

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  38D0627047	<b>(X3) Date Survey Completed</b>  08/20/2025
<b>Name of Provider or Supplier</b>  North Bend Medical Center	<b>Street Address, City, State</b>  1900 Woodland Dr, Coos Bay, OR	
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>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on review of the policies and procedures presented during survey and interview with the technical consultant (TC #2), the laboratory failed to ensure the laboratory was following the Oregon State Regulation for reporting Reportable Conditions as specified by State/Local Law OAR 333-018-0013. Findings include: 1. Upon review of the laboratory's procedure manual, no procedure or policy for reporting reportable conditions to the Oregon Health Authority (OHA) or local County Health Department could be produced. 2. OAR 333-018-0013 requires laboratories report Reportable Conditions to their state or local health authority. 3. A request for written evidence of reporting reportable conditions to OHA or the local County Health Department could not be produced. 4. Interview with the TC #2 on 08/20/2025 at 11:30am confirmed there was no written record of reportable conditions reported to OHA or local County Health Department, nor was there an approved procedure for doing so in this laboratory. 5. The laboratory reports performing 6333 reportable condition analytes per year, of which 196 were positive.</p>
<b>D5801</b>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>(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</p>

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 review of the laboratory's procedure manual and interview with the technical consultant (TC#2), the laboratory failed to have a written procedure for reporting "reportable conditions" to the State or County as specified by State/Local Law OAR 333-018-0013. Findings include: 1. Upon review of the laboratory's procedure manual presented during the survey, no procedure for reporting "reportable conditions" to the State or County could be produced. 2. Upon request for written documentation of reportable conditions that had been reported to the State or County in 2024 and 2025, no written log or other document of reporting could be produced. 3. Interview with TC #2 on 8/20/2025 at 11:30am confirmed there was no written document for reportable conditions. 4. The lab reports performing 6333 reportable condition analytes per year, of which 196 were positive.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPLEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:  
Findings include: 1. See D6046

**D6046**

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

(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. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on the lack of written annual competency assessments for 2024 for seven (7) out of twelve (12) testing personnel (TP) performing moderate complexity testing, the two (2) Technical Consultants (TC's #1 & #2) listed on the CMS 209 form submitted during survey, failed to ensure annual competency assessments for all TP performing moderate complexity testing in Hematology, Chemistry, Endocrinology, Immunology /Serology and Microbiology were performed. Findings include: 1. Upon review of the CMS 209 form, it was noted that there were two (2) persons listed as a Technical Consultant (TC #1 & TC #2) for moderate complexity testing in Chemistry, Endocrinology, Immunology/Serology and Microbiology. 2. TC #1 oversees the specialties in Chemistry, Endocrinology and Immunology/Serology. 3. TC #2 oversees the specialty Microbiology, which includes Virology, Mycology and Parasitology sub-specialties. 4. Upon request for competency assessments for all TP in 2024, it was revealed that seven (7) out of twelve (12) TP lacked any record of competency assessment in any moderate complexity testing performed in this lab. 5.

	<p>Interview with both TC #1 and TC #2 at 12:00 pm on 08/20/2025 confirmed that there were no 2024 annual competency assessments for the seven (7) individuals who lacked written documentation of competency assessment for all moderately complex tests in 2024. 6. The laboratory reports performing 1,100,128 moderate complexity assays annually.</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: Findings include: 1. See D6120</p>
<p><b>D6120</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(7)(8)</p> <p>(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; (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.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) annual competency assessment forms, review of the Quality Assurance Program (QAP) policy and interview with the technical specialist (TS) the TS failed to complete 2024 and 2025 annual competency assessments on seven (7) out of seven (7) testing personnel (TP) performing high complexity testing. Findings include: 1. Based on review of the written competency assessments for the seven (7) TP listed on the CMS 209 as performing high complexity testing, it was noted that seven (7) out of the seven (7) TP did not have competency assessments for white blood cell manual differentials in 2024 and 2025. 2. Upon request for written evidence of competency for white blood cell manual differentials, none could be produced for seven (7) TP out of seven (7) TP in 2024 and 2025. 3. The laboratory's policy titled "Quality Assurance Program" (QAP) in sub-section four (4) of the QAP: Staff competencies - Annual and Biannual Competencies, states, "competency assessments would be performed annually." 4. Interview with the TS on 08/20/2025 at 10:15am confirmed the laboratory did not perform the annual competency assessment for seven (7) out of seven (7) TP in 2024 and 2025. 5. The laboratory reports performing 73 white blood cell manual differentials annually.</p>