

# **Point-of-Care Molecular Testing**

## **Waived Testing**

**April 28, 2016**

**Raymond P. Podzorski, Ph.D., D(ABMM)**

**Ph.D. Microbiologist**

**St. Mary's Hospital Laboratory**

**Wisconsin Region SSMHC**

**Madison, WI**

**608-258-6393**

**raymond\_podzorski@ssmhc.com**



# Disclosure

**Raymond P. Podzorski, Ph.D., D(ABMM)**

**April 28, 2016**

**No relevant financial relationships do disclose.**

# Objectives

- **Discuss the benefits of POC**
- **Illustrate the unknown associated with waived POC nucleic acid amplification testing**
- **Review the technology available for waived POC nucleic acid amplification technology**
- **Examine the challenges associated with providing reliable test results with waived POC nucleic acid amplification tests**
- **Discuss how biosafety aligns with waived POC nucleic acid amplification tests**

# **POC-Benefits to Clients**

- **Reduced waiting times for laboratory results**
- **Few, or no, follow up visits needed**
- **Real-time discussion of results and treatment plan**
  - **Improve clinical outcome**
  - **Improve patient satisfaction**
- **Ready access to laboratory testing**

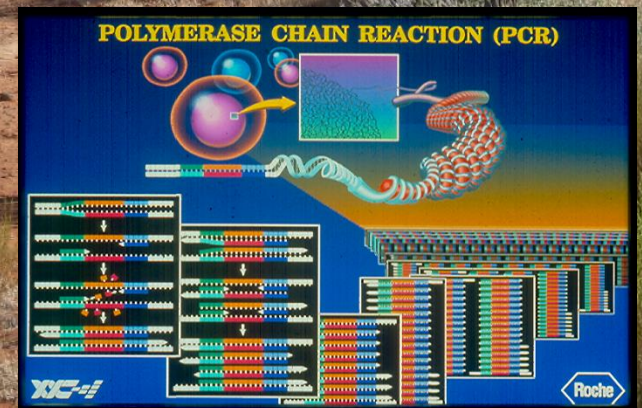
# **POC-Benefits to Provider**

- **No packaging and shipping of specimen needed**
- **No courier system needed**
- **Specimen is exposed to less risk of loss/damage**

# Waived Point-of-Care Molecular Testing

"West of the Pecos there is no law;  
west of El Paso, there is no God."

1882 description of the wild western Texas region around the Pecos River/El Paso area



# Alere™ i



- ☐ **Now CLIA Waived!**
- ☐ **Results in Less Than 15 Minutes**



# Alere™ i

**Height: 5.7"**

**Width: 8.2"**

**Depth: 7.6"**

**Weight: 6.6 lbs.**

**Cost \$**

**Consumable parts \$**

**Ideally Run in about 10-15 minutes**

**Attached Barcode Scanner**

**FDA Cleared Assays Available Today**  
**Influenza A and B, GAS**

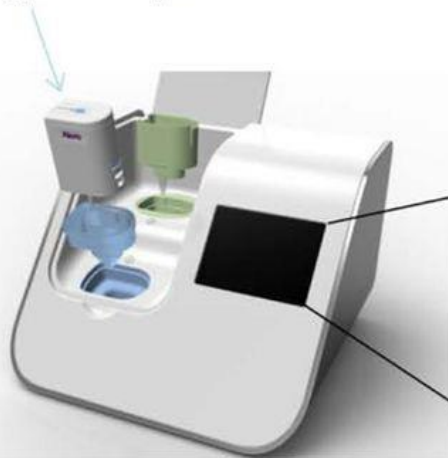




# Alere™ i NEAR

- 1 Insert parts in device and wait for warm up
- 2 Remove foil from sample receiver
- 3 Elute swab in buffer
- 4 Take Transfer Cartridge
- 5 Press on Transfer Cartridge and remove
- 6 Connect transfer Cartridge to Test Base
- 7 Transfer Cartridge indicator shows sample delivered

