# Flu Testing
# POC or Main Lab???

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# Disclosures

- None
- Clinical Lab Scientist
- Background includes clinical chemistry, blood bank, serology, microbiology, and molecular pathology/ infectious disease testing
- Graduated and passed Board of Registry in 1975
- The main lab of 1975 would be considered a dinosaur by most graduates today!

# Objective

- The Objective of this talk is to make you aware of tools available to help you make an informed decision—
- PoCT or Main Lab

# My First PoCT

- Clinical medicine is constantly evolving
- My first in-lab PoCT was a GAS screen.  Knew I was performing a GAS screen, but didn't think of it as a "PoCT"!
- Followed by Cdiff latex and influenza antigen
- Historically the idea of PoCTing would make any clinical scientist very defensive—how could someone NOT a med tech accurately perform POC tests?
- Very happy to find out a poll of my younger colleagues believe overwhelming POC testing is the way to go
- My first REAL PoCT was a pregnancy test! Done at home! (1980)

# Why do we care about the flu?

- On average 200,000 people in the US are hospitalized each year
  - Cost averages $2,147 / day
- Per POC website up to 49,000 deaths per year
  - http://www.pointofcare.net/FLU_FACTS.htm 10/12/2015

- During the 2014–15 influenza season, the percentage of deaths attributed to pneumonia and influenza (P&I) exceeded the epidemic threshold for 8 consecutive weeks from January 3 to February 21, 2015 (weeks 53–7).
  - The weekly percentage of deaths attributed to P&I ranged from 5.0% to 9.3%
  - For the previous seasons ranged from:
    - 7.9% during the 2011–12 season to
    - 9.9% during the 2012–13 season.
- Average numbers not changing
- Quick diagnosis / prevent the spread

# Affect of Flu testing

- With an average of 8% deaths from P&I in the last several seasons, can testing change this number?
- Quicker,  more reliable flu testing
- Prevent the spread, reduce the symptoms, reduce hospitalizations
- My experience:
  - 2009 H1N1 RT-PCR took about 6 hours, we had capacity for 14 patient samples/ run
  - 2014-2015 season RT-PCR took about an hour, capacity depends on platform.  Ex:
    - Cepheid up to 48 tests / hour (Infinity-80 with 48 modules)
    - BioFire multiplex panel up to 4 tests / hour (five instruments, one left open for positive bloods)

# Flu testing at Loyola

- PoCT for Flu at Loyola?
  - None at our main lab; pulled due to lack of sensitivity
- Not sure what the “satellites” had
- Evaluation of a PoCT for Influenza by our lab didn’t go very well (2012)
  - We already were doing PCR testing for flu but considered a screening test due to the cost of the PCR.
  - After assessing the evaluation it wasn’t worth saving a few dollars and going “backwards” to a much less sensitive method for use in Main Lab
- Conversely, an evaluation of a PCR PoCT for influenza by our lab 2015—phenomenal!
- Would a good PoCT make a difference?  Absolutely! No brainer!
- But wait…there’s more to the story!

# Definition of a PoCT

- Done outside the main laboratory – hospital or reference
- Waived tests under CLIA 88
- Can be performed by non-laboratory personnel
- Are performed either:
  - Bedside
  - “NEAR” patient testing
- A rapid, reliable result that aids in disease screening, diagnosis, and/or patient monitoring

# Why the increased demand for PoCT?

- HealthCare reform allowing for waived tests
- Testing available in rural locations with limited services
  - Including developing countries
- Laboratory shortages---personnel and $$, “do more with less…” However, automation and speed costs $$ and takes time!
- Patient centered care combined with Healthcare decentralization…not just in the ED or hospital
- Technology now available for better, faster testing to results

# How PoCT affects outcome:

- For a positive affect on outcome, results must impact patient management
  - Results must be timely for quick response by medical staff
- Improve access to care—ex:  CTNGs in the ED
- Community benefit:
  - Antiviral and antibiotic stewardship
  - Reduce transmission of pathogens
  - Expand capacity to monitor population exposure to infectious agents and for screening

# 2015

- Now we have the technology for better assays, but how do you define a Rapid Influenza Diagnostic Test? (RIDT)
- Definition depends on your perspective:  (POC or Main lab)
  - Method?
- Who is doing the classifying?
- Seems redundant to focus on definitions:
  - Each source has it's own definition of RIDTs, POC tests
  - How the assays are described
  - Common terminology would be helpful!

