

Influenza and other Respiratory Viruses Update--2015

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Learning Objectives

- Review of the 2013-2014 influenza season.
- Avian influenza
- Emerging diseases impacting community health.
- Review of new point-of-care nucleic acid amplification assays.
- Discuss surveillance strategy for 2015-2016



Influenza The latest information

www.cdc.gov/flu/index.htm

Centers for Disease Control and Prevention

People at High Risk

۹ Influenza (Flu) f У 🕂 Longuege: English Elu activity has returned to summer-time levels in the United States. H3N2 viruses were most common overall during this season, however, there was a wave of influenza B activity starting in early March. According to a report published in the Morbidity and Mortality Weekly Report (MMWR), the season was moderately severe overall, and severe for people 65 years and older, with very high hospitalization rates in that age group. While most flu activity occurs from October to May in the United States, flu viruses are detected year-round, including at lower levels during the summer months. Influenza antiviral drugs can treat flu Illness. CDC recommends these drugs be used to treat people who are very sick or who are at high risk of serious nformation About Avian Influenza (bird flu) in the United States flu-related complications who have flu symptoms. Early antiviral treatment works best Flu Activity & Surveillance FLU BASICS HEALTH PROFESSIONALS ptoms, How Flu Spreads, Higher Risk Groups, Past instion, Antiviral Drugs, Infectio and Current Flu Season Diamostic Testing and Training PREVENTION - FLU VACCINE FREE RESOURCES Vaccine Safety, Vaccination Coverage, Influenza VIS, Printable Materials, Photos, Podcasts, Videos, PSAs, NIVW Infection Control eCards Radges & Buttons Articles TREATMENTS INFORMATION FOR PARTNERS Drugs to Treat Flu Virus, Stay Home When Sick, Caring Campaign Highlights, Partner Activity, Media Briefings, for Someone Sick With Flu Promotional/Educational Tools Check where flu is active near you More > SUPPLY AND DISTRIBUTION QUESTIONS & ANSWERS Approved U.S. Flu Vaccines, Total Doses Distributed Answers to Flu-Related Questions International Flu The latest report on CDC's NEWS & HIGHLIGHTS PUBLIC HEALTH IMAGE LIBRARY International flu activities highlights the Flu Spotlights, Press Releas tographs, Illustrations, and Multimedia File progress that has been made over the past two fiscal years to establishing expanding and maintaining influenza Other Flu Web Sites surveillance and laboratory capacity in nore than 50 countries around the world where CDC ha provided support. Avian H3N2v Swine Pandemic Bat Canine Other There are m za A viruses; some are found in humans and others in animals such as avian flu in bird Supply & Distribution and noultry U.S. H5 Viruses: Highly pathogenic avian influenza (HPAI) H5 infections have been reported in U.S. birds and poultry. No ed! Table of Approved 2015-2016 U.S. Flu Vaccines human infections with these viruses have been detected at this time, however similar viruses have infected people in Seasonal Flu Vaccine: Total Doses Distributer other countries and caused serious illness and death in some cases. Antiviral Drug Supply More Stay Connected Info for Specific Group CDC's Facebook page

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CDC's Flu Twitter

Schools & Childcare Providers

What We're Dealing with Now



- Ebola virus
- EV-D68
- MERS CoV
- Dengue fever
- Chikungunya
- Anthrax
- Measles/mumps

... So what's the big deal with influenza?



The Changeability of Influenza *Antigenic Drift* → *Seasonal Influenza*





Antigenic Drift Manifests in HA and NA as a result of continuous and gradual accumulation of point mutations in the HA and NA genes Each year's flu vaccine contains three flu strains – two A strains and one B strain – that can change from year to year.





Estimated Annual Burden of Seasonal Influenza in the United States



Direct medical costs: \$10.4 billion



Influenza in the U.S. 2014-15

Influenza Positive Tests Reported to CDC by U.S. WHO/NREVSS Collaborating Laboratories, National Summary, 2014-15





Influenza in WI, 2014-2015

Influenza Type (%) in Wisconsin, 2014-2015 Season



A Peak (%) was 12/20/14 A Peak (# positives) was 1/3/15





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Influenza 2014-15

What was expected...

A/Texas/50/2012(H3N2), the vaccine strain

What we got instead...

- A/Switzerland/9715293/2013(H3N2)
- ... a significant antigenic drift!

What were the consequences...

- Vaccine ineffectiveness
- Difficult virus to work with and characterize

Seasonal Influenza Vaccines



How effective?

http://www.cdc.gov/flu/professionals/vaccination/ effectivenessqa.htm http://www.cdc.gov/flu/professionals/vaccination/ effectiveness-studies.htm

| Influenza Season ⁺ | Reference | Study Site(s) | No. of Patients [‡] | Adjusted Overall VE (%) | 95% CI |
|-------------------------------|-----------------------------|--------------------|------------------------------|-------------------------|---------|
| 2004-05 | Belongia 2009 | WI | 762 | 10 | -36, 40 |
| 2005-06 | Belongia 2009 | WI | 346 | 21 | -52, 59 |
| 2006-07 | Belongia 2009 | WI | 871 | 52 | 22 ,70 |
| 2007-08 | Belongia 2011 | WI | 1914 | 37 | 22, 49 |
| 2009-10 | Griffin 2011 | WI, MI, NY, TN | 6757 | 56 | 23, 75 |
| 2010-11 | Treanor 2011 | WI, MI, NY, TN | 4757 | 60 | 53, 66 |
| 2011-12 | Ohmit 2014 | WI, MI, PA, TX, WA | 4771 | 47 | 36, 56 |
| 2012-13 | McLean 2014 | WI, MI, PA, TX, WA | 6452 | 49 | 43, 55 |
| 2013-14 | Unpublished | WI, MI, PA, TX, WA | 5990 | 51 | 43, 58 |
| 2014-15 | ACIP presentation, Flannery | WI, MI, PA, TX, WA | 9329 | 23 | 7, 29 |

