National Effort to Standardize Names of Lab Tests to Avoid Confusion and Help Physicians, Patients and Payers:

How your Lab can Help with the TRUU-Lab Initiative

Ila Singh, MD, PhD

Chief of Laboratory Medicine, Texas Children’s Hospital
Professor, Baylor College of Medicine
Objectives

1. Recognize that many Lab Test Utilization Management programs utilize **Lab Test Name Change** as a major tool.

2. Recognize that the **names of lab tests** lead to considerable confusion in ordering.

3. Analyze and participate in a **process to create lab test names that are easy** to understand, use and make widely available.

**No Conflicts of Interest**
Patient Harm Related to Lab Services

1. Ordering the wrong test
2. Failing to retrieve a result
3. Misinterpreting a result

Dickerson et al, 2017, JALM, 02:02:259-68
One of out Eight Malpractice Claims feature failures to order or correctly interpret test results:

1. Failure to order the right test (55%)
2. Misinterpret a result (37%)
3. Failure to retrieve/receive result (13%)

Inappropriate Test Orders are Common

• 10%–30% of lab tests performed in the US are either unnecessary or incorrect

• ~ 30% of genetic test orders are inappropriate

• ~ 5% of genetic test orders are frank medical errors

Zhi M et al. PLoS ONE 2013, 8:1– 8
National Academy of Medicine (IOM) Study

Unnecessary lab tests cost an average hospital $1.7 million a year

For a 800 bed hospital system = $8.5 million/year
Uncertainty in Ordering Lab Tests

Study of 1,768 US primary care physicians

- 15% uncertain about **which test to order**
- 8% uncertain about **interpreting the results**

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Primary Care Physicians’ Challenges in Ordering Clinical Laboratory Tests and Interpreting Results, Journal of the American Board of Family Medicine, Mar-Apr, 2014
Why the Uncertainty?

- Laboratory tests: Increased > 4000
- Test names are confusing: Reduced
  Sometimes to zero
- Lab Medicine teaching hours in medical school: Reduced

Why the Uncertainty?

Vitamin D

25 hydroxy Vitamin D
1, 25 dihydroxy Vitamin D
How do Clinicians Compensate for this Uncertainty?

Order more tests

Use the ‘H’ and ‘L’ approach
Laboratory Test Utilization Management

Ordering fewer tests

It could, in some cases, mean more testing

Ordering the right test at the right time for the right price

Stewardship

Andrew Fletcher
Dickerson et al, 2017, JALM, 02:02:259-68 (PLUGS)
Hospitals all over the US are Setting Up Stewardship Programs
Strategies of Different Stewardship Programs Vary...

Scant basis in evidence-based outcomes
Few tests have defined parameters for testing intervals

- More information about tests
- Making tests invisible to clinicians
- Setting up a Lab formulary
- Clinical Decision Support Algorithms
- Lab-Run Algorithms/ reflexive testing
- Renaming tests
Scenario 1

Test names are well known, but lack of standardization and clarity.
Lack of Standardization

Hemoglobin A1C
Glycosylated Hemoglobin
Glycated Hemoglobin
HgbA1C
HbA1C
A1C

Makes it hard to find the test
Some Standardization...

Because there are CPT codes for these panels, their components are standardized

Basic Metabolic Profile  BMP  Chem7/8

Hepatic Function Panel
No Standardization

Liver Function Panel

- Lactate Dehydrogenase?
- Gamma Glutamyl transferase?

Respiratory Virus Panel

- Panel depends on the manufacturer

This will be a technical fix someday
Hovering over the name explode to components
A Clinical Pathologist Joke...

I am not sure why you are feeling so ill. But I am ordering some comprehensive test panels. One of them should show something.