# POC

- Basically:
- Sample is tested at the site of collection
- Go from specimen to test to result (either qual or quant) in ≤20 mins
- Testing performed by non-laboratory personnel

# Outpatient Laboratory

- I won't go into discussing the Outpatient Laboratory
- May be a fully CLIA licensed laboratory or slightly more than a phlebotomy center
- If CLIA licensed the outpatient laboratory will be considered a Main Lab for the purposes of this talk.

# Main Lab

- Performed in the Main Lab by registered Clinical Laboratory Scientists
- Could be simple to highly complex
- “Rapid”?  Depends; evolving from:
  - Batched
  - Toward random access assays
- Even “batched” systems are becoming random access to meet the needs of better and faster results

# What makes an ideal Influenza PoCT?

- Assay MUST be CLIA Waived to be performed outside the main lab
- With today's technology a MUST:
  - High sensitivity and specificity is essential.  Low sens/spec tests are a waste of resources
- When compared to complex testing high negative and positive predictive values—or true positive and negative results
- Must have reproducible results

# What makes an ideal Influenza PoCT?

- Rapid TAT  (definition of rapid? Stick with the approx. 20 mins?)
- Simple to perform—equipment easy to run, maintain
- IC
- Interface capabilities to LIS and/or EMR
- Software to centrally manage operators/ QC
- Long shelf life—stable
- Minimal footprint
- Of course, affordable
  - When compared to the cost of a hospital stay, what is the limit of affordable?

# What makes a Good Main Lab Influenza Test?

- With today's technology a MUST:
  - Molecular method
  - Rapid results
    - Main lab definition would be ≤2.5 hours, better if about 1 hour
  - High Sens/spec
  - Minimal footprint
  - High output
  - Random access
  - Capacity to interface
- Viral Culture is not compatible with rapid results

# What are CLIA 88 Waived Tests?

- Just for fun…
- Just googling “CLIA 88 WAIVED TESTS” pops the list from cms.gov. Did not give me a test count, but there are **58 pages of waived tests**. Listed by CPT code, test name, manufacturer and use
- https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf 8.31.2015
- Wow! Glad we are just talking about Flu!

# FDA Waived Tests

- FDA waived tests from 2000 doesn't even tell you how many pages!  Lists:

| Document | Test System Name<br>Analyte | Analyte Specialty | Effective Date |
|---|---|---|---|

- This website is for viewing the CLIA data for a particular test system
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm 8.31.2015
- Still learning so for example clicked on the Alere influenza A/B.  The CLIA information is still a foreign language to me!  But 'waived' status is the important piece for POC testing

# Influenza Assay Classification

- Who defines the classification?
- How do you describe the RIDTs?
- Antigen?
- Lateral Flow?
- ELISA?
- Immunochromatographic?
- NAAT?
- RT-PCR?

# http://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm 9/16/2015

| Method[1] | Types Detected | Acceptable Specimens[2] | Test Time | CLIA Waived[3] |
|---|---|---|---|---|
| Viral cell culture (conventional) | A and B | NP[4] swab, throat swab, NP[2] or bronchial wash, nasal or endotracheal aspirate, sputum | 3-10 days | No |
| Rapid cell culture (shell vials; cell mixtures) | A and B | As above | 1-3 days | No |
| Immunofluorescence, Direct (DFA) or Indirect (IFA) Antibody Staining | A and B | NP[4] swab or wash, bronchial wash, nasal or endotracheal aspirate | 1-4 hours | No |
| RT-PCR[5] (singleplex and multiplex; real-time and other RNA-based) and other molecular assays | A and B | NP[4] swab, throat swab, NP[2] or bronchial wash, nasal or endotracheal aspirate, sputum | Varied (Generally 1-6 hours) | No |
| Rapid Influenza Diagnostic Tests[6] (antigen) | A and B | NP[4] swab, (throat swab), nasal wash, nasal aspirate | <30 min. | Yes/No |

# Classifying Influenza Tests

- Here we won't cover viral cultures, rapid cell cultures or DFAs
- Last two classifications are
  - RT-PCR (singleplex and multiplex; real-time and other RNA-based) and other molecular assays
  - Rapid Influenza Diagnostic Tests (antigen)
    - Further described as Lateral Flow and Immunochromatographic

