



❖ INTRODUCING

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## NOTEWORTHY

✓ **Confirming positive urine dipstick protein results:** David J. Blomberg, MD, co-author of the soon to be published CAP Color Atlas of Urine Microscopy responded to a reader’s question in the June 2009 issue of CAP Today. Urine dipsticks react with albumin. They react to a lesser degree with globulins or abnormal free light chains such as Bence Jones proteins. If you need to perform a sulfosalicylic acid (SSA) confirmatory test to rule out proteinuria, and the urine pH >8, you must adjust the pH to between 5 and 6 to get an accurate test result. The highly alkaline urine may not precipitate with SSA resulting in a false negative results.

✓ **Helping the clinician choose the right test for the right patient:** In the July, 2009 issue of Critical Values, Michael Laposata, MD discussed his success with reflex testing and test results interpretation. To get the correct test ordered for a patient’s condition or problem, Dr. Laposata suggests “Reflex Testing”. Have order forms with more diagnostic type categories such as “hypercoagulable workup” or “prolonged PTT workup” as well as the standard PT, CBC test blocks. Then the laboratory can proceed to test the sample in order of most likely causes. This generally saves time and money. The clinicians don’t need to be laboratory experts to

properly treat their patients effectively and efficiently.

For complicated test results, such as HIV confirmatory Western Blot, include an evaluation like anatomic pathology or radiology reports do. The author’s facility did a survey in 1996 and repeated it in 2000. They asked clinicians if having the added test result evaluation helped them arrive at a diagnosis earlier. They also asked if the evaluations prevented them from making diagnostic errors. Nearly ¾ of the clinicians answered yes to both questions. Ninety eight percent asked Dr. Laposata to continue giving them the evaluations with the test results.

✓ **Finger stick CBC testing:** Winfried Reichelt, MD, PhD and Guang Fan, MD, PhD for the Oregon Health and Science University feel there may be problems with collecting capillary samples for complete blood count (CBC) testing. In the June 2009 MLO “Tips from the Clinical Experts” the authors state venipuncture is preferred for CBC testing. As collecting an adequate venous sample is less complicated than a capillary sample, they listed the following potential problems with the latter.

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If the disinfectant is not allowed to completely air dry, the smaller capillary sample will be affected more by hemolysis.

The first drop of blood from a capillary stick must be discarded to get an accurate result. This limits the amount of blood available for testing as squeezing the puncture site must also be avoided. That too causes hemolysis.

Your lab's reference intervals (normal ranges) were most likely determined from venous blood results.

Studies show venous samples have less variation and better precision than capillary.

✓ **POC Testing:** The National Academy of Clinical Biochemistry (NACB) released their guideline "Evidence-based Practice for Point-of-Care Testing" in 2007. The practice guideline resulted from studies and consensus to determine if all point of care (POC) testing was worth the time and money compared to traditional laboratory testing. Studies were conducted to determine if the rapid test results made a significant difference in patient outcome. Here are some of the report's recommendations.

Arterial blood gases (ABGs) were graded as "2" on a 3 point scale (1 being good evidence support) when done with POC lactate in the ICU. Other settings were not recommended.

Co-oximetry, electrolytes and ionized calcium were graded 2.

Glucose and Lactate were graded 1 in a critical care setting.

Magnesium and creatinine were graded 3 – no evidence of improved outcome by POC testing. The report did state there was some evidence (grade 2) for doing POC creatinine when a quick decision was needed to dose contrast agents or give other drugs.

✓ **Have you updated your reference ranges lately?** If you have the same reference ranges

(normal values) for several years, it may be time to look at recent research to see if they need changes. For example, neonatal bilirubin critical values used to be greater than 20 mg/dL at 72 hrs after birth. The recommendations changed in 2004 to greater than 8 in a 24 hour old neonate or greater than 13 at 48 hours to be above the 95<sup>th</sup> percentile and labeled critical.

You can use proficiency test results to see if your "normal" range falls within the 50 percentile of other labs using your method. If not, do your own normal range study.

If you used manufacturer's ranges, be sure they match your patient population. If you have normal patients with slightly abnormal test results, maybe those ranges don't allow for your altitude or humidity extremes. Maybe the reference ranges were determined from samples that were not collected, processed or stored correctly. Validating those ranges can be done with samples from as few as 20 reference individuals. Just make sure at least 18 of the 20 fall within the range you are validating.

