



Oregon

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To: Laboratories Licensed to Perform HIV Testing

From: Sean Schafer, MD
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Subject: Additional HIV-Related Test Reporting Requirements

New HIV-Related Laboratory Reporting Requirements

Pursuant to changes in Oregon Administrative Rule 333-018-0015 adopted April 17, 2006, beginning July 1, 2006 laboratories will assume additional reporting responsibilities for HIV-related testing. Laboratories will be required to report results of **ALL** tests of HIV RNA levels ("viral loads") and CD4+ T-lymphocyte counts ("CD4 counts"), including those tests where viral RNA is undetectable or CD4 count exceeds 200/ml³ or 14% of total T-lymphocytes. These results should be submitted **regardless of whether or not the patient is known to be HIV-infected**. This new information can be reported in the same manner as, and included with all other required reporting of HIV-related results. (A copy of the text of the revised administrative rule, 333-018-0015 is enclosed.) Also note that the existing requirement to report results "indicative of and specific for" HIV remains in effect. Such tests commonly include positive Western Blot confirmed positive antibody tests, positive p24 antigen tests, viral cultures and viral resistance testing. While the additional requirements may increase reporting burden, some benefits may be realized as labs will no longer be required to sort viral loads and CD4 counts into those that should be reported and those that should not. These requirements apply to labs conducting in-house testing as well as those responsible for referring specimens to an out-of-state laboratory. An explanation of the rationale for the changes in laboratory reporting is provided below.

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In summary, as of July 1, 2006 labs will be required to report:

- Results of **all viral loads and CD4 counts**, regardless of result or HIV status of the patient.
- Results of **all tests that are indicative of and specific for HIV**. These include positive Western Blot assays, positive p24 antigen tests, and positive viral cultures (existing requirement).

If you have any questions regarding HIV reporting, please feel free to contact the Surveillance Division at: 971-673-0153.

Electronic Laboratory Reporting of HIV-Related Tests

Beginning July 1, 2006, laboratories may begin reporting HIV-related test results electronically through the electronic laboratory reporting (ELR) system. ELR is already available for many other reportable conditions in Oregon and is expected to streamline test reporting for both the HIV Program and the laboratories. For labs that do not have the capacity for ELR or do not wish to transmit HIV results electronically, reports may be faxed to 971-673-0179, which is a secure fax line.

If you wish to arrange ELR for your laboratory or have questions regarding the ELR system, please email: ELR.project@state.or.us or contact J.A. Magnuson at 971-673-1111 or Lea Bush at 971-673-0153. The State website pertaining to ELR can be found at: <http://www.oregon.gov/DHS/ph/elr/index.shtml>

Explanation of Rationale for Additional Reporting Requirements

Increasing case ascertainment. Public health detects most new HIV and AIDS cases by laboratory reporting. Formerly, only CD4 counts <200 cells/ml³ or detectable viral loads were explicitly reportable. Removing the threshold for reporting will increase the sensitivity of this method of case ascertainment. We are aware that this change will result in receipt of duplicate results when a referring lab and reference lab report the same test result as well as receipt of reports from some patients who are not HIV infected. As is already being done already in other states where this change has been adopted, we will be implementing several strategies to help us manage the additional noise. First, electronic reporting is being adopted to reduce data entry requirements. Then, incoming reports are matched to existing cases in the registry by computer algorithm. When a match is identified, it will be appended to the existing case data. If a case is apparently new, it will be investigated depending on priority and staff

capacity. We already do this for new CD4 counts and detectable viral loads and sometimes discover that a newly reported low CD4 count is from a bone marrow transplant patient, etc. Reports from patients found not to be from patients with HIV infection will be deleted or destroyed. With the increased lab reporting, detectable viral loads will have the highest priority for investigation, followed by low CD4 counts, and non-detectable viral loads and high CD4 counts.

Improving service delivery. Another goal of public health surveillance for HIV is improvement in health services on a population level. Tracking CD4 counts and viral loads longitudinally on patients with reported HIV disease permits us to count and describe patients not receiving regular medical care (by inference from the absence of periodic CD4 or viral load results) and to inform public health efforts toward better distribution of health care and preventive services.