February 15, 2013

Thank you again for the informative presentation on your Rapid DNA (R-DNA) efforts at our January 2013 Scientific Working Group on DNA Analysis Methods (SWGDAM) Meeting.

On behalf of the R-DNA Committee, we wanted to follow up on those presentations and ensure that all invited R-DNA developers have the same information going forward. Following are the major points of the individual discussions with the R-DNA Committee.

First, it is our understanding that the discussions on the R-DNA instruments acknowledge that they are currently designed for use with known reference samples.

Second, developmental validation is governed by Standard 8.2. of the Quality Assurance Standards for DNA Databasing Laboratories (QAS) and as such, the developmental validation of R-DNA instruments must comply with those requirements. To the extent that NDIS approved typing amplification kits would be used in the R-DNA instrument, some of the listed studies may not be applicable.

Specifically, Standard 8.2.1 of the QAS requires that developmental validation studies be performed and documented to include, where applicable:

a. Characterization of the genetic marker
b. Species specificity
c. Sensitivity studies
d. Stability studies
e. Reproducibility
f. Database-type samples
g. Population studies
h. Mixture studies
i. Precision and accuracy studies
j. PCR-based studies to include
    1. Reaction conditions
    2. Assessment of differential and preferential amplification
    3. Effects of multiplexing

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4. Assessment of appropriate controls
5. Product detection studies

Please note that the studies described in a. and g. above may not be applicable if the R-DNA instruments use NDIS approved kits (i.e., the previous approved typing amplification kit has not been modified in any way for R-DNA use). If an NDIS approved typing amplification kit has been modified, approval of such a modified kit shall be obtained in accordance with Appendix F of the NDIS Operational Procedures Manual; *see* http://static.fbi.gov/docs/NDIS Procedures-Manual Final-1-31-2013 1.pdf.

Third, it is our understanding that the Expert System or automated allele calling software used by the various R-DNA instruments is not approved for use at the National DNA Index System (NDIS). A list of approved Expert Systems is contained in the NDIS and CODIS Fact Sheet available at http://www.fbi.gov/about-us/lab/biometric-analysis/codis/codis-and-ndis-fact-sheet. Submission of an Expert System for approval to use at NDIS must be sponsored by an **NDIS Participating Laboratory** who has performed the developmental validation. In accordance with the QAS requirements for the "peer reviewed publication of the underlying scientific principle(s) of a technology", we encourage the developers of this R-DNA technology, to describe and publish details of the software used for data processing and automated allele calling that are part of the R-DNA instruments. Specifically, we recommend publication of information describing the pre-allele calling processing (raw data collection, baseline subtraction, smoothing, color separation, etc…) and automated allele calling settings, such as how the software was calibrated to your specific R-DNA data (PHR threshold, peak calling thresholds for homozygous and heterozygous genotypes, etc…).

As requested at the individual Committee meetings and to ensure that all R-DNA developers receive the same information, the following communication mechanism is available for questions that may arise in the course of your validation efforts. At the www.swgdam.org site, under Public Comment, you may submit a question by marking it to the attention of the R-DNA Committee. As questions are received, they will be forwarded to the R-DNA Committee for consideration, and as appropriate, a response. On a routine basis of approximately every two to three months,

the questions and the SWGDAM responses will be posted on the SWGDAM FAQ Page. This should ensure that all R-DNA developers have the same information. Should your question be time sensitive, please note that fact in your inquiry and we will make our best efforts to respond accordingly.

I hope this information is of assistance as you continue in your development and validation efforts. If you encounter any difficulties submitting inquiries through the communication mechanism described above, please contact me at Anthony.Onorato@ic.fbi.gov.

Sincerely,

Anthony Onorato
SWGDAM Chair