

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2089854	(X3) Date Survey Completed 07/27/2018
Name of Provider or Supplier Northshore Dermatology Center	Street Address, City, State 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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's procedures manual, direct observation, and an interview with the testing personnel (TP) and the technical supervisor (TS), the laboratory failed to establish, when maintenance and function check protocols are not provided by the manufacturer, a maintenance protocol that ensures equipment, instrument, and test system performances are accurate and reliable. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. Findings: 1. On 07/27/2018 at 11:30 AM during a tour of the laboratory, the surveyor observed the following equipment, instruments, and test systems in the laboratory: 1). An Incubator, embedding station, and refrigerator; 2). A Biological hood used for tissue staining; 3). Microscope 2. The procedures manual does not include a maintenance and/or function check policy and procedure for the following equipment, instruments, and test systems: 2). Calibration of Thermometers used in incubators, water baths (embedding station), and refrigerator; and 4). Filter changes for the Biological hood used for tissue staining. 5). Preventative maintenance and service for microscope. 3. No documentation was provided as evidence that the maintenance and function checks listed in "Findings #2" were ever performed in the laboratory. 4. On a Validation survey conducted on 07/27 /2018 at 1:30 PM, the TP and technical supervisor (TS) confirmed the above findings.</p>

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's policies, procedures and records, and an interview with the technical supervisor (TS), the TS failed to evaluate and document the performance of individuals performing Histopathology testing at least annually, affecting 2 out of 2 testing personnel (TP). Findings: 1. The CMS 209 lists 2 laboratory employees, TP-KL3 (listed on line 2) and TP-M6B (listed on line 3) performing Histopathology grossing in the laboratory. 2. The personnel records presented revealed the following: a). The last documented competency for TP-M6B was performed on 03/14/2016, and b). No competency assessments were performed for TP-KL3 during the years of 2016 through 2018. 3. The laboratory's competency policy states that laboratory personnel are to be evaluated annually for competency. 4. On a Validation survey conducted on 07/27/2018 at 1:30 PM, the TS confirmed the above findings.

D6141

GENERAL SUPERVISOR

CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:

Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), employee files, and an interview with the laboratory staff, the laboratory director (LD) failed to employ individuals who meet the qualification requirements of 493.1461 for general supervisor (GS). Finding: 1. The laboratory failed to ensure laboratory personnel meet the qualification requirements for GS, who provide day-to-day supervision of testing personnel and reporting of test results in an high complexity laboratory. See D6143.

D6143

GENERAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical

technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), employee files, and an interview with the laboratory staff, the laboratory director (LD) failed to employ individuals who meet the qualification requirements of 493.1461 for general supervisor (GS). Finding: 1. Review of the employees' files and the CMS 209 revealed the following: a). The CMS 209 reports 1 GS (listed on line 2) in the laboratory; b). The GS received a Bachelor's of Arts degree in Philosophy in 2011, and has a transcript that shows the completion of 4 credit hours of Environmental Biology, 4 credit hours Contemporary Chemistry and 3 credit hours in Oceanography in November of 2014. c). No other documentation was provided to show that the employee had met the GS education requirement prior to supervising the laboratory.

2. No documentation was provided as evidence the GS position had been delegated to any other qualified personnel in the laboratory. 3. On a Validation survey conducted on 07/27/2018 at 1:30 PM, the TP and technical supervisor (TS) confirmed the above findings.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's personnel files, records, and an interview with the laboratory staff, the laboratory director (LD) failed to ensure the laboratory has individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the highly complex tests performed for Histopathology. Findings: 1. The laboratory failed to ensure laboratory staff meet the education criteria specified in 493.1489(b) (1). See D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high

school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), employee files, test records, and an interview with the laboratory staff, the laboratory failed to ensure laboratory employees meet the qualification requirements for performing highly complex testing in the specialty of Histopathology. Findings: 1. The CMS 209 list 2 testing personnel (TP) performing tissue grossing in the laboratory. 2. The education credentials of the 2 laboratory employees revealed that 2 out of 2 does not meet the education requirement as defined 493.1489(b) (1) - (7) due to the following: a). TP-KL3 (listed on line 2) has received a Bachelor's of Arts degree in Philosophy in 2011, and a transcript that shows the completion of 4 credit hours of Environmental Biology, 4 credit hours Contemporary Chemistry and 3 credit hours in Oceanography in November of 2014; and b). TP-M6B (listed on 3) has 31 continuing education credit hours through the American Society for Clinical Pathology (non-ASCP) and received a Bachelors of Liberal Arts and Sciences with a major in Communication. The transcript provided shows that the curriculum fulfilled by TP-M6B for this degree does not include the requirement of, "At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination. 3. The competencies and test records reviewed showed that TP-M6B and TP-KL3 are tissue grossing in the laboratory. 4. On a Validation survey conducted on 07/27/2018 at 1:30 PM, the TP and technical supervisor (TS) confirmed the above findings.