FAQ #1 – We are a laboratory located in another state and want to test Oregon specimens. What does Oregon require?

Q: If we are a laboratory not located in Oregon, and want to test or are testing Oregon specimens, what Oregon regulatory requirements for out of state testing should we know?

A: Oregon requires that your laboratory must have a current CLIA certificate appropriate to the level of testing performed.

Q: What if we have a collection site in Oregon and then send the specimens to our lab located in another state?

A: Oregon does not regulate the **collection** of a specimen beyond CLIA requirements for the pre-analytical portion of the test. However <u>Oregon does regulate</u> who may **order** a lab test. Please see our web document <u>Who May Order Lab Tests</u>

Q: If an Oregon clinic sends specimens to our lab do we have to verify that the test was ordered by an Oregon practitioner?

A: If that is a requirement in your state.

Q: Is there anything else we should know about?

A: Oregon has two non-CLIA regulatory programs for screening human specimens within Oregon, they are:

- Non-medical substances of abuse (SOA) screening tests, such as employment/preemployment drug or alcohol screens or school sports drug-free screens are regulated under the <u>SOA Registration Program</u>. As this type of testing does not meet the definition of 'clinical testing' there are no regulations governing who may order the test.
 - Be aware that CLIA regulates substance of abuse testing for health reasons such as drug monitoring or rehabilitation. See <u>Guidance regarding the circumstances</u> when laboratories performing drug or alcohol screening and/or testing must be <u>CLIA certified</u> Testing that meets the definition of 'clinical' would require a practitioner's order in Oregon.
- 'Health Fair' or 'Mall' testing is regulated in Oregon under the <u>Health Screen Testing</u>
 (<u>HST</u>) <u>Permit</u>. This allows for 9 specified types of screening tests allowed without a
 practitioner's orders in a 'health fair' setting.