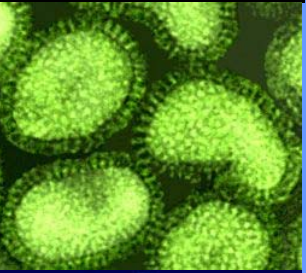
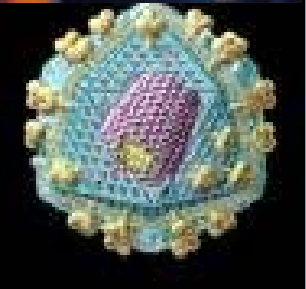
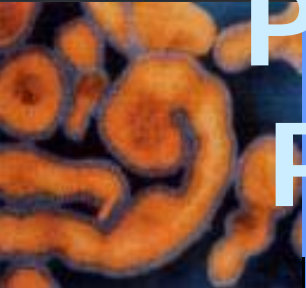


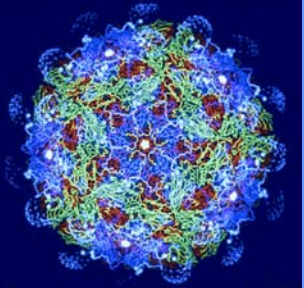
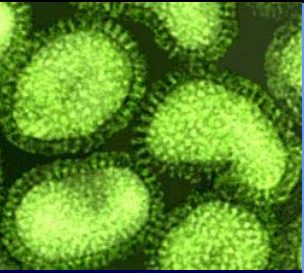
# Public Health Laboratory Pandemic Preparedness

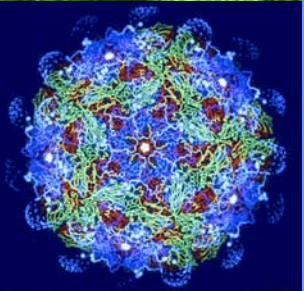
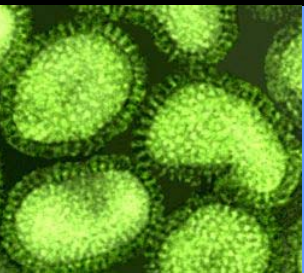
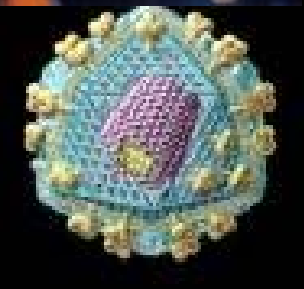


Patricia A. Somsel, DrPH  
Michigan Department  
of Community Health

# APHL Flu Algorithm

- Developed by APHL members experienced in virology at the request of the Infectious Diseases Committee
- Undergoing review by CDC
- Distributed to APHL PHL Directors in April
- Intended as guidelines to PHLs on how best to use CDC Influenza Branch and LRN assays in responding to requests for Flu A H5N1 testing





- **Algorithm 1** addresses routine flu surveillance now (WHO/USA Level 3)
- **Algorithm 2** addresses testing for H5 when a case meets risk assessment or if human cases appear in the US.
- Given current lack of any human cases in US, testing for H5 only, without PCR testing for Influenza A and subtypes other than H5 is not recommended.
- Additional algorithm in development to guide testing modifications if a pandemic occurs

# Influenza A/H5 Testing Algorithm for SPHLs (Limited H5 activity in the US or known travel/exposure history)

**Risk Assessment:**  
Consultation with epidemiology department  
Meets avian influenza/H5 case definition or other state testing requirements

**\*Specimen Collection**  
Multiple sample types recommended. Some studies demonstrate need for multiple samples collected over several days for optimal H5 detection sensitivity.

Perform PCR for Flu A/B/1/3/5  
Multiple specimen types recommended (e.g. NP, sputum, bronchial lavage if available, and throat)\*  
**DO NOT CULTURE UNTIL H5 OR OTHER NOVEL STRAINS ARE RULED OUT**  
(Influenza branch assay with/without LRN H5 depending on individual laboratory workflow)

Flu A (+)  
H5 (+)  
H3 (-)  
H1 (-)  
**DO NOT CULTURE**  
• Contact CDC immediately and forward samples for confirmatory testing

