

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2081489	<b>(X3) Date Survey Completed</b>  01/07/2026
<b>Name of Provider or Supplier</b>  North Branch Dermatology Llc	<b>Street Address, City, State</b>  7411 N Milwaukee Ave, Niles, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was completed on 01/07/2026. Deficiencies were found resulting in the following condition level deficiencies: D5200 493.1230 Condition: General laboratory systems. D5400 493.1250 Condition: Analytic systems. D6076 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. D6108 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor D6168 493.1487 Condition: Laboratories performing high complexity testing
<b>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, the lack of documentation, and interview with the laboratory representative (LR); the laboratory failed to follow written policies and procedures to assess competency for three of three testing personnel (TP) performing microscopic potassium hydroxide (KOH) wet mount testing, microscopic scabies wet mount testing in the specialty of microbiology and Mohs histopathological testing in the subspecialty of histopathology from 2024 through the date of survey, 01/07/2026 (See D5209). The laboratory also failed to follow written policies and procedures to address bi-annual method accuracy evaluations of Mohs micrographic surgery (See D5217-A) and KOH preparations (See D5217-B) from 2024 through the date of survey, 01/07/2026. Likewise, the laboratory failed to follow written policies and procedures to address bi-annual method accuracy evaluations of scabies wet</p>

preparations from 2024 through the date of survey, 01/07/2026 (See D5219). To conclude, the laboratory failed to establish procedures and conduct QA assessments of laboratory testing for microscopic KOH wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology from the beginning of testing to the date of survey 01/07/2026 (See D5291). Repeat Deficiency from previous survey, 09/10/2024.

**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 review of the laboratory's policies and procedures, laboratory records and interview with the laboratory representative (LR); the laboratory failed to follow written policies and procedures to assess competency for three of three testing personnel (TP) performing microscopic potassium hydroxide (KOH) wet mount testing, microscopic scabies wet mount testing in the specialty of microbiology and Mohs histopathological testing in the subspecialty of histopathology from 2024 through the date of survey, 01/07/2026. Findings include: 1. Review of laboratory policies and procedures revealed a document titled "Personnel Competency/ Proficiency Testing Instructions" which stated, "The competency assessment will evaluate the employee's compliance with all policy and procedure within the scope of routine job duties and will include the following methods of assessment. a.) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing b.) Monitoring the recording and reporting of test results c.) Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records d.) Direct observations of performance of instruments maintenance and function checks e.) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f.) Assessment of problem-solving skills" "Competency evaluations: [ ...] the lab director will perform an evaluation of the 6 above required competency elements twice in the first year for each testing personnel both for KOH/scabies) (aka PPM) and for the MOHS technicians performing the grossing aspect of testing) and then annually thereafter". 2. Review of laboratory records found 16 instances where the laboratory failed to assess all six elements of competency or perform competency evaluations for three of five TP who perform KOH, scabies, or Mohs testing from 2024 through to the day of survey, 01/07/2026. TP: Date: Test: A 09/24/2024 S\* A 11/03/2024 K\*\* A not performed M\*\*\* A 01/06/2025 S A 02/03/2025 K A 03/11/2025 M A 10/28/2025 M A 11/11/2025 M A 12/09/2025 M 1 10/28/2024 K 1 11/14/2024 S 1 07/08/2025 K 1 not performed S 2 11/14/2024 S 2 01/07/2025 K 2 06/05/2025 K S\* = Scabies K\*\* = KOH M\*\*\* = Mohs micrographic surgery 3. Interview with LR on date of survey, 01/07/2026 at 10:47 pm confirmed the laboratory failed to follow written policies and procedures to assess competency for three of three TP performing microscopic KOH wet mount testing, microscopic scabies wet mount testing in the specialty of microbiology and Mohs histopathological testing in the subspecialty of histopathology from 2024 through the date of survey, 01/07/2026.

**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:

A. Based on review of the laboratory's policies and procedures, laboratory records and interview with the laboratory representative (LR); the laboratory failed to follow written policies and procedures to address bi-annual method accuracy evaluations of Mohs micrographic surgery from 2024 through the date of survey, 01/07/2026.

Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the policy titled, "Quality Assurance/ Quality Control" which states, "- Semiannually, the Mohs surgeon will review randomly selected Mohs cases with a board certified dermatopathologist for correlation of histologic diagnoses. - A written record of this program shall be maintained for at least 4 years. Any discrepancies of opinion between the doctors shall be noted and discussed fully." 2. Review of laboratory records found the laboratory lacked documentation of bi-annual method accuracy evaluations for Mohs dermatopathology testing. 3. Interview with LR on date of survey, 01/07/2026 at 12:41 pm confirmed the laboratory failed to follow written policies and procedures to address bi-annual method accuracy evaluations of histopathology testing in 2024 through the date of survey, 01/07/2026

B. Based on review of the laboratory's policies and procedures, laboratory records and interview with the laboratory representative (LR); the laboratory failed to follow written policies and procedures to address bi-annual method accuracy evaluations of potassium hydroxide (KOH) preparations from 2024 through the date of survey, 01/07/2026.

Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the policy titled, "Personnel Competency/ Proficiency Testing Instructions" which stated, "3). Proficiency testing: (aka biannual method accuracy/verification), 'blind' specimens will be tested twice annually for the facility. This process can be incorporated into competency requirements. b). For PPM (both KOH and scabies), have 2 of the providers go behind the other to verify results and document this. Or provide images to the PPM providers to identify presence/ absence of fungal elements or scabies parasites". 2. Review of laboratory records found the laboratory lacked documentation of biannual method accuracy evaluations for KOH testing. 3. Interview with LR on date of survey, 01/07/2026 at 10:47 am confirmed the laboratory failed follow written policies and procedures to address bi-annual method accuracy evaluations of KOH preparations from 2024 through the date of survey, 01/07/2026.

**D5219**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(2)

(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, laboratory records and interview with the laboratory representative (LR); the laboratory failed to follow written policies and procedures to address bi-annual method accuracy evaluations of scabies wet preparations from 2024 through the date of survey, 01/07/2026. Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the

policy titled, "Personnel Competency/ Proficiency Testing Instructions" which states, "3). Proficiency testing: (aka biannual method accuracy/verification), 'blind' specimens will be tested twice annually for the facility. This process can be incorporated into competency requirements. b). For PPM (both KOH and scabies), have 2 of the providers go behind the other to verify results and document this. Or provide images to the PPM providers to identify presence/ absence of fungal elements or scabies parasites". 2. Review of laboratory records found the laboratory lacked documentation of biannual method accuracy evaluations for scabies wet preparation testing. 3. Interview with LR on date of survey, 01/07/2026 at 10:47 am confirmed the laboratory failed to follow written policies and procedures to address bi-annual method accuracy evaluations of scabies wet preparations from 2024 through the date of survey, 01/07/2026.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
Based on surveyor review of laboratory quality assurance (QA) guidelines, laboratory QA records and interview with the laboratory representative; the laboratory failed to establish procedures and conduct QA assessments of laboratory testing for microscopic potassium hydroxide (KOH) wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology from the beginning of testing to the date of survey 01/07/2026. Findings include: 1. Review of laboratory records revealed the laboratory failed to establish and document quality assurance checks from the beginning of testing through the date of survey 01/07/2026 for KOH wet mounts and microscopic scabies examinations. 2. Interview with the LR on the date of survey 01/07/2026, at 10:45 am, confirmed the laboratory failed to establish and conduct QA assessments of laboratory testing for microscopic KOH wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology from the beginning of testing to the date of survey 01/07/2026.

