Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0627047	03/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
North Bend Medical Center	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the Proficinecy Testing events from College of American Pathologists (CAP) and American Association of Bioanalysts (AAB) for the years 2022 and 2023, the laboratory failed to ensure that each testing event attestation form was signed and dated by each testing personnel (TP) and the Laboratory Director (LD). Findings include: 1. Of the PT specialties reviewed, the following PT events failed to have a signed and dated attestation by both the TP and the LD in 2022. a. Syphilis - Three (3) out of three (3) events in 2022 b. Rheumatoid Factor - Two (2) out of three (3) events in 2022 c. Coagulation - Three (3) out of three (3) events in 2022 d. Hematology with Auto Differential - Two (2) out of three (3) events in 2022 e. Blood Bank (Immunohematology) - Three (3) out of three (3) events in 2022 2. Of the PT specialties reviewed, the following PT event failed to have a signed and dated attestation by both the TP and the LD in 2023. a. Viral Markers - One (1) out of one (1) event in 2023 3. Of the total PT events reviewed, fourteen (14) out of sixteen (16) attestations were not signed and dated by the TP and the LD. 4. The Laboratory Manager and the Technical Specilist (TS) confirmed there were no signed and dated attestation statements for these PT events during interview 3/20/2023 at appproximately 3:00 pm.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing

	performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the Proficinecy Testing (PT) events from College of American Pathologists (CAP) and American Association of Bioanalysts (AAB) for the years 2022 and 2023 and interview with the Lab Manager and the Technical Supervisor (TS), the laboratory failed to ensure that each testing event was reviewed, signed and dated by each testing personnel (TP) for that event and the Laboratory Director (LD). Findings include: 1. Of the PT specialties reviewed, the following PT events failed to have a signed and dated PT review by both the TP and the LD in 2022. a. Syphilis - Three (3) out of three (3) events in 2022 b. Rheumatoid Factor - Two (2) out of three (3) events in 2022 c. Coagulation - Three (3) out of three (3) events in 2022 d. Hematology with Auto Differential - Two (2) out of three (3) events in 2022 e. Blood Bank (Immunohematology) - Three (3) out of three (3) events in 2022 2. Of the PT specialties reviewed, the following PT event failed to have a signed and dated review by both the TP and the LD in 2023. a. Viral Markers - One (1) out of one (1) event in 2023 3. Sixteen (16) out of sixteen (16) PT testing events reviewed during survey for 2022 and 2023 had no evidence of review by either the TP and / or the LD. 3. The Laboratory Manager and the TS confirmed there were no signed and dated reviews for these PT events during interview 3/20/2023 at appproximately 3:00 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 for all specialties on this CLIA certificate and interview with the Laboratory Manager, the Technical Supervisor (TS) and two (2) testing personnel (TP), the Laboratory Director (LD) failed to fulfill the duties of Laboratory Director in a high complexity CLIA laboratory. Findings include: Please see D6091, D6092, D6094, D6106 and D6107
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the Proficinecy Testing (PT) events from College of American Pathologists (CAP) and American Association of Bioanalysts (AAB) for the years 2022 and 2023, the Laboratory Director (LD) failed to ensure that each PT testing event was reviewed with the appropriate laboratory testing personnel (TP). See D5211
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)

	The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records and interview with the Laboratory Manager and the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure a written and approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory. Findings include: 1. Upon request for a written and approved Corrective Action (CA) plan for unsatisfactory /unacceptable PT performance, it was revealed that the laboratory did not have a CA plan for unsatisfactory PT performance. 2. Interview with the Laboratory Manager and the the TS on 03/20/2023 at approximately 1:30 pm revealed that there was no written and approved CA plan for PT failures available for review.
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 review of documentation provided during survey on 03/20/2023 and 03/21 /2023 and interview with the Laboratory Manager and Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure the laboratory had an established Quality Assessment/Assurance Plan (QA) in place to assure the quality of laboratory services they provide to patients. Findings include: 1. For two (2) out of two (2) years reviewed during survey, the laboratory did not have any written documentation of pre-analytical, analytical and post analytical QA activities. 2. Upon request, the laboratory was unable to provide a Standard Operating Procedure (SOP) for QA performance and documentation. 3. The Laboratory Manager and the TS confirmed during interview that the laboratory did not have an written SOP for QA and did not have documentation of QA activities since the previous recertification survey dated April 14, 2021.
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 review of five (5) laboratory procedure manuals and interview with the Laboratory Manager and the Technical Supervisor (TS) during survey 03/20/2023 and 03/21/2023, the Laboratory Director (LD) failed to ensure an approved procedure manual (signature and date for each) for four (4) out of five (5) procedure manuals was available to testing personnel (TP). Findings include: 1. Of the five (5) procedure manuals reviewed, four (4) out of five (5) were not approved by the LD by signature and date. Chemistry - no current signature and date of approval. Hematology - no

	current signature and date of approval. Immunohematology - no current signature and date of approval. Microbiology - no current signature and date of approval. 2. Immunohematology / Transfusion services were discontinued in November 2022. The current LD did not approve the retirement of the Immunohematology procedures by signature and date. 3. Microbiology department methodologies changed in 2022. The Microbiology procedure manual failed to reflect those changes and approval by the LD. 4. The Laboratory Manager and the TS confirmed that there was no further evidence of LD approval for these procedure manuals during interview at approximately 10:30 am 03/21/2023.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records and interview with the Laboratory Manager and the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that a current written and approved delegation of duties document stating the TP approved to perform patient testing for pre-analytic, analytical and post - analytical testing in each specialty/sub-specialties of testing was current and available for review. Findings include: 1. When asked for a written document approved by the LD with detail of each specialty TP are authorized to perform specimen testing , no current signed and dated document could be produced for review. 2. When asked for a written document by the LD for review of TS responsibilities and duties for competency assessment for TP, no document could be produced for review. 3. The Laboratory Manager and the TS confirmed that there were no such documents available for review during interview on 03/20/2023 at approximately 3:00 pm.