Table. Adjusted vaccine effectiveness estimates for influenza seasons from 2005-2015

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Vaccination Rates---2013-14 and 2014-15 General Population

http://www.cdc.gov/flu/professionals/vaccination/



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Influenza in the U.S. 2014-15



"There was no week 53 in the previous influenza seasons displayed above; therefore, the week 53 data point for those seasons is an average of weeks 52 and 1.



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Influenza Hospitalizations

2014-15



In contrast, 2013-14



Data from the Influenza Hospitalization Surveillance Network (FluSurv-NET), a population-based surveillance for influenza related hospitalizations in children and adults in 13 US states. Incidence rates are calculated using the National Center for Health Statistics' (NCHS) population estimates for the counties included in the surveillance catchment area.

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Influenza in the U.S. Early 2015-16

Influenza Positive Tests Reported to CDC by U.S. WHO/NREVSS Collaborating Laboratories, National Summary, 2014-15



Early 2015-2016 Season....



| PH Region | Date Received | Influenza type |
|--------------|------------------|-------------------|
| S | 8/7/2015 | Flu A (H3) |
| S | 8/18/2015 | Flu A (H3) |
| NE | 8/25/2015 | Flu A (H3), Flu B |
| S | 8/28/2015 | Flu A (H3) |
| S | 9/2/2015 | Flu A (H3) |
| | | |
| | | |
| | | |
| plus s | everal other Flu | (H3) reported |

by clinical labs, not confirmed by WSLH, in **S** and **SE** Regions



The Changeability of Influenza Antigenic Shift

www.flu.gov The genetic change that enables a flu strain to jump from one animal species to another, including humans, is called "ANTIGENIC SHIFT." Antigenic shift can happen in three ways The new strain may further Without evolve to spread undergoing genetic chang from person to Juenza A strain person. If so, a a bird strain of flu pandemie influenza A car jump directly from a duck or other aqua bird to Human Human influenza A strain antiger host A-1 A duck or other aquatic bird passes a bird C strain of influenza A to Without an intermediate host undergoing such as a chicken or pig genetic change, a bird strain of influenza A can jump directly from a A-2 A person passes a HA duck or other antigen human strain of aquatic bird to influenza A to the an intermedia same chicken or pig. (Note that reassortment can animal host and occur in a person who is infected with two flu strains.) then to humans When the viruses infect the same cell. the genes from the bird strain mix with genes from the human strain to vield a new strain Viral entry ediate bost cell The new strain can spread New influenza from the intermediate host to humans termediate Link Studio for NIAID Intermediate host (pig)

Antigenic Shift When a new subtype (a novel HA and/or NA) of influenza A emerges in the host (humans)



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Influenza A

• H1 - H17

• N1 - N10

Timeline of Influenza Viruses in Humans



Global Influenza Concerns: **A(H5N1) and A(H7N9)** http://www.who.int/csr/disease/avian_influenza/en/

Areas with confirmed human cases for avian influenza A(H5N1) reported to WHO, 2003-2013*



"All dates refer to onset of illness Data as of 24 January 2014 Source: WHO/GIP Areas reporting confirmed human cases for influenza A(H7N9) to WHO from 2013-06-01 *



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Influenza: Emergence of Novel Flu A Subtypes Chickens and turkeys take center stage

Influenza A

H1 - H17
N1 - N10







Avian Influenza Terminology

- <u>H</u>ighly <u>P</u>athogenic <u>A</u>vian <u>I</u>nfluenza
- Bird flu

- Pathogenicity refers to avian NOT human
- H5N1, H5N2 and H5N8 are collectively referred to as H5Nx



dcfeliciano.blogspot.com

H5N2 and H5N8 have both been detected in the US in 2015.

Emergence of Avian Flu (H5)



Avian Influenza (H5) emerged in North America (November 2014).

Many flocks in the area were infected by December including those in the US.

Data and image courtesy of Hon Ip, USGS, National Wildlife Health Research Center, Madison, WI

Current Situation



9:55 AM

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Detections by State

Since December 2014, the United States Department of Agriculture has confirmed several cases of highly pathogenic avian influenza (HPAI) H5 in the Pacific, Central, and Mississippi flyways (or migratory bird paths). The disease has been found in wild birds, as well as in a few backyard and commercial poultry flocks. The Centers for Disease Control and Prevention (CDC) considers the risk to people from these HPAI H5 infections to be low. No human cases of these HPAI H5 viruses have been detected in the United States, Canada, or internationally.

