Cases
in Point-of-Care Testing

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Medical Branch (2008 POCT Coordinator of the Year)

Interactive Cases Objectives:

1. Discuss professional roles & responsibilities of personnel who perform & oversee POCT.
2. Identify potential testing errors & discuss ways to avoid them,
3. Demonstrate QC & Quality Assurance Management strategies (regulatory compliance).

This is an **experimental** interactive webinar; help me out, give me feedback.

Outline

- For Each Case
  - Presentation
  - Some questions, either as multiple-choice polls or as free-response in Q&A panel. ***THROW ANSWERS OUT THERE OR WE'LL GRIND TO A HALT***
  - Some resources to go home with, mostly taken from POCT-08
- Case 1: The Flu is New, But Don't Be Blue
- Case 2: Doin' Dipstick Dunkin' Demonstrations!
- Case 3: The Trouble-Shooter Hits the Target!

The Flu Is New, But Don't Be Blue!

- You're the laboratory-based POCC for Darned Good Little Hospital (DGLH), a 100-bed facility at the edge of a metropolitan area known colloquially as The Big Kumquat.
- It's ~~April, 2009~~… April 2017
- Cue ominous music.

Scenario 1: The Stage is Set

- A brand-new strain of pandemic flu sweeps through the country.
- The state lab promises '7 day or better TAT' for their flu test.
- 'No problem', the DGLH administrator assigned to the labs says. 'We'll get rapid flu tests and give them to the ER'.
  - And then she calls ***you*** and tells you to do that.
  - It may be no coincidence that your administrator came to lab in a reorganization from the pharmacy.

Are **You** Prepared?

Real Life: UTMB Community Clinics "H1N1 Preparation" May 2009

- Distribution and collection of supply lists and inventory;
- Need for, availability of, and implementation requirements for use of rapid flu testing kits (Point of Care Testing) reviewed and discussed on individual site basis.

Hazardous Vulnerability Assessment for Human Events (Example Yr 2009)													
EVENT	**Probability**				**RISK**					**Prepared-ness**			**TOTAL**
	HIGH	**MED**	**LOW**	**NONE**	**LIFE THREAT**	**HEALTH/ SAFETY**	**HIGH DISRUP-TION**	**MOD DISRUP-TION**	**LOW DISRUP-TION**	**POOR**	**FAIR**	**GOOD**	
SCORE	**3**	**2**	**1**	**0**	**5**	**4**	**3**	**2**	**1**	**3**	**2**	**1**	
Biological Event / Epidemic, Pandemic		X				X					X		16

Risk assessment prior to the event: part of a routine 'hazardous vulnerability assessment' , while we had a plan, we weren't all that ready! *This is perhaps inevitable…*

Scenario 1: Your Mission…

- You've got two weeks to get the test into production. Your administrator promises to deal with all the contracting issues.
  - For some reason, you're not all that confident, but forge ahead regardless.
- Which test will you select?
  - Might your providers want to be able to differentiate between influenza A and B? (kit selection to meet expectation)
- How will you verify the performance of the rapid flu test?
  - Do you think it'll correlate well with PCR?
  - What if it doesn't?
- How will you educate providers on sample collection?
  - Will only providers conduct collections? (site dependent? Allow nurses but not phlebotomists/medical assistance?)
  - What is the appropriate specimen?
  - What is the appropriate patient?
- Should testing personnel wear special PPE?
- How will you report positive and negative results?
  - Will you recommend confirmation / additional testing? When?

What's Available?

	Good Ol' Flutest	FluForYou 2000	Magic POC
Format	Card lateral flow antigen test, manual read; detects flu A and B	Cassette lateral flow antigen test, manual read, detects flu A and B	Cartridge-based proprietary molecular flu test, detects and discriminates flu A and B
Readout	Single line for any influenza	Separate lines for Flu A and B	Automated readout of separate A&B channels
Sensitivity	From package insert: 80% sensitive on 400 children <3 y/o using viral culture from frozen samples as the gold standard.	From package insert: 60% sensitive on 553 children <10 y/o using viral culture as the gold standard.	From package insert: 90% sensitive on 437 children <5 y/o using PCR as gold standard; 75% sensitive on 745 adult samples using PCR as gold standard.
Specificity	From package insert: 97% in study above.	From package insert: 97% from study above	From package insert: 99.5% from study above.
Est. Cost/Test	$8	$15	$60
Workflow	Controls per shipment or lot; 5 min to result; manual read and report.	Controls per shipment or lot; 15 min to result; manual read and report.	Electronic control daily, with liquid controls weekly and with new lots; interfaceable; 15 min to result; operator ID with lockout.
Allowable specimen types	NP swab/wash	NP swab/wash sputum throat swab	NP swab/wash

What's Available?

	Good Ol' Flutest	FluForYou 2000	Magic POC
Format	Card lateral flow antigen test, manual read; detects flu A and B	Cassette lateral flow antigen test, manual read, detects flu A and B	Cartridge-based proprietary isothermal ***molecular*** flu test, instrument detects and discriminates flu A and B
Readout	Single line for any influenza	Separate lines for Flu A and B	Automated readout of separate A&B channels
Sensitivity	From package insert: 80% sensitive on 400 children <3 y/o using viral culture from **frozen samples** as the gold standard.	From package insert: 60% sensitive on 553 children <10 y/o using viral culture as the gold standard.	From package insert: 90% sensitive on 437 children <5 y/o using PCR as gold standard; 75% sensitive on 745 adult samples using PCR as gold standard.
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You Elect to Move Forward with the Magic POC

- Different places might choose differently; the machine might be a plus or a minus, depending on your degree of IT support and how your operations run.
  - The emergency allows the administrator to overrule all her instincts and allow the much-more-expensive test.
- You elect to verify the test versus PCR run at your state lab.

