JOB DESCRIPTION

About CareDx

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.

I. Specifications

Title:	Manufacturing Associate II
Manager:	Associate Director, Manufacturing
FLSA:	Non-exempt
Classification:	Regular Full Time
Department:	Manufacturing
Location:	Brisbane, CA
Management:	N/A

II. General Description

The Manufacturing Associate II will participate in manufacturing and process development activities. Relies on established SOPs and QC Testing procedures to perform the functions of the job. Works on assignments that are moderately complex in nature where judgment is requires in resolving problems and making routine recommendations. Can work independently in the lab directly from an SOP with moderate training. May determine methods and procedures on new assignments and may provide guidance to other support personnel. Has knowledge of commonly-used concepts, practices, and procedures within molecular biology. Capable of setting up materials or equipment for experiments. Can collect data for routine experiments

with limited guidance. Relies on work priority from supervisor as well as limited experience to plan and accomplish tasks or goals.

Responsibilities are as follows, but not necessarily limited to:

- Participate in routine manufacturing of AlloMap and other diagnostic products as well as development and verification activities.
- Perform quality control of reagents and routine data analysis
- Complete documentations in accordance with cGMP.
- Routine sign off, monitoring, and maintenance of quality records including manufacturing batch records, equipment records and system monitoring records to ensure compliance
- Maintain accurate inventory and inventory controls and procurement to support production activities.
- Maintain cleanliness and orderliness of the production area.
- Ensure equipment and instruments are current with calibration and preventive maintenance.
- Assist in troubleshooting and problem solving as it relates to equipment or product related issues.
- Assist in the evaluation of non-conformances including disposition and associated preventive/corrective actions.
- Performs change management plan as required to support change requirements including product and process change, document change and deviations.
- Assist in validation activities and protocol/report generation. Assist in the execution of manufacturing improvement activities.
- Act as subject matter expert for revisions or improvements to manufacturing documents.
- Utilize manufacturing knowledge to improve process operations and affect positive change.
- Assist supervisor as required to provide training to new personnel on Manufacturing and Quality work instructions.
- Interact with other support functions such as Reference Lab, Automation, Quality Assurance, IT, Software, etc.
- Perform other related duties and assignments as required
- Promote a safe work environment. May provide recommendations on maintaining the safety of the work environment. Notify supervisors of all observed hazardous conditions or unsafe work practices.

III. Qualifications

- BA/BS in biological or life sciences and 3 to 5 years related experience in a manufacturing, clinical or industrial laboratory, research or equivalent combination of related education and experience.
- Desirable experience would include high-throughput real time PCR, cGMP manufacturing, and molecular biology process development.
- Manufacturing/Development of in-vitro diagnostics would be an asset.
- Ability to handle multiple tasks and react appropriately to changing priorities and impending deadlines.
- Thrives in a highly collaborative, fast-paced, team-based environment.
- Operates well in a team-oriented, scientific environment.
- Must be able to interface and communicate effectively with work groups to ensure completion of tasks and projects.
- Strong interpersonal, verbal and written communication skills required.
- Must be very detail oriented.
- Ability to work with minimal supervision
- Proficiency with Microsoft Word, Excel, Project, PowerPoint, Adobe Acrobat and Outlook

IV. Work Environment

This is an onsite position at CareDx in Brisbane CA. Travel is not a primary aspect of this position although travel may be requested from time to time. An employee in this position may work in an environment, or visits facilities, in which safety, environmental and health concerns may demand constant attention. Adherence to the Corporate and/or Plant policies, rules, and regulations in these areas is required.

V. Physical Demands

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is regularly required to use hands and fingers, handle or feel, and talk or hear. The employee frequently is required to sit, stand and walk. There will be periods of time during the workday where you will be sitting for 3-4 hours in a row. Require regular use of hands to operate office equipment and type on the keyboard. The employee must occasionally lift and/or move up to 20 pounds. Specific vision abilities required by this job include close vision, and ability to adjust focus.