| State | Flyway | Confirmed Detections | Last Detection Reported | Total Birds |
|---------------------|-------------|-------------------------|----------------------------|-------------|
| <u>Arkansas</u> | Mississippi | 1 | March 11, 2015 | 40,020 |
| <u>California</u> | Pacific | 2 | February 12, 2015 | 247,300 |
| <u>Idaho</u> | Pacific | 1 | January 16, 2015 | 30 |
| Indiana | Mississippi | 1 | May 10, 2015 | pending |
| <u>lowa</u> | Mississippi | 75 | June 17, 2015 | 31,723,300 |
| <u>Kansas</u> | Central | 1 | March 13, 2015 | 10 |
| <u>Minnesota</u> | Mississippi | 105 | June 5, 2015 | 8,996,050 |
| <u>Missouri</u> | Mississippi | 3 | May 5, 2015 | 53,100 |
| <u>Montana</u> | Central | 1 | April 2, 2015 | 40 |
| <u>Nebraska</u> | Central | 4 | June 4, 2015 | 3,794,100 |
| <u>North Dakota</u> | Central | 2 | April 24, 2015 | 111,500 |
| <u>Oregon</u> | Pacific | 2 | February 17, 2015 | 200 |
| South Dakota | Central | 10 | June 1, 2015 | 1,168,200 |
| Washington | Pacific | 5 | February 3, 2015 | 6,710 |
| <u>Wisconsin</u> | Mississippi | 10 | May 6, 2015 | 1,950,733 |

Wisconsin:

- 10 flocks infected
- Almost 2 million infected
- Last detection in May 2015

Data source: USDA, Animal and Plant Health Inspection Service (Sept. 2, 2015)



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H5Nx Diagnostic Testing

Most commercial assays will **NOT** be able to differentiate seasonal viruses from novel strains.

- The WSLH and MHDL have PCR tests that **can** identify H5Nx strains.
- Preferred specimen are **combined NP/OP swab** in virus transport medium.
- Testing is performed on WDPH approved specimens.











Key Points

- There have been NO human cases.
- CDC considers general risk is low.
- Risk for people handling sick/dead poultry.
- No risk for eating cooked poultry products.



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Symptoms may be atypical.
 Patients with illness and close contact should contact their LHD or WDPH epidemiologist for follow-up evaluation.



It's <u>NOT</u> all about influenza.... other diseases of public health importance.....





Enterovirus D68 Current Situation

- August 2014 to Jan. 2015 >1,100 EV D68 cases.
- Majority of cases in children with asthma or a history of wheezing.
- 33% tested positive for rhinovirus or another enterovirus.
- Many experienced severe disease.



No cases reported this season 🙂

EV Image source: CDC (2015)

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Enterovirus D68



Background

- Enteroviruses are very common respiratory viruses (10-15M/year).
- Transmission respiratory route (person-toperson)
- Cause a wide variety of illnesses.
- Sometimes disease can be severe.
- There are no vaccines or antiviral therapeutics.
- Children with asthma are more vulnerable.



Enterovirus D68

FIGURE 2. Percentage of enterovirus reports, by month of specimen collection — United States, 1983–2005



MMWR (2006) Enterovirus Surveillance–US, 1983-2005. 55(SS08) 1-20.

Enterovirus D68

No. of years

TABLE 2. Frequencies, ranks, and number of years reported for individual enterovirus serotypes — National Enterovirus Surveillance System, United States, 1970–2005*