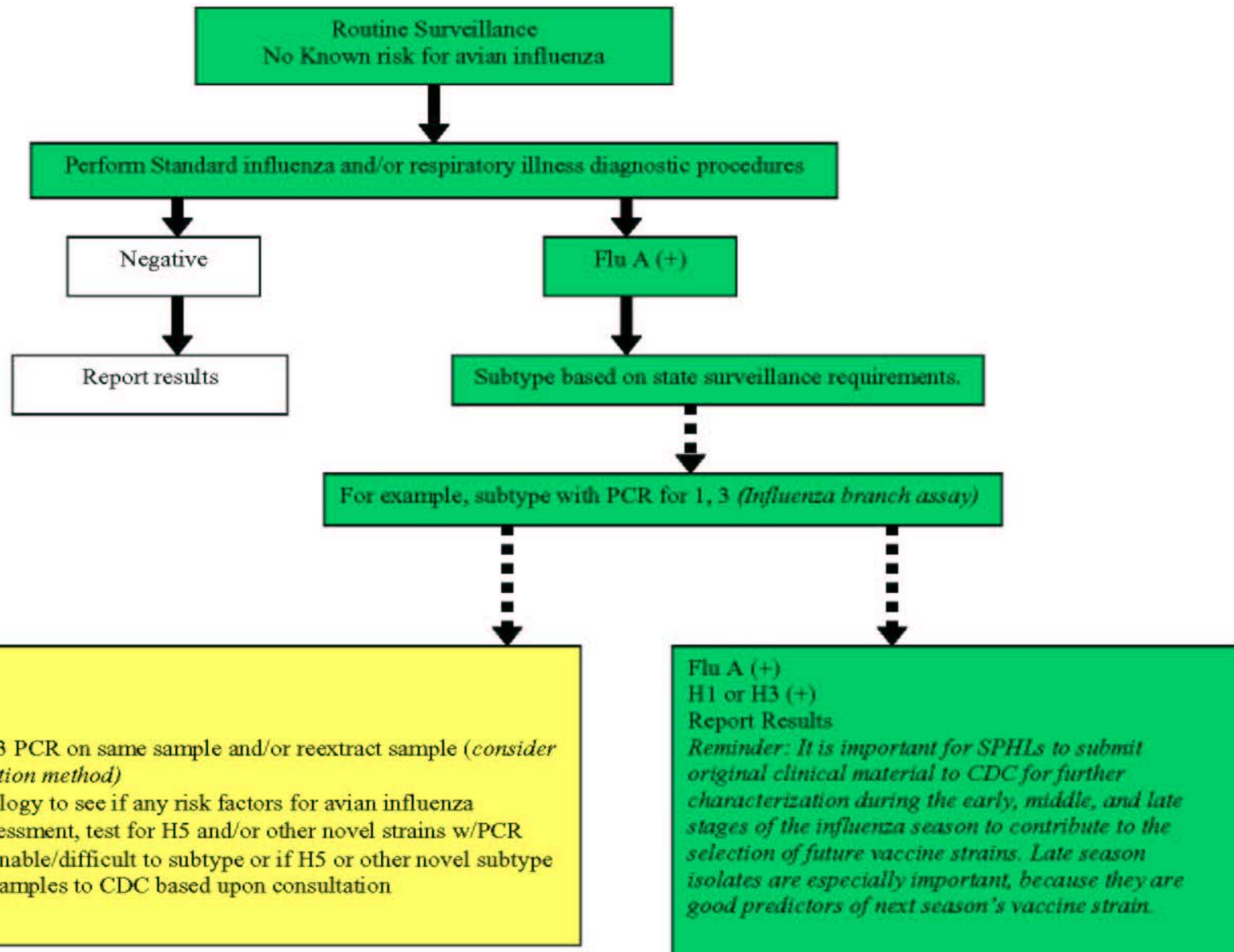
Flu A (+)  
H5 (-) or Flu B (+)  
H1 or H3 (+)  
• Report results  
• Safe to culture if isolate is needed

Flu A (+)  
H5 (-)  
H3 (-)  
H1 (-)  
**DO NOT CULTURE**  
• Contact CDC immediately due to potential for novel strain  
• Assess need to repeat tests and/or forward samples to CDC

Flu A (+)  
H5 (+)  
H1 or H3 (+)  
**DO NOT CULTURE**  
• Contact CDC due to potential for co-infection/cross-contamination  
• Assess need to reextract and repeat testing and/or forward samples to CDC

Flu A and B (-)  
H5 (-)  
H1 and H3 (-)  
• Reassess risk and if likelihood of H5 remains high, recollect samples\*, **DO NOT CULTURE: Contact CDC**  
• If risk is low, proceed with assays and/or culture for other pathogens based on clinical presentation

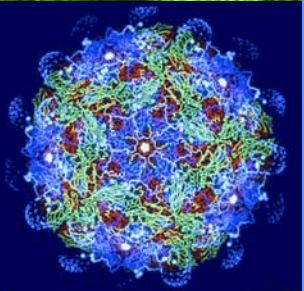
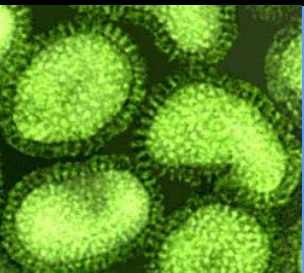
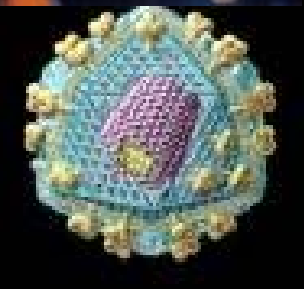
## Routine Influenza Testing Algorithm for SPHLs (WHO/USA Phase 3)

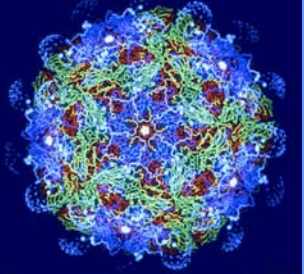
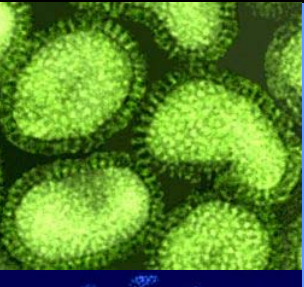




## LRN Assay

- Detects only Asian strain
- Demonstrates sensitivity for both Clade 1 and 2 strains of Asian HP H5N1 currently circulating
- **Presumptive ID only; must be performed in conjunction with other lab testing, clinical presentation, and epidemiological risk assessment; negative does not rule out infection**
- Controls and reagents available as a kit thru LRN
- Will supply of reagents become a problem as test demands increase?