If you want everyone to order a test, call it ”the COMPREHENSIVE” panel

Whole Exome Sequencing
Scenario 2
Test Names are Difficult
The Vitamin D Problem

UVB → Skin → Liver → 25-hydroxyvitamin D → Kidney

7-dehydrocholesterol (vitamin D3) → cholecalciferol (vitamin D3) → 25-hydroxyvitamin D → 1,25-dihydroxyvitamin D

Dietary intake: Fortified foods, supplements (D2 or D3), fish oils (D3)

ergocalceiferol (vitamin D2)
It all sounds so complicated ...
Two Major Forms of Vit D

25 hydroxy-vitamin D
- the best indicator of Vitamin D status in routine screening for deficiency
- Often more expensive

1,25 dihydroxy-vitamin D
- Active form of the vitamin
- Misleading in screening for deficiency
- Usually assayed by MS
- Often more expensive
The Vitamin D Problem

Total Vitamin D Testing:
- 3,351 Patients
- 5,105 Tests

Vitamin D, 1,25DIHY:
- 1,366 Patients
- 1,541 Tests

Vitamin D, 25HY:
- 3,044 Patients
- 2,564 Tests

Both tests were ordered for 906 patients (1,962 tests)

$80,733*
*based on Medicare allowable
Three Hospitals with the Same Problem

Three Different Solutions
Solution 1: Call the Ordering Clinician
March 2013 - Feb 2015

VIT D 25 HYDROXY
VITAMIN D 1,25 DIHYDROXY

Start of Intervention
End of Intervention
Solution 2: Change Test Names in CPOE

25- hydroxy vit D  ➡  Vitamin D for Deficiency Screen
1,25-dihydroxy vit D  ➡  Vitamin D Bone/Renal Disorder

Resulted in increase in the ‘wrong’ test!

Solution: To hide the ‘wrong’ test
Solution 3: Provide Clarification to Names

Provide *Clarification* to test names without completely changing them

- 25- hydroxy vitamin D
  - *(for deficiency screening)*

- 1,25 dihydroxy vitamin D
  - *(NOT for deficiency screening)*
Results with Solution 3

VD25H (Vit D 25 hydroxy) vs VITD3 (Vit D 1, 25 dihydroxy) for deficiency screening vs NOT for deficiency screening
Results with Solution 3

RATIO between for deficiency screening & NOT for deficiency screening

Name clarification
11/17/2017
Even so-called ‘Simple’ Interventions are not so simple
## Testosterone Test Utilization

<table>
<thead>
<tr>
<th>Consolidated Order Name (group)</th>
<th>% of Total Unique Orders</th>
</tr>
</thead>
<tbody>
<tr>
<td>TESTOSTERONE,FREE (DIALYSIS) AND TOTAL(LC/MS/MS)</td>
<td>40.2%</td>
</tr>
<tr>
<td>TESTOSTERONE, TOTAL, LC/MS/MS</td>
<td>34.1%</td>
</tr>
<tr>
<td>TESTOSTERONE, FREE, BIOAVAILABLE AND TOTAL, LC/MS/MS</td>
<td>22.7%</td>
</tr>
<tr>
<td>TESTOSTERONE, FREE (IMMUNOASSAY)</td>
<td>2.3%</td>
</tr>
<tr>
<td>TESTOSTERONE, TOTAL, MALES (ADULT), IMMUNOASSAY</td>
<td>0.7%</td>
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<tr>
<td>TESTOSTERONE, FREE (DIALYSIS) AND TOTAL (LC/MS/MS)</td>
<td>Cost 1X</td>
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<tr>
<td>TESTOSTERONE, TOTAL, LC/MS/MS</td>
<td>40.2%</td>
</tr>
<tr>
<td>TESTOSTERONE, FREE, BIOAVAILABLE AND TOTAL, LC/MS/MS</td>
<td>Cost 12X</td>
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<td>TESTOSTERONE, FREE (IMMUNOASSAY)</td>
<td>22.7%</td>
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Scenario 3

The clinically superior and cheaper test has a poorly-recognized name
Under-recognized APC resistance vs. Over-recognized Factor V Leiden testing

Activated Protein C resistance

Factor V (Leiden) Mutational Analysis

Specialty

- OB/GYN
- Pediatrician
- General/Family Practitioner
- Neuroligist
- Multi-Specialty Group Practice
- Ophthalmology/Optometry
- Rheumatologist
- Endocrinologist
- Surgeon