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on review of the laboratory Policies and procedures, quality control (QC) records, and interview with laboratory representative (LR); the laboratory failed to establish procedures for two of three tests performed, microscopic potassium hydroxide (KOH) wet mount testing and microscopic scabies wet mount testing in the

specialty of microbiology from the start of testing through the day of survey 01/07/2026 (See D5401). The laboratory similarly failed to outline all required components of testing procedure for Mohs micrographic surgery post-surgical specimen mapping in the subspecialty of histopathology (See D5403). The laboratory also failed to document temperature and preventative maintenance for the Leica Cryostat CM1510-3 (serial #: 043631517) used for Mohs histopathology testing on five of eight testing dates reviewed from 2024 through the date of survey, 01/07/2026, affecting five patients reviewed (See D5433). Lastly, the laboratory failed to have an alternative control procedure in place for microscopic KOH wet mount testing in the subspecialty of mycology and microscopic scabies wet mount testing in the subspecialty of parasitology for a total of 94 KOH and 12 scabies examinations during January of 2025 through January of 2026 and three of three patients reviewed (See D5485).

**D5401**

PROCEDURE MANUAL  
CFR(s): 493.1251(a)

(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 review of laboratory policies and procedures, lack of documentation, and interview with the laboratory representative (LR); the laboratory failed to establish procedures for two of three tests performed, microscopic potassium hydroxide (KOH) wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology from the start of testing through the day of survey 01/07/2026. Findings include: 1. Review of laboratory policies and procedures found the laboratory lacked procedures for: a. microscopic KOH wet mount testing in the subspecialty of mycology, b. microscopic scabies wet mount testing in the subspecialty of parasitology. 2. Interview with the LR on 01/07/2026, at 10:43 am, confirmed the laboratory failed to establish procedures for two of three tests performed, microscopic KOH wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology from the start of testing through the day of survey 01/07/2026.

**D5403**

PROCEDURE MANUAL  
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references.

(b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records and interview with the laboratory representative (LR); the laboratory failed to outline all required components of testing procedure for specimen mapping post Mohs micrographic surgery in the subspecialty of histopathology. Findings include: 1. Review of the laboratory policies and procedures revealed the procedure titled, "The Mohs Procedure" which states, "-Tissue is dyed, and a map is drawn so that the tumor found can be located on the patient. - A detailed map is made to correlate with the tissue removed." 2. Review of the policy and procedure manual found the laboratory failed to outline required components of a test procedure for Mohs micrographic surgery in the subspecialty of histopathology: a. Step-by-step performance of the procedure for Mohs mapping. 3. Interview with the LR on 01/07/2026, at 10:47 am, confirmed the laboratory failed to outline the above listed required components of testing procedure for Mohs micrographic surgery post-surgical specimen mapping in the subspecialty of histopathology.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, direct observation, manufacturer's instructions, laboratory records, lack of documentation, and interview with the laboratory representative (LR); the laboratory failed to follow manufacturer's instructions for maintenance for one of one Leica Cryostat CM1510-3 (serial #: 043631517) used for Mohs histopathology testing. Findings include: 1. Upon direct observation during a tour of the laboratory on the date of survey, 01/07/2026, at 08:09 am, surveyors observed Leica Cryostat CM1510-3 utilized for Mohs histopathology testing. 2. Review of manufacturer's instructions for the Leica Cryostat CM1510-3 identified section "11.1 General Maintenance" which stated, "To ensure reliable and trouble-free operation over several years, we recommend the following: - Have the instrument inspected by a qualified service engineer authorized by Leica at least once a year; - Enter into a service contract after the warranty period; for further details, please contact your Leica sales office. - Clean the instrument every day". 3. Review of laboratory records found a document titled, "Cryostat Quality Control" which stated, "Cryostat /microtome maintenance record every day that the cryostat is used". 4. Review of the laboratory's preventative maintenance log sheet "Cryostat Quality Control" for the Leica Cryostat CM1510-3 found for "Preventative Maintenance", "Clean air filters", and "Defrost machine" as not applicable (N/A) for 12 of 12 days recorded. Date of use: 02/18/2025 03/04/2025 04/08/2025 04/15/2025 05/20/2025 06/03/2025 07/12/2025 08/19/2025 09/05/2025 10/19/2025 11/20/2025 12/22/2025 5. Review of laboratory records for the Leica Cryostat CMS1510-3 found no documented annual maintenance by a qualified service engineer. 6. Interview with LR on date of survey, 01/07/2026, at 11:45 am, confirmed the laboratory failed to follow

manufacturer's instructions for maintenance for one of one Leica Cryostat CM1510-3 used for Mohs histopathology testing.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(1)