Verification Study on the Magic POC

Spec #	Age	Sex	Magic	PCR		Spec #	Age	Sex	Magic	PCR
1	4	M	Pos	Pos		21	22	M	Pos	Pos
2	7	F	Neg	Pos		22	3	M	Neg	Neg
3	8	M	Neg	Neg		23	7	F	Neg	Neg
4	67	F	Neg	Neg		24	22	F	Neg	Pos
5	13	F	Neg	Neg		25	19	F	Pos	Pos
6	2	M	Pos	Pos		26	83	M	Neg	Pos
7	45	M	Neg	Neg		27	3	F	Neg	Neg
8	58	F	Neg	Neg		28	45	F	Neg	Neg
9	68	F	Neg	Pos		29	3	M	Pos	Pos
10	92	F	Neg	Neg		30	23	M	Neg	Neg
11	1	M	Pos	Pos		31	4	F	Neg	Neg
12	34	F	Neg	Neg		32	2	M	Neg	Pos
13	54	F	Neg	Neg		33	1	F	Pos	Pos
14	5	M	Neg	Neg		34	47	M	Neg	Pos
15	22	M	Neg	Neg		35	52	M	Neg	Neg
16	78	M	Neg	Pos		36	1	F	Pos	Pos
127	12	F	Neg	Neg		37	36	M	Neg	Neg
18	62	M	Pos	Pos		38	65	M	Neg	Neg
19	3	F	Neg	Pos		39	7	F	Neg	Neg
20	2	F	Neg	Neg		40	87	F	Neg	Neg

A Training and Validation Tool for Emergency Preparedness

A survey to do prior to the event; assess need and system readiness:

H1N1 (swine flu) Drill for the UTMB clinics
(Questionnaire)
Please answer the following questions and return the questionnaire by 3:00pm today.
Scenario:
UTMB has been notified that H1N1 influenza is in the area and the UTMB clinics need to activate the Emerging Infectious Diseases protocol. You are to assume that H1N1 is active in the community and a patient with this disease may present at any time.

Have all your employees read the Infection Control Protocol 3.24 Infection Control for the Pandemic Phase of an Emerging Infectious Disease (EID) in Outpatient Clinics 10.21.09? ☐ Yes ☐ No

Who has been trained to perform the POCT testing for the flu rapid screening test? (List POC operators below)

If the patient has a negative rapid flu test, should you send a sample for confirmation to the UTMB lab and or ARUP?

Specimen Collection

This is an essential element of any type of respiratory virus testing.

Appendix I. Example of Sample Collection

(Instructions derived from the World Health Organization instructions at http://www.who.int/csr/disease/avian_influenza/guidelines/humanspecimens/en/Image from CDC: http://www.cdc.gov/vaccines)

Influenza Sample Collection

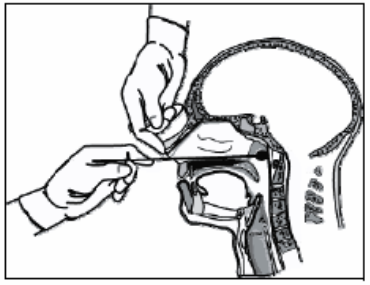
Pretty Good Clinic, Sometown, Federated States of Some Continent
Procedure prepared by: Jane the Laboratory Supervisor, January 1, 2111
Reviewed: 1/1/2112 JLS

Preparation

- Wear gloves, gown, and mask for the collection procedure, and use standard precautions when handling the sample.
- Use **only** the collection kits designated for the influenza test; stored in the top drawer to the left of the sink in room 13, labeled Viral Transport Media.
- Identify yourself to the patient and greet him or her in a friendly and reassuring manner.
- Identify the patient using both name and DOB. If the patient is unable to provide identification, ask a family member.
- Label the influenza collection kit with both patient identifiers.
- Tell the patient you are going to collect a sample to be tested for the flu, and that it may be uncomfortable, but it is not dangerous and should not last long.

Collection of Nasopharyngeal Swab

- Ask the patient to tilt his or her head back at a comfortable angle.
- Insert the flexible, fine-shafted polyester swab into the nostril and back to the nasopharynx, and leave in place for a few seconds. See the diagram below.
- You should feel some resistance as the swab passes from the external nares into the nasopharynx, and the patient will feel a burning sensation.
- Withdraw the swab with a rotating motion.
- Place the tip of the swab into the virus transport vial, and break off the shaft below the top of the vial where it is scored.
- Test immediately; if testing will be delayed, hold in the refrigerator in room 13 for no more than 24 hours before testing.



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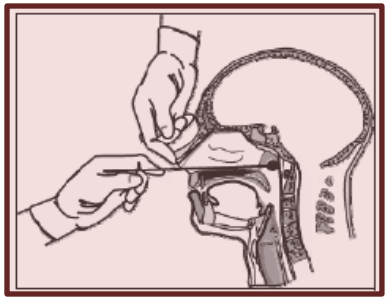

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PPE for specimen collection (much riskier than doing the test!)

