UW HEALTH JOB DESCRIPTION

LABORATORY DEVELOPMENT SPECIALIST - SENIOR

Job Code: 530002	**FLSA Status: Exempt**	**Mgt. Approval: M Marggi**	**Date: 7-18**
Department : Laboratory Services		**HR Approval: K Sawyer**	**Date: 7-18**

JOB SUMMARY

The Laboratory Development Specialist Senior is responsible for researching and developing new testing methodologies and technologies that are required for clinical application in a UW Health laboratory. Activities include developing, evaluating, establishing, writing and performing validations and clinical applied research protocols along with overseeing other personnel assisting in the validation of the new method. Laboratory Development Specialist may specialize in one area or more of the following areas based on the needs of the UW Health. The areas of science may include infectious disease, molecular diagnostics, toxicology, chemistry, hematology, pathology or other specialty area. Knowledge and expertise may include: molecular biologic and immunologic techniques, including Polymerase Chain Reaction, DNA sequencing, Next Generation Sequencing, DNA cloning, Tandem mass spec, gas chromatograph, liquid chromatograph, cellular immunologic techniques, flow cytometry, cell culture, solid phase antibody assays and immunohistochemical staining.

The incumbent works with leadership to ensure that the testing is scientifically sound and meets the testing needs of UW Health patient population. Performance of these duties permits other clinical laboratory scientists to use the reagents and methodologies developed with confidence, so they may supply physicians with accurate and timely diagnostic data on blood and body tissues. The individual in this position is allowed to make many independent judgments that pertain to laboratory function and test methodology development.

The individual is regarded as a technical leader for all testing in the specified Laboratory and is the resource for operators and management when questions or problems arise. This individual is expected to remain current on scientific literature in this area, train staff, pathology residents, medical laboratory scientists, students, and present and share knowledge at laboratory meetings and scientific seminars. Scientific reasoning and innovative thinking is routinely required to resolve complex problems. The individual must be knowledgeable of all regulatory requirements and good practices pertaining to diagnostic testing and new test validation.

Problems encountered are complex requiring investigation and initiative to reach final resolutions. Information is not readily available from documented policies, procedures and regulations. The incumbent must seek information through consultations with experts outside the institution, collaborations with researchers, clinicians and manufacturing research and development staff, by reviewing current literature, and exploration using scientific methods.

Internal contacts relationships include, but are not limited to pathologists, physicians and faculty, other laboratory staff, and data processing. External contacts include but are not limited to research and clinical staff at other medical centers, commercial research and development staff, technical and sale representatives and regulatory personnel. Contacts are made by some of the following: telephone, internet, national meetings, and technical training programs and users meetings

Organizational and project management skills are critical to effectively manage, prioritize and bring to completion multiple projects and clinical requests simultaneously.

MAJOR RESPONSIBILITIES

A. Research and development of test methodologies

1. Research literature to gain an understanding of test concepts as they relate to test methodologies development. Understand both the theoretical and practical perspectives.
2. Develop clinical applied research protocols and new methods for use in the UW Health Clinical Laboratory
    - Development and performance of new test methodologies and technologies.
    - Work with the laboratory manager and faculty to establish timelines and priorities for test development.
    - Oversee personnel evaluating and validating new instrumentation and testing protocols. That staff are proficient in the method under development, adhere in required timelines and are efficiently utilized.
    - Investigate/produce new reagents.
    - Develop evaluation protocols and validation plans protocol with leadership.
    - Perform evaluation of the new test method and investigate sources of error.
    - Collate data and participate in decisions to judge analyzer or method performance.
    - Review compliance of methodologies with elements of accrediting agencies and modify as needed to meet requirements.
    - Arrange for the introduction of the method into routine use.
    - Communicate changes and instruct laboratory personnel in the use of the new test method.
    - Assist in revising standard operating procedures manuals, references, and teaching materials.
    - Monitor test implementation and respond to problems.
    - Prepare evaluation report.
    - Develop/update written procedures for new or modified test methods in accordance with Clinical and Laboratory Standards Institute and accrediting agency standards.
    - Participate in manuscript preparations and presentations as requested.
3. Resolve related problems using previous experience, product literature, or manufacturer technical representatives.
4. Maintain a working knowledge of The Centers for Medicare & Medicaid Services/Clinical Laboratory Improvement Amendments requirements for Laboratory Developed Tests and ensure all validation and testing protocols meet with Clinical Laboratory Improvement Amendments criteria for Laboratory Developed Tests. Advise leadership and Service Team on availability of Food and

