Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0628373	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Harney District Hospital Lab	557 W Washington St, Burns, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on record review and discussion with staff the laboratory failed to provide a written procedure that provided a step by step process that ensures positive patient identification from specimen collection through reporting of results. Findings include: 1. There was no written procedure available for review that describes how the surgeon submits a tissue specimen removed surgically by Mohs micrographic surgery technique, how the tissue specimen is labeled and submitted to laboratory with Mohs map work sheet for processing. 2. Random review of microscope slides with frosted end for labeling was labeled with limited patient identification. The slides were labeled with the following: Mohs case number; initials for the patient's first and last name, Diagnosis, encounter date, and primary number of stages and slides. The selected slide was clearly labeled with OW-19-10 NC BCC 5/20/10 I2-A 3. Comparison with the other six slides from the same slide holder for Mohs case number OW-19-10 and the review of the final report, revealed the encounter date 05 /20/10 was incorrect on the randomly selected slide. 4. Comparison with the Mohs map, patient log sheet for the Mohs surgery day and the final report reveal the Mohs map is blank for location and patient log sheet and final report indicate "Right Lateral arm". 5. Discussion with laboratory manager on 06/04/2019 approximately at 11:00 am confirmed that there was no written procedure to describe the step by step process of special handling of tissue specimens to ensure positive patient identification is

	maintained through the testing process, which includes labeling of slides with at least two unique identifiers and assuring pertinent information will be a match on the slide, on the Mohs map, and final report.
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 records and discussion with staff the laboratory failed to have a complete written procedure manual for the Mohs micrographic surgery technique performed at the Harney District Hospital laboratory, which is separate from the main laboratory. Findings include: 1. The laboratory manager was interviewed regarding the Mohs procedures and he was able to provide a general histopathology policy for the Mohs procedure, however, the specific step by step instructions for the Mohs procedure performed in the surgical area outside the main laboratory was not specified. 2. There was no written procedure with step by step instructions to describe how the tissue specimen is transported to the Mohs laboratory, labeling of slides, preparation of slides, slide staining procedure, how orientation /mapping of tissue is determined, microscopic examination including feedback to the Mohs technician regarding slide, stain and labeling quality, how to enter results in the patient record, how to report patient test results and how Mohs surgeon sign off the Mohs cases. 3. There were no written procedures to descibe how, when and why documentation of the log sheets for hematoxylin eosin stain (H&E), quality control (QC) slide are performed each day of testing for Mohs surgery cases. 4. Discussion with laboratory manager, confirmed that the documentation completed on the H&E and QC log sheets were performed on each day Mohs surgery was scheduled (04/08/19, 04/22/19, 05/20 /19) however, he confirmed there was no written policy. 3. There was no written procedure for retention requirements for completed Mohs Map worksheet and slides, how and where Mohs Map and slides are stored or tracked if the slides are sent out for consult. 4. There is no written policy available for review to determine if the laboratory has established a process to document competency or verification or consult process for Mohs cases. 5. He confirmed that the general policy does not fully address the procedures that occur in the Mohs surgery laboratory, 06/04/2019 approximately 11:00 am.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and discussion with staff, the laboratory failed to include the name and address on the Mohs micrographic surgery final report. Findings include: 1. The laboratory manager was able to provide a copy of the final report for the slide OW-19-10 NC BCC . The letter head on the report has Harney District Hospital but does not include the address. The sign off of the report by the Mohs surgeon is not indicated on the copy surveyor was provided for review. 2. The final report includes a scanned image of the Mohs map worksheet. The Mohs map does not have the name or address where the test was performed or the sign off by the Mohs surgeon. The Mohs map does not have a signature as signed off by Mohs surgeon. 3. Discussion with staff confirmed the name and address are not on the Mohs Map worksheet on 06/04/2019 approximately 11:00am.