# POC Influenza Tests-Antigen

- **Lateral flow tests**[ also known as **lateral flow immunochromatographic assays**, are simple devices intended to detect the presence (or absence) of a target analyte in sample (matrix) without the need for specialized and costly equipment, though many lab based applications exist that are supported by reading equipment. Typically, these tests are used for medical diagnostics either for home testing, point of care testing, or laboratory use.  A widely spread and well known application is the home pregnancy test.
- https://en.wikipedia.org/wiki/Lateral_flow_test
- 9.5.2015

# POC Influenza Tests-Antigen

- **Immunochromatographic assay** is another modification of the **ELISA** test, in which an antigen solution flows through a porous strip, encountering labeled antibody.  It is used for pregnancy testing and for rapid identification of infectious agents.
- http://biology-forums.com/definitions/index.php/Immunochromatographic_Assay 9.5.2015

# POC Influenza Tests- Molecular

- NAAT:  Nucleic Acid Amplification Test, aka
  - RT-PCR : Real Time PCR
  - Singleplex: One target
  - Multiplex: Several targets
  - Real-time
  - RNA-based

# Sampling of RIDTs

- Just a sample of products available-not all
- Only mentioning assays that test for both Flu A & B
- Waived tests can be bought on the internet!  With a disclaimer “NOT FOR HOME USE”, and any warranty is invalid if used at home.  (Again, I am new to the POC business!)

# Alere BinaxNow® influenza A / B

- Technology: Immunochromatographic
- Method: Lateral flow
- Approved specimen: NP swab, wash, aspirate. Flexible transport media
- Assay time: 15 mins
- CLIA Waived: **Yes**

# Alere™ Influenza A & B Test

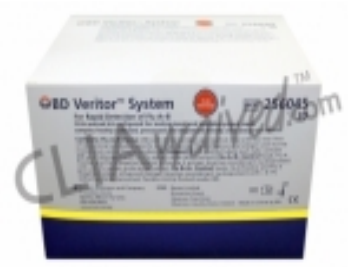
- Technology: Immunochromatographic
- Method:  Dipstick
- Approved specimen: Nasal swab
- Assay time: 10 mins
- CLIA Waived: **Yes**

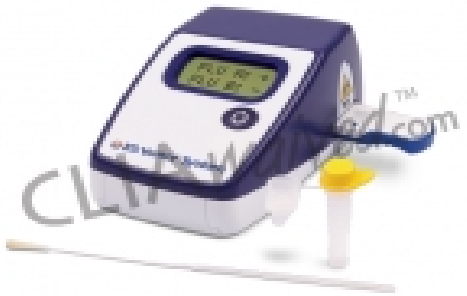
# Alere i

- Technology:  NEAR: Nicking Endonucleases Amplification Reaction
- Method:  Molecular
- Approved specimen:  Nasal swab, NP swab (with or w/o VTM)
- Assay time: about 18 mins
- CLIA Waived: **Yes**

# BD Veritor™
# System for rapid detection of Flu A+B

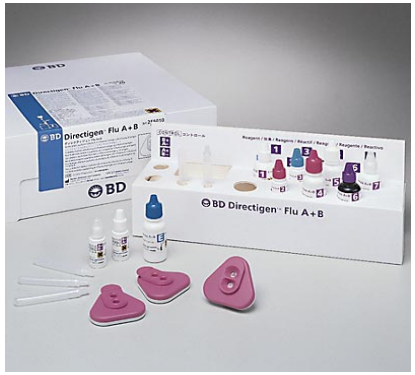
- Technology:  Strip-novel Nano Detection Particle and Adaptive Read Technology
- Method:  Chromatographic immunoassay
- Approved specimen: Nasal swab, NP swab
- Assay time: 10 mins incubation
- CLIA Waived: **Yes**



# Directigen™ Flu A+B (BD)

- Technology: Enzyme immunoassay (EIA)
- Method:  Lateral flow
- Approved specimen: Throat to BAL
- Assay time: 15 mins
- CLIA Waived: **Yes**



# Directigen™ EZ Flu A+B (BD)

- Technology: Chromatographic immunoassay
- Method:  Lateral flow
- Approved specimen: Throat swab, NP wash, nasal wash/asp
- Assay time: 15 mins
- CLIA Waived: **No**

# Illumigene Tru-Flu

- Technology: Immunochromatographic
- Method:  Lateral flow
- Approved specimen: Fresh or Frozen NP Wash samples (frozen have lower sensitivity)
- Assay time: 15 mins
- CLIA Waived: **No**

