

The Fritsma Factor
YOUR INTERACTIVE HEMOSTASIS RESOURCE

Clumsy Clinical Communication Let's Blame The Lab


What must all Medical Laboratory Scientists Know About Diagnostic Errors?
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The Fritsma Factor, Your Interactive Hemostasis Resource
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In Memory of
Cynthia [Cindy] Johns
September 8, 1953–December 24, 2017



"Enhancing Laboratory Communication
to Reduce Extra-analytical Errors"
Clinical Laboratory Educators' Conference, February 24, 2017

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The Cindy Johns Scholarship

A champion of the medical laboratory profession, ASCP board member, and ASCP patient champion, *Cynthia Johns, MSA, MASCP, MLS [ASCP]®M SHC™*, passed away December 24, 2017. In honor of Cindy's contributions, the ASCP Foundation supports an endowment to promote the future of the profession through scholarships. Your gift will allow the Foundation to provide scholarships to laboratory students across the country.

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Medical Laboratory Purposes

- Screen for risk [Hx]
- Support diagnosis [Dx]
- Monitor treatment [Rx]

"The right test at the right time for the right reason with the right results at the right cost" [Cindy Johns]

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Bottom Line at the Start [BLAST]

The participant...

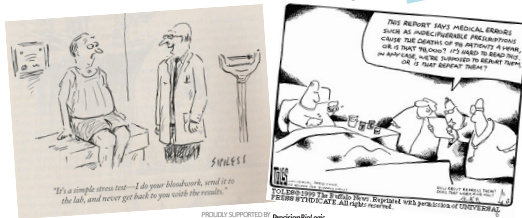
- Explores indication-based diagnostic test orders.
- Lists test utilization errors.
- Improves communication among lab personnel, providers, and patients.
- Manages blood specimens.
- Applies advanced communication approaches.

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What Could Go Wrong? Your Experience?



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Ensure Valid Laboratory Results

- Pre-pre-analytic
 - Provider selects the indicated test
 - Control (lab QI) for omissions or duplications
- Pre-analytic: whose responsibility?
 - Record history and demographics
 - Document morbidities
 - Document current Rx
 - Provide reliable specimen management
- Analytic: QA, QC, QI
- Post-analytic
 - Record results
 - Publish to ordering provider
- Post-post analytic
 - Appropriately filed results: retrieval
 - Support provider interpretation
 - Promote lab-provider communication
 - Promote provider-patient follow-up

But I thought we just did validation, accuracy, precision, proficiency, competence, and compliance


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Chronic Cough with Chest Pain

- You see your PCP for a 2-week cough with mild chest pain. She...
 - Documents Hx, records vitals plus O2 saturation, performs physical with auscultation of chest and abdomen
 - Develops a preliminary diagnosis
 - Sends you for an ECG and chest x-ray
 - Sends you to the lab for "blood work"
 - Starts Rx while awaiting results
- 24-h diagnosis: bronchitis



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"Rainbow Draws"

Your Experience?




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What Tests Could Influence Diagnosis?

- Chest x-ray: R/O pneumonia [confirms auscultation], Ca, PE
- ECG, troponin I or troponin T: R/O acute myocardial infarction
- D-dimer, spiral tomography: R/O pulmonary embolus
- CBC, PT, PTT, UA, metabolic panel, liver panel, lipids: ["rainbow"] not indication-based
 - Ordered defensively or for baseline & follow-up



Hallworth M. The [true] value of laboratory medicine. The pathologist.com/issues/2015, accessed 12-31-16.


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Diagnostic Test Utilization

- Obsolete, unnecessary, duplicate tests
 - "Defensive testing"
- TAT, from order to report too long
- Indicated test is misinterpreted
- Understand clinical efficacy of test
 - False positives or false negatives



Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Qual Saf. 2013 Suppl 2:i6-i10. doi: 10.1136/bmjqs-2012-001621.

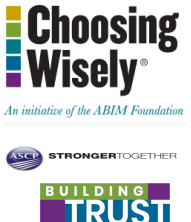
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Example CW Recommendation

Avoid routine preoperative testing for low-risk surgeries without a clinical indication. Most preoperative tests—typically a CBC, PT, and PTT, BMP and UA—performed on elective surgical patients, are normal. Findings influence management in under 3% of patients tested. In almost all cases, no adverse outcomes are observed when clinically stable patients undergo elective surgery, irrespective of whether an abnormal test is identified. Preoperative testing is appropriate in symptomatic patients and those with risks factors for which diagnostic testing can provide clarification of patient surgical risk.