| | | | | | | | | | the | e serotype | was |
|----------------------|---------|------------|-------------|-----------|-----------|--------------|-----------|---------|----------|--------------|--------------|
| | 0 | Reports v | vith known | | De | -k | | Mahaat | | Among the | Among the |
| Sarotuna | overall | serotype (| N = 49,037) | 1070 1070 | 1000 1000 | 1000 1000 | 2000 2005 | rignest | Benerted | 15 most | nve most |
| Serotype | rank | NO. | 70 | 1910-1919 | 1900-1909 | 1990-1999 | 2000-2005 | rank | neported | common | common |
| Echovirus 9 | 1 | 5,868 | 11.8 | 1 | 2 | 4 | 1 | 1 | 36 | 35 | 22 |
| Echovirus 11 | 2 | 5,038 | 10.1 | 12 | 2 | 2 | 2 | - | 36 | 20 | 10 |
| Coreackievirus 85 | 4 | 4 313 | 8.7 | 3 | 4 | å | 5 | - | 36 | 28 | 12 |
| Echovirus 6 | 5 | 3,023 | 6.1 | 5 | 5 | 4 | 6 | ÷ | 36 | 34 | 7 |
| Coxsackievirus B2 | 6 | 2,596 | 5.2 | 6 | 6 | 5 | 12 | i | 36 | 35 | 14 |
| Coxsackievirus A9 | ž | 2,399 | 4.8 | 8 | 8 | ě | 7 | ż | 36 | 35 | 17 |
| Echovirus 4 | 8 | 2,304 | 4.6 | 4 | 11 | 19 | 14 | 1 | 36 | 27 | 8 |
| Coxsackievirus B4 | 9 | 2,089 | 4.2 | 7 | 9 | 10 | 11 | 2 | 36 | 33 | 10 |
| Echovirus 7 | 10 | 2,010 | 4.0 | 9 | 10 | 7 | 9 | 1 | 35 | 22 | 20 |
| Coxsackievirus B3 | 11 | 1,945 | 3.9 | 10 | 7 | 11 | 13 | 2 | 36 | 32 | 6 |
| Echovirus 18 | 12 | 1,341 | 2.7 | 18 | 13 | 15 | 3 | 2 | 36 | 18 | 6 |
| Coxsackievirus B1 | 13 | 1,143 | 2.3 | 14 | 8 | 8 | 8 | 2 | 35 | 17 | 6 |
| Echovirus 3 | 14 | 958 | 1.9 | 11 | 16 | 20 | 20 | 1 | 32 | 9 | 8 |
| Echovirus 5 | 15 | 916 | 1.8 | 22 | 12 | 13 | 18 | 4 | 34 | 21 | 18 |
| Human Parechovirus 1 | 16 | 880 | 1.8 | 15 | 14 | 14 | 19 | 8 | 35 | 26 | _ |
| EchoVirus 14 | 1/ | /13 | 1.4 | 13 | 19 | 18 | 22 | 4 | 34 | 19 | 1 |
| Coxsackievirus A16 | 18 | 615 | 1.2 | 1/ | 1/ | 22 | 21 | 4 | 34 | 11 | _ |
| Echovirus 13 | 19 | 5/8 | 1.2 | 30 | 30-30 | 39 | 4 | 1 | 28 | 16 | 2 |
| Echovirus 25 | 20 | 597 | | 19 | 15 | 28.27 | 20 | 5 | 30 | 10 | |
| Echovirus 24 | 22 | 501 | 1.0 | 16 | 24 | 17 | 29 | 1 | 33 | 6 | 2 |
| Echovinus 21 | 22 | 458 | 0.9 | 26 | 21 | 25 | 24 | 2 | 31 | 7 | 1 |
| Echovinus 20 | 24 | 340 | 0.7 | 40 | 20 | 21 | 90-94 | 3 | 24 | 2 | ÷ |
| Echovirus 31 | 25 | 337 | 0.7 | 25 | 22 | 24 | 30-34 | ŏ | 30 | 4 | |
| Echovirus 17 | 26 | 286 | 0.6 | 27 | 17 | 23 | 46-47 | 2 | 27 | 4 | 1 |
| Enterovirus 71 | 27 | 270 | 0.5 | _ | 30 | 16 | 15 | 5 | 23 | 11 | i - |
| Echovirus 2 | 28 | 211 | 0.4 | 21 | 28 | 28 | 44-45 | 12 | 29 | 2 | _ |
| Coxsackievirus A4 | 29-30 | 180 | 0.4 | 24 | 31 | 33 | 30-34 | 14 | 25 | 2 | _ |
| Echovirus 1 | 29-30 | 190 | 0.4 | 29 | 26 | 29 | 35 | 17 | 28 | _ | _ |
| Echovirus 33 | 31 | 146 | 0.3 | 20 | 46-47 | 42 | 36 | 3 | 18 | 1 | 1 |
| Coxsackievirus A10 | 32-33 | 138 | 0.3 | 30 | 29 | 30 | 37-39 | 14 | 27 | 2 | _ |
| Echovirus 27 | 32-33 | 138 | 0.3 | 35 | 27 | 26-27 | 30-34 | 16 | 30 | _ | _ |
| Echovirus 15 | 34-35 | 120 | 0.2 | 33 | 32 | 31-32 | 27-28 | 18 | 31 | _ | _ |
| Echovirus 19 | 34-35 | 120 | 0.2 | 28 | 44 | 36 | 27-28 | 12 | 24 | 1 | _ |
| Coxsacklevirus A2 | 36 | 87 | 0.2 | 31 | 35-36 | 40-41 | 44-45 | 18 | 19 | _ | _ |
| Coxsackievirus A5 | 3/ | 72 | 0.1 | 32 | 38-39 | 48-51 | 37-39 | 12 | 20 | 1 | _ |
| Human Darashavirus 0 | 38 | 68 | 0.1 | 48 | 33 | 31-32 | 37-39 | 18 | 24 | _ | _ |
| Coveachigations AC | 39 | 50 | 0.1 | 39 | 3/ | 34 49. 4E | 40 | 17 | 45 | _ | _ |
| Coveachiovinus A6 | 40 | 55 | 0.1 | 38 | 52.54 | 43-40 | 17 | 6 | 15 | - | _ |
| Echovirus 12 | 42 | 53 | 0.1 | 37 | 40 | 35 | 41-43 | 20 | 23 | _ | _ |
| Coxsackievirus A7 | 43 | 46 | 0.1 | 34 | 41 | 52-56 | 41-43 | 20 | 15 | _ | _ |
| Coxsackievirus A21 | 44 | 42 | 0.1 | 44-47 | 38-39 | 37-38 | 30-34 | 17 | 17 | _ | _ |
| Coxsackievirus A13 | 45 | 32 | 0.1 | 41 | 42-43 | 43-45 | _ | 19 | 11 | _ | _ |
| Echovirus 29 | 46 | 27 | 0.1 | 44-47 | 45 | 37-38 | _ | 26 | 14 | _ | _ |
| Enterovirus 68 | 47 | 26 | | | | | | - 10 | - | - | |
| Echovirus 32 | 48 | 25 | 0.1 | 42 | 46-47 | 48-51 | - | 27 | 14 | - | - |
| Coxsackievirus A1 | 49 | 24 | < 0.1 | 44-47 | 55-57 | 48-51 | 26 | 11 | 7 | 1 | _ |
| Coxsackievirus A14 | 50 | 21 | <0.1 | 54 | 42-43 | 48-51 | 41-43 | 21 | 8 | _ | _ |
| Coxsackievirus A8 | 51 | 17 | <0.1 | 43 | 49 | 52-56 | _ | 24 | 10 | _ | _ |
| Echovirus 26 | 52 | 16 | <0.1 | 52 | 48 | 43-45 | _ | 33 | 9 | _ | _ |
| Coxsackievirus A3 | 53 | 13 | <0.1 | 44-47 | 50-52 | 46-47 | _ | 31 | 9 | _ | _ |
| Coxsackievirus A11 | 54 | 10 | <0.1 | 51 | 50-52 | 46-47 | _ | 31 | 8 | _ | _ |
| Coxsackievirus A17 | 55 | 8 | <0.1 | 50 | 53-54 | 52-56 | _ | 36 | 7 | _ | - |
| Coxsackievirus A20 | 56 | 5 | < 0.1 | _ | 50-52 | _ | 46-47 | 27 | 3 | _ | _ |
| Coxsackievirus A12 | 57 | 3 | <0.1 | 53 | 55-57 | | _ | 37 | 2 | _ | _ |
| Enterovirus 70 | 58 | 1 | <0.1 | _ | _ | 52-56 | _ | 26 | 1 | _ | _ |