# QuickVue® Rapid Influenza (Quidel)

- Technology:  Test strip
- Method:  Lateral flow
- Approved specimen: Nasal swab, NP wash or aspirate
- Assay time: 10 mins
- CLIA Waived: **Yes**
- **Also---QuickVue® Influenza A + B**
  - Same as above
- Both Assays have waived and Moderate Complexity package inserts.  Refer to the Quidel rep for which one would suit your purposes

# Sofia® Influenza A + B (Quidel)

- Technology: Fluorescent Immunoassay
- Method:  Lateral flow
- Approved specimen: Nasal swab, NP swab, aspirate/wash
- Assay time: 15 mins incubation
- CLIA Waived: **Yes**


# cobas® Influenza A/B (Roche Liat)

- Technology:  RT-PCR
- Method:  Molecular
- Approved specimen:  NP swab in VTM
- Assay time: 20 mins
- CLIA Waived: **Yes**

# Sampling of Main Lab Tests

- A representation of Main Lab tests.
- Range from a few targets to multiplex
- It is up to your laboratory situation to decide what is best for your patient population….and what you can get!

# Cepheid Xpert FLU/RSV

- Technology: RT-PCR
- Method:  Molecular
- Approved specimen:  NP swab, nasal wash in VTM
- Assay time: about 60 mins
- CLIA Waived: **No**
- **Also:  Xpert Flu**
- However, in the future will have a POC system available that uses the same cartridges; GeneXpert Omni

# FilmArray Respiratory Panel (BioFire)

- Technology:  RT-PCR
- Method:  Molecular
- Approved specimen: NP swab in VTM
- Assay time: about 60 mins
- CLIA Waived: **No**
- Multiplex: 20 virus and bacteria targets

# eSensor® Respiratory Viral Panel (GenMark)

- Technology: *e*Sensor Technology
- Method:  Molecular
- Approved specimen:  ????
- Assay time: about 60 mins
- CLIA Waived: **No**
- Multiplex: 14 viruses
- However, in the future will have a system that does not require external extraction

# Luminex xTAG® Respiratory Viral Panel

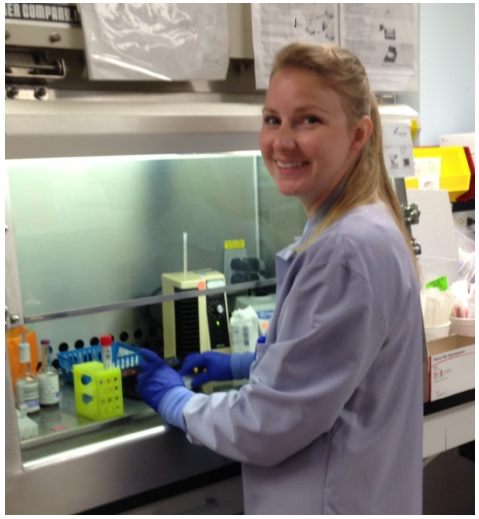
- Technology:  NAAT
- Method:  Molecular
- Approved specimen: NP swab
- Assay time:  External extraction required before assay begins.
  - New system just approved; respiratory panel in development
- CLIA Waived: **No**
- Multiplex:10 respiratory viruses

# Verigen RP *Flex* (Nanosphere)

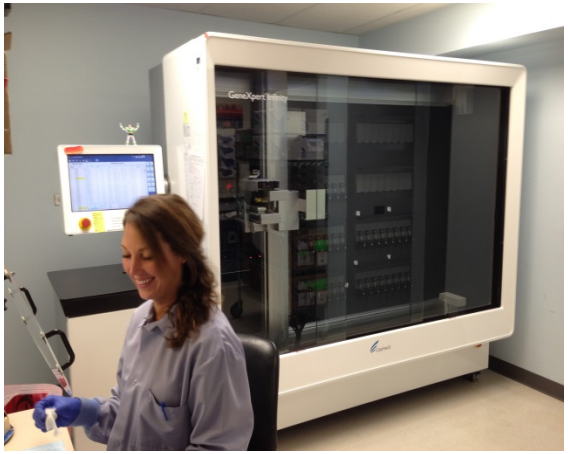
- Technology:  NAAT
- Method:  Molecular
- Approved specimen:  NP swab in VTM
- Assay time:  about 2 hours
- CLIA Waived: **No**
- Multiplex:16 viruses and bacteria; can choose combination