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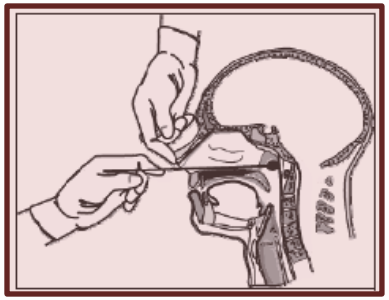

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Special Viral media

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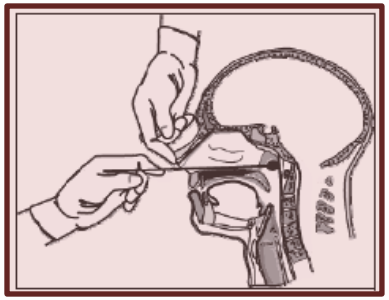

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And as usual, test immediately

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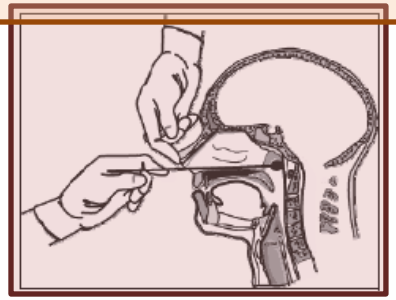


Influenza A Rapid Test Performance¶

Rapid Test¤	Sens%¤	Spec%¤	Compared With¤	Comments¤	Reference¤
Directigen ¤	**58.8¤**	99.2¤	Molecular¤	A&B performance combined¤	Liao et al JCM 47(3):527-32, 2009 Mar¤
3M↵ QuickVue ↵ BinaxNow¤	**75↵** **73↵** **55¤**	98↵ 99.5↵ 100¤	Culture¤	Archived specimens¤	Dale et al JCM 46(11):3804-7, 2008 Nov¤
BinaxNow¤	**53¤**	¤	RT-PCR¤	2 of 237 samples were flu B pos by RT-PCr but flu A by NOW. ¤	Landry et al JCV. 43(2):148-51, 2008 Oct¤
BinaxNow¤	**61¤**	100¤	RT-PCR¤	DFA was 81% sensitive¤	Rahman et al Diag Micro Infect Dis 62(2):162-6, 2008 Oct¤
RemelXpect↵ BinaxNow¤	**47.7↵** **78.3¤**	98.7↵ 98¤	Culture¤	20.3/99.8 Flu B↵ 35.9/99.9 Flu B¤	Cruz et al JCV 41(2):143-7, 2008 Feb¤
BinaxNow¤	**52¤**	¤	RT-PCR¤	70% in days 1-3 of disease¤	Nilsson et al Inf Cont & Hosp Epi 29(2):177-9, 2008 Feb¤
Directigen ¤	**42¤**	96¤	Culture¤	¤	Rahman et al Diag Micro Infect Dis 58(4):413-8, 2007 Aug¤
BinaxNow↵ Directigen↵ QuickVue¤	**73↵** **69↵** **67¤**	99↵ 100↵ 100¤	RT-PCr¤	Sensitivity only 30% vs flu B for all¤	Hurt et al JCV 39(2):132-5, 2007 Jun¤
Quickvue¤	**85¤**	97¤	RT-PCR¤	¤	Mehlmann et al JCM 45(4):1234-7, 2007 Apr.¤
Directigen + Quickvue + BinaxNOW¤	**63¤**	97¤	RT-PCR¤	Data pooled from all rapids; ¤	Grijvala et al Pediatrics. 119(1):e6-11, 2007 Jan¤

Convenience sample of recent literature; selected by Medline search + fit to single page

ALL rapid tests are insensitive!!!

When to test?

- Remember – false-positives have potentially severe consequences, e.g. non-treatment of a serious bacterial infection.
- Test during the flu season, ***only***.
- Potential strategies:
  - Seasonal: test Oct-Dec→March or so.
    - Early season – retain specimen for confirmatory testing!
  - Incidence-based testing – monitor regional influenza per CDC and State systems, begin testing only when influenza reported in the area.
- Remind providers to test early in illness; the best therapeutic results are when drugs are started within 48h of onset.

Interpreting Results of Rapid Flu Test

- A comment might be a good idea:
  - Remind providers that these tests are insensitive.
  - Remind providers that out-of-season false-positives outnumber true-positives.
  - Remind providers of known sources of error; e.g. bloody samples.
- Provide supplementary testing at least for selected patients and off-season or early-season positives.

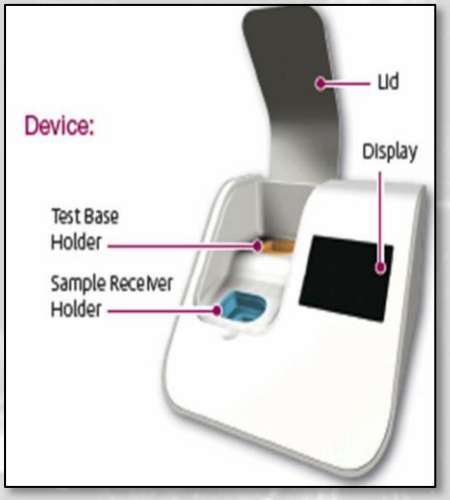
Available FDA-approved Molecular Influenza Tests