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“Medical Necessity” Patient-contained Laboratory Use Guidance Services [PLUGS]

- Health insurers restrict payments to “medically necessary” tests
 - “Covered benefit” a test necessary to Dx and manage a condition
 - Coverage varies by CPT code
- Rely on evidence from peer-review research, medical guidelines, expert opinion
- Restrictions apply especially to costly tests, cost analysis may influence benefits
- Complex paperwork and coding may add a layer of restriction
- Insurers bury “medical necessity” decision documentation
 - Unsearchable: list by number and opaque medical jargon
 - Bury in large medical documents and policies

Ashton M. Medical necessity policies: creating opportunities for better test utilization and fair payment. CLN 23, July/August: 38-9. PRECISELY SUPPORTED BY precisionBiologic

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Standard of Care Versus Evidence-based Medicine

- Standard of care:** provider diagnoses, treats, and monitors a condition
 - Assays based on expert consensus, not always robust evidence
 - Professional and governmental guidelines
 - Violators foundational to malpractice lawsuits, insurers must cover
- Evidence-based medicine:** clinical decisions based on best available research
 - Insurers evaluate research, coverage decisions vary among companies
 - Care must reflect patient values

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Diagnostic Errors

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Where are the errors [2003]?

Phases	Frequency (Percent of Requests)
Pre-Pre-Analytical, very high frequency, high risk	12%
Pre-Analytical, high frequency	2%
Post-Analytical, high frequency	2.2%
Post-Post-Analytical, very high frequency, high risk	5.0%
Total	21.4%

Stroobants AK, Goldschmidt HM, Plebani M. Error budget calculations in laboratory medicine: linking the concepts of biological variation and allowable medical errors. Clin Chim Acta 2003;333:169-76. PRECISELY SUPPORTED BY precisionBiologic

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Outpatient Error Rates [2014]

“Combining estimates from...three studies yielded a rate of outpatient diagnostic errors of 5.08%, or approximately 12 million US adults every year. Based upon previous work, we estimate that...half of these errors could potentially be harmful.”

Singh H, Meyer AN, Thomas EJ. The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. BMJ Qual Saf. 2014;23:727-31. doi: 10.1136/bmjqs-2013-002627.. PRECISELY SUPPORTED BY precisionBiologic

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Lab Utilization Barriers

Clinical laboratory tests are a cornerstone of health care. Tell Congress to STOP LAB CUTS stoplabcuts.org

- Laboratory data occupy 70–80% of EHR information at 3% of healthcare cost
 - Administrators and politicians without core competence slash lab budgets across the board rather than investing in effective use of laboratory data.
 - Combative communication among administrators and providers.
 - Requirements for MDs as laboratory directors drives them to more lucrative specialties.
- WHO released model list of 100 essential in vitro diagnostic tests in 2018.
- ABIMF and Consumer Reports hosted Choosing Wisely 2012–2023.
 - Recommendations begin with “Don’t” or “Avoid” preface >600 recommendations against inappropriate diagnostic and therapeutic efforts. ABIMF pivoted to “Building Trust” in 2023.
- WHO and ABIMF efforts are largely ineffective.

Verna R, Velazquez AB, Laposata M. Reducing diagnostic errors worldwide through diagnostic management teams. Ann Lab Med. 2019;39:121-4. doi: 10.3343/alim.2019.39.2.121. PRECISELY SUPPORTED BY precisionBiologic

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MB Marques 2014 Survey of US PCPs

- Estimated 500,000,000 PCP patient visits per year
- 1800 PCPs surveyed, mean age 51; years in practice, 21
- Mean patients seen per week, 81 each
- Averaged 25 diagnostic lab tests/week, 31% of patients
- Uncertain about what test[s] to order: 14.7% of patients who needed diagnostic tests
- Uncertain about how to interpret results: 8.3%
- Potential 23,000,000 incorrectly ordered or interpreted tests/year


Marques MB, Hickner J, Thompson PJ, Taylor JR. Primary care physicians and the laboratory: now and the future. *Am J Clin Pathol* 2014;142:738-46.

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2021: What are PCPs Up Against?



- Time pressure and environmental chaos
- Inefficient diagnostic test ordering
- Depersonalization—virtual visits
- Health care commoditization
- Insurance limitations
- Inefficient EHR entry
- Vague symptoms

Olson APJ, Linzer M, Schiff GD. Measuring and improving diagnostic safety in primary care: addressing the "twin" pandemics of diagnostic error and clinician burnout. *J Gen Intern Med*. 2021;36:1404-6. doi: 10.1007/s11606-021-06611-0.

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2014: PCP Post-analytical Diagnostic Errors

- Errors that occur after results are delivered
 - Incorrect interpretation, 37%; inappropriate or inadequate follow-up, 45%; failure to refer, 26%
- Post-analytical process breakdowns
 - Inadequate judgment, 70%; vigilance, 59%; knowledge, 48%; patient-related, 46%; handoffs, 20%
 - Multifactorial: 54% of errors involve 3 process breakdowns; 29%, 4 or more
 - Multi-clinician: 43% of errors involve 2 or more physicians; 16% 3 or more
- Wall Street Journal, 2013: "Patients would be safer if doctors did not...diagnose alone. Physicians should...bring pathologists and radiologists into the loop to make sure the correct test is ordered and the right diagnosis is offered."