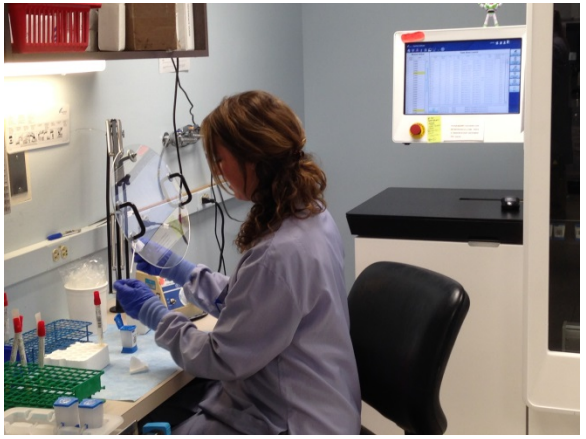
# Flu testing at Loyola

- Pictures of what the flu testing looks like in the Main Lab at Loyola



# Flu testing at Loyola





# Summarize…

- It is obvious PoCT is the best alternative for a rapid, reliable result that aids in disease screening, diagnosis, and/or patient monitoring
- Who in the organization makes the decisions?
- Before choosing one, I recommend you check out if the sensitivity and specificity are acceptable (low can defeat the purpose)
- Then recommend considering:
  - How the assay fits in with workflow
    - Ease of use and timely results
    - Want to have the assay done before the patient sees the physician
  - Footprint
  - How results get to the chart?
  - Are you willing to pay a bit more for a far better test?

# But wait, there's more!

- What about that Main Lab?
- Some situations do require multiplex results
  - Ex: not flu season, other targets significant
  - Patient population considerations
- How soon could the specimen reach the main lab?
  - Is it worth it to wait?
  - Will POC staff be looking for results the next morning?

# Classification by FDA

- Can’t forget about the FDA!
- 1980 FDA published regulation for classification of immunology and microbiology devices into one of three categories (classes) based on the regulatory controls needed to provide reasonable assurance of the devices’ safety and effectiveness.
  - Class I = general controls
  - Class II = special controls
  - Class III =  premarket approval required

# Classification by FDA
## Risk Based Regulation

- Knowledge mitigates risk:
- Class I - Low likelihood of harm
- General Controls Class II - Moderate likelihood of harm
  - Risk can be mitigated
- General and Special Controls Class III - High or unknown likelihood of harm
  - How to mitigate the risk is unknown
  - Pre-market Approval

# Risk Based Regulation

- Class I vs. Class II Class I
  - Subject to general controls, e.g. Registration and listing
  - Notifications of risks, repair, replacement, or refund
  - Adverse event reporting

- Generally exempt from 510(k) requirement unless exceed limitations of exemptions
- Subject to GMPs but generally exempt from design controls requirements

- Class II
  - Subject to general and special controls, e.g. Performance standards
  - Postmarket surveillance
  - Guidelines

- Subject to GMPs, including design controls
- Majority must submit premarket notification (510k) to FDA
- To be cleared, must demonstrate substantial equivalence

# Current Regulations of Influenza Diagnostics

- §866.3330 **Influenza virus serological reagents, Class I**
- Devices detecting antigens using specific labeled antibodies (RIDTs, DFAs, DSFAs)
- Can detect and often differentiate the presence of influenza A and B viruses

- § 866.3332 **Reagents for detection of specific novel influenza A viruses, Class II**
  - Devices based on nucleic acid amplification principle
  - Detect novel virus RNA in human respiratory specimens or viral cultures
    - Special Controls: : Guidance document which includes specific post-market monitoring
    - Limited distribution to laboratories with experienced personnel and biosafety equipment

- § 866.3980 **Respiratory viral panel multiplex nucleic acid assay system, Class II**
  - Devices based on nucleic acid amplification principle
  - Simultaneously detect multiple viruses in respiratory specimens or viral culture
  - Influenza A and B, including Flu A subtypes, may be components of the panel
    - Special control guidance documents addresses safety and effectiveness
    - Provide minimum performance criteria - sensitivity and specificity

# Current Class I Influenza Diagnostics

- §866.3330 Influenza virus serological reagents, Class I
- Devices detecting antigens using specific labeled antibodies (RIDTs, DSFAs, DFAs)
  - Rapid Influenza Diagnostic Tests (RIDT) intended for the detection of the influenza virus **directly** in clinical specimens exceed the limitations of the exemption and require a 510k submission
- This also applies to DFA's which we will not cover.

