Requirements for Complete Validation of an STR Product

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The subject of what constitutes proper validation of a DNA typing product has been a frequent point of discussion in the field of forensic science for well over a decade. The issue of validation has developed into a controversial problem for the field as a whole due to the varying opinions voiced by different members of the community. Occasionally, this controversy has spilled over into the courtroom as the judicial system wrestles with this issue (1,2). It is probable that these cases will eventually be resolved favorably and the results of DNA typing will be accepted in all courts. However, courtroom acceptance does not truly measure the success of a given validation procedure.

One of the inherent problems when developing a plan for product validation is that different stakeholders of the process have different views and agendas. The easiest views to understand are those of manufacturers and laboratories. From the manufacturer's viewpoint, the key issues center around reproducibility and performance. Batch variability must be minimized and performance must be robust enough for use in a wide variety of laboratory circumstances. The laboratories not only expect consistent performance but also assurance that the manufacturing protocols used for these products give reproducible and measurable end results.

However, manufacturers and laboratories are not the only constituents reviewing validation efforts. In its management of NDIS, the FBI is obligated to ensure that new reagent systems produce results that are consistent with those obtained using existing reagent systems. Otherwise, the national database's value for law enforcement could be greatly reduced and compromised.

In addition, individuals directly involved in the criminal justice system, whether they be suspects or victims of crimes, have an enormous personal stake in the validation process. The results of DNA typing tests can have a major impact on their lives. At times, test results may spell a life or death decision. Courtroom participants expect the entire system of product and laboratory results to be error-free. The courts support this expectation and go further. Legal standards dictate that the use of any STR system must be grounded in scientific fact that has had sufficient peer review to ensure its reliability and accuracy. Perhaps even more important, the court requires this review to be completely documented and open to peer review.

There is merit in the many points of view expressed in the validation debate. Therefore, any validation process should address the issues important to all parties. In the past, Promega has taken the issue of validation seriously and has endeavored to meet the needs of all those involved in the forensic community, including taking such actions as providing primer sequence data. During the recent validation of the PowerPlex® 16 System[a,b], Promega expanded its efforts to ensure that the needs of all parties were met.

WHAT ARE THE FOUNDING PRINCIPLES THAT UNDERLIE A COMPLETE VALIDATION PROCESS?

I. Validation of a product must be an effort by the forensic community. It is not simply an exercise to be done by the manufacturer. Since the forensic community consists of laboratories of various sizes and levels of experience, the validation process should not be an effort of a few very large and technically experienced laboratories. Laboratories of all experience levels and sizes should be included.

II. Given that validation is a community effort, the entire process as well as the results must be open to and made available for critical review. Results that are available only under limited conditions, such as a court order, do not meet the needs of the community for peer and open review.

III. Validation studies must be performed on products that have been manufactured under finalized standard operating procedures. This ensures that the products tested are the same as those that can be purchased. Products evaluated while still under development can only be considered to be useful research data.

With these basic principles in place, validation studies can be divided into several parts. First, the manufacturer's validation studies demonstrate that the system is optimized and detail the performance requirements of the system. Second, any new system must undergo a concordance study to ensure that the results obtained are in close agreement with other systems used in NDIS. Third, a casework study needs to be completed showing the system's robustness on real forensic samples. Finally, each laboratory needs to affirm that their standard operating procedures result in optimal performance of the system. A more complete outline of the studies that should be performed is provided in Promega's *Validation of STR Systems Reference Manual* (3).

Once the principles and studies outlined above are considered and implemented, the concerns of all the validation study stakeholders will be addressed. The needs of the manufacturers, the laboratories, the courts, NDIS and the individuals involved in the criminal justice system will be met. Consequently, the results obtained using a validated system can be accepted by the entire criminal justice system with a high degree of confidence. As a community, we owe that to ourselves and to our society.

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REFERENCES

1. State of Vermont v. Michael Pfenning, District Court, Grand Isle County, Case No. 57-4-96 GiCr.
2. The People of the State of Colorado v. Michael Eugene Shreck, District Court, Colorado, Case No. 00SA105.
3. *Validation of STR Systems Reference Manual* #GE053, Promega Corporation.

(a,b)Refer to patent and disclaimer statements on page 2.