Large diversity of enteroviruses circulate seasonally.

EV D68 has been <u>**rare</u>**</u>

* The 15 most common serotypes are shown in bold. Coxsackieviruses A19 and A22, enterovirus 69, and recently identified enteroviruses numbered 73 and higher have not been reported during the study period.



Enterovirus D68 Diagnostic Testing

- Genetically very similar to rhinoviruses.
- Most PCR assays cannot accurately discriminate!
- Some commercial PCR assays may have variable sensitivities for EV D68.
- Testing is limited to cases that are WDPH approved.
- Combined NP/OP is the preferred specimen.
- WSLH is performing Enterovirus PCR on *approved* specimens.
- Specific EV D68 typing at CDC.
- EUA test will be available should the situation warrant.

http://www.slh.wisc.edu/enterovirus-d68-confirmed-in-wisconsin/



MERS-Coronavirus

52 Ξ

36

(d) WHO | Middle East respira 🗙

www.who.int/emergencies/mers-cov/en/ G ←





United Kingdom, United States of America, Yemen

Please note that the underlying data is subject to change as the investigations around cases are ongoing. Onset date estimated if not available. Source: WHO

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MERS-CoV What we know!

- Virus is *different* than SARS-Coronavirus and seasonal coronavirues.
- First cases in 2012.
- All cases linked to the Arabian Peninsula.
- Virus does not easily transmit from person-toperson.
- Requires close personal contact.
- Genetically stable.
- Bats and camels play a role in host transmission; dynamics not well understood.
- Healthcare workers at higher risk.



Rapid Influenza Diagnostic Tests (RIDTs) A perennial discussion

| | | CDC A-Z INDEX 😒 |
|---|---|--|
| Influenza (Flu) | | |
| Seasonal Influenza (Flu) | Seasonal Influenza (Flu) > Health Professionals > Clinical Description & Lab Diagnosis | |
| 2015-2016 Flu Season | * Guidance for Clinicians on the Use of Rapid Influenza Diagnostic Te | ests |
| Influenza - Flu Basics | + F 🔽 Format: Selector | ie v Language: English v |
| Prevention - Flu Vaccine | + | |
| Treatment - Antiviral Drugs | + Background | On this Page |
| Specific Groups | + Rapid influenza diagnostic tests (RIDTs) are Immunoassays that can identify the presence of | Background |
| Questions & Answers | Influenza A and B viral nucleoprotein antigens in respiratory specimens, and display the result in a qualitative way (positive vs. negative) (1). In the United States, a number of RIDTs are commercially | Use of RIDTs in Clinical Decision- |
| Health Professionals | available. (See *Table 1: Influenza Virus Testing Methods* and *Table 2: Characteristics of Rapid | Use of RIDTs for Public Health |
| ACIP Recommendations | Influenza Diagnostic Tests") The reference standards for laboratory confirmation of influenza virus infection are reverse transcription-polymerase chain reaction (BT-PCR) or viral orithme. BIDTs can | Purposes to Detect Influenza |
| Vaccination | + yield results in a clinically relevant time frame, i.e., approximately 15 minutes or less. However, | |
| Antiviral Drugs | RIDTs have limited sensitivity to detect influenza virus infection and negative test results should be Intermeted with caution the notential for faire periods are dis | Interpretation of Rapid Influenza |
| Infection Control | The process who cannot provide a potential normalize respective resolution The process of influence diamostic test that The process of the process of the potential of the process of the potential o | Diagnostic Test Results Information on Local Influenza |
| Clinical Description & Lab | _ use isothermal nucleic acid amplification for viral detection. At present, only one rapid molecular assay is | Activity |
| Diagnosis | FDA-approved for use in the United States. | When to Consider Further Influenza Tection |
| Influenza Symptoms and the Role of Laboratory | Advantages and Disadvantages of RIDTs | • Figure 1 |
| Diagnostics | Advantages | Figure 2 |
| Rapid Diagnostic Testing: Information for Health | Produce quick result in 15 minutes or less, simple to perform | Higure 3 |
| Care Professionals | Some RIDTs are approved for office/bedside use | Table 1 |
| Rapid Diagnostic Testing: | Disadvantages | Table 2 |
| Information for Clinical Laboratory Directors | Sub-optimal test sensitivity, false negative results are common, especially when influenza | References |
| Cultures for Chatalons | activity is high | |
| on the Use of Rapid | Although specificity is high, false positive results can also occur, especially during times when | |
| Influenza Diagnostic Tests | influenza activity is low | |
| | Some RIDTs distinguish between influenza A or B virus infection while others do not. RIDTs that p | provide results on type of influenza virus (e.g. |
| Guidance for Clinicians on the Use of RT-PCR and | influenza A or B virus), do not provide information on influenza A virus subtype (e.g. A/H1N1 ver | sus A/H3N2) or specific strain information |
| Other Molecular Assays | (e.g. degree of similarity to vaccine strains) | |
| Visus Infection | | a Top of Page |