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How do PCPs Deal with Test Interpretation Uncertainty?

- Review patient history: 70%
- Follow up with patient: 66%
- Review e-references: 46%
- Order more lab tests: 34%
- Refer to a specialist: 29%
- Consult fellow PCP: 23%
- Check guidelines and references: 22%
- Repeat the same test: 19%
- Consult with lab scientist or clinical pathologist: 6%
 - Helpful? 35%




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What PCPs Hate about Labs

- Confusing test names
- Lengthy turnaround time
- Reference interval disharmony
- Varied report info format
- Whom to call?




MB Marques, MD, "I know for certain that most of my relevance as a member of the medical staff stems from my direct relationships and collaboration with physicians from other departments."

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Lab Scientist ↔ Provider Communication



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NEW! Now you can enhance laboratory provider communication!

"This concludes my lecture on non-verbal communication. Any comments or questions?"

Rose AM. What have we learned about vitamin D? *MLQ* 2017, pp 18-22


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Two-way Diagnostic Communication

- Intra-laboratory directors [CPs] ↔ managers ↔ scientists ↔ technicians ↔ clerks
- Laboratory scientists ↔ providers
 - Diagnostic management team
- Laboratory scientists ↔ patients




What?

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Communication Barriers and Solutions



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Critical Result Calls and Provider Read-backs

Thanks to deNay Kirkpatrick, NP, UAB Pulmonology

- Lab staff must contact provider with critical results, provider must read back
- Example from pulmonary NP: MTB triple cultures, AFB positive generates 3 calls requiring read-backs
 - Repeat upon periodic patient visits
 - Communication fatigue



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Responses from Andrea Prinzi Ph.D., MPH, SM [ASCP] Clinical Microbiologist bioMérieux, Inc.

- Our original critical AFB result is called with a read-back, but we transmit additional positive results from the same collection period without read-back.
- We have a time interval when we would have to do a repeat callback.
- We had previously experienced communication fatigue for our providers and ourselves.

Lippi G, Mattiuzzi C. Critical laboratory values communication: summary recommendations from available guidelines. *Ann Transl Med.* 2016; 4(4): 400. doi: 10.21037/atm.2016.09.36. [Open Access describes CLSI, CAP, and other guidelines.]

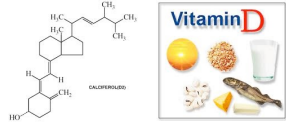
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Test Names

An order arrives with a serum-separator tube requesting "Vitamin D." How do you log it?



- Kleerekoper M, Schleicher RL, Eisman J, et al. Clinical applications for vitamin D assays: what is known and what is wished for. *Clin Chem* 2011;57:1227-32.
- Pasiment E, Meisai JL, Fontana J, Fritsma GA, Alenyan S, Marques M. Decoding laboratory test names: a major challenge to appropriate patient care. *J Gen Intern Med* 2013. DOI 10.1007/s11606-012-2253-8

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Test Names: The Vitamin D Puzzle

Experts identify multiple vitamin D forms with no naming consensus:

- calciferol, calcidiol, calcitriol
- 1,25 dihydroxycholecalciferol
- ergocalciferol
- vitamin D
- vitamin D₂
- vitamin D₃
- 25-OH vitamin D (this is it)
- 25-OH vitamin D₂
- 25-OH vitamin D₃
- 25 dihydroxy vitamin D
- 25 hydroxy vitamin D₂
- 25 hydroxy vitamin D₃
- 25 (OH)₂ vitamin D
- 1,25 (OH)₂ vitamin D
- 1,25 (OH)₂ vitamin D₂
- 1,25 dihydroxy vitamin D
- 1,25 dihydroxy vitamin D₂
- 1,25 dihydroxy vitamin D₃

Which is correct?

Lab director coins arbitrary assay names, IT director creates arbitrary LIS nomenclature:

- Vitamin D, VITD
- 25-OH vitamin D
- 25-OH VITD

Result: 60 ng/ml

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What's in a name?

You're going to call me WHAT!?

PC APCR PTT LAC FX
 APCC APTT
 CSA CRP AT ATIII FV FXa
 C3 FVIII PT
 FVL FVII VWF Antd-FXa

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Initiation: vascular wall injury exposes fibroblast (FB) tissue factor (TF)

Do you like Roman numerals?

Why keep?
 • Tradition
 • If you change you get two systems
 • Distinguish phenotype from genotype
 • The whole world knows Roman numerals

FVIII gene is F8

Propagation on activated platelet (P) surfaces

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Initiation: vascular wall injury exposes fibroblast (FB) tissue factor (TF)

Do you prefer Arabic [Western, European] numerals?

