Development of SRM 2372 Human DNA Concentration Standard to Help Assure Accuracy in Forensic Testing

Candidate Standard Reference Material 2372 Human DNA Quantitation standard (SRM 2372) is being developed by NIST's Human Identity Project team in response to numerous requests from the forensic human DNA identity community. SRM 2372 is expected to provide a well-characterized, homogenous, and stable DNA quantitation standard to this community and others where DNA concentration is a major factor in the quality of downstream applications results. While the certified values for each component are the absorbances at five ultraviolet wavelengths, these values define a "conventional" DNA concentration and several DNA quality metrics. An interlaboratory study involving 32 laboratories using 12 different DNA quantification methods was conducted to evaluate the practical utility of the conventional concentration assigned to each component.

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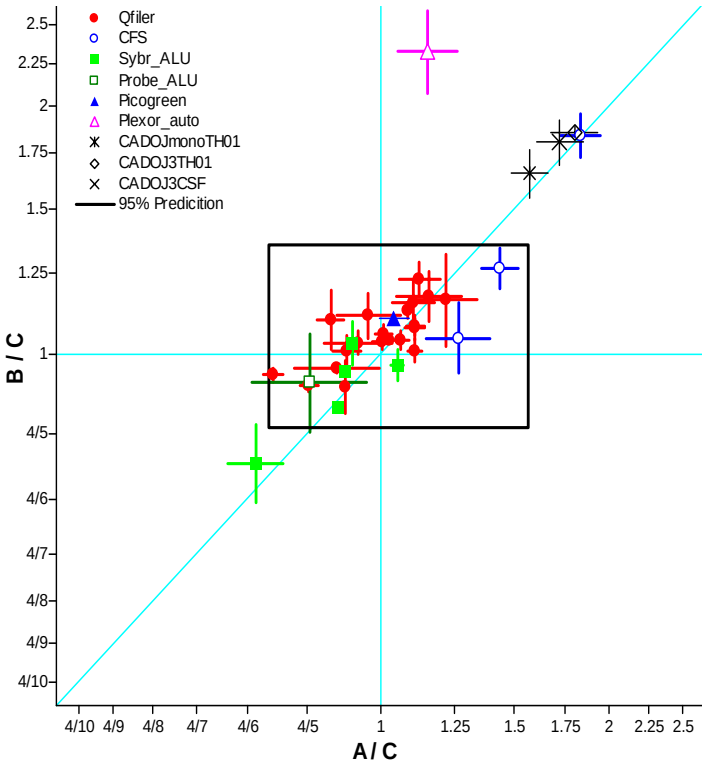
The NIST team characterized SRM 2372 components to assure they are fit-for-purpose for calibrating secondary standards for human DNA quantification assays, including the various quantitative Polymerase Chain Reaction (qPCR) methods. In addition to establishing traceability for secondary and working standards, this SRM will allow individual laboratories to validate the DNA calibration of materials included in commercially available DNA quantification kits. The DNA concentration in some widely used commercial materials has varied by up to a factor of two.

NIST will release a new Standard Reference Material to enable accurate accounting for the amount of DNA starting material used by forensic scientists performing human identity testing. This will help to assure the accuracy of the assays and, in turn, the integrity of the criminal prosecution process.

The three components of SRM 2372 have been prepared and packaged: component "A" is a single-source male material prepared at NIST, "B" is a multiple-source female material prepared at NIST, and "C" is a commercially prepared mixed male and female material. The three materials were prepared to have very similar DNA concentration of approximately 50 ng/µL. Absorbance measurements from NIST's second generation National Reference Spectrophotometer were used to define a "conventional" DNA concentration for each component. An interlaboratory study was conducted to establish the commutability of the conventional DNA concentration assigned to the results of 12 different field methods comparing the components to one another. Homogeneity testing within each component has been completed.



The figure shows a comparison of interlaboratory results for SRM 2372 components A and B, each standardized to component C.

The resulting relative values, labeled A/C and B/C, indicate that the materials are commutable among most of the quantification methods but that a few assays are sensitive to the elevated salt concentration of component C and one assay is sensitive to the relative male/female composition of the materials. Error crosses represent approximate 95% confidence intervals. The boxed area defines an approximate 95% confidence interval on the mean ratios.

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Future Plans: We will complete the certification process, release it for sale, and educate the target community on how to most efficiently use the SRM 2372 materials.

To support this user community we will publish a paper on the preparation and use of the SRM materials.