www.cdc.gov/flu/professionals/diag nosis/clinician_guidance_ridt.htm

www.jointcommission.org/siras.aspx

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| ome > Strategies for Imp Strategies fo Ambulatory S | roung Rapid Influenza Testing and Treatmen r Improving Rapid Influ settings (SIRAS) | t in Ambuliatory Settings (SIRAS) Ienza Testing an | d Treatme | Twitter 🚺 Facebook Tor ent in | Boogle+ Share Print esiday 9:38 CST, September 8, 2015 | |
| - 1 | Take Advantag Four 30-minute cours | e – Free Online Education es created with the busy of | Courses. dinician in mir | nd. Videos | ond the quick swab: | |
| Antiviral medications or influenza | Did you know? | Enroll Now > | m each vear in th | Podca | ng spid influenza | 88 |
| łow available! | United States, and is hospitalizations each | associated with more than 200, year. | 000 | Take 5 w Rapid Inf | Ath The Joint Commission: On Ruenza Testing | f |
| Updated for the curren Season | Healthy people are at those with chronic illn | risk of complications from influe ess and vulnerable populations. | inza too, not just | By Joint | Commission Use More | ρ |
| Improved Course Des Four short, 30-minute course | ign • You do NOT need to 4 s every patient who exh influenza. | order a Rapid Influenza Diagnost ibits flu symptoms in order to m | ic Test (RIDT) for take a diagnosis (| How | is Your ctice Handling | in 8' |
| Free CE credits Ability to view and print transcripts anytime | Influenza antiviral drug Early antiviral treatme | gs play an important role in treat nt works best. | ing flu illnesses. | Flu S | Season? | |
| Available on I-pads & Tablets Easy access to videos | How is Your Practice Han • Learn WHEN to order | dling the Flu Season? a Rapid Influenza Diagnostic In | ifluenza Test (RID | т) 193 | | |
| Enroll in the course | Know HOW to interpr Understand HOW to in | et RIDT results use local epidemiologic informati | ion, clinical | | Y | |
| Specimen Collecti Videos | on of influenza in your pr Learn HOW to proper | r results to assist with the diagn actice setting ly collect respiratory samples fo | osis and treatme | nt View R | ew Infographic | |
| Aspirate Nasal Wash | | | | | Jenza Pandemic | |
| Nasal Stopper Swab | Resources | External Web | sites | in Ar | mbulatory Settings | |
| Nasal Swab | Is it a Cold or the Flu? | Influenza Vaccine | e Information | Course | e Related Questions | |
| | | f DID'Te Informational Influ | enza Activity | > Ema | 10 | |



Improving RIDT Performance There are new regulations in our future

https://www.federalregister.gov/articles/2014/05/22#foodand-drug-administration

• New nomenclature proposed: **I**nfluenza **V**irus **A**ntigen **D**etection test

Room 100, Wichita, Kanasa 67209; phone 316-946-4174; fax: 316-946-4107; errai ben .tynon@fan.gov. Der Jynor@jac.gov. (2) For service information identified in this AD, contact Rockwell Collins, Inc., Collins Aviation Services, 350 Collins Road NE., M/S 153–250, Codur Rupide, IA 52406– 0001: telenhoue: 088–267–5467 (U.S.) or

ion at the FAA, Small Airplane ite. 901 Locust, Kanaus City, shility of this material at the FAA, call 329-4148.

Issued in Kansus City, Missouri, on May Earl Lawre

FR Doc. 2014-11846 Filed 5-21-14; 8:4 BUILDED CODE AND AD D DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration 21 CFR Part 866 Docket No. FDA-2014-N-04401

Microbiology Devices: Reclassification of Influenza Virus Antigen Detection Test Systems Intended for Use Directly With Clinical Specimens

ACENCY: Food and Drug Administrat

ACTION: Proposed order MARY: The Food and roclassify antigon based rapid inf 1251 virus antigen detection test systems intended to detect influenza virus directly from clinical specimens that are currently regulated as influenza virus class II with special controls and into a new device classification regulation. DATES: Submit either electronic or written comments on the proposed order by August 20, 2014. See section XI for the proposed effective date of any final order that may publish based on this proposed order. ADDRESSES: You may submit commonts

Identified by Docket No. FDA-2014-N-0440, by any of the following methods: Electronic Submissions Submit electronic comments in the

following way: Federal eRules aking Portal: http:// www.regulations.gov. Follow the Instructions for submitting comments.

Federal Register/Vol. 79, No. 99/Thursday, May 22, 2014/Proposed Rules Written Submissions Submit written submissions in the

following ways: Mall/Hasd delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm.

