



## **Job Description – Systems Engineer II/Medical Devices**

Reporting to the Vice President of Product Development, this hands-on position is responsible for the Systems Engineering and Evaluation activities associated with the verification and validation of a novel coagulation test approach, the Multiple Coagulation Test System (MCTS), comprised of an instrument and disposable cartridge containing lyophilized reagents. This individual works with external engineering and manufacturing firms in order to complete the qualification of the MCTS system as a medical device. Knowledge and demonstrated expertise in design of experiments (DOE) and statistical data analysis in support of an FDA and EU submissions. Working knowledge of In-Vitro Diagnostics validation including Precision, Repeatability, Reproducibility, Stability, Interferences and Linearity is desirable. This position requires laboratory skills, knowledge of good laboratory practices and sound technical writing.

Duties will include preparing the samples for examination, using automated equipment and specialized instrumentation, performing numerous complicated tests simultaneously, and accurately interpreting the results.

### **General Responsibilities:**

- Design and Development
  - Researching publications relevant to the MCTS application in areas of coagulation and blood biochemistry
  - Troubleshooting performance issues and providing guidance for corrective action
  - Creative thinking and repurposing of established technologies in addressing performance issues
  - Developing and implementing design changes to enhance system performance
- Sample Preparation and Analysis
  - Testing samples according to controlled protocols
  - Establishing and monitoring programs that ensure data accuracy
- Product Testing and Data Analysis
  - Preparing samples to exhibit specific coagulation factor deficiencies
  - Preparing and sending samples to external laboratories for analysis
  - Design statistically sound experiments for understanding sources of variability between system elements
  - Develop analysis methods to aide in the demonstrating product performance
  - Developing and presenting test reports
- Logistics and Laboratory Management
  - Operating and maintaining laboratory equipment
  - Maintaining appropriate inventory levels of supplies for the lab
  - Maintaining blood draw and donor management to support planned experiments

This full-time position will reside at the company's Bar Harbor research and development facility. Some travel may be required in supporting other company locations and clinical trial site support.



Coagulation Sciences LLC  
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**Educational Requirements:**

- BS degree in Biomedical Sciences or Engineering; MS preferred
- Work experience weighted with education

**Work Experience:**

- 1-3 years' experience working in a laboratory environment
- Experience with In-Vitro Diagnostics is preferred
- Proven ability to work independently with minimal supervision

**Salary and Benefits:**

- Salaried position with paid vacation and holidays
- Equity position within the company
- Initial salary commensurate with experience; Range: \$70K to \$80K
- Employee reimbursement for health insurance
- Bonuses based upon company and individual performance