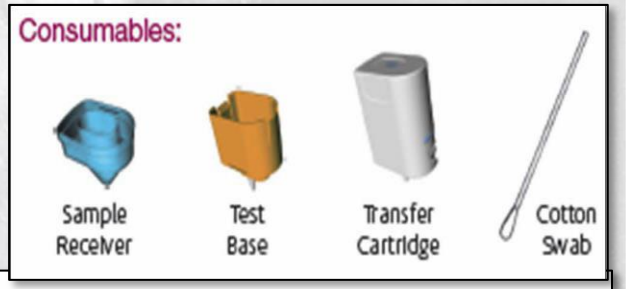
- Waived complexity
  - Alere i Influenza A and B
  - Roche LIAT Influenza A/B Assay
  - Cepheid Flu/RSV XPress
- Moderate or High complexity
  - Cepheid Xpert Flu Assay
  - eSensor Respiratory Viral Panel
  - FilmArray Respiratory Panel
  - Prodesse PROFLU and PROFAST
  - Quidel Molecular Influenza A+B Assay
  - Qiagen Artus Influenza A/B Rotor-gene RT-PCR kit
  - Simplexa Flu A/B & RSV and Flu A/B & RSV Direct and Influenza A H1N1 (2009)
  - Verigene Respiratory Virus Nucleic Acid Test and RV+ Test
  - X-TAG Respiratory Viral Panel and RVP-FAST

http://www.cdc.gov/flu/pdf/professionals/diagnosis/molecular-assay-table-1.pdf

Alere i Influenza A&B

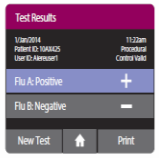
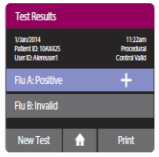
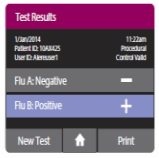
- CLIA-waived
  - Bring supplies to room temperature
  - Put test base and sample receiver on instrument; allow to warm
  - Place swab in sample receiver, mix
  - Apply transfer cartridge to sample receiver
  - Move transfer cartridge to test base
  - Close lid; test runs 10 minutes





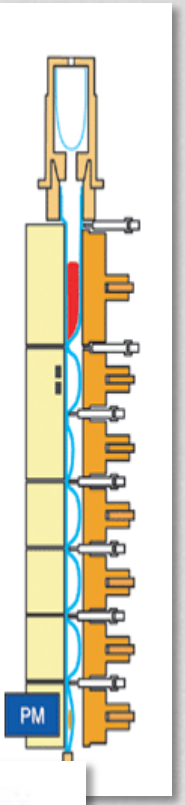
RESULT INTERPRETATION

When the test is complete, the results are clearly displayed on the instrument screen. An individual result for both influenza A and influenza B will be provided.

Instrument Display	Interpretation of Results and Follow-up Actions
	**Flu A Viral RNA Detected; Flu B Viral RNA Not Detected.** This result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.
	**Flu A Viral RNA Detected; The presence or absence of Flu B Viral RNA cannot be determined.** This result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.
	**Flu B Viral RNA Detected; Flu A Viral RNA Not Detected.** This result does not rule out co-infections with other pathogens or identify any specific influenza B virus lineage.

Roche LIAT Influenza A/B Assay

- CLIA waived
- LIAT stands for Lab-In-A-Tube
- Detects Influenza A and B
- Sample to answer: .5h



Cepheid Xpert Flu Assay

- Moderately complex
- Detects Flu A and B; discriminates 2009 H1N1.
- Flu + RSV cartridge available
- Sample to answer ~1h
- GeneXpert Xpress waived in 12/2015

