

OREGON STATE PUBLIC HEALTH LABORATORY

SOP Title: Access to and Reporting of Results

Director Authorization: Reporting and the access to laboratory test results

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Document Number: ADM 1

Version: 2.0

Document Category: ADM-Information Management

Current Version Authorized By: Mike Skeels, Laboratory Director

Authorization/Review Date: 16-Apr-2014

Annual Review Due: 15-Apr-2016

Last Update: 15-Apr-2014 17:08

Organization Unit: Administration

Authorized

Access to and Reporting of Results

POLICY: The Oregon State Public Health Laboratory (OSPHL) has the responsibility of testing specimens submitted in support of public health programs. Test results are reported to the submitter or physician ordering the test, the local health department as required, and to other authorized state, local, or federal agencies in a timely manner.

DEFINITIONS:

Authorized person - A state-licensed medical, osteopathic, podiatric, chiropractic or naturopathic physician; licensed physician assistant; certified nurse midwife; licensed direct entry midwife; certified nurse practitioner; certified nurse anesthetist, optometrist or dentist.

Custodian of Records- The Quality Management Officer functions as the OSPHL Custodian of Records and handles all requests for laboratory test reports from anyone not involved in the medical care of the patient.

Submitter - A person authorized to submit a laboratory test; a local health department; or any clinical laboratory with an authorized person's request.

Local Health Department - A city, county, or health district authorized to submit specimens or receive test reports.

Out-of-State Report - A test result that has been obtained on a specimen received from outside of Oregon.

Significant positive (newborn screening) - A patient test value that is outside a stated expected range for any test.

Epidemiology - The Acute and Communicable Disease Program (ACDP) of Oregon Health Authority's Center for Public Health Practice

GENERAL REPORTING POLICIES

Managers of the General Microbiology, Newborn Screening, and Virology/Immunology laboratory sections are responsible for the accurate, timely reporting of all results. These results shall be reported as described in the following sections of this policy.

The report must contain the following elements: name and address of testing laboratory, patient name and other unique identifier; physician/submitter name; collection date; date received, report date; test result; units of measurement, when applicable; statement of expected or normal results as applicable; specimen source; and any other information required for the interpretation of the result such as specimen condition. All OSPHL test result reports are reviewed by two separate technical staff members prior to the release of the final report.

Reports for Laboratory-developed or modified tests (LDT) must contain the following statement:

“This was developed and its performance characteristics determined by OSPHL. It has not been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.”

The laboratory reporting the test result directly to the authorized person caring for the patient shall also be responsible for the reporting to the Local Health Department in the county of the patient’s residence or the Acute and Communicable Disease Program if required by Reportable Condition Administrative Rules. A faxed or electronic report is considered a written report. It must contain the information required of any other written report.

Laboratory staff shall request a “read back” of results when critical values are communicated verbally or by phone and will document the name of the person receiving the results.

WHO CAN RECEIVE RESULTS:

Laboratory test results shall be released as authorized by Oregon law under ORS 438.430(2): “Specimens taken from and reports made only to persons authorized to use results. A person may not report the result of any test, examination, or analysis of a specimen submitted for evidence of human disease except to the patient and a physician, dentist, their agents, or other person authorized by law to employ the results thereof in the conduct of a practice or in the fulfillment of official duties.

Not sooner than seven days after receiving a request from a patient for the results of any test, examination or analysis of a specimen submitted by the patient, a clinical laboratory shall provide the results in writing to the patient.”

- a. When a patient requests copies of their laboratory results from OSPHL, send

or fax the Patient Request for Release of Laboratory Test Results (FADM 368). The completed form is given to the Custodian of Records who will send patient their test results seven days after the request is received and identity verified. Document the release of the results as described in Disclosures of Confidential Laboratory Results and Disclosure Tracking (ADM 125).

b. Results may be given to an attorney, if a written release is obtained from the patient. The release is given to the Custodian of Records who will make the release and document as described in Disclosures of Confidential Laboratory Results and Disclosure Tracking (ADM 125).

c. If an authorized person, other than the submitter, requests copies of patient's results, staff must query the individual requesting the results, to assure the provider is involved in the care of the patient. **Document the release as detailed in Disclosures of Confidential Laboratory Results and Disclosure Tracking (ADM 125).**

Any other request by health care provider not involved in the care of the patient shall be referred to the submitter for a copy of the test results.

d. OSPHL shall notify the Local Public Health Authority of the patient's residence for Communicable Disease reporting per 333-018-0000 through 333-018-0015 when OSPHL is the laboratory reporting results to the authorized person caring for the patient.

e. Communicable disease reports may be reported directly to OHA-ACDP through the Electronic Lab Reporting System (ELR).

f. OSPHL will cooperate with a Public Health Authority and OHA-ACDP when they are requesting more information related to an outbreak investigation. This may include reporting positive and negative results or responding to an inquiry from a county that is not the submitter or the patient's county of residence,

Any known accidental disclosure of patient information, such as a report sent to the wrong address, must be documented as described in Disclosures of Confidential Laboratory Results and Disclosure Tracking (ADM 125)

ACCOUNTING OF DISCLOSURE

If a patient requests an accounting of disclosures of his/her laboratory test results:

- a. Requests are handled by the Custodian of Records.
- b. Only disclosures not related to health care operation, payment or treatment need to be provided.