Why change?
 • LIS can't handle Roman numerals
 • Easy to mix IX and XI
 • Easy to misspell VII and VIII
 • Factor X = factor "ten"
 • Schools don't teach Roman numerals
 • Easier for provider to order

Coagulation

Propagation on activated platelet (P) surfaces

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The Patient-facing Provider

- What is a CBC? CBC-D?
- Worst test names in coagulation, BB, genetics
- Children's of ATL: 12-page test ordering guide
 - No abbreviations?
 - 255-character space for names in EHR

Carier AB, Berger AL, Schreiber R. Laboratory test names matter: a survey on what works and what doesn't for orders and results. Arch Pathol Lab Med. 2023 . doi: 10.5858/arpa.2021-0314-OA.

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Best Practices

- Categorize tests by logic, not alphabetical
- Give analyte first, then characteristic such as sample, fasting
- For drugs, use "levels"
- For antibodies, don't use "anti-" prefix, just the target, then IgM or IgG except for anticardiolipin
- For reflex testing, list reflex after main test name e. g. TSH w/ reflex T4

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LOINC

- Federal Logical Observation Identifiers Names and Codes
 - o Meant to end naming problems
 - o All reference labs must assign LOINC codes
- Glucose: 978 LOINC codes
- Tests with different RIs have one LOINC code

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Table 3. Rules for Good Laboratory Naming Practice*	
First word or term	Use specific analyte or panel name or its ubiquitous abbreviation (eg, WBC)
Analyte and panel names	Spell out completely if possible Must be ubiquitously understood, even if abbreviated Full name may be followed by equivalent and more commonly used abbreviation enclosed in parentheses
Analytes with conjugated forms	Use the full name, not conjugated form
Necessary components	Include all necessary components for correct interpretation (does not apply to panels)
Medication (drug) levels	Put "level" after the name of the analyte (eg, Vancomycin Level)
Antibody tests	Do not prefix with "anti" Include specific antibody (eg, IgG, IgM) just after the analyte name, or use "antibody" or "Ab" for total antibody tests
Panels	Specify components analyzed when ≤3 and when sufficient character space
Special characters	Do not use forward slashes to represent "and" except for "w/for" and "w/o" for "without." Forward slashes can be combined with ratios, "divided by," etc. Do not use single apostrophe ('), asterisk (*), the at symbol (@), pound sign (#), less-than sign (<) or greater-than sign (>), as they may perform unanticipated functions in information systems
Specimen types	Do not include specimen type in the name if the specimen type is peripheral blood, a peripheral blood derivative (eg, serum, plasma) or a test performed on multiple specimens (eg, tissue culture) unless necessary to differentiate from a similarly named test
Condition or time	For all other tests performed on single specimen types, add the specimen type after the test name if the test should only be used for a specific condition or time, add it after the analyte name (eg, fasting, peak)
Reflex tests	Add the word "reflex" after the analyte name to indicate to the ordering clinician that the test includes a reflex test. Identify included reflex test names if sufficient space available
Superfluous information	Do not include information that is unnecessary for the ordering provider to know (eg, do not include test method if there is only one method available for this analyte)

Abbreviations: IgG, immunoglobulin G; IgM, immunoglobulin M; WBC, white blood cell.

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Specimen Management

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Specimen Management 2021 Hospitalizations

- Feb 22, rural ICU: HGB 9.2 g/dL
- May 21, rural ER: HGB 15.1 g/dL
- May 22, rural ER: HGB 7.1 g/dL, 2 RBC Units
- May 23, rural ER: Syringe collection, clotted X2
- May 23–29, transfer to urban ICU: PICC line, HGB 9.6

A common theme: poor specimen?

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2021 Round Table, Denver, CO; Specimen integrity

- Collectors never see the lab, out all day
- Turnover: improve collector pay, give recognition, require certification
- Tube specimens to lab [not PFTs]
- Infusion set "butterfly" increases short draws, hemolysis, clotting
 - Dennis Ernst: butterfly 5X expense, 5X accidental sticks
- Small hospital, ER docs on locum, weekly changes, order variance
- Line draws associated with hemolysis
 - PIVO design meant to alleviate hemolysis
- Small volume [ped] tubes: poor vacuum, short draws, clots
- Rainbow draws, volume of blood, if not, re-sticks and add-on orders
- Unnecessary daily orders
- Ghost patient orders, died or gone home
- Patients with name changes
- Naming newborns, unnamed patients

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Hemolysis, Icterus, Lipemia

Simundic AM, Baird G, Cadamuro J, Costelloe SJ, Lippi G. Managing hemolyzed samples in clinical laboratories. Crit Rev Clin Lab Sci. 2020;57:1-21. doi: 10.1080/10408363.2019.1664391.