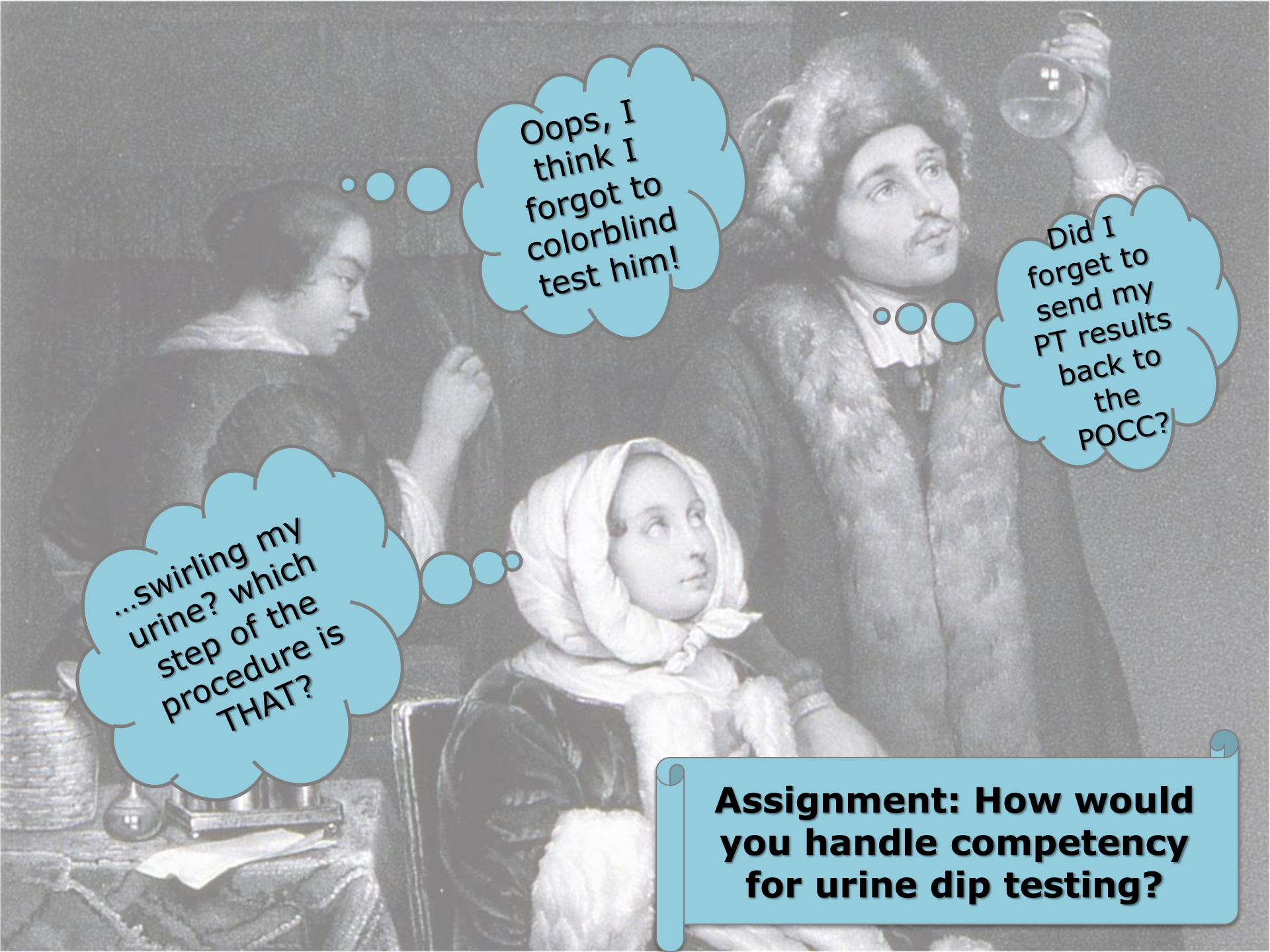
Emerging Virus Issues

- A new virus is a ***new virus*** – do old tests perform as well on it as they do on the existing strains?
- Per CDC, rapid tests vary by orders of magnitude in sensitivity for different flu strains.
- Verify your test's performance against reference standards with new strains of influenza viruses.
  - Manufacturers will do this, probably.

Case 2

Doin' Dipstick Dunkin' Demonstrations!

- As the POCC of Great Big Honkin' Healthcare (GBHH), you're responsible for supporting POC urinalysis in a dozen locations:
  - 3 ERs
  - 5 Primary Care Clinics
  - 1 Labor & Delivery Suite
  - 3 Units: Pediatric unit-NICU/PICU & Term Nursery
- Manual UA Performed by:
  - Licensed Nurses (RN, LVN): report to Nursing
  - Physicians/PA/NP: report to Medical Staff (required to fill out declaration to acknowledge if perform WT; GBHH Hospital Credentialing; TJC surveys hospital)
  - Health Techs/Medical Assistants: report to Medical Admin in hospital; report through Nursing Department in clinics
  - Phlebotomists: report to Lab in hospital, report through Nursing in clinics
- GBHH WT currently Accredited by:
  - **CAP** (L&D Suite, Inpatient units – Pedi/NICU_PICU/Term Nursery)
  - **COLA** (Offsite Primary Care Clinics)
  - **Joint Commission (TJC)** - ER


Oops, I think I forgot to colorblind test him!
Did I forget to send my PT results back to the POCC?
...swirling my urine? which step of the procedure is THAT?
Assignment: How would you handle competency for urine dip testing?

Scenario 2: Break Down the Tasks

- For one area (assigned to groups)
  - ERs
  - Outpatient clinics
  - Inpatient areas: L&D, NICU/PICU/Nurseries
- List what you are **required** to do for competency for these different groups?

TJC

Standard	Intent	Notes:
WT.03.01.01	Staff and licensed independent practitioners performing waived tests are competent.	At least two of four methods mandated by CLIA regulation must be used to assess competency:
		Performance of a test on a blind specimen
		Periodic observation of routine work by the supervisor or qualified designee
		Monitoring of each user's quality control performance
		Use of a written test specific to the test assessed
WT.05.01.01	The hospital maintains records for waived testing.	

CAP

Standard	Intent	Notes:
POC.06900	There is a documented program to ensure that each person performing POCT maintains satisfactory levels of competence.	Elements of competency assessment include but are not limited to:
For waived test systems, it is not necessary to assess all elements at each assessment event: the POC program may select which elements to assess.		Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
		Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
If elements of competency are assessed by routine supervisory review, the competency procedure must outline how this routine review is used to evaluate competency.		Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
		Direct observation of performance of instrument maintenance and function checks, as applicable
		Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
		Evaluation of problem-solving skills

COLA & CLIA

- COLA: Is in line with CAP 0.6900.
- CLIA: Follow manufacturer's recommendations.

Scenario 2: More Questions

- Who will perform the competencies? (do you include float, agency, students?)
- How will competencies be **delivered**?
- How do you **verify** that the program is working?

Scenario 2: Another Exercise

- Design an exercise for one of the six CAP **dimensions** of competency. Be efficient.

The CAP Competency Domains:
Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
Direct observation of performance of instrument maintenance and function checks, as applicable
Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
Evaluation of problem-solving skills

Checkpoint (Training)

You bring a new test kit into your laboratory, or a new person uses it. Each person who will run the test needs to do the following:

- Read the written procedure.
- Learn how to collect the sample properly (if applicable).
- Observe the performance of the test.
- Run known samples under observation, perform the steps correctly, and get the right answers.
- Know where to record results including QC and to whom to report results.
- Know when and how to run control samples.
- Know common sources of error and documented interferences.
- Know how to solve common problems.
- Know when to ask for help.