- c. Require the patient to complete a MSC 2096 Accounting of Disclosures Request Form
- d. Make a reasonable attempt at validating the identity of the patient by date of birth, picture ID or unique patient identifier.
- e. Verify if any disclosures have occurred and print a report from Copia or MSDS and give to patient.
- f. Attach a copy of the information provided to the submitted MSC 2096 "Disclosures of Protected Health Information (PHI)"

WEB ACCESS:

Submitters, Local Health Departments and authorized Oregon Health Authority employees may be granted Internet based access to laboratory results through Web access following the approval process described Approval Process for Web Access to OSPHL Laboratory Reports (ADM 118). Access is restricted based on the tests ordered by the submitter or by the requirements of public health reporting outlined in OAR 333-018-0015.

REPORTING OF REFERRED TESTING

Specimens that are referred to other laboratories for testing and subsequently reported on OSPHL report forms with the Laboratory Director's approval:

- a. The name and address of the referral laboratory must be clearly stated on the report. The report must acknowledge that the testing was performed at the referral laboratory.
- b. The report must also contain all elements of the original report that are needed to evaluate the results. These include dates of collection and reporting, results, units used, if applicable, and any interpretation provided.

SUBMITTER NOTIFICATION FOR CHANGES IN METHOD OR NORMAL RANGES

Each section must give notice to submitters and other interested parties when there has been a change of method or interpretive range for testing performed in the OSPHL. Notification must include the date of the change and the new expected values. The notification may take one or more of the following forms:

- a. Written notification to all submitters for the specific test being changed; this may be in the form of a separate letter sent by fax or email.
- b. A comment included on each test report, for 2 months after the change, indicating the nature of the changes.

CHANGED OR EDITED REPORTS

If an erroneous result has been reported by the OSPHL, including results generated by reference laboratories on OSPHL specimens, the procedure The Process for Revising Released Reports (GEN 108) must be followed.

PUBLIC HEALTH REPORTING

The OSPHL shall report on the identification or suspected identification of disease-causing organisms or conditions as required by OAR 333-018-0000 through -0015. Reports shall be made within one working day of identification of initial test report. Possible cases of novel influenza will be reported to the Epidemiologist on call at 971-673-1111 as soon as identified.

RESULT RETENTION

All results will be retained according to the OSPHL's policy Record Inventory and Retention (ADM 103). Original or duplicate copies of all completed results must be available within four (4) hours, whether they are on file or stored in a computer program.

A mechanism to retrieve current test results in the event of an unexpected computer system interruption must be available. This policy is defined in OPHL Policy ADM 106, Manual Reporting Procedure During Information System Downtime.

HIPAA forms MSC 2093 and 2096 will be filed in the Administration file room and kept for six years.

FILES AND RECORDS

Only OSPHL staff or Public Health Division employees shall access all OSPHL files/records unless authorized by the Laboratory Director. Local Health Departments and submitters will be allowed electronic access to their test results performed by the OSPHL, using approved Web access. Files/records must be discarded through bonded contractors or shredded by staff.

Most records in the clinical laboratory regulatory program, Laboratory Compliance (LC) section are public documents. The public may, upon written request, access regulatory records. However, each file must be reviewed and approved for release by qualified LC personnel before the public has access to the records. All laboratory files must be viewed on the premises in the presence of LC staff. Copies may be made for the public as needed. Refer to the CMS "State Operators Manual" (SOM) for further information. Reports on the accreditation status of laboratories accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP) are public information and are available upon request. Although many laboratory accreditation documents are public records, program files may also contain confidential documents. All documents on file must be reviewed and approved for release by qualified personnel before copies

are released upon public request.

FAX REPORTING:

Faxed reports must include all information that would appear on a final report including the laboratory name and location. Every effort should be made to assure faxes reach their intended receiver. Submitters include a fax number identified as being secure as part of their signed request for Web access.

TELEPHONE REPORTING

When results are phoned, staff will document who was called and when and request a read back of the results to assure that the correct results are received. All phoned results must be followed by a written report. This is to be done by mail or fax. A written report helps to alleviate errors that may have occurred when the report was received over the phone, and it gives the receiver a permanent result.

The results that must be phoned to the submitter within one working day are:

- a. all positive rabies test results
- b. significant positive newborn screening tests
- c. uncommon illness of public health significance to ODPE
- d. positive tests for *Bordetella pertussis*, *Clostridium botulinum*, *Neisseria gonorrhoeae* and *Neisseria meningitidis* all serotypes
- e. positive drinking water tests
- f. any positive identification of parasites which require public health reporting
- g. possible identification of a select agent as defined in 42CFR73 must be called immediately day or night

Other positive results are sent automatically through the ELR.

TURN AROUND TIMES

Routine turn around times (TAT) are determined within each section, depending on the test. The routine times are defined in the test information found on the OSPHL website at <http://public.health.oregon.gov/LaboratoryServices>.

ACTIONS WHEN TURN AROUND TIMES DO NOT MEET STANDARDS

If a test system becomes inoperable, alternative testing methods such as use of a secondary instrument or back up method will be considered by the section manager. When turn around times are exceeded, or are expected to exceed the expected standard for each individual test by more than three working days, the section shall notify submitters by phone or fax of the delay, the nature of the cause, and the expected time frame for resolution of the problem. OSPHL policy ER-COOP 101

Access to and Reporting of Results - Version: 2.0. Index: ADM 1. Printed: 17-Apr-2014 09:42

Authorized on: 16-Apr-2014. Authorized by: Mike Skeels, Laboratory Director. SOP Unique Reference: view_only. Due for review on: 15-Apr-2016

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Newborn Screening Referral of Specimens During Work Stoppage outlines the steps to be taken in case of an inability to normally process specimens.

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