Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2089854	03/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northshore Dermatology Center	925 Sherwood Dr, Lake Bluff, IL	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and an interview with the testing personnel (TP1); the laboratory failed to establish and follow written procedures that meet the requirement to assess employees performing grossing and tissue processing for Histopathology, affecting 1 out of 1 testing personnel (TP). Findings include: 1. The procedures manual and personnel records were reviewed. 2. The laboratory failed to have a written competency procedure that includes the following requirements: *If applicable, the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; *The direct observation of performance of instrument maintenance and function checks. *The assessment of problem solving skills. 3. The personnel records revealed that the laboratory failed to train and evaluate the competency of TP1, prior to processing patients specimens. 4. TP1 confirmed the findings on 03/14/2019 at 2:30 PM and stated that they were unaware the laboratory had a competency procedure.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and

	rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP1); the laboratory failed to establish written policies and procedures for specimen submission, handling, and referral, prior to receiving patient specimens for Histopathology. Findings include: 1. The laboratory procedures manual was reviewed. 2. The manual failed to included the following written policies and procedures: * Patient preparation. * Specimen collection. * Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. * Specimen storage and preservation. * Conditions for specimen transportation. * Specimen processing. * Specimen acceptability and rejection. * Specimen referral. 3. Further review of the "General Laboratory Policies and Procedures Manual" revealed it was not written or signed by the laboratory director (LD); the LDs name was hand written on the signature page by the TP1. 4. On 03/14/2019 at 1:30 PM, the TP1 confirmed the manual given to them was from the previous laboratory and not signed by the new laboratory director, and did not reflect the actual specimen processing procedure that is performed currently in the laboratory.
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, the lack of documentation, and an interview with the testing personnel (TP1); the laboratory failed to follow written quality control procedures for the Hematoxylin and Eosin (H&E) staining procedure performed. Findings include: 1. The laboratory procedures manual was reviewed. 2. Both the Pathologist and histotechnologist are required to document the daily evaluation (or check) of the routine H&E stained slides. 3. Documents revealed H&E slides were produced on the following dates: 2/05/2019, 2/11/2019, 2/14/2019, 2/21/2019, 2/27/2019, 2/28/2019, 3 /07/2019, and 3/13/2019. 4. Further, review revealed no documentation of H&E stain quality checks performed on the above dates. 5. TP1 stated during the interview on 03 /14/2019 at 2:30 PM that they were unaware of the quality control check procedure and created their own quality control procedure.
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 the testing personnel (TP1); the laboratory failed to ensure test reports indicate the name of the laboratory where the test was performed. Findings include: 1. The requisitions and final reports of slides sent to a reference laboratory were reviewed. 2. The requisitions reviewed were from the following dates: 2/05-06/2019; 2/08-09/2019; and 2/19-21/2019; which totaled 24 patients. 3. The patients' slides from the above dates were sent to the reference laboratory for interpretation. 4. The final reports from the reference laboratory for 24 out of 24 patients failed to state the correct name of the laboratory that submitted the slides. 5. TP1 confirmed the findings on 03/14/2019 at 2:15 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 review of laboratory records and an interview with the testing personnel (TP1). 1. The laboratory director (LD) failed to be accessible to provide onsite consultation when needed (See D6080). 2. Failed to establish quality assurance (QA) programs for the laboratory's processes and procedures (See D6094). 3. Failed to ensure laboratory personnel was trained and competent, prior to testing patients (See D6102). 4. Failed to have an approved standard operating procedure manual available to all personnel (See D6106).
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on direct observation, record review and an interview with the testing personnel (TP1); the laboratory director (LD) failed to be accessible to provide onsite telephone or electronic consultation as needed affecting 1 out of 1 TP. Findings: 1. The laboratory manual, maintenance logs, quality control (QC) record, and personnel documents were reviewed. 2. The laboratory begin tissue processing for Histopathology on 02/01/2019. 3. Review of the procedures manual revealed the LD failed to establish written policies and procedures for all aspects of the testing process. Refer to D6106 and D6094. 4. The LD failed to be available to perform quality control checks on H&E stained slides prior to shipping to reference laboratory. 5. During the laboratory walkthrough on 03/14/2019, the surveyor observed maintenance logs for the following equipment: Refrigerator, Freezer, Reagents, Microtome, Tissue-Tek, and embedding station. Further review of the logs revealed the LD failed to review and monitor these instruments which are used in the grossing, and production of tissue slides. 6. Documents showed the LD failed to train and evaluate the competency of TP1, prior to grossing and producing tissue slides. 7. During survey

	date 03/14/2019 at 2:15 PM, the surveyor's findings were confirmed by TP1, who also stated that they had not heard from the LD since they were hired as testing personnel on 02/01/2019.
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 testing personnel (TP1); the laboratory director (LD) failed to establish quality assurance (QA) programs for the laboratory. Findings include: 1. The laboratory's standard operating procedures manual was reviewed. 2. The LD failed to establish an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions for the following phases of the testing process: *Preanalytic - assessing practices/issues related to test requests, specimen submission, handling and referral. *Analytic - assessing:practices/issues related to test procedures; accurate and reliable test systems; equipment, instruments; reagents; materials; and supplies; specimen and reagent storage condition; equipment/instrument/test/system maintenance and function checks; control procedures; comparison of test results; corrective actions; and test records. *Post-analytic -assessing practices/issues related to test reports. 3. TP1 confirmed the findings on 03/14/2019 at 2:15 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, the lack of documentation, and an interview with the testing personnel (TP1), the laboratory director (LD) failed to ensure prior to testing patients' specimens, all personnel have the appropriate training and have demonstrated that they can perform all testing operations reliably to provide and report accurate results, affecting 1 out of 1 testing personnel (TP). Findings include: 1. The laboratory personnel documents were reviewed. 2. The LD failed to train and evaluate the competency of TP1 for grossing, tissue processing and staining, prior to processing patients specimens. 3. During survey date 03/14/2019 at 2:45 PM, the surveyor's findings were confirmed by the TP1, who also stated that they had not seen the LD since they were hired as personnel.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to

	all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review, and an interview with the testing personnel (TP1), the laboratory director (LD) failed to ensure that an approved procedure manual is available to the personnel responsible for any aspect of the Histopathology testing process, affecting 1 out of 1 TP. Findings: 1. The laboratory's standard operating procedures manual was reviewed. 2. The LD failed to establish and make available the following procedures to TP1: *Specimen submission, handling and referral procedures, *Hematoxylin and Eosin (H&E) quality control procedures, and *quality assurance procedures for preanalytic, analytic, and postanalytic phases of the tests. 3. Further review revealed the laboratory is using another laboratory director's procedure manual. The LD failed to review the policies and procedures of the above manual to verify it's appropriateness to the current laboratory. 4. During survey date 03/14/2019 at 2:30 PM, the TP1 confirmed the above findings and stated that many of the procedures in the manual does not reflect the procedures and processes performed in the laboratory.