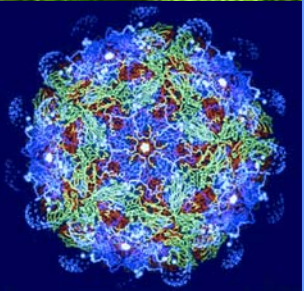
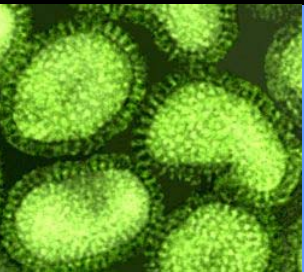
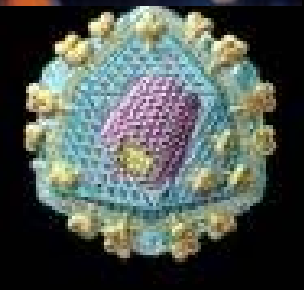


## Flu Branch Assay

- Detects only Asian strain
  - Demonstrates sensitivity for both Clade 1 and 2 strains of Asian HP H5N1 currently circulating
  - Validation issues
  - Controls from CDC; reagents from commercial suppliers
  - Procedures limited to public health labs
- 
- **Sharing assays with clinical labs?**

# H5: The Agent

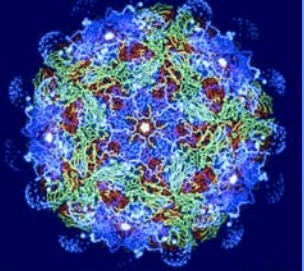
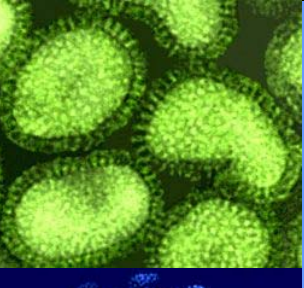
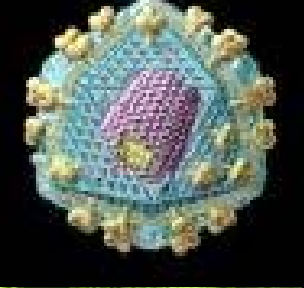
- HPAI (high pathogenicity avian influenza) present a substantial danger to US agribusiness
  - Restricted by USDA to culture in BSL-3 biocontainment with enhancements
  - Listed as select agents
- Specimens must not be placed into cell culture until avian influenza ruled out





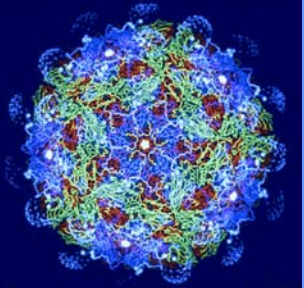
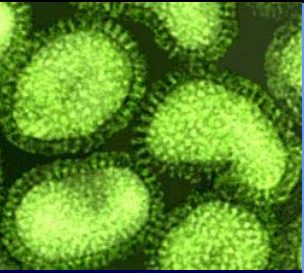
# Take Home Points

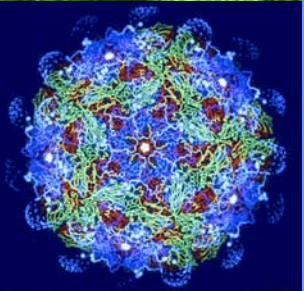
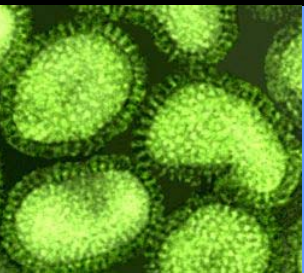
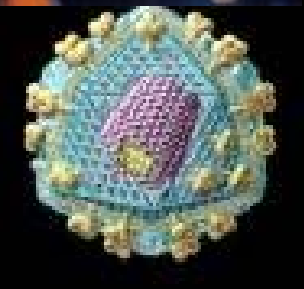
- Testing should be guided by *risk assessment* by state and local epidemiologists.
  - Indiscriminate testing will endanger the LRN reagent supply needed in a true pandemic
  - Due to potential for false-positive results, especially in the face of low prevalence, testing should be limited to patients who meet case definition
- Consequences of FP
  - Increased utilization of costly medical care resources, public panic, and unnecessary PH intervention
  - Potential for increased resistance of FluA to antiviral agents



# Take Home Points, cont.

- PCR testing should be performed on *multiple specimens* types collected over *multiple days*
  - Sputum, n/p wash/aspirate, bronchial lavage are recommended; throat swab may be used.
  - N/P swab *only* not recommended due to localization of the infection in tissues of the lower respiratory tract.
  - *Negative* results do not rule/out avian influenza
- Performance of assays may change with increased prevalence, so *procedures and algorithms will change*





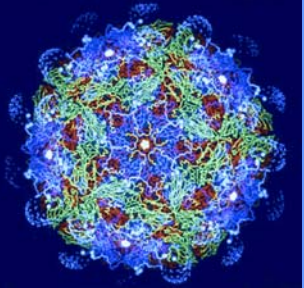
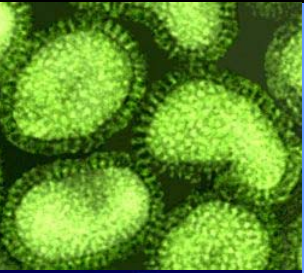
# Take Home Points, cont.

