Information regarding submission of application

1. Please complete the 5-page CLIA application form CMS-116 which can be found here:

https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf

- Laboratories performing moderate (including PPMP) and/or high complexity tests must also complete the 'Director Qualification Appraisal' form and provide indicated supporting documents. Form is found here: https://www.oregon.gov/oha/PH/LABORATORYSERVICES/CLINICALLABORAT_ORYREGULATION/Documents/dir.pdf
- 3. Submit Director Qualification Appraisal form with supporting documents and the CLIA application.
 - *Please note:
 - Director Qualification Appraisal form is NOT required for application for Certificate of Waiver.
 - ✓ The individual designated as Laboratory Director for any type of CLIA
 certificate assumes responsibility and legal liability for all laboratory testing
 conducted under the authority of the CLIA certificate issued.
- 4. Oregon laboratories mail or email applicable forms to the Oregon State Agency:

Laboratory Compliance Section 7202 NE Evergreen Parkway Suite 100 Hillsboro, OR 97124-7251

Email:

lc.info@odhsoha.oregon.gov

For laboratories <u>not located in Oregon</u> please copy the link below into your web browser or search the web for 'CLIA State Agency Contacts' and find the CLIA State Agency for the state the lab will be located in. Send the application to that state's CLIA agency.

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/ State Agency and Regional Office CLIA Contacts