(b)(1)(i) 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. (b)(1)(ii) 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 review of laboratory policies and procedures, direct observation, preventative maintenance records, lack of documentation, and interview with the laboratory representative (LR); the laboratory failed to document temperature for the Leica Cryostat CM1510-3 (serial #: 043631517) used for Mohs histopathology testing on five of eight testing dates reviewed from 2024 through the date of survey, 01/07/2026, affecting five patients reviewed. Findings include: 1. Upon direct observation during a tour of the laboratory on the date of survey, 01/07/2026, at 08:09 am, surveyors observed Leica Cryostat CM1510-3 utilized for Mohs histopathology testing was turned off and at room temperature. 2. Review of laboratory policies and procedures revealed the procedure titled, "Quality Assurance/ Quality Control", which stated, "The temperature of cryostat is checked daily and recorded. The temperature range to be -20 to -25 Celsius." 3. Review of laboratory preventative maintenance logs for "Cryostat Quality Control" revealed the laboratory lacked documentation of the cryostat temperature for five of eight dates of patient testing dates reviewed. Date of use: 04/08/2025 09/02/2025 11/18/2025 12/16/2025 01/06/2026 4. Review of Mohs micrographic surgery patients reports revealed five patients were reported when cryostat temperatures were not recorded: Date of Testing: Patient ID/Case: 04/08/2025 1406/25-039 09/02/2025 11667/25-108 11/18/2025 12831/25-163 12/16/2025 13190/25-186 01/06/2026 13363/26-02 5. Interview with LR on date of survey, 01/07/2026, at 11:45 am, confirmed the laboratory failed to document temperature and preventative maintenance for Leica Cryostat CM1510-3 (serial #: 043631517) used for Mohs histopathology testing on five of eight testing dates reviewed from 2024 through the date of survey, 01/07/2026, affecting five patients reviewed.

**D5485**

**CONTROL PROCEDURES**

CFR(s): 493.1256(h)

(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. (a) The laboratory must check the following for positive and negative reactivity using control organisms:

This STANDARD is not met as evidenced by:

Based on review of the laboratory policies and procedures, laboratory records, quality control (QC) records, test volume records, random sampling of patient results and interview with the laboratory representative (LR); the laboratory failed to have an alternative control procedure in place for microscopic potassium hydroxide (KOH) wet mount testing in the subspecialty of mycology and microscopic scabies wet mount

testing in the subspecialty of parasitology for three of three patient testing dates reviewed, affecting a total of 94 KOH and 12 scabies examinations during January of 2025 through January of 2026. Findings include: 1. Review of laboratory procedures revealed a lack of KOH and scabies testing procedures, including defined alternative control procedures (See D5401). 2. Review of laboratory policies and procedures revealed the document titled, "Quality Assurance/Quality Control" which states, "Quality control logs are to be completed daily." 3. Review of three of three patient test results for KOH and scabies wet mount testing found no documented alternative controls. Date: Patient Identification: Test: 02/25/2025 11616 scabies 05/02/2025 10882 KOH 07/08/2025 4583 KOH 4. Review of test volume records from January of 2025 through January of 2026 found the laboratory performed 94 KOH wet mount and 12 scabies wet mount examinations. 5. Interview with the LR on 01/07/2026, at 10:45 am, confirmed the laboratory failed to have an alternative control procedure in place for microscopic potassium hydroxide (KOH) wet mount testing in the subspecialty of mycology and microscopic scabies wet mount testing in the subspecialty of parasitology for three of three patients reviewed, affecting 94 KOH and 12 scabies examinations during January of 2025 through January of 2026.