- Specimens from patients meeting case definition ***should not be placed in cell culture!!!***
- **Communications,**  
Collaboration, Coordination,  
Consultation, Cooperation



# Michigan PHL Preparations

- Guided by HHS Checklist
- Collaboration with:
  - Bureau of Epidemiology
  - Clinical Laboratories
  - MI Veterinary Diagnostic Laboratory
  - MI Agricultural Laboratory
  - MI Dept Natural Resources
  - USDA, APHIS staff in MI



## Avian Influenza Interagency Working Group

Michigan Departments of Agriculture, Community Health and Natural Resources,  
and U.S. Department of Agriculture

### Contact Numbers

**Suspected Avian Influenza illness and deaths consistent with novel strain influenza (for example HPAI H5N1)**

#### Domestic birds and poultry **Michigan Department of Agriculture**

To report illness and death: Contact  
MDA, Animal Industry Division.  
The State Veterinarian may be reached at  
517-373-1077 from 8:00 am – 5:00 pm.  
After hours Emergency Management  
Coordinator: 517- 373-0440.

-or-

#### **USDA Veterinary Services**

USDA, Veterinary Services may be  
reached regarding domestic poultry from  
7:00 am - 5:00 pm at 517-324-5290.  
After Hours (toll free): 866-536-7593.

For More Information:

<http://www.aphis.usda.gov/vs/birdbiosecurity/hpai.html>

#### Wild birds **Michigan Department of Natural Resources**

To report a die-off (especially 6 or more)  
of waterfowl or shore birds: Contact the  
DNR Wildlife Disease Lab at  
517-336-5030 from 8:00 am – 5:00 pm.  
After hours: 1-800-292-7800.

-or-

#### **USDA Wildlife Services**

USDA Wildlife Services may be reached  
regarding wild birds at 866-487-3297  
from 8:00 am – 5:00 pm.

**To report all other sick or dead wild  
birds (including single bird reports):**

<http://www.michigan.gov/emergingdiseases/0,1607,7-186-38757---,00.html>

For More Information:

<http://www.michigan.gov/emergingdiseases>

#### People **Michigan Department of Community Health**

To report suspected human illness and  
deaths consistent with novel strain  
influenza, or for testing approval:  
Contact MDCH Communicable Disease  
Division at 517-335-8165 from 8:00 am –  
5:00 pm.

After hours: 517-335-9030

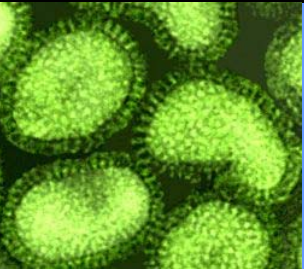
For More Information:

<http://www.michigan.gov/influenza>  
<http://www.michigan.gov/emergingdiseases>



# HHS Checklist: Public Health and Clinical Laboratories

- Surveillance for ILI among lab staff working with novel viruses
- Surge capacity of PH and clinical labs
- Assess flu diagnostic testing proficiency and adherence to biosafety/biomonitoring
- Inform frontline physicians and laboratorians of protocols for safe specimen collection, testing and submitting, and for reporting potential cases



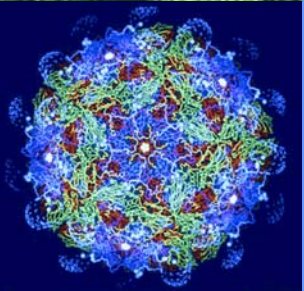
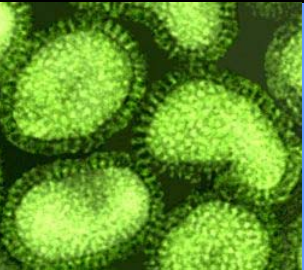
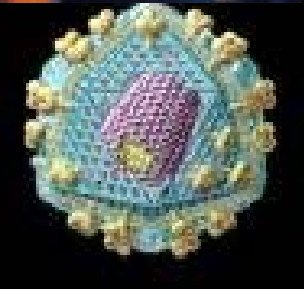


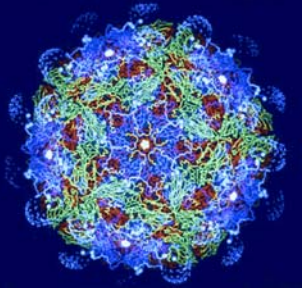
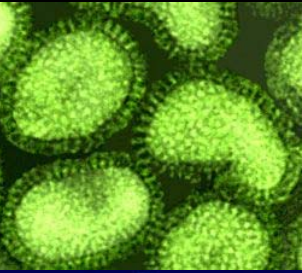
# MI PHL Preparations

- **Algorithms**

- Developed in collaboration with Bureau of Epidemiology (BOE) and clinical colleagues
- Distributed to LPH, clinical laboratories, posted on web

\*Note: In current stage (WHO Level 3),  
*no testing without pre-approval  
by BOE*



