Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0656805	10/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Central Oregon Regional Pathology	1348 Ne Cushing Drive, Bend, 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
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: Based on review of the Proficiency testing (PT) documentation and bi-annual competency documentation presented during survey and interview with the facility's Technical Specialist, the laboratory failed to ensure bi-annual verification of performance for Gram stain (GS) and Acid Fast Bacterial (AFB) stain for each provider interpreting these stains on human tissue. Findings include: 1. Upon review of competency records for 2023 and 2024, it was noted that there was no evidence of bi-annual competency/performance verification for providers performing diagnostic interpretation of GS or AFB stain on human tissue. 2. Interview with the Technical Specialist at 2:00 pm confirmed that the laboratory was not currently performing bi-annual verification of performance for providers performing interpretation of GS and AFB stain. 3. The laboratory reports performing thirty (30) GS on human tissue in 2023 and twenty two (22) GS in 2024, as of date of survey. 4. The laboratory reports performing one hundred ninety (190) AFB stains in 2023 and one hundred thirty four (134) AFB stains in 2024, as of date of survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 the procedure manuals provided for review during survey and interview with the Technical Specialist, the laboratory failed to ensure a current and approved procedure for Gram stain (GS) and Acid Fast Bacteria (AFB) stain on human tissue specimens was in place and being followed by testing personnel (TP). Findings include: 1. Upon review of the procedure manuals presented for review during survey, the laboratory failed to have a current, Laboratory Director (LD) approved standard operating procedure (SOP) for GS and AFB stain as required under this regulation. 2. Interview with the Technical Specialist at 2:30 pm confirmed that there was no current SOP readily available for review for GS and AFB stain. 3. Email communication on 10/04/2024 and phone conversation with the Technical Specialist 10/07/2024 beginning at 2:22 pm confirmed that there was no current, approved SOP for either GS and AFB stain, stating that the manual AFB stain had not been performed at this laboratory "for years". No approved/updated/change in procedure for AFB was available for review. 4. The laboratory reports performing thirty (30) GS on human tissue in 2023 and twenty two (22) GS in 2024, as of date of survey. 5. The laboratory reports performing one hundred ninety (190) AFB stains in 2023 and one hudered thirty four (134) AFB stains in 2024, as of date of survey.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation in the laboratory and interview with the Technical Specialist, the laboratory failed to ensure that when reagents were transferred from the original container to a smaller container, the secondary container contained the required information per the regulations. Findings include: 1. Upon walking through the laboratory areas with the Technical Specialist and observing, examination of a secondary container of Acetic Acid and a second container of ninety five (95) percent alcohol, revealed that both containers did not contain the date the reagent was

	transferred from it's parent bottle, it's expiration date or lot number or it's storage temperature requirements. 2. The Technical Specialist confirmed this information was lacking on both vessels during interview at 2:30 pm.
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 Technical Specialist, the Laboratory Director (LD) failed to ensure a current and approved list of all testing personnel (TP) performing laboratory testing on human tissues was in place. Findings include: 1. Upon request for a current, LD approved list of all laboratory personnel performing testing at this facility, none could be produced. 2. Interview with the Technical Specialist at 1130 am confirmed that there was no current, LD approved list of duties each person was approved to perform. 3. The laboratory reports performing 40,292 tests on human tissue annually.