

❖ INTRODUCING

Joseph Jepson      Newborn Screening

analytical variation can explain such a difference in test results. For repeat sample collections, the author suggests the person have venipuncture at the same time of day, in the same laboratory using the same testing method.



**NOTEWORTHY**

✓ **CDC Viral Hepatitis C (HCV) Fact Sheet:**

- ~80% infected persons have no symptoms
- ~75% to 85% of infected persons develop chronic infection
- ~20% of chronically infected persons develop liver cirrhosis
- ~Transmitted by infected blood
- ~Transmitted by mother to fetus
- ~Testing recommended for persons injecting drugs; received clotting factors made before 1987; on hemodialysis; received blood or solid organs before 1992; undiagnosed liver problems; and born to an HCV positive mother.
- ~Testing suggested for healthcare / public safety workers and persons having sex with multiple partners or an infected partner.
- ~No vaccine available
- ~50% of persons with certain genotypes are successfully treated with a combination of interferon and ribavirin
- ~Estimated 3.2 million Americans have chronic infection

✓ **TSH variation in a patient:** In the July, 2009 issue of CAP Today a reader asked about thyroid-stimulating hormone (TSH) results that changed within one week when the clinician said nothing changed in the patient's condition. The answer was taken from studies showing testing in normal persons vary from 15% to 35% on different days. Biological and / or

✓ **Diagnosing diabetes with HbA1c test:**

An international committee of experts announced their consensus that the hemoglobin A1c test is accurate in diagnosing diabetes in adults and children – but not in pregnant women. They made this announcement at the 69<sup>th</sup> annual meeting of the American Diabetes Association this year.

✓ **Test specimens become hemolyzed during transport:** Dennis J. Ernst MT(ASCP) is the director of the Center for Phlebotomy Education. He answered a question in the August 2009 issue of MLO about specimens spun (no hemolysis), transported from a collection station to a testing laboratory, and test reports coming back saying the specimens were received hemolyzed. Mr. Ernst offers the following possibilities.

The reference lab may be re-spinning the tubes.

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Samples may experience temperature extremes (transported on ice or in extreme heat).

Specimens in a gel separator tube spun in a fixed-angle centrifuge will have a very thin layer on one side of the tube. Red cells may pass into the serum and hemolyze during transport.

Persons at the phlebotomy center may not have the same criteria for determining hemolysis as personnel at the reference lab.

✓ **pH measurement on body fluids:** Brad Karon, MD, PhD answered a reader's question on the stability of pH in body fluids in the August 2009 issue of MLO. Dr. Karon said there is little information on this topic in the literature except for pleural fluid. Studies indicate testing should be performed on samples collected in heparinized syringes and kept on ice until tested on a blood gas analyzer – not on a pH meter. He stated pH in pleural fluid changes over time and the laboratory should establish a 'collection to testing' time limit.

✓ **Persistent wound infections:** An article titled "*Rhodococcus equi* Infection in a Surgical Wound" by Stuart R. Paasche, CLS in the Summer 2009 issue of Clinical Laboratory Science made an interesting point regarding cost cutting in the microbiology laboratory. A diabetic, recovering from ventral hernia surgery, received a minor trauma to the wound area a month later. Infection developed at the wound site with purulent drainage. Routine wound cultures produced "normal skin flora" consisting of diphtheroids and coagulase negative *Staphylococcus*. After several antibiotic treatments failed to clear the infection, the wound was surgically opened and an infected patch removed. One month following the initial wound culture the laboratory isolated *Rhodococcus equi* from the wound site. Antibiotics were changed and the wound healed.

The organism may have been recovered earlier from the "normal flora" in the wound cultures except the distinctive red color took 4 days to appear and the laboratory's policy was to hold wound cultures 3 days only. As microbiology laboratories continue to cut costs, it might be a good idea to establish a policy to keep a wound culture from a chronic infection site a few more days – and make certain the wound collection process is not just a skin swab!

✓ **Vortexing EDTA tubes when analyzer reports platelet-clumping error:** David Gray, MD and Guang Fan, MD from Pathology at the Oregon Health and Science University stated in the September 2009 issue of MLO a vortex may be used to decrease platelet clumps in some cases. While there is a theoretical risk of hemolysis during vortexing, a study of 188 human whole-blood specimens with platelet clumps found other CBC parameters were not affected by the process. They also found in 50% of the specimens clumps were gone on smears and there was an average 73% increase in the platelet count. For the other half, there was partial clumping resolution with a 111% platelet count increase. Just be certain the vortexing is done under a biological safety cabinet so the process does not release contaminated aerosols into the laboratory.

✓ **Variation in a patient's HDL value:** There are two sources of variation inherent in HDL test values – biological and analytical. Since HDL levels in a person are mainly determined by heredity, clinicians may feel values taken several months apart should give very similar results. However, there are so many biological factors affecting precision, the National Cholesterol Education Program's guidelines recommend multiple tests be done on a patient before making a diagnosis or beginning any lipid treatment program.