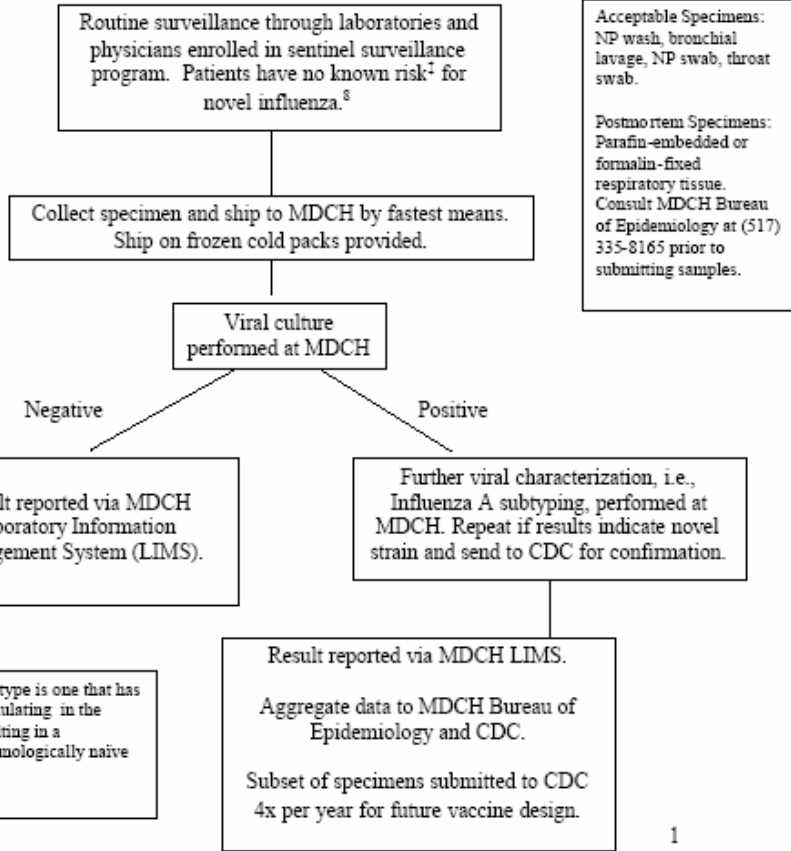


## Seasonal Influenza Algorithm Michigan Department of Community Health Instructions for Clinical Labs

**NOTE:** MDCH has added year around surveillance to seasonal testing. This algorithm will be updated as the situation evolves. Please visit the MDCH website at [www.michigan.gov/flu](http://www.michigan.gov/flu) and MIHAN for updates.

<sup>7</sup>Risk factors for novel influenza include signs and symptoms suggestive of influenza (fever, headache, tiredness, cough, sore throat, muscle aches, and radiograph evidence of pneumonia) along with travel to a country with confirmed cases of avian influenza with direct or unprotected exposure to infected birds (including feathers, feces and under-cooked meat and egg products). For a current listing of affected regions, go to [www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm)

### Routine Influenza Testing:



<sup>8</sup> A novel influenza subtype is one that has not previously been circulating in the human population, resulting in a population that is immunologically naive to the virus.



### Novel/Avian Influenza Algorithm Michigan Department of Community Health Instructions for Clinical Labs at WHO Level 3

NOTE: This algorithm will be updated as the situation evolves. Please visit the MDCH website at [www.michigan.gov/flu](http://www.michigan.gov/flu) and MIHAN for updates.

WHO Level 3 –No or very limited human-to-human transmission.  
WHO level may be found at the WHO web site: [www.who.int](http://www.who.int)

#### Novel/Avian Influenza Suspect Case:

Patient risk assessment and pre-approval for Novel/Avian Influenza testing required by Bureau of Epidemiology (BOE), 517-335-8165 or 517-335-9030 after hours.

Collect specimens and ship to MDCH by fastest means. Ship on frozen cold packs. The submitting lab should not set-up or order viral cultures but may continue with routine culture testing for alternative non-viral agents.  
Samples should be submitted to MDCH for novel influenza testing **regardless** of results of any other influenza tests (i.e., even if rapid flu tests are negative).

PCR at MDCH for PanFlu Panel  
(Flu A/B/H1/H3/H5)

Flu A +, H1+ or H3 +, OR B + and H5 -

Telephone notification to BOE.  
Result reported via MDCH LIMS.  
Viral culture or further viral characterization may proceed at MDCH. (Sputum specimens are unacceptable for viral culture.)

Viral culture result reported via MDCH LIMS.

Flu A+ and H5 +

Telephone notification to BOE/OPHP.  
Local health department (LHD) and submitter notification by BOE.  
Result reported via MDCH LIMS.  
**DO NOT CULTURE**  
Specimens sent to CDC for confirmation.

CDC result reported upon receipt.

Flu A+, H1-, H3-, H5-

Telephone notification to BOE.  
**DO NOT CULTURE.**  
Result reported via MDCH LIMS.  
Specimens sent to CDC for confirmation.

Multiple sample types collected over multiple days are recommended including sputum, NP wash, bronchial lavage. NP and throat swabs are acceptable but less productive than other sample types. **DO NOT SUBMIT ONLY SPUTUM.**

Postmortem Specimens:  
Paraffin-embedded or formalin-fixed respiratory tissue. Consult MDCH Bureau of Epidemiology at (517) 335-8165 prior to submitting samples.