✓ **New York State Department of Health (NYSDOH) loses lawsuit:** New York State has a law that clinical laboratories who accept samples from their residents must be licensed by New York in addition to standard CLIA certification. In 1999 the American Association of Bioanalysts (AAB) brought a lawsuit stating NYSDOH was intentionally overcharging clinical laboratories for inspections to supplement other activities. On September 24, 2008, the Judicial Hearing Officer, Justice Edward R. Sheridan, agreed. He stated "In effect, [NYSDOH] has turned the clinical laboratory reference system special revenue account into an unauthorized and unsupervised revenue stream limited only by the bounds of the defendant's creativity."

Lesson learned: Keep accurate records. Review expenditures regularly. Spend that grant or fee money only on items you can show in court is necessary to the program.

✓ **Understanding hemoglobin A1c:** This quiz appeared in the June 2009 issue of CAP Today.

**What is the estimated average glucose for a hemoglobin A1c (hgb A1c) of 9%?**

- a) 126 mg/dL
- b) 140 mg/dL
- c) 154 mg/dL
- d) 183 mg/dL
- e) 212 mg/dL

The article summarized a study reported in *Diabetes Care*. 2008;31:1437-1478. Nathan DM, et al studied 507 patients with type 1, type 2, and no diabetes over a 3 month period. Each patient had an average of 2,700 glucose tests during the study. Night time testing was done by interstitial glucose monitoring and day readings were from finger-stick testing.

The authors used a simple formula to calculate the estimated average glucose (eAG) for each patient's A1c ( $28.7 \times A1c - 46.7 = eAG$ ). The study's authors feel reporting the eAG along with the A1c will help patients and clinicians understand their diabetes control better as it correlates to their own glucose monitoring values. Factors affecting hgb A1c values affect eAG results such as decreased red cell survival, increased red cell survival (after splenectomy), sickle cell and other hemoglobinopathies, etc.

✓ **Case report: Simian malaria:** The March 13, 2009 issue of MMWR reported on a case of a possible new human malarial parasite *Plasmodium knowlesi*. Of the more than 20 species that are known to infect nonhuman primates, this is the first one identified in human disease. Since 1965 the *knowlesi* species has been found in patients (US Army employee returning from Southeast Asia, patients in Malaysia, Sarawak, and Borneo).

The MMWR case report is on a US woman born in the Philippines, living in the US for the past 25 years, visiting her native country in October, 2008 and returning with malaria symptoms. This form of malaria is often diagnosed as an atypical *P. malariae*. It is

believed the Anopheles mosquito transfers the parasite from an infected primate to a human host.

✓ **Pharmacogenetics testing = individualized treatment:** Studying the relationship between drugs and genes (pharmacogenetics) may ultimately improve patient care. The first real success was the HER-2/neu-Herceptin test that helps determine who will benefit from certain breast cancer therapies. New to the test arena is thiopurine methyl transferase (TPMT) testing. While only 0.33% of Western populations have this polymorphism that prevents complete drug metabolism, these patients are at high risk for drug-induced leukopenia. New draft pharmacogenetic testing guidelines from the National Academy of Clinical Biochemistry are available on [www.aacc.org](http://www.aacc.org).

✓ **New Cardiovascular risk assessment player:** Robert L. Wolfert, PhD advocates adding lipoprotein-associated phospholipase A<sub>2</sub> (Lp-PLA<sub>2</sub>) to high-sensitivity C-reactive protein (hs-CRP) to better detect patients at high risk for a heart attack or stroke. In the May 2009 MLO issue he states an independent consensus panel including cardiologists, neurologists and laboratorians endorse a >200 ng/mL Lp-PLA<sub>2</sub> cut off point to identify such patients.

The panel said abnormal Lp-PLA<sub>2</sub> levels should be used with more traditional risk factors to justify an aggressive risk-reduction strategy such as treatment to lower LDL-C.

Dr. Wolfert concludes the enzyme level rises in the bloodstream as atherosclerotic plaque becomes more unstable. As Lp-PLA<sub>2</sub> blood levels increase so does the chance for plaque rupture and a resulting thrombotic event.