1061, Rockville, MD 20852. Instructions: All submissions received must include the Agency name and Docket No. FDA-2014-N-0440 for this

rulemaking. All comments received may be posted without change to http:// www.regulations.gov, including any personal information provided. For additional information on submitting ents, see the "Commonts" has

of the SUPPLEMENTARY INFORMATION section Dockel: For access to the docket to read background documents or comments received, go to http://

www.regulations.gov and Insert the docket number, found in brackets in the ading of this document, into the search" box and follow the prompts t/or go to the Division of Dockets A sagement, 5630 Fishers Lane, Rm. 041, Rockville, MD 20852.

URTHER INFORMATION CONTACT: tie Akselrod, Center for Devices adiological Health, Food and Drug inistration, 10903 New Hampshire Bidg. 66, Rm. 5517, Silver Spring, 20993–0002, 301–796–6188.

PLEMENTARY INFORMATION: Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94– 295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115), the Modical Device User Fee and Modernization Act of 2002 (Pub. L. 107– 250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-Administration Safety and Innovation Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and offoctivoness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

protocol, and promarket notification (a promarket notification is generally eferred to as a "510(k)" after the section of the FD&C Act where the regularement Is found). The purpose of a premarket notification is to demonstrate that the new device is substantially equivalent to a legally marketed predicate device Under section 513(1) of the FD&C Act. a device is substantially equiva has the same intended use and technological characteristics as a predicate device, or has different technological characteristics but data demonstrate that the new device is as safe and effective as the predicate device and does not raise different ssues of safety or effectiveness. FDA determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807). Section 510(k) of the FD&C Act and the Implementing regulations in part 807, subpart E, require a person who intend to market a modical device to submit a premarket notification submission to FDA before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device Intended for human use

Under the FD&C Act, FDA clears or

approves the three classes of medical devices for commercial distribution in the United States through three

regulatory processes: Premarket

approval (PMA), product develops

29387

In accordance with section 513(f)(1) of the FD&C Act, devices that were not in commercial distribution before May 28 1976, the date of enactment of the 1976 amendments, generally referred to as postamendment devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless FDA classifies the device into class I or class If by issuing an order finding the device to be substantially equivalent, in accordance with section 513(1) of the FD&C Act, to a predicate device that does not require premarket approval or the device is reclassified into class I or class II. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807 of FDA's regulations. Section 513(f)(2) of the FD&C Act establishes procedures for "de novo" risk-based review and classification of postamendment devices automatically classified into class III by section





If you are an RIDT(IVAD) user...

- What would the new regulations entail?
 - Reclassifying RIDTs from Class I to Class II
 - Add "special controls" to ensure device safety and effectiveness
 - Set minimum clinical performance criteria for sensitivity and specificity
 - Identify appropriate comparator tests for new assays
 - Accuracy assessed by manufacturers each year and when novel strain emerges
- When will this happen?
- Possible impacts:

Better tests? Fewer tests?



Rapid Influenza Diagnostic Tests The Next Generation

- Incorporates reader
 instrument
- Reduces subjectivity
- Improved sensitivity
- CLIA-waved
- Data transmission capabilities
- A step in the right direction





Quidel Sofia sites within WI Summer 2014-15



Temte, et al study, 2015 The power of rapid real-time reporting

Influenza A Influenza B



ICEID meeting, Atlanta, GA

Rapid Influenza Diagnostic Tests

Molecular Results in Minutes!

