

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2081489	<b>(X3) Date Survey Completed</b>  09/10/2024
<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>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 the laboratory's policy and procedure manual, proficiency testing records, and interview with the laboratory representative, the laboratory failed to establish a competency policy for testing personnel (See D5209) and failed to perform bi-annual method accuracy evaluations for two provider performed microscopy (PPM) tests: potassium hydroxide (KOH) preparations and scabies wet preparations and Mohs dermatopathology testing (See D5217).</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, and interview with laboratory representative; the laboratory failed to follow the competency policy established by the laboratory. The laboratory failed to ensure competency assessments</p>

were performed for nine of nine testing personnel. Findings Include: 1. Review of laboratory policy and procedure manual revealed a document titled "Personnel Competency Testing" which stated "Objective To establish a system where the competency and performance of technical personnel are evaluated and documented upon initial employment, 6 month evaluation and then annually thereafter. Such a system will ensure proper training, skills and will maintain accuracy and consistency of all procedures performed." 2. The competency assessment policy failed to address the following criteria: a) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. 3. Review of competency assessment records found the laboratory lacked documentation of competency assessments for nine of nine testing personnel. 4. On survey date 09-10-24, at 12:24 pm the laboratory representative confirmed the laboratory failed to follow the competency assessment policy for nine of nine TP and the competency policy failed to include an assessment of test performance through previously analyzed samples

**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 laboratory records, lack of documentation, and interview with laboratory representative; the laboratory failed to perform bi-annual evaluations for two of two Provider Performed Microscopy tests performed, potassium hydroxide (KOH) preparations and scabies wet preparations. Findings Include: 1. Review of laboratory records found no bi-annual method accuracy evaluations for (KOH) preparations and scabies wet preparations. 2. Interview with laboratory representative on 09-10-24 at 12:41 pm revealed the facility began KOH and scabies wet preparation testing when the site opened in 2022. 3. Additional interview with the laboratory representative at 12:45 pm on 09-10-2024 confirmed the facility had no procedure for biannual method accuracy evaluation of KOH preparations and scabies wet preparations. B. Based on review of laboratory records, lack of documentation, review laboratory policy and procedure manual and interview with laboratory representative; the laboratory failed to perform bi-annual evaluations for one of one high complexity test system: Mohs dermatopathology testing. Findings Include: 1. Review of laboratory policy and procedure manual titled "Quality Assurance/ Quality Control" stated: "Semiannually, the Mohs surgeon will review randomly selected Mohs cases with a board-certified dermatopathologist for correlation of histologic diagnoses." 2. Review of laboratory records found no bi-annual method accuracy evaluations for Mohs dermatopathology testing. 3. Interview with laboratory representative on 09-10-24 at 12:41 pm revealed the facility began Mohs dermatopathology testing on 02-14-2023. The laboratory representative also confirmed that no bi-annual method accuracy had been performed for Mohs as outlined in the laboratories policy and procedure manual.

**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, review of laboratory's policy and procedure manual, preventative maintenance records, lack of documentation, and interview with the laboratory representative the laboratory failed to perform and document annual maintenance for one of one microscope (Nikon - serial number: 247395) to ensure accurate and reliable test performance for potassium hydroxide (KOH) preparations, scabies wet preparation, and Mohs dermatopathology testing in 2023 and 2024. Findings Include: 1. Direct observation on 09-10-2024 at 01:00 PM in the laboratory identified a Nikon microscope, serial number 247395. 2. Interview with the laboratory representative on 09-10-2024 at 1:00 pm, revealed the microscope was used for potassium hydroxide (KOH) preparations, scabies wet preps, and Mohs dermatopathology testing. 3. Review of the laboratory's policy and procedure manual titled " Quality Assurance / Quality Control" stated the following: "Preventive maintenance of microscope is performed annually and such is documented." 4.. Review of the laboratory preventative maintenance records found no documented maintenance as described in the above policy for the microscope in 2023 through the date of the survey, 09-10-2024. 5. On survey date 09-10-2024 at 2:07 pm the laboratory representative confirmed the annual microscope maintenance had not been performed for the Nikon microscope serial number 247395.

**D6045**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on review of laboratory records, CMS-209 (laboratory Personnel report) form, lack of documentation, and interview with laboratory representative; the laboratory technical consultant (TC) failed to ensure the training needs for five of five testing personnel (TP) authorized to perform potassium hydroxide (KOH) preparations and scabies wet preparations. Findings Include: 1. Review of laboratory personnel records found TP #1, #2, #3, #4 and #5 as identified on the CMS-209, were authorized to perform potassium hydroxide (KOH) and scabies wet preparation. 2. Review of training documentation found TP #1, #2, #3, #4 and #5 had no documented training for potassium hydroxide (KOH) and scabies wet preparations. 3. Interview with the laboratory representative on 09-10-2024, at 01:03 pm, the laboratory representative confirmed five of five TP failed to have documented training for KOH preparations and scabies wet preparations.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Review of laboratory personnel records, the CMS-209 (laboratory personnel report), lack of documentation, review of policy and procedure, and interview with the laboratory representative; the technical consultant (TC) failed to ensure competency evaluations were completed for five of five testing personnel (TP) that performed potassium hydroxide (KOH) preparations and scabies wet preparations. Findings Include: 1. Review of the laboratory policy and procedure revealed a document titled "Personnel Competency Testing" that states: "Objective To establish a system where the competency and performance of technical personnel are evaluated and documented upon initial employment, 6 month evaluation and then annually thereafter. Such a system will ensure proper training, skills and will maintain accuracy and consistency of all procedures performed." 2. Review of laboratory personnel records revealed no competency assessments for five of five TP listed on the CMS-209 as TP #1, #2, #3, #4 and #5 for KOH preparations and scabies wet preparations. 3. On survey date 09-10-24, at 12:41 pm, the laboratory representative confirmed that the laboratory TC failed to perform competency assessments for five of five TP that perform KOH and scabies wet preparations.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of laboratory personnel records, the CMS-209 (laboratory personnel report), lack of documentation, review of laboratory policy and procedure, and interview with laboratory representative; the laboratory technical supervisor (TS) failed to evaluate the competency of four of four testing personnel (TP), for Mohs dermatopathology testing. Findings Include: 1. Review of the laboratory policy and procedure revealed a document titled "Personnel Competency Testing" that states: "Objective To establish a system where the competency and performance of technical personnel are evaluated and documented upon initial employment, 6 month evaluation and then annually thereafter. Such a system will ensure proper training, skills and will maintain accuracy and consistency of all procedures performed." 2. Review of laboratory personnel records revealed no competency assessments for four of four Mohs dermatopathology TP listed on the CMS-209 as TP #6, #7, #8, and #9. 3. On survey date 09-10-2024, at 12:24 pm, the laboratory representative confirmed that the laboratory TS failed to perform competency assessments for four of four Mohs dermatopathology TP.