



# DEVELOPMENT OF A RESEARCH GRADE TEST MATERIAL FOR SUPPORTING COMMUNITY-WIDE VALIDATION EFFORTS



P-175

Erica L. Romsos, Carolyn R. Steffen & Peter M. Vallone  
U.S. National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899-8314, USA

APPLIED GENETICS  
Email: Erica.Romsos@nist.gov

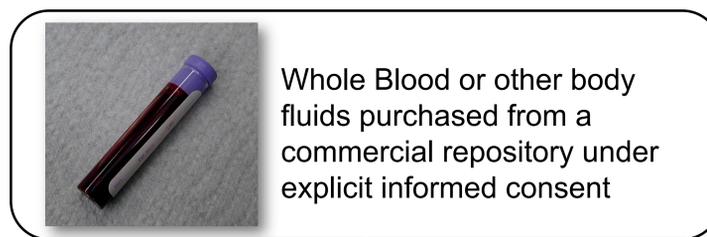
A Research Grade Test Material (RGTM) is a new classification of exploratory material produced by NIST, which aims to evaluate fit-for-purpose needs within a community. An RGTM does not have the same high level of characterization as a Standard Reference Material but can be disseminated more quickly to address potential measurement needs. As current privacy issues often preclude forensic DNA laboratories from sharing STR profiles in the public domain, the motivation to release an RGTM is to aid validation efforts by offering a set of DNA extracts with explicit informed consent which allow for public sharing of STR profiles. This will also facilitate an increased transparency between laboratories and law enforcement stakeholders.

The RGTM material will be comprised of a set of well-quantified DNA extracts to be sent to interested forensic DNA laboratories. Initially, NIST will provide allele calls for the U.S. core loci. The extracts may be used to support the validation of methods employed in a forensic laboratory and an interface will be developed to facilitate feedback to NIST. This data will aid in supporting future studies focused on material stability and additional types of materials to support the forensic DNA community.

## What is a Research Grade Test Material (RGTM)?

- An exploratory material developed for feedback from stakeholders
- NOT a Standard Reference Material (SRM) or Reference Material (RM)
- Can be developed and released faster than SRMs/RMs
- Not as highly characterized
- Not traceable to the SI
- Subjected to continuous stability measurements
- Customer feedback may drive the production of new RMs or SRMs
- Provided at no cost in exchange for your feedback/data

## Forensic RGTM Exploratory Concepts



Whole Blood or other body fluids purchased from a commercial repository under explicit informed consent

Different forms of source material to aid in measurement needs

Body Fluids

Substrates with single source whole blood

Substrates with mixtures of whole blood

Substrates with single source saliva

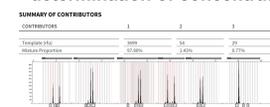
Substrates with mixtures of saliva

Additional body fluid combinations

Extracted DNA

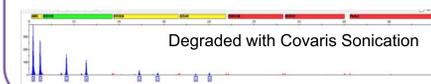
Single source extracted DNA with a highly specific known concentration

Concentration determined via droplet digital PCR allows for more accurate and precise determination of concentration

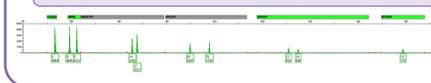


3 Person Mixture (98:1:1)  
Samples were quantified with ddPCR

Degraded single source extracted DNA



Inhibited samples



Set of well characterized extracted DNA mixtures



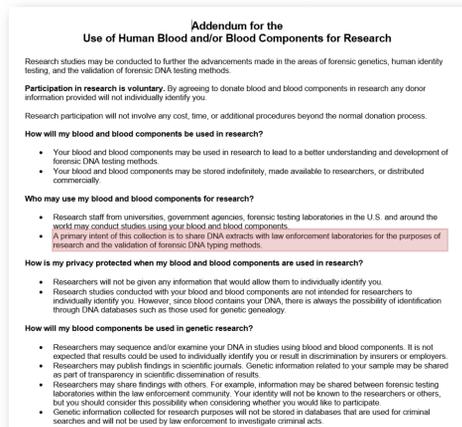
Source

Candidate RGTM Material

## Human Subjects Considerations for Materials

Explicit informed consent of sample donors to allow for public sharing of STR Data

Donor consent is to allow for public sharing of genotyping and sequencing data specifically with law enforcement laboratories and researchers both domestic and international



### Benefit to NIST:

Examination of future production methods for RMs and SRMs

Production, stability, and storage of material

Addition of Carrier RNA

Material type: DNA vs Swabs

High vs Low Concentration

Tube type: Polypropylene vs Teflon

Materials developed with customer input (substrate, extracted DNA, sample sets, etc)

## Community Input

Community collaboration and interest driven

RGTM development allows for community input for samples to help with measurement challenges, including support for validation efforts within laboratories



Please provide input!

## Previous RGTM Produced by the Applied Genetics Group

RGTM 10169: SARS-CoV-2 Synthetic RNA Fragments



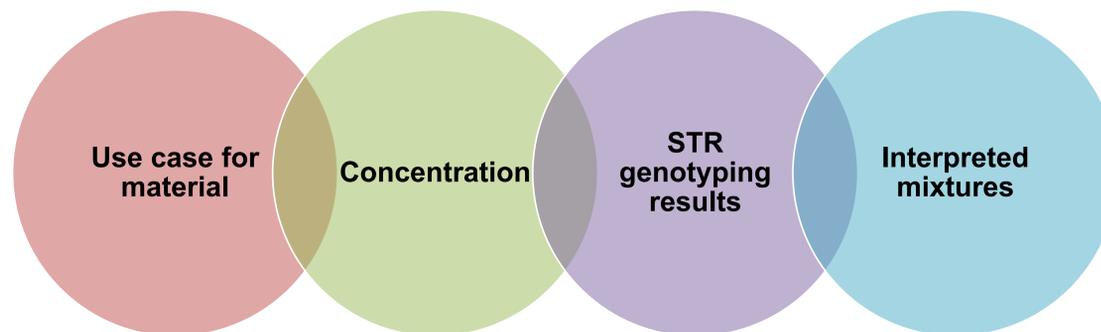
Developed by the Applied Genetics Group in response to the COVID-19 pandemic

RNA fragments can assist in the development and validation of RT-qPCR assays for SARS-CoV-2 detection

Development ~ 90 Days Distribution

Fit-for-purpose materials for current community need

## Examples of requested feedback/data



Data portal and repository under consideration to facilitate feedback and anonymous comparison between laboratories

Customers will be required to provide feedback and results to NIST to participate in future RGTM iterations

Customer Feedback

For more information or questions please contact: ForensicRGTM@NIST.gov

Download a PDF copy of this poster



Disclaimer: Points of view in this document are those of the authors and do not necessarily represent the official position or policies of the U.S. Department of Commerce. Certain commercial software, instruments, and materials are identified in order to specify experimental procedures as completely as possible. In no case does such identification imply a recommendation or endorsement by NIST, nor does it imply that any of the materials, instruments, or equipment identified are necessarily the best available for the purpose.

Human Subjects: All work has been reviewed and approved by the National Institute of Standards and Technology Research Protections Office. This study was determined to be "not human subjects research" (often referred to as research not involving human subjects) as defined in U. S. Department of Commerce Regulations, 15 CFR 27, also known as the Common Rule (45 CFR 46, Subpart A), for the Protection of Human Subjects by the NIST Human Research Protections Office and therefore not subject to oversight by the NIST Institutional Review Board.

Funding: This work was supported by the NIST Special Programs Office: Forensic Genetics.