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BD PIVO® Collection from Venous Access Device

"Using the PIVO® device for blood collection decreased the rate of preanalytical errors by 56% compared with other collection methods, including venipuncture and conventional line draws." Pendleton B, LaFaye R. Multicenter study of needle-free blood collection system for reducing specimen error and intravenous catheter replacement. J Health Qual. 2022;44:e24-e30.

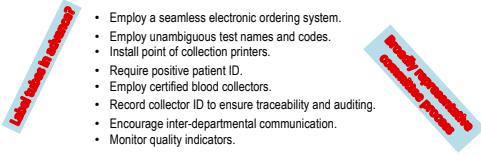
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ICSH Recommendations

- Employ a seamless electronic ordering system.
- Employ unambiguous test names and codes.
- Install point of collection printers.
- Require positive patient ID.
- Employ certified blood collectors.
- Record collector ID to ensure traceability and auditing.
- Encourage inter-departmental communication.
- Monitor quality indicators.





ICSH INTERNATIONAL COUNCIL FOR STANDARDIZATION IN HAEMATOLOGY
Kitchen S, Adcock LM, Lauer K, et al. International Council for Standardisation in Haematology (ICSH) recommendations for collection of blood samples for coagulation testing. Int J Lab Hematol. 2021;43:571–80. PREVIOUSLY SUPPORTED BY PrecisionBioLogic

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More ICSH Recommendations

- Scan wrist bands and print labels at the point of collection, avoid centralized label printing.
- Label specimens immediately after blood collection, not before, with patient's first and last name, an ID number and/or DOB, and the date and time of collection.
- Confirm ID with the patient.
- Gently invert anticoagulated specimens immediately 3–4 times.
- Publish a specimen rejection policy in consultation with providers.





Ernst DJ, Fritsma GA, McGlasson DL. Labeling tubes before collection threatens patient safety. Ann Blood 2018. DOI: 10.21037/aob.2018.02.06 PREVIOUSLY SUPPORTED BY PrecisionBioLogic

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CLSI Guideline GP41-A5



- Provide collector orientation, competence assessment, recurrent training, remediation, and CQI.
- Provide accessible manual for blood collectors.
- Patient to verbalize—not affirm—name [spell], address, DOB.
 - Inpatients: compare statement with ID band
 - Outpatients: compare with labels/orders.
- Provide secure collection site with arm rest.
- Avoid scarred, inflamed, infected site, hematoma.
- Don't collect above or below infusion.
- Use safety device when transferring from a syringe to tube.
- Fill tubes to stated volume.

Courtesy: Dennis J. Ernst, MT(ASCP), NCP(T)N(CCT) PREVIOUSLY SUPPORTED BY PrecisionBioLogic

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Hemostasis Specimens: CLSI GP21-A5*

- Use 19–21g needles for good venous access, 22–23 for poor access, peds
- Do not use a "discard" tube except when collecting with infusion set
- Collect blue-closure tube first or just after blood culture tube
- Maintain and transport at 18–25° C "ambient," do not chill, provide courier regulations
- Keep tubes sealed and upright
- PT: 24h uncentrifuged; PTT, centrifuge, separate and test within 1h
- Freeze platelet-poor plasma [$\leq 10,000/uL$] at $-20^{\circ}C$ for $\leq 2w$, or $-70^{\circ}C$ $\leq 1y$
- Thaw at $37^{\circ}C$, mix, and test in $\leq 2h$

***A5 due 9-1-23**

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Does the Lab Set Courier Times and Temps?

Lab	Ambient, Chilled, Frozen	Warm Weather	Cold Weather	Lockbox Placement	Time Restriction	Number of Cold Packs
1						✓
2		✓				✓
3				✓		
4	✓					✓
5		✓				✓
6	✓					✓
7		✓	✓			✓

Ambient: 18°C–25°C Standard Temp

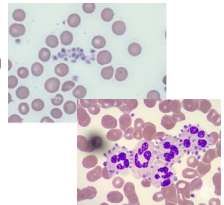
Dibbern ME, CC, Wienczek JR. Outdoor courier lockboxes in summer are a significant source of preanalytical error. Am J Clin Pathol 2021;156: 866–70. https://doi.org/10.1053/app/2021.037 PREVIOUSLY SUPPORTED BY PrecisionBioLogic

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Platelet Clumping; Spurious Thrombocytopenia

- EDTA-dependent antibodies: satellitism
 - Collect in sodium citrate or heparin
- Time delay between collection and testing
- Inadequate or delayed mixing: clot
- Agitated specimen: tube delivery
- Over-filled or underfilled tubes
- Chilled specimen