Appendix G. Example of Training/Competency Assessment

G1. Example of Competency Checklist

Name: _____

Facility: _____

	URINE PREGNANCY COMPETENCY	Met
1	Reviews kit lot number and ensures kit is within expiration date.	
2	Puts on gloves.	
3	Understands QC performance and documentation requirements: ☐ QC is done on each new shipment and each new lot number of urine pregnancy test kits. ☐ The results for each control and internal controls are documented on the Urine Pregnancy Test Log.	
4	Removes the test device from the foil pouch; places it on a flat, dry surface; and labels it with patient identification.	
5	Using the pipette supplied in the kit, dispenses three drops of sample into the sample well.	
6	Reads a positive result after a red procedural control line appears next to the "C" and a red line appears next to the "T." Knows to wait at least three minutes (no longer than 10 minutes) to read a negative (only a red line next to the "C").	
7	Knows that a specific gravity less than 1.010 can cause a false-negative result.	
8	Reruns sample if a red line fails to appear next to the "C" (Control).	
9	Records results on the patient's chart along with initials of testing personnel (or enters results in the computer). Records that "Ctrl OK."	

By signing below, I verify that I was trained and am competent to perform the Urine Pregnancy (hCG) procedure. I verify that I read the procedure, and acknowledge that it is my responsibility to renew competency validation annually.

Signature: _____ Date: _____

I observed this individual perform the Urine Pregnancy (hCG) procedure, and consider this person competent to perform this procedure.

Signature: _____ Date: _____

Competency Assessment based on procedure

Go through your procedure to find elements to test: high-risk steps, easily missed steps, critical elements.

Urinalysis, ChemStrip (BMC)

Purpose

This document provides instruction for performing a chemical analysis using a urine dipstick. The testing may consist of any or all of the following: pH, protein (semiquantitative), glucose, bilirubin, ketone, hemoglobin (blood), urobilinogen, nitrite, leukocytes (leukocyte esterase) and specific gravity.

Audience

The information in this document is applicable to all medical, nursing (RN, LVN, HTA, NA) and laboratory personnel

Policy

Test requires order from primary care provider (Physician, Nurse Practitioner, Physician Assistant). At the discretion of the provider, test results where clinical indication or departmental protocol suggest confirmatory testing, (specimen) may be sent to the laboratory.

Test Principle

- Urine is a physiological fluid of widely varying composition formed by the kidney from the blood. The principle constituent of urine is water (92 - 99% in normal urine).
- Thousands of compounds have been identified in normal urine and the vast majority are derived from the blood. The major urine components are creatinine, urea, uric acid, sodium, potassium, chloride, calcium, magnesium, phosphates, sulfates, and ammonia.
- A considerable portion of the urine solids is waste products which have been filtered through the kidneys and are being excreted from the body. Some of the constituents are considered to be regulatory substances, which may be either retained or excreted by the kidney.

Urine is a principle pathway for excretion of body waste and for homeostatic regulations of body water and body electrolytes.

- The chemical principles of the reagent pads on the strips are:
  1. pH - this test is based on a double indicator principle that gives a broad range of colors covering the urinary pH range from 5 to 9. Colors range from orange through yellow and green to blue.
  2. Protein - This test is based on the protein-error-of-indicators principle. At a constant buffered pH, the development of any green color is due to the presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.
  3. Glucose - This test is based on a double sequential enzyme reaction. The reaction utilizes the enzyme glucose oxidase to catalyze the formation of gluconic acid and hydrogen peroxide

Continued on next page

A Thought-Experiment: Urinalysis Quiz

Thought questions:

- How many questions?
- Level of comprehension to target?
- How to set 'passing score'? Allow repeats until 100%?
- Who does remedial training if unable to pass test?
- How often does POCC change test questions?

Writing Good Questions

- Make sure the item can be answered without looking at the options OR that the options are 100% true or false.
- Include as much of the item as possible in the stem; the stems should be long and the options short.
- Avoid superfluous information.
- Avoid "tricky" and overly complex items.
- Write options that are grammatically consistent and logically compatible with the stem; list them in logical or alphabetical order. Write distractors that are plausible and the same relative length as the answer.
- Avoid using absolutes such as 'always', 'never', and 'all' in the options; also avoid using vague terms such as 'usually' and 'frequently'.
- Avoid negatively phrased items (eg, those with except or not in the lead-in). If you must use a negative stem, use only short (preferably single word) options.

Good question – Bad question

If the top is left off a bottle of urinalysis strips overnight, the best first action to take is to:

A. Discard the strips and use a new bottle.
B. Run controls and use the strips if controls are OK.
C. Call the POCC and ask for help.
D. Investigate who left off the top and institute a corrective action report.
E. Run tests as usual.

One morning, you walk in and find the POCT testing area is a mess, with urine spilled on the countertop and an open bag of Fritos sitting in it. The top is off the bottle of urinalysis strips. Do you:

A. Discard the strips and use a new bottle.
B. Running controls is the best way to check the strips.
C. I call the POCC and ask for help.
D. A and B
E. All of the above

Competency Assessment Best Practices

- Operator Training and Competency
  - **To ensure quality testing**, prior to patient testing, new POC operators must receive orientation, training and demonstrate competency for each test they will perform.
  - Periodic reassessment by Accreditation is CAP = 6 month & annual; TJC = annual
  - **Training includes 'risk evaluation'** (pre-, analytical, post-)
- Observation of technique during patient care activities;
- Routine QC performance demonstrating ongoing competency;
- Applying content – transferring check-off/demonstration to patient testing.