Distinct count of Unique Order Id (copy)

$5
APCR will pick up 10% more cases than just the FV Leiden mutation
Algorithm - APCR screen followed by factor V Leiden mutational analysis

$60
Prices from NEJM, 2014
Many Test Names are Confusing

- Lupus Anticoagulant
- Measles
- HSV 1/2
- eGFR vs EGFR  Many EMRs convert all names to Uppercase
- Panels
  - for Celiac Disease
  - for Leukemia Flow Cytometry
- Viruses
- Allergies
- LYMPH LEUK FLW CYT  = 18 characters
- Free PSA
Considerable Confusion

Even with common, ‘easy’ to understand test names
Genetic Tests can be even more confusing

Condition, gene, or protein name overlap:
Rett syndrome (MECP2 gene) vs
Multiple Endocrine Neoplasia type 2 (RET gene)

GLUT1 deficiency syndrome (SLC2A1 gene) vs
Congenital Hyperinsulinism (GLUD1 gene)

Allelic disorder: Which methodology is for somatic vs germline testings? -BRAF, KRAS, PTPN11 gene analysis for germline Noonan spectrum syndromes vs for somatic cancers/malignancies

Courtesy Darci Sternan, Seattle Children’s
Genetic Tests can be even more confusing

**COL2A1 gene:** achondrogenesis, chondrodysplasia, early onset familial osteoarthritis, spondyloepiphyseal dysplasia congenita, Langer-Saldino achondrogenesis, Kniest dysplasia, Stickler syndrome type I, and spondyloepimetaphyseal dysplasia Strudwick type

**Ambiguous Test Names:** more than one common method to work up a condition, “Thalassemia Screen” – Genetic test? Biochemical test?

Courtesy Darci Sternan, Seattle Children’s
How did we end up here?
Traditionally Test Names are Chosen by

- Pathologists and Clinical Scientists at each institution
- Without a Style Guide
- Without consulting with clinicians

**SOURCES OF NAMES**

1. **Analyte**: Sodium
2. **Reagent**: Anti-Cardiolipin Abs
3. **Etiologic Agent**: EBV PCR
4. **Patient**: Hageman factor (XII)
5. **Physician**: von Willebrand factor
6. **Vendor**: SuperQuant HBV PCR
7. **??**: RPR, Rapid Plasma Reagin
How do we fix this?

Local fixes
National Fix
Stewardship Committees

- Pathologist or Clinician-led
- Physicians
- Chief Residents
- Nurses
- Informaticians
- Evidence-based Outcomes team
- IS

Chair: Division Chief of Laboratory Medicine
Process for Name Change

1. Stewardship Committee
2. Clinician experts
3. Change in EMR, testing, validation
4. Test to see if the name change is working

• The process can take several months for ONE test
What if we could do this at a National Level?
Previous Attempts at Renaming Tests

1. Identifying the Naming Problem, CLIHC, CDC

2. Creating an alternative list of names, linked to Regenstrief Institute’s LOINC
Why begin another Test Naming Initiative?

• Timing...
  • Many hospitals have Stewardship committees
    • slow process for *each test* in *each hospital*
  • Unprecedented numbers of Hospital and Lab M & As
    • different names for same tests
  • Greater awareness that this is a Safety and Quality issue
  • EMRs have relaxed character limits for test names
  • Machine Learning Studies will need standardized test names across institutions to get the large, useful datasets
TRUU-Lab
TRUU-Lab aims to

Bring together health care providers, professional societies, and industry groups to address problems caused by ambiguous, incomplete, and non-standard laboratory test names, by

• Generating a consensus guideline for test naming
• Generating consensus names for existing lab tests
• Promoting the adoption and implementation of consensus lab test names and guidelines
TRUU-Lab Members