**Pandemic Influenza Algorithm  
Michigan Department of Community Health  
Instructions for Clinical Labs**

**NOTE:** This algorithm is to be used once sustained human-to-human transmission has occurred. It will be updated as the situation evolves. Testing beyond H5 will depend on resources and surveillance needs. Please visit the MDCH website at [www.michigan.gov/flu](http://www.michigan.gov/flu) and MIHAN for updates.

**Pandemic Influenza Suspect Case – H5 Screen:**

Ship specimens to MDCH by fastest means. Ship on frozen cold packs. Retain an aliquot and proceed with additional testing only after notification of negative H5 results. Consider H5 testing regardless of results of any other influenza tests (i.e., even if rapid flu tests are negative).

Multiple sample types collected over multiple days are recommended including sputum, NP wash, bronchial lavage. NP and throat swabs are acceptable but less productive than other sample types. **DO NOT SUBMIT ONLY SPUTUM.**

Postmortem Specimens: Paraffin-embedded or formalin-fixed respiratory tissue. Consult MDCH Bureau of Epidemiology at (517) 335-8165 prior to submitting samples.

H5 PCR by MDCH\* lab or a lab specified by MDCH.

H5 Negative

H5 Positive

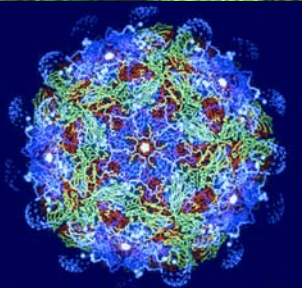
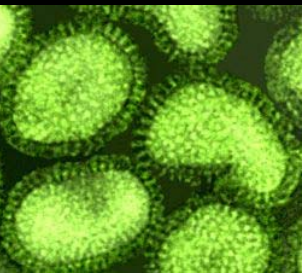
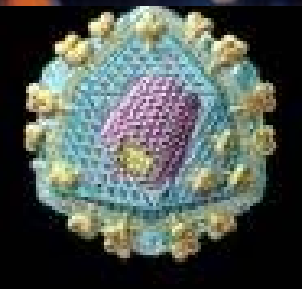
H5 PCR result reported via MDCH LIMS.

H5 PCR result reported via MDCH LIMS.

Further viral characterization may proceed at MDCH, submitting lab or reference lab.

Results confirmed at CDC upon request of CDC.

\* Bureaus of Laboratories and of Epidemiology will jointly determine when routine H5 testing is no longer indicated. Testing for surveillance purposes will continue as needed. Further guidance on testing will be provided at that time.

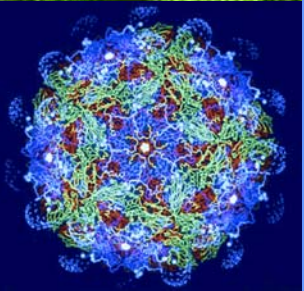
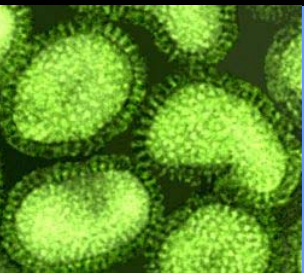
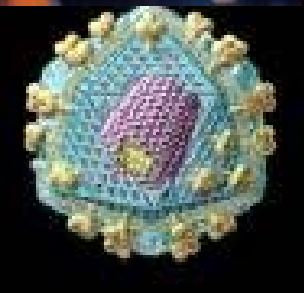




# MI PHL Preparations

## Surveillance for ILI

- ILI Surveillance Plan established
- Serum Bank initiated
- Medical Alert All-Hazards Card
- Plans for prophylaxis?



# *A Healthy You, Promotes Good Health*

## **ARE YOU SICK? STAY HOME!**

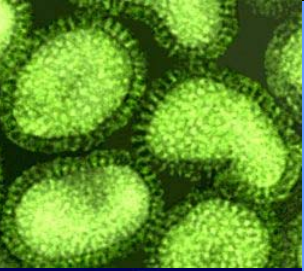
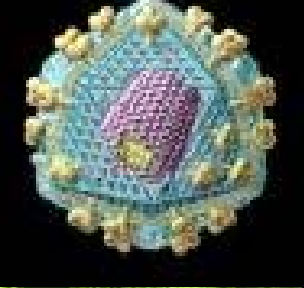
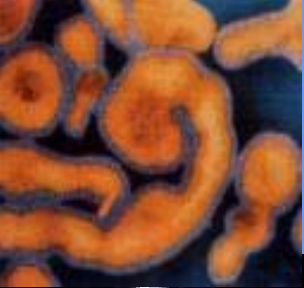
- 👤 **When you are sick or have flu symptoms, stay home, get plenty of rest, & check with a health care provider as needed.**
- 👤 **Remember: Keeping your distance from others may protect you or another from getting sick.**

### **Common symptoms of the flu include:**

- 👤 **Fever (usually high)**
- 👤 **Headache**
- 👤 **Extreme Tiredness**
- 👤 **Cough or Sore Throat**
- 👤 **Runny or Stuffy Nose**
- 👤 **Muscle Aches**
- 👤 **Nausea, vomiting, and diarrhea, (much more common among children than adults)**
- 👤 **Duration of Flu: 3-10 days usually**

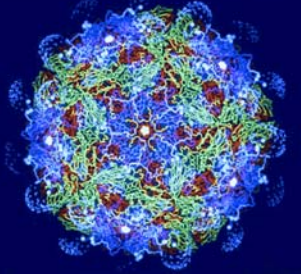
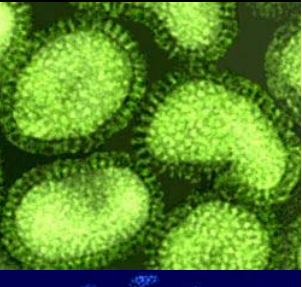


**Still Contagious?** You can spread the flu to others before your symptoms start & for another three to four days after your symptoms appear.