# ☆ Feature ☆

## MMWR

August 7, 2009

### Evaluation of Rapid Influenza Diagnostic Tests for Detection of Novel Influenza A (H1N1) Virus – United States, 2009

CDC evaluated 3 commercially available rapid influenza diagnostic test kits for their ability to detect influenza novel A (H1N1 - known as swine flu) or seasonal influenza A (H1N1) or (H3N2) virus in clinical respiratory specimens. They used 65 specimens collected during April and May 2009. All specimens were positive for one of the 3 virus by real-time reverse transcription – polymerase chain reaction.

CDC used the Inverness Medical BinaxNOW influenza A & B, Becton Dickinson Directigen EZ Flu A+B, and Quidel QuickVue Influenza A+B for their evaluation. They used kits from 4 other companies with limited numbers of specimens, but didn't include those results in the MMWR.

The overall rapid kit sensitivity for positive predictive value was 40% to 69%. The higher the viral titer in a specimen, the higher the probability the kit would test positive. CDC advises **“a negative result does not rule out infection with novel influenza A (H1N1) virus infection”**. If the rapid kit test is negative, they recommend treatment as indicated by symptoms, underlying medical conditions, illness severity, or risk of complications.

For the nine specimens with high viral titers, one kit had 9 positive results and the other two

had 8 positive results. The statistics for the three kits on all 45 specimens that were PCR positive for novel influenza A (H1N1) are:

BinaxNOW	= 40%
Directigen	= 49%
QuickVue	= 69%

The report's editorial note stated “Overall, the findings in this report demonstrate that these (kits) are capable of detecting novel influenza A (H1N1) in respiratory specimens, but that many infections will be missed, especially in specimens with low viral titers.” Other notes include:

- Sensitivity might vary by influenza subtype.
- A negative result should not be interpreted as the absence of infection.
- The sensitivity of the kit can be affected by the timing of specimen collection (viral titers are highest in the first three days of illness); by the patient's age (children usually shed more virus longer than adults); the type of specimen collected; specimen transportation and / or storage conditions.



**The Utah Public Health Laboratories is currently accepting confirmation samples from hospitalized patients with serious respiratory illness (regardless of the rapid influenza test result). The FDA approved CDC H1N1 confirmation method has strict**

**specimen requirements. Acceptable specimens include nasopharyngeal swabs (n/p), nasal swabs, throat swabs, dual n/p and throat swabs, nasal aspirates and viral culture isolates. Nasal washes CANNOT be used for testing. Contact the Molecular Biology section at 801.584.8400 for submission details.**



- ° Clarity Mono (serum, plasma, whole blood)
- ° Early Detect *H. pylori* (whole blood rapid test) and Pro Influenza B Test
- ° IMI Signify Strep A Dipstick, *H. pylori* (whole blood), and Strep A cassette
- ° INC. Thyroid Test Rapid TSH Cassette (whole blood)

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**CLIA Waived / Non-waived test kits**

Check your kit test package insert carefully. Some test kits are categorized by FDA as waived or non-waived depending on the quality control requirements. For the test to be waived, there is generally extra quality control needed such as each box must be tested with an external positive and negative control by each user.

*"First, say to yourself what you should be – and then do what you have to do."*

*Epictetus*

*Equals  
"1 millionth of a fish: 1 microfiche"*

**Quality Assessment Spotlight**



**CLIA BITS**

**ADDITIONAL WAIVED TESTS:**

- ° Early Detect Pro Influenza A Test
- ° Lil' Drug Store Products Inc. Vagi-Screen Vaginal Health
- ° 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z-Split Key Cup II
- ° Twin Spirit, Inc. DrugSmart Cup
- ° Acceva Mono II (whole blood)



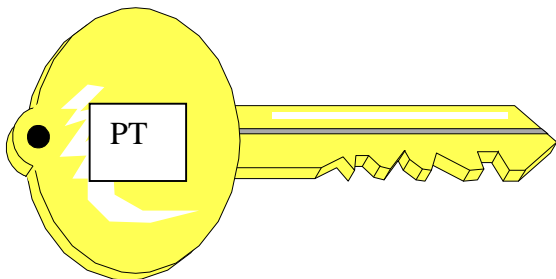
**One facility discovered a simple computer programming change for one process can adversely affect a different computer process. The laboratory shares a computer program with a sister lab in a different state. Medicaid test submission requirements were different between the two states. The billing computer program was altered to code multiple tests – same day – same patient**

(such as a glucose tolerance test) as billing CPT code X 3 instead of billing the code three separate times. Months of investigation later, the laboratory discovered this programming change removed the main lab's suffix coding (a test such as a patient physical was billed at different amounts to different accounts) that told the computer what the bill should be. It took a multi-discipline work group to find the seemingly unrelated computer change affected a different billing process. A great deal of money was lost as bills that used to have a suffix were never submitted for payment.

