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Y-screen validation from our Human Identification Professional Services (HPS) team

Sexual assault kit (SAK) samples are among the most difficult sample types encountered by many forensic laboratories. Conventional serology screening and differential extraction procedures used as part of a sexual assault workflow are time-consuming and labor-intensive. Samples collected from female victims may contain very low amounts of male DNA mixed with high amounts of female DNA. It is critical to be able to quickly and accurately assess whether swab evidence from an SAK contains a male contributor before labor-intensive differential extraction procedures are performed.

"Direct to DNA" for high-throughput processing

As an alternative to onerous and laborious conventional serology screening and differential extraction, we have developed the DNA Y-screen assay, which is designed to assess swab evidence from SAKs to rapidly detect the presence of a male contributor, facilitating a "direct to DNA" workflow. Using the Applied Biosystems™ Quantifiler™ Trio DNA Quantification Kit, the Y-screen assay provides a fast, sensitive, and reliable method for screening SAKs for the presence of male DNA.

Legislation requiring the submission of unsubmitted cases and specifying turnaround times will lead to an unprecedented increase in the number of SAKs submitted to laboratories, necessitating speedy processing to prevent backlogs. Conventional serology screening is not only time-consuming and labor-intensive, but it may be missing male DNA that could yield probative STR profiles with highly sensitive next-generation STR kits. The Y-screen assay allows forensic laboratories to process SAK samples more efficiently, decreasing overall turnaround times.

"Although the detection and characterization of body fluids in a forensic laboratory has not changed considerably over time, DNA testing has dramatically increased in sensitivity. Processing the swabs from an SAK for DNA first allows for potential reduction in false-negative serology results of swabs that are not moved on for DNA analysis because they fell below the serological test's limit of detection."

– Draft SWGDAM Guidelines for the Processing of Sexual Assault Evidence Kits in a Laboratory (July 2016)

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HPS Y-screen validation service

During your validation, standardized semen:buccal swab mixtures will be utilized to assess the **sensitivity** of the assay for the detection of male DNA, which will be confirmed with **known and nonprobative samples** provided by your laboratory. Replicate analysis will evaluate the **precision and reproducibility** of the assay. Quantifiler Trio DNA Quantification Kit results generated with Applied Biosystems™ HID Real-Time PCR Analysis Software will provide a **mixture** ratio of the quantity of male DNA vs. female DNA, as well as an indication of degradation and/or inhibition of the sample. Finally, the Y-screen workflow will be evaluated to help ensure that the process can be performed without introducing **contamination**.

Benefits of HPS Y-screen validation:

- Decide how the Y-screen assay will best fit into your SAK workflow to increase sample throughput
- Determine whether enough male DNA is present in the SAK to yield a probative STR profile
- Assess how your serology screening methods correlate to Y-screen results

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A validation application specialist (VAS) will perform the following steps during your validation:

- The Y-screen assay will be performed using the cuttings stored in Applied Biosystems™ PrepFiler™ LySep™ Columns
- Extracted DNA will be quantified with the Quantifiler Trio kit
- Sperm fraction extracts from sensitivity swabs will be amplified with the Applied Biosystems™ GlobalFiler™ and Yfiler™ Plus PCR Amplification Kits
- Extracts from nonprobative samples will be amplified with the GlobalFiler and Yfiler Plus kits
- Quantification and STR results will be analyzed and compared to serology results provided by your laboratory
- A comprehensive report will be prepared and presented to your laboratory

Partner with HPS to get your lab online without going offline

Our HPS team will collaborate with you to customize an experimental design to suit your specific validation needs. A Y-screen assay is just the first step in an efficient and robust sexual assault kit processing workflow that helps maximize the results from forensic evidence. We understand that each laboratory may incorporate the Y-screen assay into their workflow differently. Quantifiler Trio kit results from the Y-screen studies will be correlated to downstream data using next-generation STR analysis methods such as the GlobalFiler and Yfiler Plus kits. Our experienced VAS team will perform the validation studies in your laboratory, conduct comprehensive data analyses, and issue a detailed report. Upon project completion, we'll deliver the report to your lab and provide training to help ensure your laboratory is equipped with the expertise needed to perform the validated protocol and develop interpretation criteria and standard operating procedures.

