

# How To Make NIST Traceable Materials

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The National Institute of Standards and Technology (NIST) is a non-regulatory federal agency within the U.S. Commerce Department's Technology Administration. NIST's mission is to develop and promote measurement, standards, and technology to enhance productivity, facilitate trade, and improve the quality of life. NIST ensures accurate and compatible measurements through the development, certification, and distribution of Standard Reference Materials (SRMs). Approximately 1300 SRMs are currently available for use in: (1) industrial materials production and analysis; (2) environmental analysis; (3) health measurements, and (4) basic measurements in science and metrology.

NIST's first SRM for the forensic and paternity DNA typing communities was released in 1992, SRM 2390 "DNA Profiling Standard" for RFLP typing. As the methodologies of DNA typing evolved SRM 2391 "PCR-based DNA profiling standard" was released in 1995. The forensic DNA typing community awareness and usage of NIST SRMs and the need to know the meaning of NIST traceability increased primarily because DNA Advisory Board (DAB) Standard 9.5 which states that a laboratory "shall check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material or standard traceable to a NIST standard."

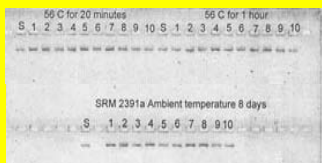
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## Standard Reference Materials SRM®

Well characterized material  
Evaluated for:

- 1) Homogeneity
  - a) calibration of dispensing instruments
  - b) protective apparel (to protect the product from contamination).

### 2) Stability



### 3) Reproducibility Current SRMs of Forensic Interest DNA Only

SRM #	Use	Total #	FY 2000	YTD	AVG	Supply	Price
2390 8/92	RFLP	107	14	4	19	67 mo	\$543
2391a 3/00	PCR STR's	122	158	82	134	11 mo	\$559
2392 12/99	Mito Seq	227	8	5	7	99 mo	\$782

Data from August 14 2001 inventory  
Prices subject to change without notice.

### In progress:

- Renewal of SRM 2391a as SRM 2391b
- Modification of SRM 2392 adding cell line HL60
- Preparation of SRM 2394 mitochondrial DNA heteroplasmy
- Preparation of SRM 2395 for Y-Chromosome STRs

High Priority for Renewal of 2391a  
New Packaging, Same DNA Materials



## OFFICE OF MEASUREMENT SERVICES



"Provide the U.S. with access to the Measurement traceability that promotes innovation, increases competitiveness, and facilitates trade so as to maximize the impact, importance, relevance, and effectiveness of NIST measurement technology."

## SRM Program

... implements policies and coordinates priorities for the development, production, and certification of SRMs and serves as the main contact point for all NIST reference material activities interfacing with similar efforts in the private sector, other federal agencies, and other nations. This includes programs with the American Society for Testing Materials (ASTM) and the International Organization for Standardization (ISO).



## NTRM™

A NIST Traceable Reference Material (NTRM) is produced by a commercial supplier with a well-defined traceability linkage to the National Institute of Standards and Technology (NIST). Traceability is established via criteria and protocols tailored to meet the needs of the metrological community served. The NTRM programs leverage NIST's limited human and financial resources.

NTRM producers - and only NTRM producers - are allowed to use the NIST "NTRM" certification mark. Standards prepared according to the NTRM program are related, within known limits of uncertainty, to specific primary standards maintained by NIST

NTRM quality is assured by NIST through active quality assurance measures. oversight of production and analysis

- analysis of representative samples
- direct involvement in the assignment of certified value and associated uncertainty
- documentation including: NTRM certification, Certificate of Traceability, material labels
- oversight of the long-term maintenance of the NTRM batch by the producer

### "Traceable to NIST"

If it's not SRM® or NTRM™

### BUYER BEWARE!!!!

The company claiming traceability should be able to document direct lineage to the appropriate SRM

You **can** make your own quality assurance / control materials TRACEABLE to NIST for use in your laboratory

The Certificate of Analysis for SRM 2391a states:  
This SRM can also be used for quality assurance when assigning values to **in-house** control materials

## Make Your Own (MYO) Traceable Material

Prepare a "lot" of DNA samples: stain, swab, cell pellet, extract, etc.  
*Get human use approval first!*

Assure that the MYO samples are:  
Homogenous  
Stable  
Reproducible

Analyze the **appropriate SRM** and MYO "in parallel"

Confirm that your results for the SRM are correct (agree with certificate) and your results for the MYO are consistent (agree with your prior results).

Maintain the records of the now **traceable** MYO and the SRM analysis.

You may use the MYO as frequently as you desire in your Laboratory System **instead of** the SRM. Keep a record of the use of the MYO and results.

**IF AT ANY TIME THERE IS A DISCREPANCY WITH THE RESULTS OBTAINED FOR THE MYO A NEW LOT MUST BE MADE!!!!**

### Remember:

There must always be a direct comparison to the SRM.  
The "Lot" is Traceable **not** the source of the material.

### Example:

- Obtain human use approval for 10 mL whole blood.
- Obtain blood and appropriate stain cards / stain-media
- Following protocol, prepare 500 stains (20 µL/stain)
- Dry and store for at least a week
- Analyze at least 5 randomly selected samples
- Evaluate results: are they all qualitatively identical?
- Now** analyze at least two samples in parallel with SRM
- Maintain records that the SRM data obtained was correct as well as the data from your stain.
- Package and store stains appropriately (**dry and cold!**)
- Use MYO as traceable to NIST material.