Biological conditions that can affect HDL measurements include acute illness; changes in weight, diet, alcohol use or smoking habits; or

the use of over-the-counter medications that affect lipids.

Analytical variables include assay imprecision (getting the same answer on the same specimen tested multiple times) – the goal being no more than 13% (a few assays have reached this standard); fasting versus non-fasting samples; method by which the assay detects HDL (some being more prone to sample variation); and results from different assay methods (whole blood versus serum or plasma). There are at least 7 different assay methods available.

✓ **Massive transfusion problems:**

Transfusing massive amounts of blood in a short period of time to save a life after trauma (i.e. automobile accident), surgery (i.e. bleeder), or disease (i.e. DIC) can also create acute and chronic life-threatening problems.

**Risks:**

The body trauma producing the need for large amounts of blood may create increased heart rate; vasoconstriction; and the production of clotting factors, hormones and cytokines. Body temperature may drop affecting coagulation pathways and allowing metabolic acidosis to begin. If the transfused blood products are still cold, this will increase body temperature related problems.

Citrate toxicity from anticoagulants in blood products may cause a drop in calcium and magnesium affecting heart rhythm.

The blood products can have an increase in potassium which may affect the patient's kidney function.

Older stored blood may have an increase in 2, 3 DPG which will affect the red blood cell's ability to let go of oxygen into the body tissues that need it.

The list goes on and on. Solutions? Ricci Jo Ackley, MT(ASCP) and Karen M. Byrne, MDE recommend each transfusion facility have a plan to combine a set amount of fresh frozen plasma and platelet packs to accompany various amounts of red blood cell units ordered.

These protocols need to be established through a multidisciplinary consensus group (physicians, nursing, blood bank, pathologist). The protocol needs to be well known by all affected disciplines on all shifts. It should be posted and must be followed for best patient outcome. For the complete article see the April 7, 2008 edition of *Advance for Medical Laboratory Professionals*.

✓ **Luminex' xTAG Respiratory Viral Panel for influenza testing:** The FDA updated the panel's clearance to reflect information from two new studies. The product can be an aid in detecting 2009 Influenza A/H1N1 but **cannot** identify the hemagglutinin gene of the novel H1N1 strain in clinical specimens. [www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm163739.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm163739.htm).

## ★ Feature ★

### Establishing Critical Values Part II

Here are some key points from a talk given by Anand S. Dighe, MD, PhD (Massachusetts General Hospital pathology) at the Roche SmartLab meeting in Chicago, 2008.

**Critical Values:** test results that could cause death or severe patient outcome if not acted upon immediately (i.e. prothrombin time INR = 9/0, high potassium, low platelets).

**Vital Values:** test results that while not considered life-threatening, may strongly impact patients (i.e. positive tuberculosis culture).

**Critical Tests:** also known as STAT tests that may need urgent reporting for a specific patient

– but not all patients (i.e. troponin T in the Emergency Department).

For the staff, make the test lists and what is required very clear. As stated in the November 2008 Lab Bulletin issue, ask for clinician input – but realize the laboratory’s legal responsibility to the patient to notify the clinician of life-threatening results even when the notification is inconvenient. Dr. Dighe cautions the list should be reviewed and updated at least annually. Take old information off that is no longer relevant and change the critical values when patient care indicates such changes should be made.

Hospitals doing blood gases may have clinicians in delivery ordering cord blood gases. Do you have a “normal” range established for this test? Are there critical values associated with the PO2? Does your critical value list differentiate the source of the blood gas so you are not calling delivery with a “normal” cord blood value that would represent a life-threatening value in infant blood?

*“Age is no barrier. It’s a limitation put on your mind.”*  
*Jackie Joyner-Kersey*



## CLIA BITS

### ADDITIONAL WAIVED TESTS:

- Binax NOW Influenza A & B Test
- NDC Pro-Advantage *H. pylori*, Infectious Mononucleosis Device (whole blood)

- Inverness Medical Innovations Signify ER Drug Screen
- Siemens Clinitek 50 Urine Chemistry Analyzer
- UPC Home Drug Screening Test Card & Test Cups
- INC. Rapid Strep A Test

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### Calibration Verification – 6 months

CFR 493.1255(b) describes the requirements for calibration and calibration verification for non-waived tests. Verifying the calibration every six months requires at least a minimum (or zero) value, a mid-range value, and a maximum value near the upper test range to verify the reportable range. There are some exceptions listed in the guidelines (automated cell counters i.e. CBC instruments, instruments requiring 3 levels of control more than once a day – i.e. blood gas analyzers).

