| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 38D0656825 | 09/23/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ohsu Immunogenetics Transplant Lab | 2611 Sw Third Ave Suite 360, Portland, 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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Human Leukocyte Antigen (HLA) typing procedure manual and interview with the Technical Supervisor (TS), the laboratory failed to have a written policy and procedure when the primary test system becomes inoperable. Findings include. 1. The laboratory performs approximately 9000 to 10, 000 HLA typing annually using the Thermo Fisher Quant Studio 5 Real Time - Polymerase Chain Reaction (RT-PCR) test systems as the primary test system. 2. The laboratory |

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| | just have one (1) Thermo Fisher Quant Studio 5 RT-PCR analyzer. The laboratory lacked a written procedure in case the primary test system becomes inoperable. 3. Interview with the TS on 09/23/2022 @ 16:00 concurred with this finding. |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(7)(8)<br><br>(7) The technical supervisor is responsible for 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; (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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of competency assessment (CA) records and interview with the Technical Supervisor (TS), the laboratory failed to assess and document competency of the testing personnel. Findings include. 1. One(1) out of five (5) Testing Personnel (TP) performing virtual crossmatch compatibility for kidney transplant lacked documentation of CA for 2021 and to date 09/23/2022. 2. The laboratory performs approximately 3000 virtual crossmatch compatibility tests per year. 3. Interview with the TS on 09/23/2022 @ 16:00 concurred with this finding. |