Single use disposable test cartridge supplied in 3 parts



Colour touchscreen



# Cobas Liat



**Assay tube  
Sleeve removed**

# Cobas Liat

**Height: 7.5"**

**Width: 4.5"**

**Depth: 9.5"**

**Weight: 8.3 lbs.**

**Cost \$**

**Assay Tube \$**

**Ideally Run in about 20 minutes**

**Built in Barcode Scanner**

**FDA Cleared Assays Available Today**

**Influenza A and B, GAS**





# Cobas Liat RT-PCR

1. Scan assay tube then scan sample tube



2. Add sample to assay tube

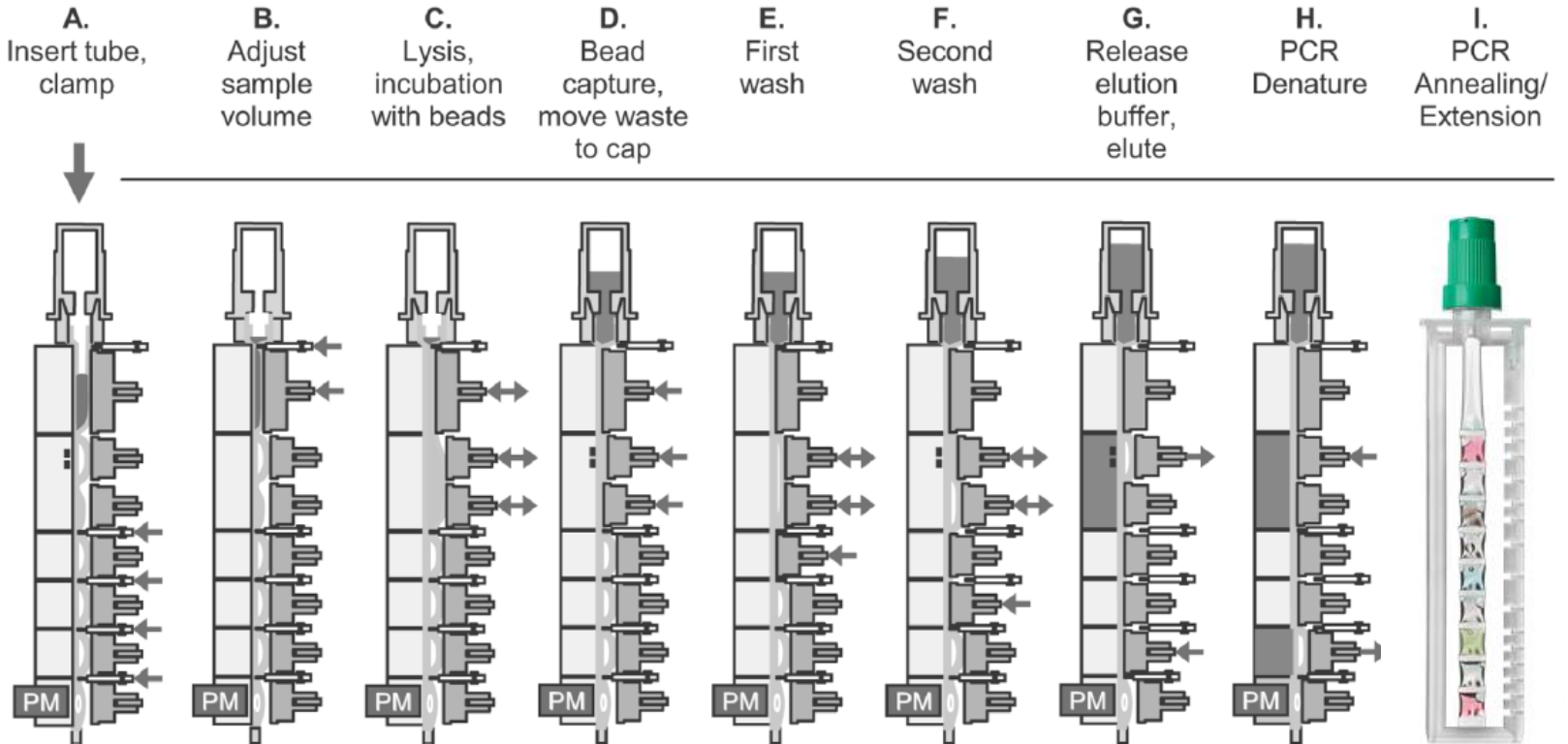


3. Scan Assay tube again  
to confirm test and  
sample



4. Remove sleeve and load,  
instrument starts

# Cobas Liat RT-PCR



# Genexpert Express System



**Runs only the Xpert Flu+RSV Xpress Test**

# GeneXpert Omni

**Height: 9.1"**  
**Width: 3.0"**  
**Depth: 4.2"**  
**Weight: 2.2 lbs.**

**Integrated Rechargeable Battery**  
**Supplemental Rechargeable Battery**

**Cost \$3,000**  
**Cartridge ?**  
**Ideally Run in 15-30 minutes**

**Wireless, run by mobile device**

**Point-of-Care – Late 2016, early 2017**



**Xpert Flu/RSV Xpress**

# GeneXpert Omni

*Total hands-on time: <1 Minute*