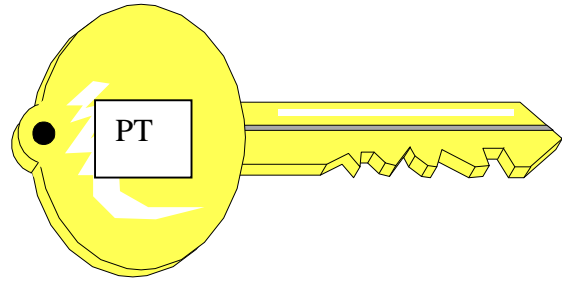
These exceptions do not apply to non-waived coagulation tests (PT, PTT) or instruments requiring a calibration every six months with only one or two points rather than the three in the ranges listed above. If the manufacturer requires calibration with the three points at least every six months, this reportable range verification is met.

You can meet this requirement with a calibrator kit recommended for your instrument, proficiency test samples with known values, or quality control or calibrator samples from another lot number than the ones routinely used to calibrate or control a daily patient test run. For example, your six month calibrator is one point (mid-range) required every six months by the instrument’s manufacturer. You can add a low and high control from a different lot number than the one routinely used to show a patient run is acceptable – just once every six months to prove your instrument is still operating within its stated range.

## Celebrity Trivia

*In which current western state was Geronimo (Chiricahua Apache) born?*

[AK, AZ, CA, CO, HI, ID, MT, ND, NV, OR, SD, WA, WY, UT]



## Proficiency Test Quality Assurance

Check Laboratory Improvement's website for help with proficiency test management.  
<http://health.utah.gov/lab/labimp>.

Click on Clinical Laboratory QA Tools and check out PT Failure and PT Flowchart.

## Quality Assessment Spotlight



The Quality Council of India was appointed by the Indian government's Ministry of Health to write standards for medical laboratories based on the international medical laboratory standard ISO 15189. At a conference in Madhya Pradesh to launch the new standardization quality management system, a physician offered CARE as an acronym for laboratorians to contribute to patient safety.

- C = Concern, Consideration, Capability and Competence
- A = Attentiveness, Action, Accountability
- R = Respect, Reliability, Responsibility
- E = Empathy Excellence

### Kudos Laboratorians of India

### Ponderables:

How come we choose from just two people for President and fifty for Miss America?



## SAFETY

### Healthcare workers infected with H1N1

The *Los Angeles Times* reported about half the healthcare workers in the USA infected with the novel H1N1 strain were likely infected at work. To prevent such infections, CDC recommends persons caring for infected patients be fit tested and use N95 respirators, use eye protection and contact precautions. They also recommend all healthcare workers be vaccinated and take prophylactic antiviral medication.

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### Biosafety hazards in surgical pathology

The same hazards that exist in microbiology patient samples also exist in pathology samples reported Nancy Cornish, MD from Methodist and Children's hospitals in Omaha for a CAP

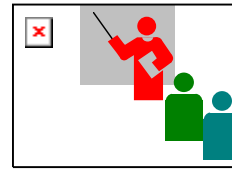
Today article in the September 2009 issue. Dr. Cornish states if you are cutting fresh tissue or doing a frozen section you must use CDC's Standard Precautions to protect yourself from infectious disease agents. She further states if formalin fixed tissue does not have the correct ratio of formalin to tissue, organisms may not be killed.

There are reports of viable tuberculosis bacteria in formalin fixed autopsy cases – 138 samples in a 2004 study. Do physicians and histotechs have annual PPD skin tests? CLSI guidelines "Protection of Laboratory Workers from Occupationally Acquired Infections" 2005 state "Gloves and an N-95 particulate respirator should be worn during frozen sectioning." Annual fit testing is necessary before using an N-95 mask. A person must be fit tested for every different brand of N-95 mask they use.

Dr. Cornish also recommended cryostat users ask manufacturer's to make the instruments like the microbiology biological safety cabinets that remove infectious organisms – not just remove fumes! The histotech may use appropriate precautions, but what about other office workers exposed to aerosols produced during tissue processing (especially spraying steps or even people disturbing airflow when walking by the cryostat)?

CAP requires a cryostat used daily be disinfected weekly with a disinfectant that kills tuberculosis. Check the label on the tuberculocidal agent you use. Most EPA approved products must be used at room temperature to be effective. Some laboratories use absolute alcohol – but a 60% to 90% solution will work better as the water denatures proteins more quickly and is a better tuberculosis killing agent. Even 70% isopropyl alcohol can be used. The contact time is also important, the surface must be kept wet for the time the manufacturer states will accomplish the task of killing organisms.

## CONTINUING EDUCATION



### Education on the CLIA Website

There are several interesting downloads available such as "Identifying Best Practices in Laboratory Medicine – a Battelle Project for the Centers for Disease and Control and Prevention (CDC)" and "Micro sample pipetting information for laboratories".

[www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia)

### Understanding Our Universe

**"My theology, briefly, is that the universe was dictated but not signed."**

**Christopher Morley**

Answer to Celebrity Trivia: The rebel leader of the Chiricahua Apache was born in what is now the state of Arizona, though he spent a lot of vacation time in Mexico!