**AACC**
- Patti Jones, PhD
- Sridevi Devaraj, PhD

**ACLPS**
- Neal Lindeman, MD

**AMP**
- Rick Nolte, PhD
- Mary Williams
- Robin Temple-Smolkin

**API**
- Monica de Baca, MD
- David McClinton, MD

**ASCP Choosing Wisely**
- Lee Hilborne, MD
- Iman Kundu, Edna Garcia

**ASM**
- Paula Revell, PhD
- Dona Wigetunge, PhD

**CAP**
- Peter Perotta, MD

**CDC**
- Reynolds Salerno, MD
- Jasmine Chaitram, MPH
- Maribeth Gagnon, MS CT

**EMR/LIS/Terminology Groups**
- Nick Trentadue (Epic)
- Jigar Patel, MD (Cerner)
- Jeff Watson (Sunquest)
- Amanda Caudle (Atlas/Sunquest)
- Holly van Kleeck JD (Health Language)
- Dale Davidson (Health Language)
- Nancy Sokol (UpToDate)
- Cheryl Mason

**FDA**
- Michael Waters, PhD

**Nudge Unit**
- Mitesh Patel MD, PhD, MBA

**PLUGS**
- Mike Astion, MD, PhD
- Jane Dickerson, PhD

**Reference Labs**
- Brian Jackson, MD, MS (ARUP)
- Andrew Fletcher, MD (ARUP)
- Jon Nakamoto, MD, PhD (Quest)
- Mohamed Salama MD (Mayo)

**Instrumentation Makers**
- Ross Molinaro MD (Siemens)

**Clinical Pathologists and Scientists**
- Ila Singh, MD, PhD (Texas Chil/Baylor)
- Gary Procop MD (Cleveland Clinic)
- Charlene Bierl, MD, PhD (Cooper)
- Swapna Abhayankar MD (Regenstrief)
- Elissa Passiment, PhD
- Michael Laposata MD, PhD (UTMB)
- Chris Zahner, MD (UTMB)
- Anand Dighe, MD, PhD (MGH/Harvard)

**Trainees & Students**
- Julia Wang, MD PHD Student (Baylor)
- Delia Garcia RN, DNP Student (UT Houston)
- Emily Garnett PhD, Chemistry fellow (Baylor)
- Judy Trieu MD, MPH (UTMB)
How does TRUU-Lab Work?
<table>
<thead>
<tr>
<th>Steering Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>AACC</td>
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</tbody>
</table>
Governance

Steering Committee

Work Groups by Specialties

Work Groups by Task

Structure with project lead and project manager
Current TRUU-Lab Subcommittees

1. Developing guidelines
   • Brian Jackson

2. Selecting perplexing names to pressure test
   • Gary Procop

3. Whitepaper
   • Ila Singh

4. Developing guidelines for action (~NDA)
   • Nancy van Kleeck
ASCP Choosing Wisely Lab Test Stewardship Project

The ASCP Effective Test Utilization Steering Committee plans to conduct a survey on laboratory test naming conventions that cause issues or are problematic in laboratories. This survey will help identify problematic laboratory test name and offer recommendations for clearer and more understandable test names.

Have you experienced issues in test naming conventions in your laboratory?

- Yes
- No

Please name the test(s) that have been problematic in your laboratory as well as suggestions for renaming the test.

<table>
<thead>
<tr>
<th>#1</th>
<th>Current name of test</th>
<th>Suggestion for renaming the test</th>
</tr>
</thead>
<tbody>
<tr>
<td>#2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Which best describes you?

- Pathologist
- Laboratory Professional (other than Pathologist)
- Other (please specify):

Please provide your contact information so we may follow up if we have any questions.

- Name:
- Email Address:
- Institution:

[Save] [Submit]

https://app.keysurvey.com/f/1287048/33eb/
Survey for Confusing Test Names

ASCP Choosing Wisely/TRUU-Lab Survey: > 250 Responses on > 100 test names, with suggestions for renaming

Heparin/ Anti-Xa Assays
1. anti Xa level
2. Antifactor Xa assay
3. anti Xa
4. Anti-XA LMW vs Anti-XA UM
5. Heparin activity level
6. Heparin assay, LMW Heparin assay
7. Unfractionated heparin
8. Factor 10 with factor 10A
9. Rivaroxaban
10. Apixaban