1

Transfer 300µl of prepared sample into the opening



2

Insert cartridge and start test





# GeneXpert Cartridge

## RT-PCR



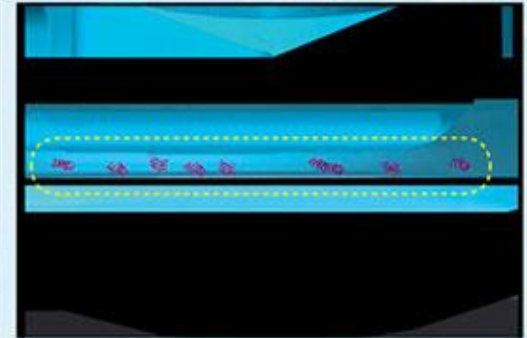
1. Liquid reagents on board



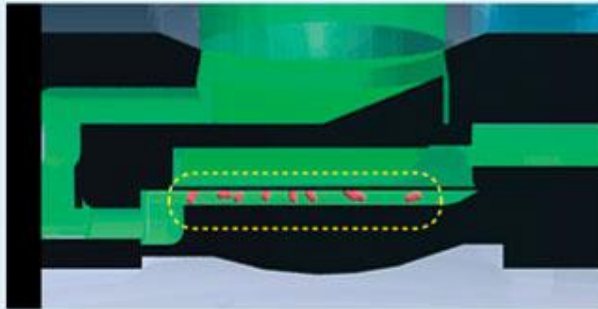
2. Adding sample suspension



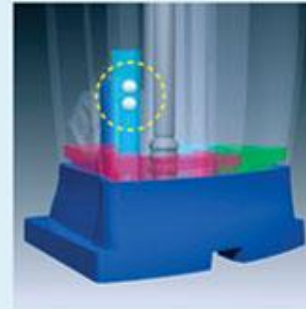
4. Sonic horn breaks up organisms and releases DNA



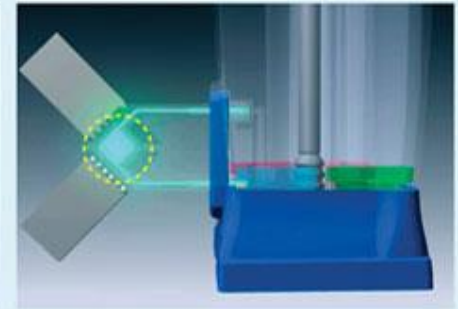
5. DNA passes through filter and then into first reagent chamber



3. Organisms fixed on filter



6. DNA mixed with rehydrated reagents and pushed into reaction vial



7. PCR reaction and detection occurs

All of the complex steps required for polymerase chain reaction, including the addition of components as needed, programming of reaction times and temperatures, and monitoring fluorescence development as it occurs, take place in the cartridge without operator intervention.