Assess Your Competency Process!

Assessing (Testing) how well you are doing in competency assessment:

- ✓Audit 'train the trainers'? Observe!
- ✓Audit successful routine QC performance?
- ✓Do Operators apply content – transfer check-off/demonstration to patient testing?

Scenario 3 – The Trouble-Shooter Hits The Target

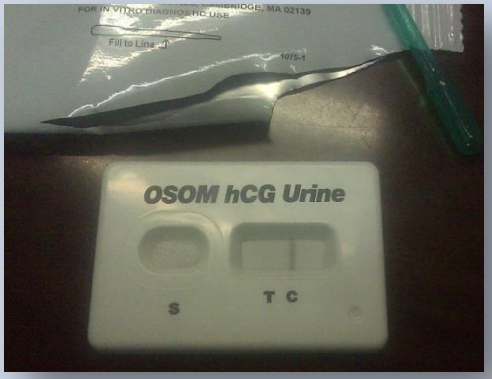
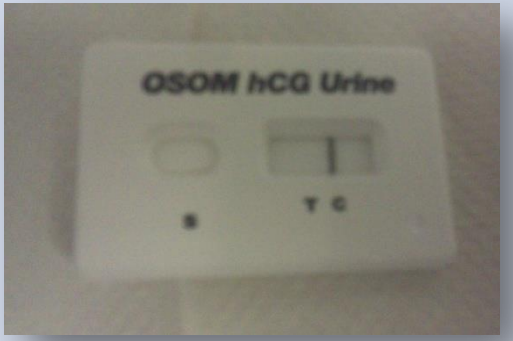
- As the POCC at GBHH you're responsible for a couple of clinics performing urine pregnancy testing.
- You get a frantic call from one…

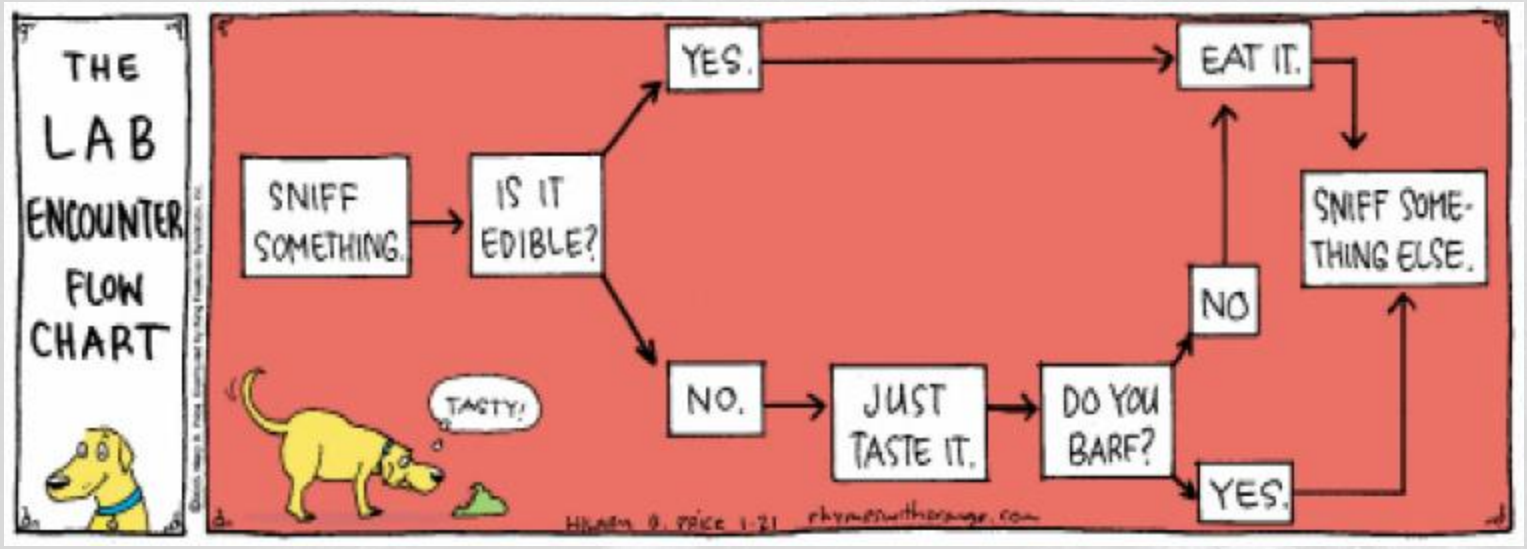
"The pregnancy test failed and we're in trouble."

The Problem

- A patient was tested yesterday, and was negative.
- She still 'felt pregnant', so went to Mighty Drug and bought a Super-Preggers kit.
  - **It was positive!!!**
- She came back to the clinic today, cell phone picture in tow.
  - **The clinic's test was still negative.**

The Tell-Tale Pics!

1st urine hcg performed in clinic	Patient choice kit "positive at home"	F/up urine hcg performed in clinic
		



How would YOU proceed/investigate/ solve?

Assignment

- What do you do? How do you work-up this problem?
- List the steps you would take and what you'd do with various outcomes.

…don't miss the boat…

- Effective troubleshooting
  - Identify where things can go wrong
  - Pre-
  - Analytical (CLSI terminology is 'examination')
  - Post-

HCG Limitations

Limitations of the Procedure

1. Very dilute urine samples, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be collected 48 hours later and tested.