Courtesy of Bob Gosselein PREVIOUSLY SUPPORTED BY PrecisionBioLogic

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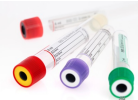
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2020 Pandemic Fake Tubes

- PT tube is used for **blo-o-d** coagulation test and applicable to fibrinolytic system.
- PT tube is used for **b-l-o-o-d** coagulation tests, and applicable to fibrinolytic system.
- This tube is used for **b-l-o-o-d** coagulation test, PT, APTT and applicable to fibrinolytic system
- It is also used for **b-l-o-o-d** storage.
- The **Nixing** Ratio Is 1 Part Citrate to 9 Parts Blood. Accurate Ratio Can Guarantee Effectivity of the Testing Result and Avoid Misdiagnosis.
- The **Nixing** Ratio Is 1 Part Citrate to 9 Parts **Blood**. Accurate Ratio Can Guarantee Effectivity of the Testing Result.
- The **nixing** ratio is 1 part citrate to 9 parts **b-l-o-o-d**.

Courtesy of Bob Gosselin



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Back to the Choosing Wisely Recommendation

Do not order daily blood from inpatients without indications.
"Think twice, stick once."

- Patient fragility, exsanguination, iatrogenic anemia, anemia of chronic inflammation
- Many assays don't change overnight: A1C, lipid panels, thyroid, serology assays
- False positives create additional phlebotomy, workload
- Patient experience scores affect Medicare payments.
- Most daily collections produce unused information.
- 2.1 per patient per day; "think twice, stick once"
- Costs to facility, charges to patient



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Hemostasis Pre-analytical Issues; What to Do?

- PTT ordered for LMWH, fondaparinux, rivaroxaban, dabigatran, how to test for DOACs?
- Order PT and PTT when lupus anticoagulant is present?
- LA, LAC, DRVVT screen, DRVVT confirm, Sta-Clot LA; PTT-LA, what does it all mean?
- What is in a thrombophilia profile?
- What is all this: VWF multimers, VWF:RCo, VWF:ac, VWF:ag, VWF:CB, VWF:GP1bM, VWF:GP1bR, VWF:B?



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Example: Thrombophilia Profile

Assay	Patient	RI
Protein C activity	35%	>70%
Protein S activity	39%	>65%
Antithrombin activity	57%	78-126%
Factor VIII	125%	50-186%
APCR	2.4	>1.8
Factor II 20210	Wild-type	Wild-type
PTT-LA	39 s	30-40 s
Homocysteine	3.9 η mol/L	<4.3 η mol/L

60-YO man, DVT; warfarin 3 W

- Triple heterozygote?
- Increase Coumadin?
- Start heparin?
- Consult with the lab?



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Thrombophilia Profile Narrative Report

Assay	Patient	RI
Protein C activity	35%	>70%
Protein S activity	39%	>65%
Antithrombin activity	57%	78-126%
Factor VIII	125%	50-186%
APCR	2.4	>1.8
Factor II 20210	Wild-type	Wild-type
PTT-LA	39 s	30-40 s
Homocysteine	3.9 η mol/L	<4.3 η mol/L

Or: "Protein C, S, and AT appear deficient, probably warfarin interference, reflex INR = 2.1, suggesting warfarin is present. Other risk factor assay results are within reference interval. No evidence for thrombotic risk, repeat profile 2 weeks after discontinuing warfarin."

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Pre-op Screen: Isolated Prolonged PTT

Assay	Patient	RI
HGB	14.2 g/dL	13.5-15.6 g/dL
PTT	59 s	25-35 s
PT	12.4 s	9.8-12.6 s
TT	18.2 s	<21 s
PLT count	310,000/ μ L	250-450,000/ μ L
Fibrinogen	270 mg/dL	150-400 mg/dL

No bleeding Hx, surgeon postpones

- Heparin present?
- Risk: bleeding? Thrombosis?
- Repeat PTT until negative?
- Consult with laboratory?
- Laboratory immediate reflex to...



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Pre-op Screen: How About This?

Assay	Patient	RI
HGB	14.2 g/dL	13.5–15.6 g/dL
PTT	59 s	25–35 s
PT	12.4 s	9.8–12.6 s
TT	18.2 s	<21 s
PLT count	310,000/ μ L	250–450,000/ μ L
Fibrinogen	270 mg/dL	150–400 mg/dL
No bleeding Hx, surgeon postpones procedure		

"Isolated prolonged PTT may indicate coagulation factor deficiency, coagulation factor inhibitor, or lupus anticoagulant. Normal TT indicates no heparin present. Laboratory reflex to PTT mixing study, results follow."

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Mixing Study: New Specimen, Next Day

Assay	Result	RI	Comment
PTT	57 s	25–35 s	Confirms prior PTT
PTT/NP 1:1 immediate mix	38.5 s	NP 27.5 s	Mix is >10% prolonged over the normal plasma

- Uncorrected?
- Should lab have done incubated mix?
- Do you send this result to the surgeon?
- Continue to delay surgery?
- Consult with laboratory?
- Laboratory immediate reflex to...



