LUNG CANCER PROTEOMICS
Early Detection of Lung Cancer
TargetDx LABORATORY

6541-B Via Del Oro, San Jose, CA 95119 | 219-510-0120 | www.targetdxlab.com

R&D Director

Position Summary

Lung Cancer Proteomics is a growing biotechnology company with a mission of developing sensitive and specific blood tests to detect high mortality cancers early. By adhering to a data driven approach and using rigorous scientific processes, we strive to innovate, simplify, and improve early diagnostic tools, which lead to an increase survival rate and better quality of life for cancer patients.

As an **R&D Director**, you will lead and direct research and product development team to deliver commercial-scale assays to serve impactful areas of clinical need. You will be responsible for driving new product introduction to completion by leading teams through the validation and regulatory submission phases of product development. The ideal candidate should have extensive experience developing and validating assays in LDT- and IVD-regulated environments, including successful interactions with the FDA, as well as knowledgeable with CLIA, CAP, OSHA, HIPAA regulations. The role will report to Executive team and work closely with cross-functional leaders, including Marketing, Legal/Compliance, and Product Development.

Primary Responsibilities:

- Ensure protocols provide quality data for all phases of testing: pre-analytic, analytic, and post-analytic phases.
- Ensure verification procedures are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method.
- Ensure that all personnel have the appropriate training and experience prior to testing patient specimens; and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.
- Ensure that policies and procedures are established for monitoring employees who conduct pre- analytical, analytical, and post-analytical phases of testing to verify that they maintain competency: process specimens, perform test procedures, report test results proficiently, and identify remedial training and/or continuing education needs to improve skills.
- Lead product development team through planning, design, and execution of technical validation activities for regulatory submissions.
- Perform and review complex analyses of study data sets to address verification/validation study objectives in collaboration with bioinformatics & biostatistics teams.
- Report project updates, data analyses, and experimental conclusions at technical meetings.
- Drive study documentation in compliance with good laboratory practices & quality systems requirements to support regulatory filings.
- Provide technical leadership for the timely resolution of complex process issues.
- Ensure that required documentation is created per quality and regulatory requirements.

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- Ensure that quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.
- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.
- Ensure that corrective actions are taken and documented, whenever significant deviations from the laboratory's established performance characteristics are identified, and patient test results are reported only when the system is functioning properly.
- Be well versed in FDA, CLIA, CAP requirements for SOP and validation processes.
- Stay up to date with new platforms and technologies as it relates to company product lines.
- Maintain and create annual laboratory budget.

Qualifications:

- Ph.D. in Molecular Biology, Biochemistry, or related scientific discipline.
- 8+ years in assay development required. IVD experience a plus.
- Knowledge of regulatory lab guidelines: FDA, CMS, CDC, ICH, OSHA, HIPAA, ISO, GLP
- Current California Clinical Laboratory License, General (Preferred, but not required).
- Experience and expertise in high complexity testing in diagnostic immunology preferred
- Hands-on experience and knowledge of methods and platforms related to developing immunoassay and genotype tests.
- Strong technical and problem-solving skills and deep knowledge of molecular biology and biochemistry.
- A strong drive to deliver high quality results and meet aggressive timelines is required.
- Ability to lead and take initiative in an environment of fast paced innovation.
- Experience launching LDT products in high volume clinical settings is highly desired.
- Experience with statistical programming and software (e.g., R, JMP) is a plus.
- Ability to interface and drive change from team members of various disciplines: Development, Marketing, Regulatory, Quality Assurance, and Operations.
- Strong verbal and written communication skills and willingness to collaborate cross-functionally in a fast paced and dynamic environment.

Lung Cancer Proteomics is proud to be an Equal Opportunity Employer. We are committed to ensuring a diverse and inclusive workplace environment, and welcome people of different backgrounds, experiences, abilities, and perspectives. Inclusive collaboration benefits our employees, our community, and our patients, and is critical to our mission.
All qualified applicants are encouraged to apply, and will be considered without regard to race, color, religion, gender, gender identity or expression, sexual orientation, national origin, genetics, age, veteran status, disability, or any other legally protected status.