For some assays, as soon as the product is detected, the reaction ends and the result is presented on the screen. This result can be directly interfaced to a laboratory information system, avoiding yet another opportunity for error.

# POC Testing – Integrity & Biosafety?

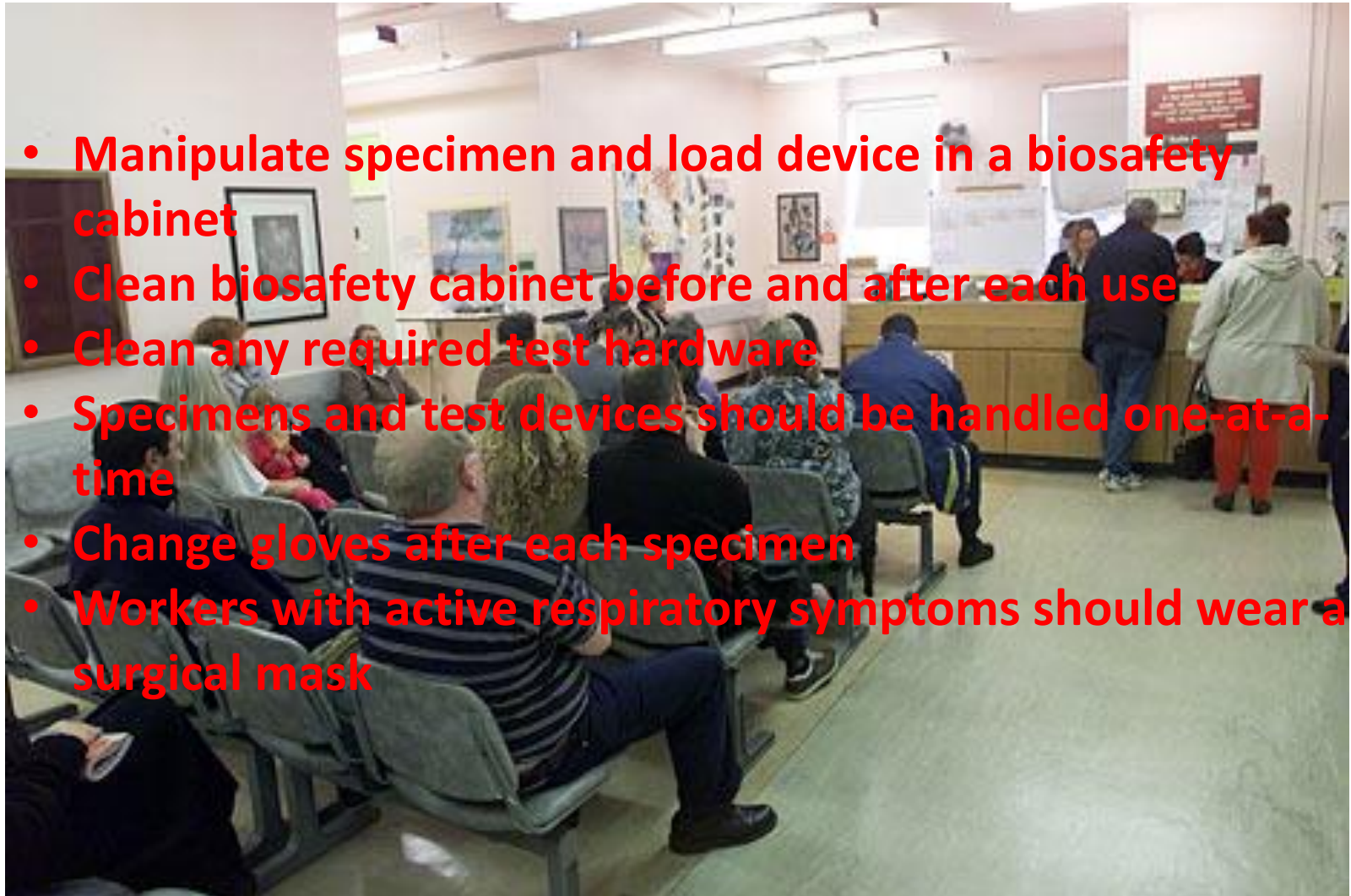


# Preventing Test Contamination

- **Manipulate specimen and load device in a biosafety cabinet**
- **Clean biosafety cabinet before and after each use**
- **Clean any required test hardware**
- **Specimens and test devices should be handled one-at-a-time**
- **Change gloves after each specimen**
- **Workers with active respiratory symptoms should wear a surgical mask**

# Preventing Test Contamination

## POC Test Integrity?



- Manipulate specimen and load device in a biosafety cabinet
- Clean biosafety cabinet before and after each use
- Clean any required test hardware
- Specimens and test devices should be handled one-at-a-time
- Change gloves after each specimen
- Workers with active respiratory symptoms should wear a surgical mask

# Laboratory Biosafety

- **Wear a laboratory coat and disposable gloves**
- **Manipulate specimen and load device in a biosafety cabinet**
- **Clean biosafety cabinet before and after each use**
- **Clean any required test hardware**
- **Change gloves after each specimen**



# Laboratory Biosafety

## POC Test Biosafety?

- Wear a laboratory coat and disposable gloves
- Manipulate specimen and load device in a biosafety cabinet
- Clean biosafety cabinet before and after each use
- Clean any required test hardware
- Change gloves after each specimen



# A CAUTIONARY TALE

- In December of 2010 a large hospital based reference laboratory received 7 nasal wash specimens from a pediatrician's office for *B. pertussis* testing