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Mixing Study: How About This?

Assay	Result	RI	Comment
PTT	57 s	25–35 s	Confirms prior PTT
PTT/NP 1:1 immediate mix	38.5 s	NP 27.5 s	Mix is >10% prolonged over the normal plasma

Interim report: *"Patient plasma mixed 1:1 with normal plasma, PTT performed immediately after mix remains prolonged [uncorrected]. Presumptive evidence of lupus anticoagulant. LA profile follows."*

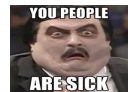
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LA Profile: Third Day of Hospital Stay

Assay	Result	RI	Comment
PTT-LA	47.9 s	30–40 s	Confirms PTT
PTT-LA/control 1:1	38.5 s	Control 34.5 s	Possible LA
Staclot LA kit	12 s	> 8 s correction	Confirms LA
DRVVT	52.5 s	35–45 s	Possible LA
DRVVT confirm	1.4 ratio	> 1.2 correction	Confirms LA



- Send this result to the surgeon w/o comment?
- Delay surgery?
- Consult with laboratory?

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LA Profile: How About This?

Assay	Result	RI	Comment
PTT-LA	47.9 s	30–40 s	Confirms PTT
PTT-LA/control 1:1	38.5 s	Control 34.5 s	Possible LA
Staclot LA kit	12 s	> 8s correction	Confirms LA
DRVVT	52.5 s	35–45 s	Possible LA
DRVVT confirm	1.4 ratio	> 1.2 correction	Confirms LA

Or: *"Patient plasma tested using LA-sensitive PTT reagent and dilute Russell viper venom reagent, both prolonged, both corrected by high phospholipid neutralization reagent, confirming LA. No bleeding risk, may indicate thrombosis risk if LA is chronic. Repeat after 12 weeks to determine persistence."*

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Current Efforts at Communication

Communication




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Assistive Algorithm [2013]

- IOM says, "facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families"
- Provider selects or enters indications gathered from patient Hx and physical.
- Algorithm returns recommendations for imaging, tests and test profiles
- Provider makes choices.


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Indication-based Laboratory Utilization [2016]

- Team of clinical and technical practitioners establishes algorithms
- Hemostasis indication examples
 - Current complaint—chest pain, shortness of breath, bruising, swollen leg
 - History of prior events, first-degree relatives
 - Age, sex, BMI, race, habits
- List applicable hemostasis assays: D-D, PT, PTT, TT, FG, PC, PS, factor assay, PLT count, PLT aggregometry
- List hemostasis assay profiles: thrombophilia, anatomic bleeding, systemic bleeding, arterial thrombosis
- Match selected lists of indications with hemostasis laboratory assays and profiles.

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Web-based Narrative Reports [2014]

- Reporting system with 119 coagulation & 38 viscoelastometry [VET] synoptic templates.
- Enter up to 29 coag findings: PT, PTT, TT, PLT count and aggs, VWD profile, LA profile, more
- Enter VET findings: R, a, MA, Ly30, shake and bake
- "Baseline PTT is prolonged, corrected with mix, TT is normal. Impression: results intrinsic pathway factor deficiency: VIII, IX, XI, XII, VWF. CPT 85390."

Quesada AE, Jabouga CE, Nguyen A, et al. Interpretation of coagulation test results using a web-based reporting system. Lab Medicine 2014;45:343-56.

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Diagnostic Management Team Accomplishments

- Emerging molecular assays pinpoint diagnosis.
- Molecular pharmacogenomics pinpoint effective treatment.
- DMTs successfully implemented in coagulation, leukemia and lymphoma, transfusion medicine, microbiology/infectious disease, and child abuse.
- Assembly of disorder-based DMTs with access to lab and imaging data
 - o Remote systems allow for direct contact among specialties and with PCP and patient.
 - o Shortens inpatient stay for coagulation disorders from ~4 days to ~2.
 - o Reduces readmissions for relapse or missed diagnosis.
 - o Accurate treatment begins at an earlier stage.

Verna R, Velazquez AB, Laposata M. Reducing diagnostic errors worldwide through diagnostic management teams. Ann Lab Med. 2019 ;39:121-4. doi: 10.3343/alim.2019.39.2.121.



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Pathology Explanation Clinics

Providers from a tertiary care center were asked, "How interested would you be in having your patient see a pathologist to discuss their path report and see their tissue image?"

Providers ranked their interest, then expanded on concerns and benefits.


Of 35 providers interviewed, 83% suggest that highly educated and motivated patients could benefit from a PEC.

PECs could improve understanding and emotional processing, but information must be balanced with the potential for cognitive overload and emotional distress.