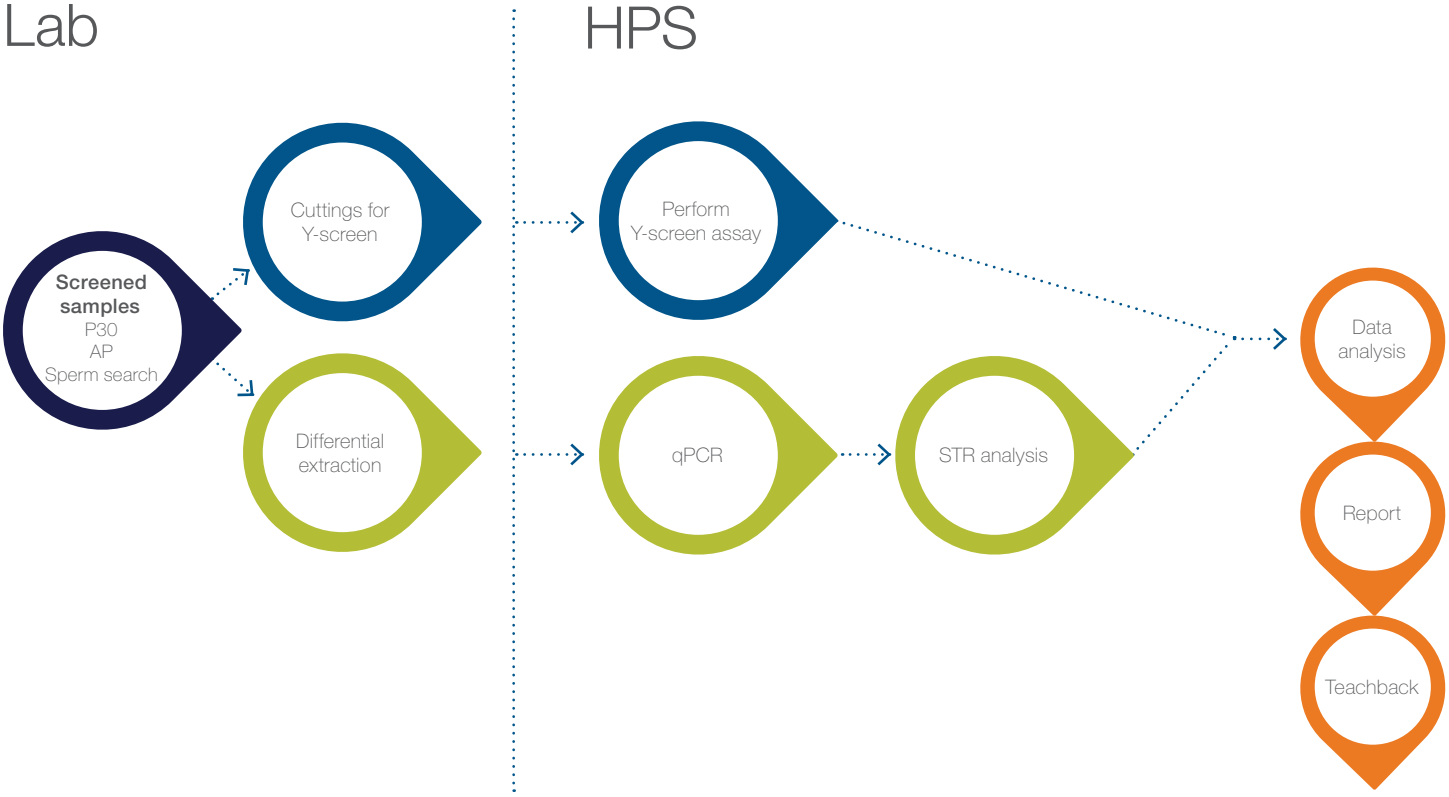

Figure 1. Schematic of HPS partnership with laboratory.

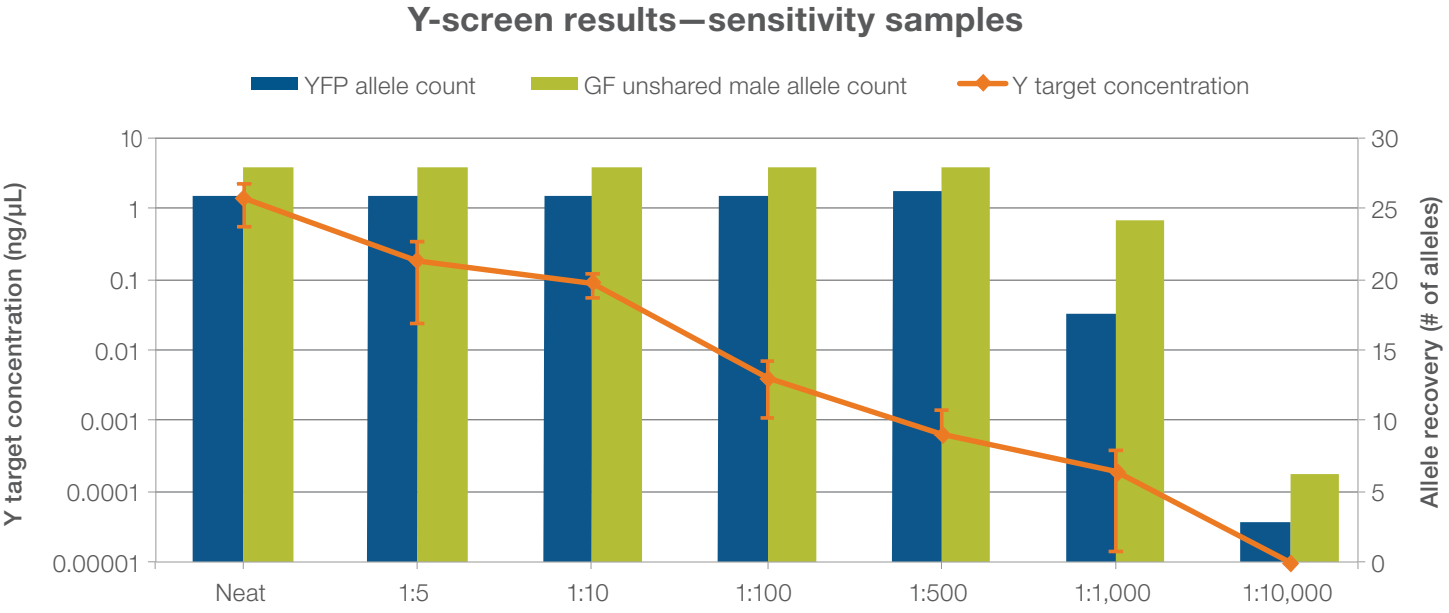

Figure 2. Example validation data demonstrating the correlation of Y-screen results with downstream STR testing.

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With over 300 projects completed around the world, you can trust the Thermo Fisher Scientific HPS team to accelerate your implementation of new workflows. Our global group of forensic scientists has over a century of combined industry experience to help drive the optimization of your workflow and minimize the impact to your lab's daily operations. We help you save valuable resources, so you can focus on productivity.

Contact your local HPS representative for more information at **thermofisher.com/hps**

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