



CareDx, Inc., headquartered in Brisbane, California, is a global molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients. CareDx offers AlloMap[®], a gene expression test that aids clinicians in identifying heart transplant patients with stable graft function who have a low probability of moderate to severe acute cellular rejection. CareDx is developing additional products for transplant monitoring using a variety of technologies, including AlloSure[®], a proprietary next-generation sequencing-based test to detect donor-derived cell-free DNA after transplantation.

CareDx, with its presence through Olerup, also develops, manufactures, markets and sells high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. Olerup SSP[®] is a set of HLA typing used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation. XM-ONE[®] is the first standardized test that quickly identifies a patient's antigens against HLA Class I, Class II or antibodies against a donor's endothelium. For more information, please visit: www.CareDx.com.

Development/Technology Transfer Scientist

The Development/Technology Transfer Scientist will be responsible for the validation of high complexity molecular diagnostics tests, transfer of these tests to the CLIA/CAP accredited clinical laboratory at CareDx and ongoing technical and scientific support following transfer. Under the direction of the VP, Laboratory Operations, the scientist will be primarily responsible for late-stage development/refinement of testing and workflow processes, designing and executing verification and validation testing protocols, and technology transfer to the clinical laboratory. This scientist will be the interface between R&D and the clinical laboratory, and work closely with the Clinical Laboratory Manager, Clinical Laboratory Scientists, R&D, Automation and biostatisticians on all activities. This is a hands-on position which includes performance of testing at the bench.

Responsibilities include, but not necessarily limited to:

- Work effectively within the Laboratory Operations group on late-stage development, verification and validation of high-complexity laboratory-developed tests, modified test methods and new instrument validation
- Transfer high-complexity laboratory-developed tests from the CareDx R&D laboratory to the clinical laboratory, including training of the clinical laboratory staff
- Assist the Manufacturing group to design and conduct reagent stability and guardband testing; develop incoming reagent QC methods

- Assist the Manufacturing group with development of manufacturing methods and QC processes for reagent production
- Design and execute stability, verification and validation studies following CLSI guidelines and to CAP/CA/NY standards
- Develop/refine test workflow and develop/write SOPs and work instructions; assist with defining workflow requirements for the LIMS system
- Keep complete and accurate records

Qualifications:

- PhD or Masters degree in Molecular Biology, Chemistry, Biochemistry, or related field
- Minimum 5 years of experience in product or assay development or technology transfer positions
- Experience optimizing and validating diagnostics using design control procedures for transfer to a CLIA or GMP lab and/or experience optimizing NGS tests a plus
- Ability to independently design experiments, analyze data, and work effectively in a team setting.
- A working knowledge of statistics is required; experience with sequence analysis, statistical software, and databases is a plus
- This position will require strong problem-solving ability and excellent written and verbal communication skills, and the ability to work effectively in cross-functional groups and teams; Must have effective interpersonal skills.
- Excellent record keeping and the ability to work with, and control large data sets
- Experience with LIMS, electronic document control and databases is a plus

Additional Information:

Benefits & Perks: We provide Medical, Dental, Vision and Life Insurance, Flexible Spending and Dependent Care, Commuter Accounts, 401(k) match, 3 weeks of vacation, 5 days sick leave, 1 personal floating holiday, 9 paid holidays, gym reimbursement, yoga onsite, ping pong, foosball, BBQ's, social hours, and more!

Please send cover letter and resume to: HR@CareDx.com

CareDx, Inc. is an Equal Opportunity Employer.

Staffing Agencies and Recruiters:

We appreciate your interest in CareDx, Inc. To develop a working relationship with us, we ask that you please contact our Human Resources Dept. at HR@CareDx.com. All employment openings are managed through our Human Resources Dept. The CareDx, Inc. hiring managers and employees will not accept unsolicited resumes from any source. Submission of unsolicited resumes in advance of an agreement between the Human Resources Dept. and the recruiter does not create any implied obligation on the part of CareDx, Inc. **Therefore, we request that recruiters do not contact employees directly in an attempt to present candidates.** We thank you in advance for your cooperation and look forward to possible job search collaboration in the future!