

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0627030	(X3) Date Survey Completed 09/13/2023
Name of Provider or Supplier Bay Clinic Llp	Street Address, City, State 1750 Thompson Rd, 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
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of written laboratory protocol regarding a Quality Assurance (QA) plan and lack of documentation of QA monitoring events or activities for this facility, the Laboratory Director (LD) failed to ensure that there was a current written QA Plan / Procedure with active QA monitors / activities in place for this facility. Findings include: 1. Upon request for a written procedure / QA plan, none could be produced. 2. Upon request for review of written QA monitors /activities conducted for all three (3) levels of testing, within the past two (2) years, none could be produced. 3. The TS confirmed during interview at 12:30 that no written QA Plan existed nor was there any evidence of QA activities conducted bi-annually at a minimum, for 2021, 2022 or 2023 to date.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must 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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of testing personnel (TP 1) competency records presented for review during survey and interview with the Technical Supervisor (TS). the Laboratory Director (LD) failed to ensure TP1 had annual competency evaluations by a CLIA qualified TS or designee. Findings include: 1. Upon review of the competency file for TP 1, there were no competency records for 2022 or 2023 for any assay (both moderate and high complexity assays) TP 1 performs in this laboratory. 2. The TP 1, who is also the TS, confirmed during interview at 1:30 pm that no competency assessment for any assay that is moderate or high complexity in this laboratory had been assessed for her in 2022 or 2023 to date. 3. The laboratory reports performing 164,674 moderate and high complexity tests annually.

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 the laboratory procedure manual and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that laboratory testing personnel (TP) had access to a current LD signed/ dated/approved standard operating procedure manual for all tests performed in this laboratory. Findings include: 1. Upon review of the laboratory procedure manual presented during survey, it was revealed that the hematology procedure with document ID as HEM.CBC.140, titled "Criteria for Smear Review by Pathologist", for a pathology review in the case of a patient presenting with immature white blood cells or other hematologic pathophysiology on a manual blood smear for differential and cell morphology had no LD signature or date of approval. 2. The effective date of HEM.CBC.140 was December 2006. 3. The revision date last shown for HEM.CBC.140 was March 2007. 4. The "Approved By", on HEM.CBC.140, which shows it to be the Pathologists's Name and Date under the signature line, is blank. 5. TP 1 (also the TS) confirmed during interview at 1:30 pm that there was no other current approved/ signed and dated SOP for sending manual blood smears out for pathology review and that she would make the decision to send it to Pathology based on her assessment of the peripheral blood smear. 6. The laboratory reports performing 33 manual cell differential/counts in the past year and 45,366 total hematology assays annually.