

## **OREGON REQUIREMENTS WHICH EXCEED CLIA REQUIREMENTS**

The Following is a list of laboratory requirements for clinical laboratories in Oregon which exceed CLIA regulations or are unique to Oregon laboratories. This is not intended to be a complete list but rather the most significant of the differences between state law and CLIA.

---

- , The laboratory license (CLIA certificate) must be displayed in a prominent place in view of the public, such as the phlebotomy area.
- , The laboratory must have an order from an “authorized” individual for all tests performed, except non-medical substance of abuse tests and tests allowed by the “health screen testing” regulations (OAR 333-024-0370 through 333-024-0400).
- , The laboratory may give tests results only to the individual(s) ordering the test except when the ordering individual gives permission for test results to be given to other individuals; exceptions in the law include reports to local health departments or to the Department of Human Services/Health Services, (Department) (OAR Chapter 333, Division 018), and non-medical substance of abuse test results (ORS 438.435 and OAR 333-024-0305 through 333-024-0365).
- , The laboratory must report, to the local health department or state, the “reportable conditions” as indicated in OAR Chapter 333, Division 018.
- , Confirmation testing is required on all non-medical substance of abuse (SOA) screening if the SOA test results are to be used to deprive or deny any person any employment or any benefit.
- , Director requirements are more stringent for performance of “health screen testing” (example: mall testing without a practitioner’s order) and substance of abuse testing.
- , The law regulating substance of abuse testing exceed CLIA in several ways; labs performing such tests should keep a copy of the ORS and OAR for reference and maintain compliance to Oregon regulations.
- , The law regulating the performance of health screen testing (HST) without a practitioner’s order is more stringent than CLIA, even if the lab is performing only waived tests; for example, there are special requirements for personnel, consultation, quality assurance and reporting of testing events to the Department. Either on-site survey or an alternate “paper” survey is required to be conducted for all HST entities, including those performing only waived tests.
- , OAR 333-024-0260 through 333-024-0265 contains specific language for the performance of maternal serum alpha fetoprotein which is not specifically addressed by CLIA.