**Kudos Cheryl Deming and BYU Student Health Center staff**

**Ponderables:**

**If a 911 operator has a heart attack, whom does he / she call?**



**Proficiency Test Samples as QA Tools**

Proficiency test samples are a good source of “outside” test quality verification. They can be used to check personnel competency, test back up or secondary methods, teach new employees, etc. Just remember to wait until after the proficiency testing submission

deadline before using the samples. This will preclude any suspicion that you are retesting the samples to get a better result from the proficiency testing company.



**SAFETY**

**Law suit – Misbranded Test Kits**

Quest Diagnostics and Nichols Institute Diagnostics (NID, a subsidiary) agreed to pay \$302 million to resolve False Claims Act allegations relating to the Advantage Intact PTH assay and four other assays manufactured by NID. Quest also agreed to pay various state Medicaid programs about \$6.2 million to resolve similar civil claims. NID pleaded guilty to felony misbranding as part of the criminal case and will pay a \$40 million fine. NID closed three years ago.

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**Identifying the right patient for the right test**

Patient safety is dependent on correct patient identification. The laboratory must assure test results are collected, tested and reported on the correct patient. New non-invasive technology may make the identification problem more accurate and painless than previous methods. ValleyCare Health System in Pleasanton, California is using such a system. The near-infrared light illuminates veins in a patient's palm and records the “print” image. Since a person's vein pattern is unique (even between identical twins), this makes an excellent unique patient identifier and can be added to the permanent medical record. ValleyCare hospital spokesperson, Rogel Reyes states, “Palm-vein biometric authentication is 100 times more accurate than a fingerprint . . . registration is faster because patients returning

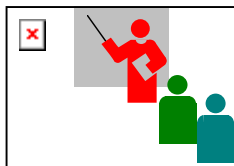
for repeat services are not asked to provide their ID or insurance cards each time. They just place their palms on the scanners and, within seconds, the system displays their medical records.” For the entire report, see the February 2009 issue of MLO.

receive training in Tucson’s University Medical Center clinical laboratories.

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**NLTN**

**CONTINUING EDUCATION**



**Did You See That?**

The University of Iowa Hygienic Laboratory’s training department developed a DVD game for “Pathways to a Career in the Public Health Laboratory”. The game is intended for Junior High, High School and college students. It can be obtained as a DVD or played online at <http://www.uhl.uiowa.edu/educationoutreach/diyouseethat/>. For additional information you may contact Beth Hochstedler, Training and Outreach Coordinator at 319.335.4303.

Investigation of Foodborne Illness: A Laboratory Perspective” is a laboratory workshop to go. For information, call 800.536.6586 or email [registrar@aphl.org](mailto:registrar@aphl.org). The cost is \$35.

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**Educational Helps – Hand Washing**

Check out these sites:

[www.washup.org](http://www.washup.org) = downloadable education materials and survey results

[www.cdc.gov/Features/CDCtv/HandsTogether.html](http://www.cdc.gov/Features/CDCtv/HandsTogether.html). = Video

[www.uhl.uiowa.edu](http://www.uhl.uiowa.edu) = Color Me Healthy children’s coloring book

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**Clinical Laboratory Science Degree Program**

The Department of Biochemistry and Molecular Biophysics at the University of Arizona (UA) and the Department of Pathology at the UA College of Medicine have teamed with the University Medical Center to create the US Clinical Laboratory Science Program at the Arizona Health Sciences Center. The UA program integrates an undergraduate degree in biochemistry with the CLS distance-learning program at the University of North Dakota – Grand Forks. US students can take the North Dakota CLS courses online as electives and

**Understanding Our Universe**

**“Programming today is a race between software engineers striving to build bigger and better idiot-proof programs, and the Universe trying to produce bigger and better idiots. So far, the Universe is winning.”**

**Rick Gook**