**DROPLETS IN A SNEEZE  
TRAVEL AS FAST AS  
150 FT/SECOND**

**AND AS FAR AS 12 FEET!**



Michigan Department of Community Health  
Bureau of Laboratories

## Medical Alert Card

Call (517) 335-8063 or (517) 335-9030 after hours for additional information and empiric therapy recommendations. For specimen collection and packaging, see [www.michigan.gov/mdchlab](http://www.michigan.gov/mdchlab)

Front

## Attention Medical Personnel

This person may have been occupationally exposed to certain novel or zoonotic diseases which are not routinely considered in the differential diagnosis of febrile illnesses. Please submit a specimen to MDCH Bureau of Laboratories to rule out infection with the following:

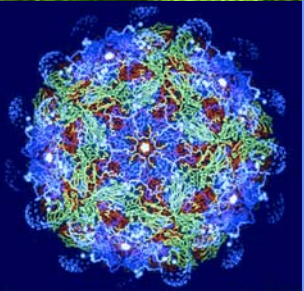
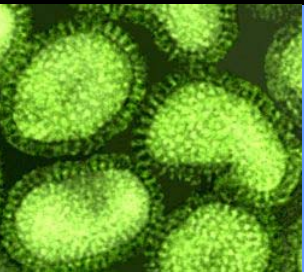
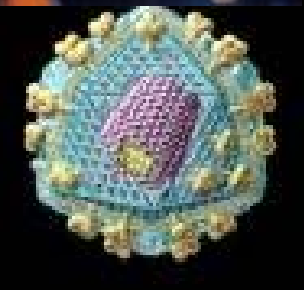
- |   |  |   |
|---|--|---|
| <input type="checkbox"/> Novel Flu virus  | <input type="checkbox"/> Brucella            | <input type="checkbox"/> Rabies                   |
| <input type="checkbox"/> Francisella      | <input type="checkbox"/> Arbovirus           | <input type="checkbox"/> <i>Burkholderia</i> spp. |
| <input type="checkbox"/> Bacterial toxins | <input type="checkbox"/> Coxiella            | <input type="checkbox"/> <i>Y. pestis</i>         |
| <input type="checkbox"/> Poxviruses       | <input type="checkbox"/> <i>B. anthracis</i> |   |

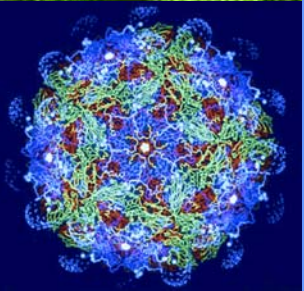
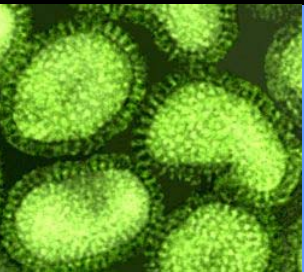
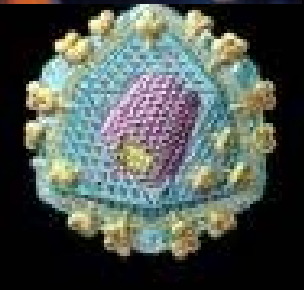
Back



# Surge Capacity

- Cross-training within BOL (20)
- High thru-put specimen preparation robot
- Validated LRN H5 procedure on Light Cycler
- Staff of Regional Labs and Veterinary and Agricultural labs cross-trained to assist in PHL
- LCs to 6 Regional Labs (3 ABI 7000s, 1 ABI 7500, 10 LC in our total system)
- Survey of clinical labs to establish those with advanced molecular capabilities
- Discussing with clinical partners options for sharing procedures, establishing reporting mechanisms

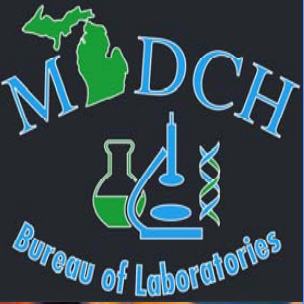




# Testing Proficiency/Employee Biosafety

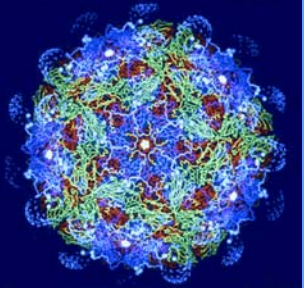
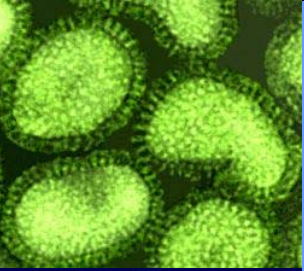
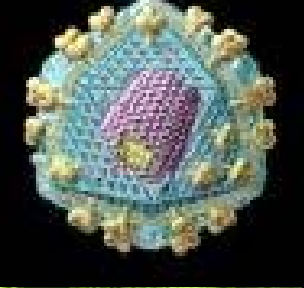
- Specimen collection instructions posted on BOL web
- Lab Biosafety Guidelines posted on BOL web
- BOL program for routine BSC and BSL-3 inspection
- Employee competency and proficiency restructured to be platform specific rather than assay specific.