# Rapid Influenza Diagnostic Tests

- RIDTs are widely used simple lateral flow immunoassays
- •Detect viral proteins (antigens) using specific labeled antibodies
- •Usually can detect and differentiate Flu A and B in respiratory specimens in less than 30 minutes
- •Usually demonstrate high specificity, poor sensitivity
- •Factors contributing to sub-optimal performance:
  - Quality and timing of the collected specimen
  - Genomic variations and newly emerging viruses
  - Proficiency of the operator
  - Quality/appropriateness of reagents

# What are the Issues?

- **Low sensitivity and failure to detect emerging influenza viruses**
- Sensitivity reported in the labeling for devices cleared since 1998:
- Flu A 73.8% (95% CI: 64.4%-81.9%) - 94.2% (95% CI: 91.0%-96.3%)
- Flu B 60.0% (95% CI: 45.2%-73.6%) - 97.8% (95% CI: 88.7%-99.6%)
- Tests not used as intended; negative results frequently not followed up by culture or molecular test as indicated in labeling
- Insufficient post-market monitoring to ensure that tests **continue to detect newly emerging influenza virus strains**
  - Risk to Health: False negative results may lead to non-use/delay of antiviral therapy and failure to institute proper infection control procedures

# Reasons for Re-classification

- FDA believes that general controls are insufficient to reasonably assure safety and effectiveness of RIDTs
- •The addition of special controls would mitigate the known risks associated with the use of Class I RIDTs
- •Establish and maintain more appropriate minimum performance criteria for influenza tests throughout their total product life cycle (TPLC)
- •Promote the development and manufacturing of new and improved diagnostics for influenza that will meet the needs of patients, physicians, and public health

# FDA's Proposals

- **Create a new Class II regulation for rapid influenza diagnostic devices currently regulated under 866.3330 as Class I**
- •Add special controls to the new regulation to:
  - Specify performance criteria that meet public health needs
  - **Evaluate device performance against an appropriate current comparator method**
  - **Test reactivity with contemporary circulating viruses annually**
  - In the event of a declared public health emergency or potential public health emergency, evaluate the ability of the device to detect the newly emergent influenza virus

- •Design controls required for Class II devices would improve the reliability of RIDTs throughout the product life-cycle.
- •Update Class II regulation 866.3980 (respiratory viral panel multiplex nucleic acid assay system) to **include annual reactivity testing for devices detecting influenza viruses**

# Scope of the Proposed Regulation

- Create a new Class II regulation for rapid influenza detection tests (RIDTs) with special controls
- •The proposed reclassification regulation would apply to all RIDTs currently regulated under 21 CFR 866.3330
- •If reclassified, all the currently marketed and new RIDTs based on immunoassay technology would be subject to the new regulation

# Proposed Special Controls

- FDA proposes the following special controls to be included in the new regulation:
- 1. More appropriate minimum clinical performance criteria requirement
- 2. Use currently appropriate reference method for clinical studies
- 3. Requirement for annual reactivity testing
- 4. Provision for testing in a declared emergency or potential emergency once viral samples available

# #1 Minimum Performance Criteria

- Specificity
- All influenza detection devices should demonstrate specificity with a lower bound of the 95% CI exceeding 90% for Flu A and Flu B
- Sensitivity
- When compared to viral culture as the reference method:
  - Flu A - Point estimate of 90%; 95% CI lower bound 80%
  - Flu B - Point estimate of 80%; 95% CI lower bound 70%

- When compared to a molecular comparator method:
  - Flu A - Point estimate of 80%; 95% CI lower bound 70%
  - Flu B - Point estimate of 80%; 95% CI lower bound 70%

# #2 Reference Method

- Clinical performance should be evaluated by comparison to the currently appropriate reference/comparator method
- •Two methods are currently appropriate
  - Viral culture
  - FDA-cleared nucleic acid amplification based assays

# Scope of Proposed Reclassification

- **If reclassified, all molecular and rapid influenza diagnostic tests will be subject to the following requirements:**

- **Minimum clinical performance criteria must be met by all FDA-cleared and future RIDTs**
- **Currently marketed devices not meeting performance criteria must be withdrawn from the market one year after the rule is finalized**
- All device modifications will be subject to design controls
- **Conduct annual testing of analytical reactivity with contemporary influenza strains**
- Timely testing of newly emergent influenza viruses if a public health emergency or a potential for a public health emergency is declared
- If device is non-reactive with any of the tested viruses, labeling must be revised to reflect the limitation