Other Coagulation tests
1. Factor II
2. Factor V
3. Activated Protein C Resistance

Cancer Genetics tests
1. BCR-ABL tests
2. Multiplex gene expression analysis/ Pancancer NGS panel
3. t(15;17) PML-RARA - qualitative gets confused with FISH
Choose a small set of tests to rename

1. Use the survey to choose a small set of problematic names

2. Rename using new guidelines, “pressure test”
Develop Rules for Naming

- Most labs/EMRs do not follow specific guidelines

- Examine existing Guidelines or Preferred list of names
  - ARUP Style Guidelines
  - ONC Tiger Team’s guidelines
  - LOINC’s list of names
  - Standards for Pathology Informatics in Australia Guidelines
  - RCPA Pathology Units and Terminology Standardization Project (Australasia)
  - Canadian guidelines
<table>
<thead>
<tr>
<th>Substance analyzed by the test (compound, drug)</th>
<th>Form of analyte measured (Free, Fractionation, Total, Quantitative, Qualitative, Quantitation, Level, Functional, Enzymatic)</th>
<th>Always</th>
<th>When it is necessary to clarify the exact nature of the test to assist in ordering the correct test.</th>
<th>Carbamazepine, Free and Total Carnitine, Free Protein, Total, Plasma or Serum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative and qualitative are required when there are 2 tests for the same analyte and 1 is qualitative while the other is quantitative. Highly recommended that they be used whenever possible for applicable tests.</td>
<td>Adrenal Steroid Quantitative Panel by LC-MS/MS Glutaryl carnitine Quantitative Bence Jones Protein, Quant. Free Lambda Light Chains BCR-ABL1, T315I Mutation Detection, Quantitative Bence Jones Protein, Qualitative Free Kappa and Lambda Light Chains Drug Screen (Non forensic), Qualitative Malaria Detection &amp; Speciation, Qualitative by RT PCR Cryoglobulin, Qualitative wi Reflex to Quant. IgA, IgG, &amp; IgM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quantitation is generally reserved for Drugs of Abuse</td>
<td>Drugs of Abuse Confirmation/Quantitation - Opiates - Meconium Confirmation/Quantitation - Serum or Plasma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level is generally reserved for antimicrobial drug level testing</td>
<td>Ticarcillin, Antibiotic trough and peak Level Vancomycin, Antibiotic Peak Level</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional and Enzymatic Activity are generally reserved for coagulation-type test (Protein C)</td>
<td>Protein C, Functional Antithrombin, Enzymatic Activity Galactosemia, (GALT) Enzyme Activity and 9 Mutations</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### ONC Tiger Team Guidelines

| **ANALYTE IDENTIFICATION** | 1. The identifier of the substance (analyte) being measured must come first.  
2. Use the more common name rather than scientific name where possible, except as tradition dictates or clinical experts believe it is required to avoid confusion.  
3. Do not use double names, pick only one name for the analyte.  
4. First letter of a test name shall be upper case, use mixed case. | Identification of organisms, use the scientific name. |
<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>ANIONIC NAME FOR CHEMICALS</strong></td>
<td>Use anionic name.</td>
<td>Use the acid name when it is more commonly accepted and space is not an issue.</td>
</tr>
</tbody>
</table>
| **ANTIBODY/ANTIGEN** | 1. Distinguish between antigens and antibodies. For immunologic test: Use Ab for Antibody and Ag for antigen.  
2. The noun form of the target antibody should be used.  
3. The word anti should not be used for naming antibodies.  
4. Preferred convention for measurement of parent immunoglobulin is "Total IgG" or "IgG level".  
5. Delete redundant identifiers, example Apple IgE Ab should be Apple IgE because it is measuring an immunoglobulin, it is an Ab. | Antinuclear Ab and Anti D Quantitative Assay; Use of Anti for inhibitory activity e.g. Anti Xa.  
If this an immunoglobulin level, then include “level” at the end (e.g. IgG level) -- to differentiate it from IgG given as a therapeutic. |
Generate draft consensus guidelines

Look at various existing guidelines to create a working draft
Iterative Process

Choose test names to change

Apply new guidelines

1. Implement on a small scale
2. Disseminate for widespread adoption
3. Foundation Build of EMR, LIS
4. Basis for sharing lab results between systems
Whitepaper

Describe the problem, and our approach to solve it

Secure funding
What have we done so far?