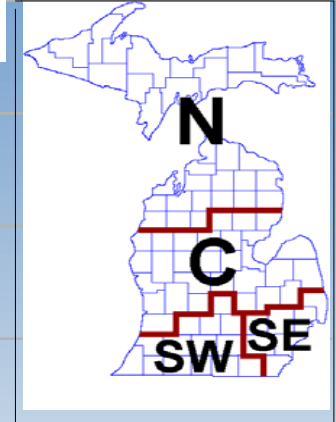
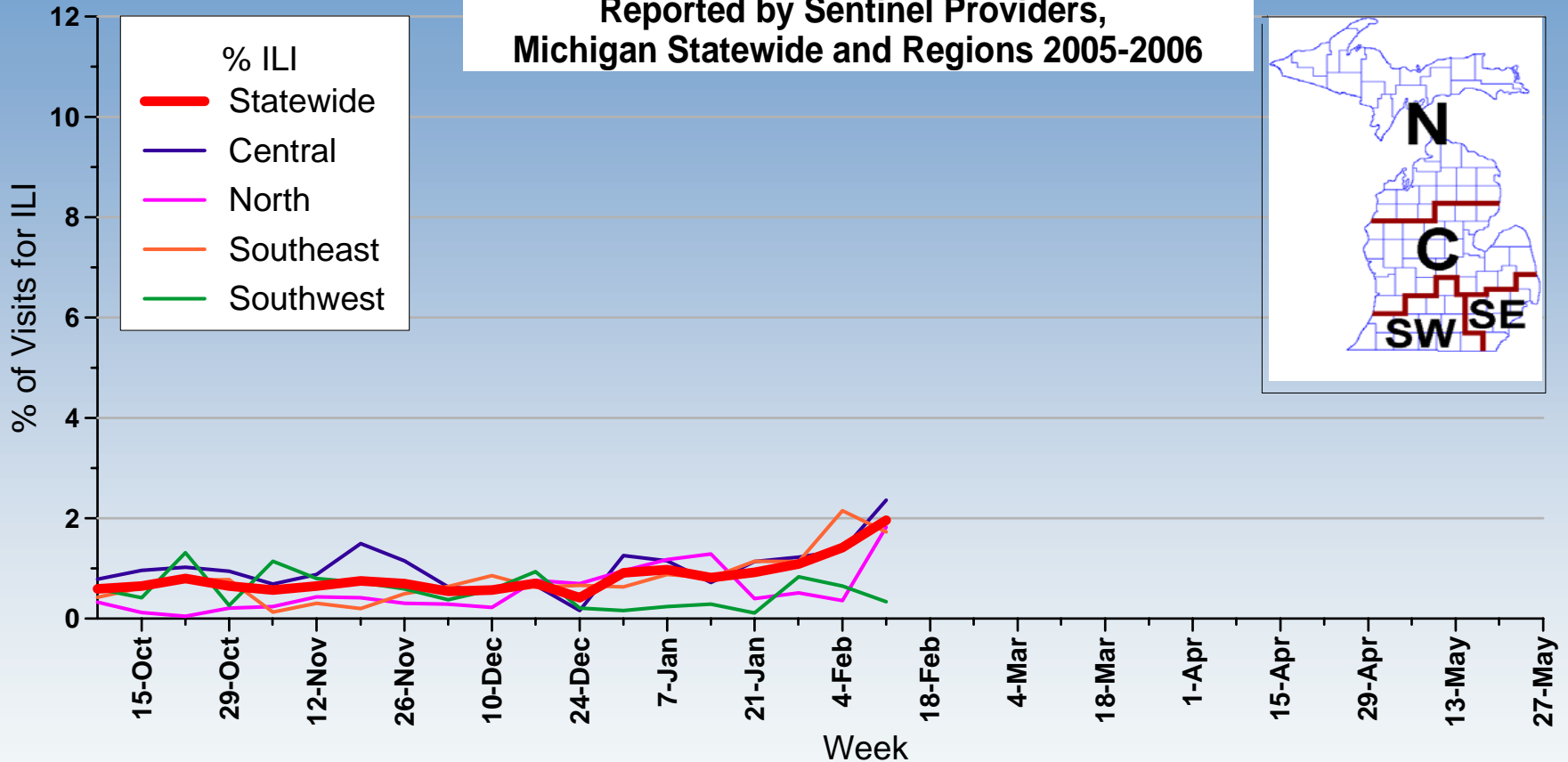
# Communications

- Weekly Flu Facts sent to all LHDs, laboratories, sentinel physicians
- Flu Plan posted on web and shared with labs and physicians via HAN
- Flu Plan presented at numerous venues to LHDs, clinical labs, physicians.



# 2005-2006 Season to Date

Percentage of Visits for Influenza-like Illness (ILI)  
Reported by Sentinel Providers,  
Michigan Statewide and Regions 2005-2006



MADCHE



*Bureau of Laboratories*