**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 policies and procedures, preventative maintenance records, quality control (QC) records, laboratory quality assurance (QA) guidelines, laboratory QA records, random sampling of patient results, Laboratory Personnel Report (CMS-209), laboratory personnel records, lack of documentation, and interview with the laboratory representative (LR); the laboratory director (LD) failed to ensure the laboratory established procedures and conduct QA assessments of laboratory testing for microscopic potassium hydroxide (KOH) wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology from the beginning of testing to the date of survey 01/07/2026 (See D6093). Secondly, the LD failed to ensure the laboratory confirmed one of two testing personnel (TP) was qualified for high complexity grossing of tissue for Mohs micrographic surgery (See D6102). Tertiary, the LD failed to ensure the laboratory has established procedures for two of three tests performed, microscopic KOH wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology (See D6106) and failed to ensure the laboratory had alternative control procedure in place for KOH wet mount testing and microscopic scabies wet mount testing for a total of 94 KOH and 12 scabies examinations during January of 2025 through January of 2026 and three of three patients reviewed (See D6106). Additionally, the LD failed to ensure the laboratory followed written policies and procedures to assess competency for three of three TP performing KOH wet mount testing and microscopic scabies wet mount testing and Mohs histopathological testing from 2024 through the date of survey (See D6103). To conclude, the LD failed to ensure the laboratory followed written policies and procedures to address bi-annual method accuracy evaluations of KOH preparations, Mohs micrographic surgery, and scabies wet preparations from 2024 through the date of survey, 01/07/2026 (See D6103).

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and 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 review of laboratory policies and procedures, laboratory records, lack of documentation, and interview the laboratory representative (LR); the laboratory director (LD) failed to ensure the laboratory had an alternative control procedure in place for microscopic KOH wet mount testing in the subspecialty of mycology and microscopic scabies wet mount testing in the subspecialty of parasitology for a total of 94 KOH and 12 scabies examinations during January of 2025 through January of 2026 and three of three patients reviewed (See D5485). The LD also failed to ensure the laboratory established procedures and conduct quality assurance assessments of laboratory testing for microscopic potassium hydroxide (KOH) wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology from the beginning of testing to the date of survey 01/07/2026 (See D5291).

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

(e)(12) 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 review of the Laboratory Personnel Report (CMS-209), laboratory personnel records and interview with laboratory representative (LR); the laboratory director (LD) failed to ensure the laboratory confirmed one of two testing personnel (TP) was qualified for high complexity grossing of tissue for Mohs micrographic surgery (See D6171).

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation, and interview with laboratory representative (LR); the laboratory director (LD) failed to ensure the laboratory followed written policies and procedures to assess competency for three of three testing personnel (TP) performing microscopic potassium hydroxide (KOH) wet

	<p>mount testing, microscopic scabies wet mount testing in the specialty of microbiology and Mohs histopathological testing in the subspecialty of histopathology from 2024 through the date of survey, 01/07/2026 (See D5209). The LD also failed to ensure the laboratory followed written policies and procedures to address bi-annual method accuracy evaluations of KOH preparations (See D5217-A) and Mohs micrographic surgery (See D5217-B) from 2024 through the date of survey, 01/07/2026. Likewise, the laboratory failed to follow written policies and procedures to address bi-annual method accuracy evaluations of scabies wet preparations from 2024 through the date of survey, 01/07/2026 (See D5219).</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation, and interview with the laboratory representative; the laboratory director (LD) failed to ensure the laboratory has established procedures for two of three tests performed, microscopic potassium hydroxide (KOH) wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology from the start of testing through the day of survey 01/07/2026 (See D5401).</p>
<p><b>D6108</b></p>	<p><b>LABORATORY TECHNICAL SUPERVISOR</b> CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation and interviews with the laboratory representative (LR); the technical supervisor (TS) failed to ensure annual competency assessments were completed for one of two testing personnel (TP) performing microscopic scabies wet preparations in the subspecialty of parasitology (See D6127-A). The TS also failed to ensure annual competency assessment covered all elements of competency for three of three testing personnel performing microscopic potassium hydroxide (KOH) wet mount testing in the subspecialty of mycology, microscopic scabies wet mount testing in the subspecialty of parasitology, and Mohs histopathological testing in the subspecialty of histopathology testing in 2024 through the date of survey, 01/07/2026 (See D6127-B).</p>
<p><b>D6127</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(9)</p> <p>(b)(9) 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>