Providers worried about the pathologist's communication skills, care fragmentation, and increased clinician workload.

If performed well, providers felt PECs could raise efficacy and improve quality of care.

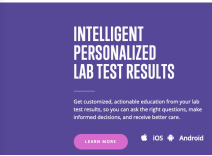
Bergholtz SE, et al. A mixed-methods study of clinicians' attitudes toward pathology explanation clinics. AJCP 2023;159, 437447, <https://doi.org/10.1093/ajcp/aqac175>

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Diagnostic Algorithm Services



- Test ordering support
- Specimen collection
- National lab network
- Connectivity: web and mobile
- Result support
- Consumer friendly content
- Provider oversight

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Testing.com®
Formerly Lab Tests Online

Disease Detection and Monitoring

What is Disease Detection and Monitoring?

Understand your lab tests, understand your health

healthwise®
for every health decision

LAB uses Healthwise connected to portal

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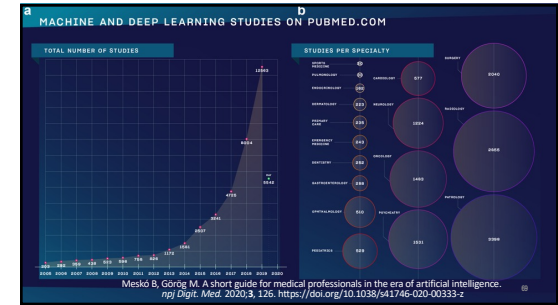
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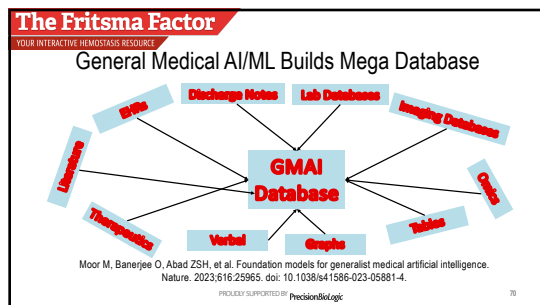
AI-AI-AI

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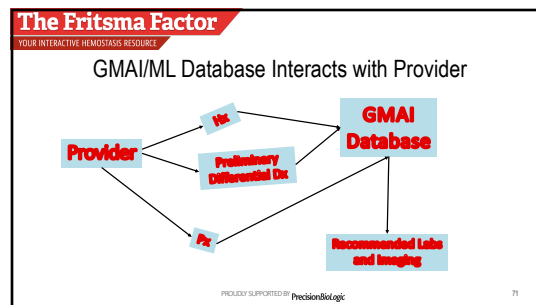
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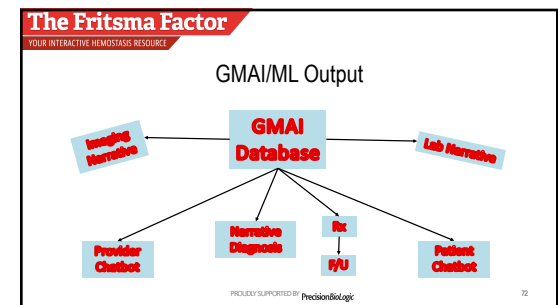
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Machine Learning of Cognitive/Functional Decline Markers

For cognitive and functional decline, the most important determinants were platelet count, platelet-leukocyte ratio, neutrophil-leukocyte ratio, hemoglobin, RDW, hematocrit, erythrocyte count, eosinophil count, basophil count, monocyte count, globulin, cortisol, glucose, B12, creatinine, GGT, ALT, AST, triglycerides, and HDL-c. Cognitive decline accuracy=0.79, functional decline accuracy=0.92. Routine laboratory variables could be applied to predict cognitive and functional decline in populations ≥ 75 YOA using ML algorithms.

Gomes KB, Pereira RG, Braga AA, et al. Machine learning-based routine laboratory tests predict one-year cognitive and functional decline in a population aged 75+ years. Brain Sci 2023;13. <https://doi.org/10.3390/brainsci13040690>


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AI/ML-Based Software as a Medical Device Action Plan

- Further develop the proposed regulatory framework, including through issuance of draft guidance on a predetermined change control plan [for software's learning over time];
- Support the development of good machine learning practices to evaluate and improve machine learning algorithms;
- Foster a patient-centered approach, including device transparency to users;
- Develop methods to evaluate and improve machine learning algorithms; and
- Advance real-world performance monitoring pilots.

 Digital Health Software Precertification (Pre-Cert) Pilot Program FDA 2022

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Bottom Line at the End [BLEAT]

The participant...

- Explores indication-based diagnostic test orders.
- Lists test utilization errors.
- Improves communication among lab personnel, providers, and patients.
- Manages blood specimens.
- Applies advanced communication approaches.

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