1. Recruited Members – officially agreed to be a part of TRUU-Lab
2. Chose Skype as a way to meet
3. Had 5 meetings – one each month
4. Developed a Mission statement, Scope, Goals, Workflow
5. Selected a name (TRUU-Lab was chosen out of 10 possibilities)
6. Secured a domain, twitter handle, Gmail address
7. Developing a website and logo - truulab.org
8. Sent out a survey (with ASCP Choosing Wisely)
9. Reviewed existing guidelines worldwide
10. Sub-committees: Guidelines, ‘bad’ test names, whitepaper
11. Ways to work together – Basecamp, Slack, Google doc
The mission of TRUU-Lab is to bring together health care providers, professional societies, and industry groups to address problems caused by ambiguous, incomplete, and non-standard laboratory test names.

The objectives of TRUU-Lab are:

- Generate a consensus guideline for lab test naming
- Generate consensus names for existing lab tests
- Promote the adoption and implementation of consensus lab test names and guidelines
Why TRUU-Lab?

The problem with laboratory test names

Names for lab tests have traditionally been chosen by clinical pathologists and scientists. While these test names make perfect sense to anyone in the clinical laboratories, that is not always the case with clinicians. Clinicians often order the wrong test or a sub-optimal test, or more tests than necessary, because the relevant test names are unclear, abbreviated, obscure, or inconsistent across institutions. Often the wrong orders lead to safety and quality issues.

Three root issues can be identified when naming a laboratory test in electronic ordering systems:

- One test may have multiple names (e.g. Hemoglobin A1c/glycosylated hemoglobin/Hgb A1c) or abbreviations (e.g. FBS/FGLU/FGLUC/FG for “fasting blood glucose”). This redundancy may lead to confusion and inefficiencies in ordering laboratory tests.
- Tests that are different but carry similar variations of the name (e.g. 25-hydroxy vitamin D and 1,25- dihydroxy vitamin D) may result in choosing suboptimal or multiple tests for patients.
- Names that include the methods by which the laboratory performs the test may confuse clinicians (e.g. dialysis or LC/MS/MS).

TRUU-Lab is a collaborative effort among pathologists, clinicians, professional organizations, accreditation agencies, large reference labs and terminology groups to create a consensus guideline for giving laboratory test more rational and consistent names.

The ultimate goal is to bring these consistent and easy-to-understand lab test names into electronic health records (EHR) and laboratory information systems (LIS) everywhere.
ASCAP Choosing Wisely Lab Test Stewardship Project

The ASCP Effective Test Utilization Steering Committee plans to conduct a survey on laboratory test naming conventions that cause issues or are problematic in laboratories. This survey will help identify problematic laboratory test name and offer recommendations for clearer and more understandable test names.

Have you experienced issues in test naming conventions in your laboratory?

- Yes
- No

Which best describes you?

- Pathologist
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- Other (please specify): [ ]

Please provide your contact information so we may follow up if we have any questions.

Name:

Email Address:

Institution:

Join As A Sponsor

TRUU-Lab is looking for sponsors to bring our members together for an annual conference. Please contact trulab@gmail.com if you have an interest in sponsoring at any level.

Join As A Participant

Our initiative is organized by a steering committee and multiple sub-committees for specific tasks and goals. When you send us an email (trulab@gmail.com) or a feedback form, please note the following information: your name, degree(s), job title, institution, and describe in 1-2 sentence your interest in our initiative so we can move forward with the appropriate next steps.

Contact Us

Contact us at trulab@gmail.com

Your Name (required)

Your Email (required)

Your Message
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How you can participate in TRUU-Lab...

Learn More about TRUU Lab

Take the ASCP Choosing Wisely/TRUU-Lab Survey for perplexing Test Names

Join Us

Sponsor Us

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Truulab.org