2. False-negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine sample should be collected 48 hours later and tested.

3. Very low levels of hCG (less than 50 mIU/mL) are present in a urine sample shortly after implantation. However, because a significant number of first-trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine sample collected 48 hours later.

4. A number of conditions other than pregnancy, including trophoblastic disease and certain nontrophoblastic neoplasms, such as testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in a urine sample should not be used to diagnose pregnancy unless these conditions are ruled out.

5. This test provides a presumptive diagnosis for pregnancy. A physician should make a confirmed pregnancy diagnosis only after all clinical and laboratory findings are evaluated.

Appendix F: CLSI POCT 08A

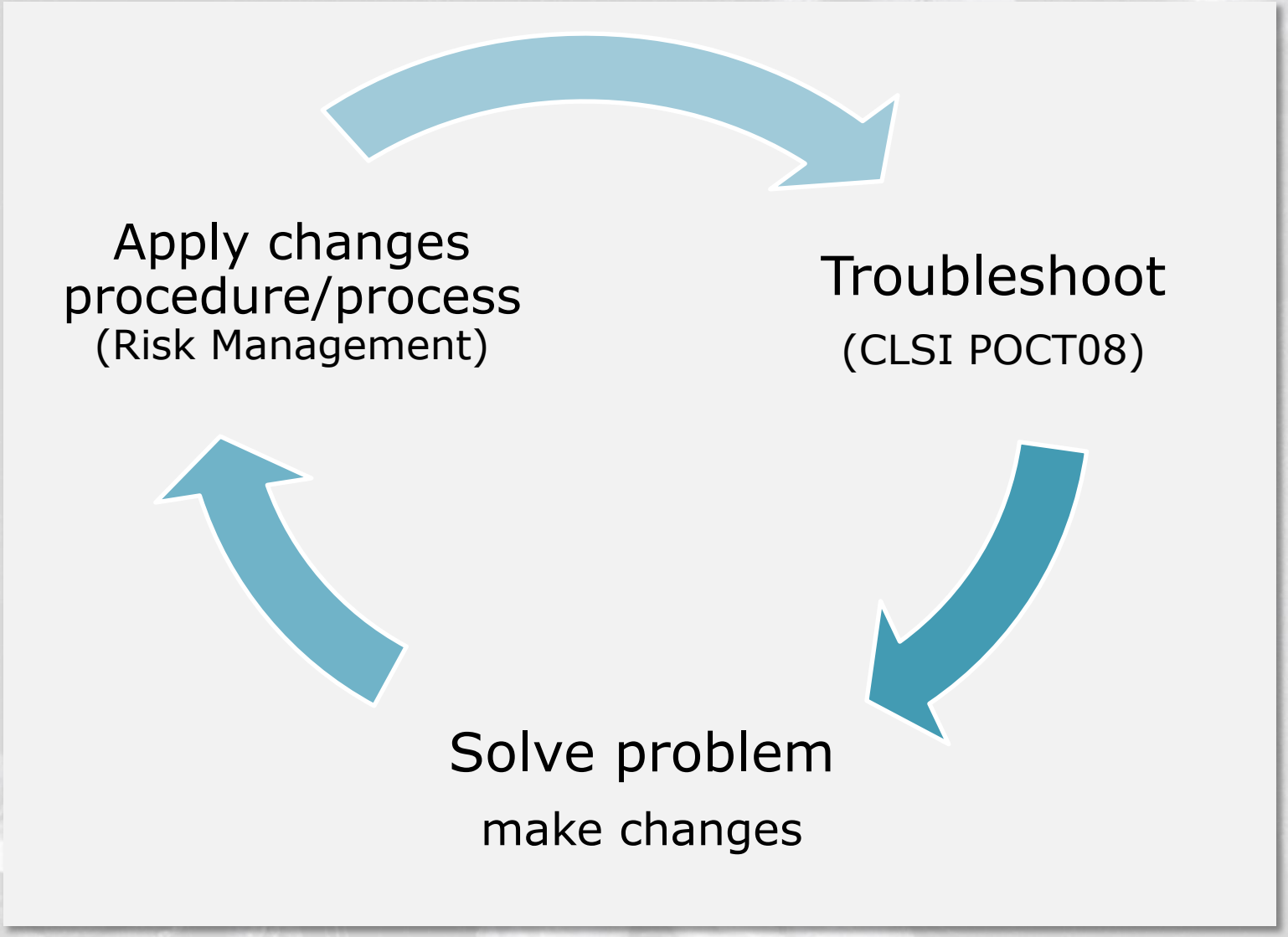
HCG 'Best Practice'

- A way to determine if a 'prozone false negative' (clinician suspicious that the woman is >1 month pregnant) = dilute 1 drop of the urine with 20 drops of saline (or ~ 0.5-1 mL), mix and rerun the test.
  - If the dilute urine = positive result 'false negative', evaluate another kit to replace existing; not all tests have this flaw.
  - Review literature for reports of 'false negative' as part of your evaluation of urine HCG kits.
- For end-users – recommend sending blood for quantitative HCG.

Significance of Risk Management

- CLSI EP-23
- Murphy's Law
- Process of controlling what can go wrong
  - Patient complaints
  - Errors in test reporting
  - Safety issues

Best Practice



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Share Your Pain

Your 'best'* phone call/encounter with POC Operator ever ?

* 'Best = most entertaining