the quality assessment program was maintained effectively to assure the quality of laboratory services provided and to identify failures in H&E stain quality as they occurred. All patient tissue biopsy slide interpretations had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Policy and Procedures for Histopathology 2018", approved, signed and dated by the Laboratory Director on 06/02/2018, and provided on the date of the inspection, found the following instructions: "Each month reconcile each diagnosis on charts by randomly pulling 5 charts and cross reference with Histopathology Log Book to ensure the information in the Histopathology Log Book matches the information on the patients chart. Using the Monthly Log Book

	/Chart Reconciliation form write what is written for each in the appropriate spaces provided." 2. The Inspector requested the laboratory's 2018, 2019 and 2020 quality assessment documentation from the Laboratory Director and the office staff. The office staff provided worksheets titled "Slide/Parafin Block Quality Control Form". The office staff stated that the patient tissue biopsy cases were pulled, re-interpreted by the testing personnel and documented on the above mentioned form as a double check on the original interpretations. The laboratory failed to provide and the inspector failed to find any other quality assessment documentation that included any type of an ongoing mechanism to monitor, assess and identify errors in the general laboratory, pre-analytic, analytic and post-analytic phases of Histopathology testing. The interviews occurred on 10/26/2020 at 4:35 PM.