



RECRUITMENT JOB DESCRIPTION

Job Title:	IVD Kit Manufacturing Associate	Apply To:	www.apbiocode.com biz-development@apbiocode.com
Position Objective:	Manufacture in vitro diagnostic (IVD) and research use only (RUO) products.		
Essential Functions:	<ul style="list-style-type: none">• Responsible for preparation of reagent components used in Applied BioCode IVD products; manufactures medical devices, performs process optimization and validation, and performs product calibration and stability studies. Meets deadlines specified in overall project schedules.• Makes detailed observations. Analyzes data using statistical methods. Interprets results, documents conclusions, and submits to appropriate individual.• Prepares technical reports, summaries, protocols and quantitative analyses that accurately and clearly communicate necessary information.• May be involved in new product scale-up, process optimization, process validation, and technology transfer.• Follows all Standard Operating Procedures and Quality System Requirements.• Maintains clear and accurate documentation (DMR).• Maintains adequate supplies and tools.• Conducts experiments under the direction of department manager.• Calibrates, monitors and ensures equipment performance.• Contributes ideas toward process improvement.• Maintains a high degree of safety awareness.• Maintains a clean orderly work area.		
Education:	<ul style="list-style-type: none">• Relevant experience in manufacturing of diagnostic products, familiar with general laboratory techniques.• Bachelor's degree in life science, and 5-7 years related work experience.		
Experience/Requirements:	<ul style="list-style-type: none">• Working knowledge of IVD manufacturing, and Quality System Requirements.• Basic knowledge of immune/molecular chemistry principles, theories and practices.• Demonstrates a sense of urgency, strong work ethics and a "can do" attitude.• Demonstrates competence in data analysis and report writing.• Good verbal and written communication skills.• Good interpersonal skills; ability to work as an effective team member.• Working knowledge of PC software, preferably Word and Excel.• Embraces and leverages diversity of culture and thought.		
Working Conditions:	Works in a laboratory environment. Is required to lift up to 20 lbs. May be required to sit or stand for long periods of time while performing duties. Ability to work safely with hazardous chemicals and infectious agents. Willingness to work overtime and flexible schedule as needed is a plus.		