Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0684946	04/05/2018
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
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 record review and interviews with the Laboratory Director and Medical Assistant Processor (MAP), the laboratory failed to blindly verify the accuracy of the tissue biopsy interpretation procedures performed at least twice annually. Findings Include: 1. Review of the laboratory's tissue biopsy "Quality Control/Quality Assessment Procedures" policy and procedure, approved, signed and dated by the Laboratory Director on 07/28/2016 and provided on the date of the inspection, revealed instructions to blindly verify the tissue biopsy interpretation procedures with one case every six months. 2. Review of the laboratory's 2016 and 2017 test accuracy verification (TAV) documentation, found only one tissue biopsy interpretation case was sent out in each 2016 (05/21/16) and 2017 (01/06/17) for blind reinterpretation. 3. The Surveyor requested any additional documentation of the laboratory's 2016 and 2017 blind tissue biopsy interpretation TAV activities from the Laboratory Director and MAP. The Laboratory Director and MAP stated there were multiple consultation cases sent out each year and confirmed that the laboratory did not conduct at least two blind TAV activities for the tissue biopsy interpretation procedures performed in 2016 and 2017, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 04/05/2018 at 2:28 PM.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and Medical Assistant Processor (MAP), the laboratory failed to document all evaluations of test accuracy verification (TAV) activities for the tissue biopsy interpretations performed. Findings Include: 1. Review of the laboratory's tissue biopsy "Quality Control/Quality Assessment Procedures" policy and procedure, approved, signed and dated by the Laboratory Director on 07/28/2016 and provided on the date of the inspection, found the following instructions: "...Mark on the Cleveland Skin Pathology Blind Diagnosis Form 'LD name' and Cleveland Skin Pathology's Diagnosis and whether or not they are concurrent." 2. The Surveyor requested the laboratory's 2016 and 2017 evaluation documentation of the laboratory's 2016 and 2017 blind tissue biopsy interpretation TAV activities from the Laboratory Director and MAP. The Laboratory Director and MAP stated both sets of results were reviewed and confirmed that the laboratory did not document the evaluations, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 04/05/2018 at 2:28 PM.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and Medical Assistant Processor (MAP), the laboratory failed to follow their written policies and procedures for test accuracy verification (TAV) activities. Findings Include: 1. Review of the laboratory's tissue biopsy "Quality Control/Quality Assessment Procedures" policy and procedure, approved, signed and dated by the Laboratory Director on 07/28/2016 and provided on the date of the inspection, revealed instructions to blindly verify the tissue biopsy interpretation procedures with one case every six months and to "...Mark on the Cleveland Skin Pathology Blind Diagnosis Form 'LD name' and Cleveland Skin Pathology's Diagnosis and whether or not they are concurrent." 2. The Laboratory Director and MAP confirmed that the laboratory did not follow their written policy and procedure instructing the laboratory to send out one blind tissue biopsy interpretation every six months and to document whether or not they were concurrent, as required. The interviews occurred on 04/05/2018 at 2:28 PM.
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 direct observation, record review, and interviews with the Laboratory Director and Medical Assistant Processor (MAP), the laboratory failed to establish and document a maintenance protocol that ensured microscope performance which was necessary for accurate and reliable Histopathology test results and test result reporting. Findings Include: 1. Direct observation of the histopathology laboratory on the date of the inspection revealed a microscope utilized for histopathology tissue biopsy slide and stain quality interpretations. 2. Review of the laboratory's policies and procedures did not find any mention of daily/as needed microscope maintenance procedures. 3. The Surveyor requested the laboratory's microscope maintenance policy and procedure and 2016, 2017, and 2018 daily/as needed microscope maintenance documentation from the Laboratory Director and MAP. The Laboratory Director and MAP stated that the laboratory cleans the microscope as necessary, would call for service if needed and confirmed the laboratory had not established a microscope maintenance policy and procedure, had not documented internal daily/as needed microscope maintenance activities in 2016, 2017, and 2018, and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 04/05/2018 at 2:30 PM.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and Medical Assistant Processor (MAP), the laboratory failed to identity the testing personnel (TP) who performed the patient tissue biopsy interpretation and the intended hematoxylin and eosin (H & E) stain reactivity quality control (QC) procedures. Findings Include: 1. Review of 12 out of 12 of the laboratory's 2016, 2017 and 2018 patient tissue biopsy test records (the log book) and test reports (5X7 index cards), provided on the date of the inspection, did not find any indication of the TP who performed the tissue biopsy interpretation procedures. 2. Review of the laboratory's 2016, 2017 and 2018 "Histopathology Quality Stain Control Form" found 42 out of 71 days of documented QC of which was not initialed by a listed and qualified TP, however by the individual transcribing the verbal dictation from the TP. 3. Review of two out of two of the "Cleveland Skin Pathology Laboratory, Inc. Consultation Report" did not find indication of the TP who provided the interpretation of the tissue slide biopsy. 4. The Surveyor requested the laboratory's documentation indicating the TP who performed the tissue biopsy interpretation procedures whether conducted in this laboratory or another laboratory and the stain QC from the Laboratory Director and MAP. The Laboratory Director and MAP confirmed the laboratory did not consistently document the TP who performed the patient tissue biopsy interpretation and QC procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/05/2018 at 1:45 PM.

