

ACQUISITION AND MANUFACTURE OF BIOLOGICAL SAMPLES FOR VALIDATION, TRAINING, COMPETENCY AND PROFICIENCY

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Validation, training, competency, and proficiency are important requirements of a forensic laboratory's quality assurance (QA) program. Aside from the daily challenges forensic analysts face in completing their workload, they must comply with these requirements. We have designed a program, the manufacture of qPAK™ (quality performance assessment kit) samples, to assist forensic laboratories, quality managers, technical leaders, and forensic DNA analysts by providing pre-characterized samples to meet these quality assurance needs. As required by national standards, databasing and forensic DNA laboratories must perform internal validation studies prior to using a procedure for databasing or forensic applications. In the United States, new forensic DNA analysts are required to complete a minimum of six months training prior to beginning forensic casework. Competency tests are assigned once an analyst has completed training and prior to conducting forensic casework, while awaiting a regularly scheduled proficiency test due to an extended absence, and upon implementation of new protocols. Forensic DNA analysts are also required to successfully complete proficiency tests twice annually.

In order to provide pre-characterized biological samples, human subjects are necessary. The University of North Texas Health Science Center (UNTHSC) Department of Forensic and Investigative Genetics has worked closely with the university's Office for the Protection of Human Subjects and the Institutional Review Board (IRB) on developing an appropriate protocol to obtain and manage such sensitive samples and information, resulting in minimal risk to human subject donors. Persons volunteering to participate in the program are provided with informed consent documents and the appropriate biospecimen instructions. Some sample types are of a sensitive nature (*e.g.*, semen donations); therefore, adults are actively recruited. For such biospecimens, the donors are instructed to abstain from sexual activity for a specified number of hours in order to ensure the program is successful by providing single source biospecimens. In order to use the donated biospecimens, the participants must be negative for Hepatitis B, Hepatitis C, and HIV. All features of this collection program are carefully described and presented to donors for maximum participation, subject awareness, and compliance with human research regulations.

The Department of Forensic and Investigative Genetics has developed procedures to manufacture and ensure high quality qPAK™ samples. Standard operating procedures and a review process is in place for the manufacture of homogeneous qPAK™ samples. Each lot of the representative set is quality control tested for the test design. Quality

control testing may include biological screening (presumptive and confirmatory) and/or DNA (autosomal STRs, Y-STRs, and mtDNA) as required by the test design specifications. In summary, we have designed a program to manufacture pre-characterized homogeneous samples to meet the quality assurance requirements and the needs of the forensic community.