Drug Administration approved testing kits. When requested, submit Laboratory Developed Tests to Food and Drug Administration for approval or licensure.

- Provide high quality instrument resources for resolution of measurement problems.
- Review problem situations and determine tasks necessary to identify the analytical problem. These tasks may include checking of standards or calibration materials and assay of reagents to determine activity or purity.
- Confirm method performance or correct the procedure as required. Communicate corrective action needed and advise on better alternatives, if appropriate. Document technical reports that summarize results and plan for feedback activity to ensure effective problem resolution.

5. Monitor and maintain a safe working environment around the analyzer to comply with all laboratory, hospital, and industry safety regulations.
6. Participate in continuing education such as workshops, lectures, reading journal articles, etc.

B. Performance of technical leader duties

1. Resolve analytical related problems using previous experience, product literature, or manufacturer technical representatives.
2. Review new product literature for calibration, quality control and reagents that may improve performance of current methods.
3. Consult with leadership, quality specialists, and team members to identify problems. Initiate solutions.
   - Assist team members, quality control specialists, and laboratory technologists in interpreting quality control data for problem solving.
   - Investigate and initiate changes in procedures, reagents, and supplies that may be required to optimize testing procedures.
   - Document changes in the processes/operations that may impact patient data or quality control results.
4. Advise and assist manager, quality control specialists and team members in discovering ways to improve laboratory operations. Lead and contribute to discussion regarding operations improvement in laboratory meetings.
5. Inform laboratory personnel of revisions to laboratory methods via laboratory meetings.
6. Develop and maintain a systematic approach to initial training of technologists and subject matter experts on new tests and technologies.
   - Maintain pertinent training materials including: training outline, checklists, training objectives, performance standards, student quizzes, audiovisuals, case studies, and teaching aids.
   - Conduct training in a professional manner.
   - Monitor trainee's progress, provide constructive feedback and reinforcement to ensure trainee has learned and mastered the vital aspects of instrument operation.
   - Evaluate trainee's abilities, attitude, initiative, etc. and communicate to manager's specific training needs that have not been met.
7. Perform competency assessment and use innovative approaches to ensure all instrument operators maintain competency.

C. Perform duties required to fulfill the commitment to UW Health laboratory operations

1. May perform patient testing as applicable.
   - Performing test methods for clinical diagnosis of disease states and medical conditions. In addition to reporting results to ordering source using laboratory computer and/or telephone.
   - Perform and document required quality activities, such as proficiency testing, quality assurance monitors, participation on process improvement teams, etc.
   - Maintain performance of analytical equipment. Perform preventive maintenance, scheduled startup or shutdown procedures, calibrations, and troubleshooting.
2. Detect, isolate, and correct procedure problems. Document corrective actions. Suggest preventive measures.
3. Observe all safety policies and procedures.
4. Contribute suggestions about process and other laboratory improvements.

ALL DUTIES AND REQUIREMENTS MUST BE PERFORMED CONSISTENT WITH THE UW HEALTH PERFORMANCE STANDARDS.