D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and Medical Assistant Processor (MAP), the laboratory failed to have an adequate manual system in place to ensure the tissue biopsy gross measurements, tissue description, tissue interpretation and other patient specific information were accurately and reliably documented on the final test report. Findings Include: 1. Review of 12 out of 12 of the laboratory's patient tissue biopsy final test reports, provided on the date of the inspection, found them to be hand written on 5X7 index cards and did not find any documentation to include tissue biopsy gross measurements and tissue descriptions, as performed by the technical component laboratory, tissue biopsy interpretations were reported in abbreviations with no legend of definitions, specimen source, if documented, were unreadable, and result report dates were not documented on seven out of 12 reports reviewed. 2. Further review of the laboratory's 2017 and 2018 test records (log book) and final test reports (5X7 index cards) revealed the results as listed below: Date of Log Book/Final Test Service Report Result 08/10/17 1)SCC, 2) SCC, 3)SCC no report date 08/11/17 AK no report date 09/14/17 1)cyst, 2)AK, 3)AK no report date 09/14/17 1)Seborrheic keratosis/SK, 2)fibroma no report date 10/24/17 1)angioma, 2)intra nevus no report date 10/30/17 cyst no report date 03/13/18 1)SK, 2) SK no report date 3. The Laboratory Director stated that the grossing and processing laboratory did not provide the tissue gross measurements and tissue descriptions and the laboratory did not question the lack of the grossing results. The Laboratory Director and MAP confirmed the above mentioned results were missing from the final test reports, the tissue biopsy diagnoses were documented in abbreviations with no legend of definitions, the Laboratory Director/testing personnel's hand writing was unreadable and the report dates were not consistently indicated on the test reports. The interviews occurred on 04/05/2018 at 2:45 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 interviews with the Laboratory Director and Medical Assistant Processor (MAP), the laboratory failed to indicate the name and address of the laboratory location where the test was performed, the test report date, the test performed, the specimen source, and the test result and interpretation on the final test report. Findings Include: 1. Review of 12 out of 12 of the laboratory's 2016, 2017 and 2018 patient tissue biopsy final test reports, provided on the date of the inspection revealed the following missing components: a. name and address -12 out of 12 did not find the name and address of the grossing (technical component) laboratory -six out of 12 did not find the name and address of the interpreting (professional component) laboratory -four out of four did not find the name and address of the consulting laboratory b. test report date seven out of 12 did not indicate the report date as follows: -08/10/17 no report date -08/11/17 no report date -09/14/17 no report date -09 /14/17 no report date -10/24/17 no report date -10/30/17 no report date -03/13/18 no report date c. test performed 12 out of 12 did not indicate the test "biopsy" was performed d. specimen source 12 out of 12 test reports did not clearly indicate the specimen source for 21 out of 21 tissue biopsies taken. The hand written reports were unreadable. e. test result and interpretation 12 out of 12 test reports did not include the gross tissue measurements and tissue description (technical component) five out of 12 test reports did not indicate the test result and interpretation for the abbreviations -08 /10/17 1)SCC, 2)SCC, 3)SCC -08/11/17 AK -09/14/17 1)cyst, 2)AK, 3)AK -09/14/17 1)Seborrheic keratosis/SK -3/13/18 1)SK, 2)SK 2. The Laboratory Director and MAP confirmed the laboratory did not include the above mentioned components on the final test reports as required. The interviews occurred on 04/05/2018 at 2:45 PM.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interviews with the Laboratory Director and Medical Assistant Processor (MAP), the Laboratory Director failed to provide overall management and direction in the high complexity Histopathology laboratory. Findings Include: 1. The Laboratory Director failed to ensure all test accuracy verification (TAV) activities for the tissue biopsy interpretations were reviewed, evaluated and documented by the appropriate staff to evaluate acceptability and to identify any discrepancies that required corrective action. (Refer to D6091) 2. The Laboratory Director failed to ensure that a quality assessment program was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred. (Refer to D6094) 3. The Laboratory Director failed to ensure the tissue biopsy test reports included pertinent information which was required for interpretation of the results. (Refer to D6098)
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

	This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and Medical Assistant Processor (MAP), the Laboratory Director failed to ensure all test accuracy verification (TAV) activities for the tissue biopsy interpretations were reviewed, evaluated and documented by the appropriate staff to evaluate acceptability and to identify any discrepancies that required corrective action. Findings Include: 1. The the laboratory failed to document all evaluations of test accuracy verification (TAV) activities for the tissue biopsy interpretations performed. (Refer to D5221)
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 an interview with the Medical Assistant Processor (MAP), the Laboratory Director failed to ensure that a quality assessment program was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred. Findings Include: 1. Review of the laboratory's "Policy and Procedures for Histopathology 2016" policy and procedure, approved, signed and dated by the Laboratory Director on 07/28/16 found the follow 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." 2. Review of the laboratory's 2016, 2017 and 2018 quality assessment documentation revealed that the laboratory's quality assessment procedures were not effectively identifying failures in quality according to the regulations. 3. The MAP confirmed the laboratory's quality assessment process did not effectively identify the failures in quality across the whole testing process according to the CLIA regulations. The interview occurred on 04/25/2017 at 11:26 AM.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and an interview with the Medical Assistant Processor (MAP), the Laboratory Director failed to ensure the tissue biopsy test reports included pertinent information which was required for interpretation of the results. Findings Include: 1. The laboratory failed to have an adequate manual system in place to ensure the tissue biopsy gross measurements, tissue description, tissue interpretation and other patient specific information were accurately and reliably documented on the final test report. (Refer to D5801) 2. The laboratory failed to indicate the name and

	address of the laboratory location where the test was performed, the test report date, the test performed, the specimen source, and the test result and interpretation on the final test report. (Refer to D5805)