# Significance of Reclassification

- Meeting sensitivity/specificity performance criteria Seven (7) manufacturers market tests that would fail the proposed sensitivity criteria
- Three (3) of these seven (7) manufacturers market new/improved tests that meet the proposed special controls
  - Options for meeting the requirements if performance criteria are not met: **withdraw the device from the market**
  - Modify the device and submit a new 510k within 1 year of the final rule

# Reclassification by FDA

- Reclassification is practical as alternative tests are available:
- A new generation of rapid influenza diagnostic devices – digital immunoassay (DIA)
  - Analytical performance improved due to new detection technologies and the interpretive software to go with it
- Molecular NAATs
- MLO. The changing landscape of POC diagnostics for influenza virus infections; Sept 2015
- https://www.asm.org/index.php/publicpolicy-2/statements-testimony/137-policy/documents/statements-and-testimony/93035-fda-8-20
  - ASM submitted comments to FDA with concerns of these devices

# Action by the FDA

- Information slides presented at a Classification Panel Meeting June 13, 2013
- Published in the Federal Register 5/22/2014
- Proposed Effective Date:
- One year after date of publication of proposed order in Federal Register
  - Actually really in effect now
- There will be a meeting at the end of November for further discussion.
- www.**fda**.gov/.../Microbiology**Devices**Panel/UCM357346.pdf

# What all this means….

- FDA proposed reclassification of RIDTs from Class I to Class II
  - (First Class I test-1990—25 years ago)
  - Many of the RIDTs had poor analytical and clinical sensitivity; plus emergence of new strains not covered by these assays.
- Manufacturers will have to ‘beef-up’ some Class I assays to Class II
- **Ask your vendor how the reclassification will affect what you are using!**

# It's All About the Specimen!

- But wait, there's more!
- **Collection is key!**
- "If you don't have time to do it right, when are you going to have time to do it over?"
  - Mantra ingrained into the med tech class of 1975 Hines V/A!
- If you need a nasopharyngeal swab, don't collect a nasal swab.  Reject! Reject! Reject!
- If the vendor calls for a certain site, you must comply!
  - The manufacturer has been cleared for a certain specimen, so just do it!
  - Garbage in-Garbage out!

# Specimen

- Not sure how to collect?
- YouTube it!
  - NEJM instructions for collecting a nasopharyngeal swab https://www.youtube.com/watch?v=v5A4H9q4JVA
  - Ask the vendor!!!  Many educational materials can be provided by the assay vendor
- Enough of the clichés? !

# Strategies for Improving Rapid Influenza Testing and Treatment in Ambulatory Settings (SIRAS)

- http://www.jointcommission.org/siras.aspx
- 2 hour free course

# $$$ Reimbursement $$$

- But wait…there's even more!
- Everyone wants to get paid!
- Will your PoCT get reflexed to a multiplex?
- CPT coding….don't get in trouble for double billing
  - Ex: Molecular PoCT reflex to Molecular Main Lab multiplex
  - Need to work with the billing people

# Take-Away Message

- Yes, PoCT is a no-brainer
- Which one?
- Fit your:
  - Patient needs
  - Workflow
  - Space
  - Pocket-book
  - Who decides?
- If you have a choice, choose up

# Tri-State POC Network Mission Statement

- **Mission Statement** Serving Illinois, Indiana, and Michigan, our meetings will provide an excellent educational opportunity for all who attend. At each meeting you will hear guest speakers bringing us valuable information on today's Point of Care issues. There will also be vendors displaying and presenting their products. We will also provide round table discussions on some "HOT" Point of Care topics. The mission of the Tri-State Point of Care Network is to support and maintain the integrity of the POC coordinator's goal, which is to give the highest quality patient care in this rapidly growing field. Through this network, POC professionals from Illinois, Indiana, Michigan, and Wisconsin, will have the opportunity to share ideas, information and practices and to collaborate on new technologies and trends in Point of Care testing.

# Thanks!  Any Questions?

- Superhero!
- Who knows what his POC testing future will look like!

# References


- http://kff.org/other/state-indicator/expenses-per-inpatient-day/
- https://en.wikipedia.org/wiki/Positive_and_negative_predictive_values 8.31.2015
- http://www.cdc.gov/flu/about/qa/hospital.htm