JOB REQUIREMENTS

Education	Minimum	Master's degree in Immunology, Molecular Biology, Genetics, Biochemistry, Toxicology, Microbiology, or related science or equivalent experience
	Preferred	PhD or MD degree in Immunology, Molecular Biology, Genetics, Biochemistry, Toxicology, Microbiology, or related science or equivalent experience
Work Experience	Minimum	Three years of relevant laboratory experience and track record of research productivity
	Preferred	Five years of experience demonstrating successful performance conducting research and/or development
Licenses & Certifications	Minimum	
	Preferred	
Required Skills, Knowledge, and Abilities		• Experience and knowledge of analytical instrumentation • Experience in evaluating established research protocols and developing new research protocols. • Background knowledge of procedures for collection and preparation of blood and tissues prior to analysis.

	• Extensive knowledge of general laboratory techniques including solution preparation, titration, electrophoresis and recombinant nucleic acid techniques. • Experience in teaching and training • Experience in working with clinical laboratory procedures • Background knowledge in concepts performed in specialty area of hire including an understanding of methods and tests. • Demonstrated proficiency in experimental design and statistics • Strong detail orientation and analytical ability to evaluate and ensure accuracy of data related to laboratory results and patient information; • Effective decision making and problem solving skills • Demonstrated skill in project management • Effective oral and written communication skills • Strong laboratory and teaching skills • Ability to provide effective leadership • Ability to work independently and as a team member • Effective time management and organizational skills to coordinate a broad base of laboratory functions and appropriately prioritize multiple tasks simultaneously

AGE SPECIFIC COMPETENCY (Clinical jobs only)

Identify age-specific competencies for direct and indirect patient care providers who regularly assess, manage and treat patients.

Instructions: Indicate the age groups of patients served either by direct or indirect patient care by checking the appropriate boxes below. Next,

X	Infants (Birth – 11 months)	**X**	Adolescent (13 – 19 years)
X	Toddlers (1 – 3 years)	**X**	Young Adult (20 – 40 years)
X	Preschool (4 – 5 years)	**X**	Middle Adult (41 – 65 years)
X	School Age (6 – 12 years)	**X**	Older Adult (Over 65 years)

JOB FUNCTIONS

Review the employee's job description and identify each essential function that is performed differently based on the age group of the patient.

PHYSICAL REQUIREMENTS

Indicate the appropriate physical requirements of this job in the course of a shift. *Note: reasonable accommodations may be made available for individuals with disabilities to perform the essential functions of this position.*

	Physical Demand Level	**Occasional** Up to 33% of the time	**Frequent** 34%-66% of the time	**Constant** 67%-100% of the time
	Sedentary: Ability to lift up to 10 pounds maximum and occasionally lifting and/or carrying such articles as dockets, ledgers and small tools. Although a sedentary job is defined as one, which involves sitting, a certain amount of walking and standing is often necessary in carrying out job duties. Jobs are sedentary if walking and standing are required only occasionally and other sedentary criteria are met.	**Up to 10#**	**Negligible**	**Negligible**
X	**Light:** Ability to lift up to 10 pounds maximum and occasionally lifting and/or carrying such articles as dockets, ledgers and small tools. Although a sedentary job is defined as one, which involves sitting, a certain amount of walking and standing is often necessary in carrying out job duties. Jobs are sedentary if walking and standing are required only occasionally and other sedentary criteria are met.	**Up to 20#**	**Up to 10#** or requires significant walking or standing, or requires pushing/pulling of arm/leg controls	**Negligible** or constant push/pull of items of negligible weight
	Medium: Ability to lift up to 50 pounds maximum with frequent lifting/and or carrying objects weighing up to 25 pounds.	**20-50#**	**10-25#**	**Negligible-10#**
	Heavy: Ability to lift up to 100 pounds maximum with frequent lifting and/or carrying objects weighing up to 50 pounds.	**50-100#**	**25-50#**	**10-20#**
	Very Heavy: Ability to lift over 100 pounds with frequent lifting and/or carrying objects weighing over 50 pounds.	**Over 100#**	**Over 50#**	**Over 20#**
List any other physical requirements or bona fide occupational qualifications:				

Note: The purpose of this document is to describe the general nature and level of work performed by personnel so classified; it is not intended to serve as an inclusive list of all responsibilities associated with this position.