

## UW HEALTH JOB DESCRIPTION

### LABORATORY DEVELOPMENT SPECIALIST

<b>Job Code: 530001</b>	<b>FLSA Status: Non-Exempt</b>	<b>Mgt. Approval: M Marggi</b>	<b>Date: 7-18</b>
<b>Department : Laboratory Services</b>		<b>HR Approval: K Sawyer</b>	<b>Date: 7-18</b>

### JOB SUMMARY

The Laboratory Development Specialist is responsible for researching existing testing methodologies which may be used for clinical application in a UW Health laboratory. Activities include evaluating, establishing, writing and performing clinical applied research protocols along with overseeing other personnel assisting in the validation of the method. This is an area of high-complexity testing. This position works under the guidance of the Laboratory Development Specialist Senior or faculty on technical issues to ensure that the clinical needs for the testing meets testing needs of the UW Health patient population.

Laboratory Development Specialist may specialize in one area or more of the following areas based on the needs of UW Health. The areas of science may include infectious disease, molecular diagnostics, toxicology, chemistry, hematology, pathology or other specialty area.

Individual will assist in development of bid specifications, evaluation, and implementation of potential test systems in the laboratory. Along with reviewing calibration, quality control, reagents that become available in the market to determine if they would improve laboratory operations. 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.

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 skill is 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. Assist in the development of clinical applied research protocols and methods for use in the UW Health Clinical Laboratory.
  - 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 protocol with manager and quality control specialist.
  - Perform evaluation of the 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.
  - Revise manuals, references, and teaching materials.
  - Monitor test implementation and respond to problems.
  - Prepare evaluation report.
  - Develop/update written procedures for test methods in accordance with Clinical and Laboratory Standards Institute and accrediting agency standards.
  - Participate in manuscript preparations and presentations as requested.
3. Investigate 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 Director 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.

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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. Review product literature for calibration, quality control and reagents that may improve performance of current methods.
2. Consult with manager, Laboratory Development Specialist Senior, faculty, 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.
3. Advise and assist manager, quality control specialists and team members in discovering ways to improve laboratory operations. Contribute to discussion regarding operations improvement in laboratory meetings.
4. Inform laboratory personnel of revisions to laboratory methods via laboratory meetings.
5. Assist with staff training.
  - Utilize 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.
6. Assist manager with competency assessment and use innovative approaches to ensure all instrument operators maintain competency.

### C. Perform duties required to fulfill the commitment to UW Health Clinical Laboratory operations

1. As necessary when workload dictates, individual may need to help out with patient testing.
  - 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.
5. Participate in continuing education such as workshops, lectures, reading journal articles, etc.

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

### JOB REQUIREMENTS

Education	Minimum	Bachelor's degree in Immunology, Molecular Biology, Genetics, Biochemistry, Microbiology, or related science or equivalent experience.
	Preferred	Master's degree or in Immunology, Molecular Biology, Genetics, Biochemistry, Microbiology, or related science or equivalent experience.
Work Experience	Minimum	Two years of complex laboratory experience
	Preferred	Three years of experience demonstrating successful performance conducting research and/or development
Licenses & Certifications	Minimum	
	Preferred	
Required Skills, Knowledge, and Abilities		<ul style="list-style-type: none"> <li>• Experience in evaluating established research protocols and developing new research protocols.</li> <li>• Background knowledge of procedures for collection and preparation of blood and tissues prior to analysis.</li> <li>• Knowledge of general laboratory techniques including solution preparation, titration, electrophoresis and recombinant nucleic acid techniques</li> <li>• Background knowledge in molecular biology concepts performed in specialty area of hire including an understanding of methods and tests</li> <li>• Demonstrated problem-solving skills</li> <li>• Demonstrated analytical skills</li> <li>• Demonstrated organizational skills</li> <li>• Demonstrated multi-tasking skills</li> </ul>

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	<ul style="list-style-type: none"> <li>• Knowledge of The Joint Commission, College of American Pathologists and Clinical Laboratory Improvement Amendments regulations related to work area</li> <li>• Knowledge of quality control and quality assurance principles and proficiency in testing procedures</li> <li>• Knowledge of adult training methods and teaching skills</li> </ul>
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### 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,

<b>X</b>	Infants (Birth – 11 months)	<b>X</b>	Adolescent (13 – 19 years)
<b>X</b>	Toddlers (1 – 3 years)	<b>X</b>	Young Adult (20 – 40 years)
<b>X</b>	Preschool (4 – 5 years)	<b>X</b>	Middle Adult (41 – 65 years)
<b>X</b>	School Age (6 – 12 years)	<b>X</b>	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
<b>Sedentary:</b> 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.	<b>Up to 10#</b>	<b>Negligible</b>	<b>Negligible</b>
<b>X</b> <b>Light:</b> Ability to lift up to 20 pounds maximum with frequent lifting and/or carrying of objects weighing up to 10 pounds. Even though the weight lifted may only be a negligible amount, a job is in this category when it requires walking or standing to a significant degree.	<b>Up to 20#</b>	<b>Up to 10#</b> or requires significant walking or standing, or requires pushing/pulling of arm/leg controls	<b>Negligible</b> or constant push/pull of items of negligible weight
<b>Medium:</b> Ability to lift up to 50 pounds maximum with frequent lifting and/or carrying objects weighing up to 25 pounds.	<b>20-50#</b>	<b>10-25#</b>	<b>Negligible-10#</b>
<b>Heavy:</b> Ability to lift up to 100 pounds maximum with frequent lifting and/or carrying objects weighing up to 50 pounds.	<b>50-100#</b>	<b>25-50#</b>	<b>10-20#</b>
<b>Very Heavy:</b> Ability to lift over 100 pounds with frequent lifting and/or carrying objects weighing over 50 pounds.	<b>Over 100#</b>	<b>Over 50#</b>	<b>Over 20#</b>
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.