- All 7 specimens tested positive for *B. pertussis*, Ct = 38.0 - 40.9 cycles (IS481 target)
- The next day the laboratory received 6 nasal wash specimens from the same pediatrician's office
- All 6 specimens were positive for *B. pertussis*, Ct = 38.0 – 40.9 cycles
- All other specimens tested for *B. pertussis* on the runs those two days were negative
- All negative controls performed as expected those two days
- Wipe tests performed in the laboratory on the second day were negative for all targets tested in the laboratory
- ????????????????????

# A CAUTIONARY TALE

## Pediatrician's Office

- Nasal wash solution not detected
- Bulb collection device not detected
- Washing from empty Dtap vial *B. pertussis* detected (Ct 29.1)

### Unopened vaccine vial from pharmacy

- Dtap contents *B. pertussis* detected (Ct 15.1)
- Adacel contents 1:100 *B. pertussis* detected (Ct 17.7)

## Pediatric Clinic Associated with the Laboratory

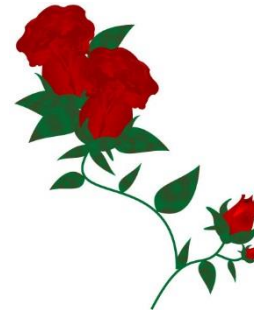
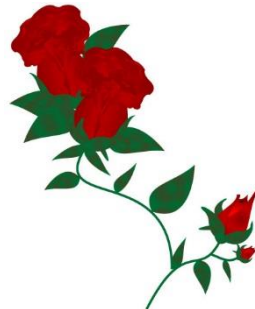
- Computer keyboard *B. pertussis* detected (Ct 36.8)
- Examination table *B. pertussis* detected (Ct 34.0)
- Wall above work table *B. pertussis* detected (Ct 32.0)
- HCW A, hand before work not detected
- HCW A, hand after work *B. pertussis* detected (Ct 36.1)
- HCW B, hand before work not detected
- HCW B, hand after work *B. pertussis* detected (Ct 37.0)



April 2016

## **In late flu season, early signs of new tests' impact**

*“Those implementing rapid molecular flu testing systems from Roche and Alere are seeing highly accurate performance and real-world turnaround times of less than an hour.”*



# The End



**Setting Up The cobas Liat At The Urgent Care Clinic?**