



Senior Director of Lab Operations

SUMMARY

The primary role of the Sr. Director of Lab Operations will be to oversee the CLIA-certified CAP-accredited clinical laboratory, manage staff and ensure daily operations success. The Sr. Director of Lab Operations will report directly to the Chief Medical Officer and interact closely with the laboratory and provider relations teams. This role requires understanding of immunology and advanced testing methods. This is a unique opportunity to be a major contributor to the success of a well-positioned, well-financed growth stage biotechnology company.

DUTIES & RESPONSIBILITIES

Note: Other duties may be assigned.

- Responsible for the technical and managerial oversight of the clinical laboratory as delegated by the CLIA laboratory director.
- Oversees daily operations of the clinical lab.
- Oversees laboratory personnel performance and competency.
- Troubleshoots technical or operational issues.
- Ensures maintenance of SOPs, reports and Quality Assurance, Quality Control and personnel documentation.
- Ensures proficiency testing samples are tested and reviewed by appropriate staff.
- Carries out corrective actions recommended by Lab Directors, CLIA or other regulatory/accrediting bodies.
- Ensures and supervises the quality assessment and quality control programs.
- Plans for training or continuing education needs.
- Works closely with direct laboratory management.
- Integral part of the laboratory leadership team.

QUALIFICATIONS

Note: To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

EDUCATION AND/OR EXPERIENCE

- Required M.S
- Required CLS license
- Preferably MD, DO or DPM, current in-state medical license AND 1 year training/experience in high-complexity testing in specialty; **or** PhD in clinical lab science, chemistry, physical or biological science AND 1 year training/experience in high-complexity testing in specialty; **or** MS in med tech, clinical lab science, chemistry, physical or biological science AND 2 years training/experience in high-complexity testing in specialty
- Deep understanding of the field of autoimmune diseases and clinical diagnostics
- 5+ years laboratory/industry experience with supervisory experience
- Extensive lab experience with ELISA, CIA, IFA and flow cytometry assays
- Experience with automation
- Molecular knowledge desirable
- Knowledge of CAP, CLIA and NY regulatory requirements
- Must have excellent communication and organizational skills
- Excellent time- and project management

PHYSICAL DEMANDS

Note: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of the 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 sit, walk, stand and talk or hear.
- The employee must occasionally lift and/or move up to 40 pounds.
- Specific vision abilities required by this job include close vision, ability to adjust focus and viewing computer period monitors for an extended of time.

WORK ENVIRONMENT

Note: The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable



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- Standard lab environment.
- The noise level in the work environment is usually moderate.
- Interaction with laboratory equipment, samples, supplies, and laboratory personnel may be required whereby appropriate precautions are to be taken per the Company's Safety and Injury, Illness and Prevention Plans.

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