This STANDARD is not met as evidenced by:

A. Based on review of laboratory policies and procedures, laboratory records, lack of documentation and interviews with the laboratory representative (LR); the technical supervisor (TS) failed to ensure annual competency assessments were completed for one of two testing personnel (TP) performing microscopic scabies wet preparations in the subspecialty of parasitology. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Personnel Competency/ Proficiency Testing Instructions", which stated, " ... the competency and performance of technical personnel are evaluated and documented upon initial employment, 6 month evaluation and then annually thereafter." 2. Review of laboratory records revealed TP#1's date of hire as prior to September 2024. 3. Review of competency records found no documented annual competency assessments for scabies for TP #1 performing scabies wet preparations examinations in 2025. 4. Interview with the LR on the date of survey, 01/07/2026, at 02:54 pm, confirmed the TS failed to ensure annual competency assessments were completed for one of two TP performing microscopic scabies wet preparations in the subspecialty of parasitology. B. Based on review of laboratory records and interview with the laboratory representative (LR); the TS failed to ensure annual competency assessment covered all elements of competency for three of three testing personnel performing microscopic potassium hydroxide (KOH) wet mount testing in the subspecialty of mycology, microscopic scabies wet mount testing in the subspecialty of parasitology, and Mohs histopathological testing in the subspecialty of histopathology testing in 2024 through the date of survey, 01/07/2026. Findings Include: 1. Review of the laboratory policy and procedure manual identified the policy, "Personnel Competency/ Proficiency Testing Instructions", which includes a competency evaluation form titled, "North Branch Competency and Proficiency Assessment" which evaluates the following 6 components: a.) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing b.) Monitoring the recording and reporting of test results c.) Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records d.) Direct observations of performance of instruments maintenance and function checks e.) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f.) Assessment of problem-solving skills" 2. Review of competency assessment records for three of three testing personnel (TP - #1, #2, and A) performing KOH and scabies testing and one of one TP performing Mohs micrographics surgery (TP A) failed to have complete competency assessments documented in 2024 and 2025 through to the day of survey, 01/07/2026 (Reference D5209). TP: Test: Assessment Date: 1 KOH 10/28/2024 1 Scabies 11/14/2024 1 KOH 07/08/2025 2 Scabies 11/14/2024 2 KOH 01/07/2025 2 KOH 06/05/2025 A Scabies 09/24/2024 A KOH 11/03/2024 A Scabies 01/06/2025 A KOH 02/03/2025 A Mohs 03/11/2025 A Mohs 10/28/2025 A Mohs 11/11/2025 A Mohs 12/09/2025 M\* = Mohs micrographic surgery 3. Interview with the LR on the date of survey 01/07/2026, at 02:54 pm, confirmed the TS failed to ensure annual competency assessment covered all elements of competency for three of three testing personnel performing microscopic KOH wet mount testing in the subspecialty of mycology, microscopic scabies wet mount testing in the subspecialty of parasitology, and Mohs histopathological testing in the subspecialty of histopathology testing in 2024 through the date of survey, 01/07/2026.

**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 review of Laboratory Personnel Report (CMS-209), laboratory personnel records and interview with laboratory representative (LR); the laboratory failed to ensure one of two testing personnel (TP) was qualified for high complexity grossing of tissue for Mohs micrographic surgery (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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Personnel Report (CMS-209), laboratory personnel records and interview with laboratory representative (LR); the laboratory failed to ensure one of two testing personnel (TP) was qualified for high complexity

grossing of tissue for Mohs micrographic surgery. Findings include: 1. Review of the CMS-209 revealed TP #4 listed as a high complexity TP. 2. Review of personnel educational documentation revealed TP #4 failed to meet the minimum chemistry and biology science course work requirements to qualify as a high complexity TP regarding 493.1489 (b)(3). 3. Interview with the LR on of date survey 01/07/2026, at 09:53 am, confirmed the laboratory failed to ensure one of two TP was qualified for high complexity grossing of tissue for Mohs micrographic surgery.