https://usdiagnostics.roche.com/en/cobas-liatlab.html#overview





http://www.alere.com/us/en.html

Influenza Molecular Tests - PCR

Commercially Available - FDA Cleared

| Products | Manufacturer(s) | Influenza Virus Type Detected | Virus Subtype(s) Differentiated | Other Respiratory Viruses Differentiated | Acceptable Specimens ¹ | Test Time ² / Complexity |
|--|---|----------------------------------|---|---|--|--|
| DC Human Influenza /irus Real-Time RT- /CR Diagnostic Panel ⁴ | CDC Influenza Division | Influenza A and B | HI, H3, 2009 H1, H5N1 (Asian lineage) | None | Nasopharyngeal swabs, nasal swabs, nasal aspirates, nasal washes, dual nasopharyngeal/ throat swabs, broncheoalveolar lavages, tracheal aspirates, bronchial washes, and viral culture | ~4 h/ High |
| Cepheid Xpert Flu Assay | Cepheid | Influenza A and B | 2009 H1 | None | Nasopharyngeal swabs, nasal aspirates, and nasal washes, | 1.0 h/ Moderate |
| Sensor⊕ Respiratory ∕iral Pauel (RVP) | Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. | Influenza A and B | H1, H3, 2009 H1 | Respiratory Syncytial Virus subtype A. Respiratory Syncytial Virus subtype B. Parainfluenza 1, 2, and 3 virus, Human Metapnetumovirus, Adenovirus Species B/E, Adenovirus Species C, and Human Rhinovirus | Nasopharyngeal swabs | ~8 h/ High |
| ilmArray Respiratory Panel | Idaho Technologies | Influenza A and B | H1, H3, 2009 H1 | Respiratory Syncytial Varus, Parainfluenza 1, 2, 3 and 4 virus, Human Metapneamovirus, Rhinovirus/Enterovirus, Adenovirus, Coronavirus HKU1, Coronavirus NL63 | Nasopharyngeal swabs | 1.0 h/ Moderate |
| bis PLEX-ID Flu | Ibis/Abbott | Influenza A and B | H1, H3, 2009 H1 | None | Nasopharyngeal swabs | ~8 h/ High |
| Quum Liat Influenza VB Assay | IQuam | Influenza A and B | None | None | Nasopharyngeal swabs | 0.5 h/ Moderate |
| rodesse PROFLUTM+ | GenProbe | Influenza A and B | None | Respiratory Syncytial Virus | Nasopharyngeal swabs | <4h/ High |
| rodesse ProFAST ^{TM+} | GenProbe | Influenza A | H1, H3, 2009 H1 | None | Nasopharyngeal swabs | <4h/ High |
| Quidel Molecular nfluenza A+B Assay | Quidel | Influenza A and B | None | None | Nasopharyngeal swabs and nasal swabs | ~4 h/ High |
| hagen Artus Influenza UB Rotor-gene RT- CR kit | Qiagen | Influenza A and B | None | None | Nasopharyngeal swabs | -4 h' High |
| Simplexa™ Flu A/B & RSV | Focus Diagnostics, 3M | Influenza A and B | None | RSV | Nasopharyngeal swabs | <4h/ High |
| | | | | | | |
| Simplexa™ Flu A/B & RSV Direct | Focus Diagnostics, 3M | Influenza A and B | None | RSV | Nasopharyngeal swabs | <2h/ Moderate |
| Simplexa™ Influenza A H1N1 (2009) | Focus Diagnostics, 3M | Influenza A | 2009 H1 | None | Nasopharyngeal swabs, nasal swabs, and nasopharyngeal asoirates | <4h/ High |
| U.S. Army JBAIDS Influenza A/H5 ⁴ | Idaho Technologies | Influenza A | H5N1 (Asian Lineage) | None | Nasopharyngeal and throat swabs | -4 h/ High |
| U.S. Army JBAIDS Influenza A&B Detection Kit ⁴ | Idaho Technologies | Influenza A and B | None | None | Nasopharyngeal swabs and Nasopharyngeal washes | -4 h/ High |
| U.S. Army JBAIDS Influenza A Subtyping Kit ⁴ | Idaho Technologies | Influenza A | H1, H3, 2009 H1 | None | Nasopharyngeal swabs and Nasopharyngeal washes | ~4 h/ High |
| Verigene® Respiratory Virus Nucleic Acid Test | Nanosphere, Inc | Influenza A and B | None | Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B | Nasopharyngeal swabs | 3.5 h/ Moderate |
| Verigene [®] Respiratory Vara Plas Nucleic Acid Test (RV+) | Nanosphere, Inc | Influenza A and B | H1, H3, 2009 H1 | Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B | Nasopharyngeal swabs | 3.5 h/ Moderate |
| x-TAG& Respiratory Viral Panel (RVP) | Luminex Molecular Diagnostics Inc. | Influenza A and B | Н1, Н3 | Respiratory Syncytial Virus subtype A. Respiratory Syncytial Virus subtype B, Parainfloenza 1, 2, and 3 virus, Human Metapneumovirus, Rhinovirus, and Adenovirus | Nasopharyngeal swabs | -8 h∕ High |
| x-TAG® Respiratory Viral Panel Fast (RVP FAST)) | Luminex Molecular Diagnostics Inc. | Influenza A and B | H1, H3 | Respiratory Syncytial Virus Human Metapneumovirus, Rhinovirus, and Adenovirus | Nasopharyngeal swabs | 6 h/ High |

- CDC periodically updates list
- More and more clinical labs using these
- Literature in general indicates high level of performance

• Concerns:

- Detection of novel influenza A's
- Variable subtyping capabilities

http://www.cdc.gov/flu/professionals/diagnosis/molecular-assays.htm





WISCONSIN STATE LABORATORY OF HYGIENE - UNIVERSITY OF WISCONSIN

"Right-Sizing" Influenza Virologic Surveillance The Importance of "Alternative Data"





Alternative data is existing virologic data from non-PHL sources that can be used to supplement PHL data for improved situational awareness

Right Size Roadmap

http://www.aphl.org/aphlprograms/infectious/influenza/Pages/Influenza-Virologic-Surveillance-Right-Size-Roadmap.aspx



Influenza Virologic Surveillance Increasing Role for the <u>Clinical Lab</u>

- Provide situational awareness
 - Clinical lab testing data
 Via WSLH or directly
 CDC
- Detect novel or reassortant viruses
 Inform vaccine strain selection
 Detect and monitor antiviral resistance
 - Specimens/isolates \rightarrow WSLH \rightarrow CDC from clinical labs



Laboratory Surveillance Plan, 2015-2016

What YOU need to know!



Influenza Surveillance in Wisconsin

<u> Multi-element approach</u>

- Rapid Influenza Diagnostic Testing (RIDT) Sites
 - >50% of Influenza testing in WI.
 - Confirmatory testing during periods of low prevalence!

WSLH can provide confirmatory testing for out-ofseason positives and the <u>first two positive influenza</u> <u>A and influenza B specimens</u>.

Influenza Surveillance in Wisconsin

<u> Multi-element approach</u>

- **2.** Enrolled Surveillance Sites
 - 18 labs in 5 public health regions.
 - Provide randomized specimens weekly.



Request to continue to submit the <u>first 3 specimens per</u> <u>week</u> with influenza test requests to WSLH.

Influenza Surveillance in Wisconsin

<u>Multi-element approach</u>

3. PCR Labs

- "Gold Standard" testing.
- Provide weekly testing data summary reports.
- 48 WI PCR labs!



Request to report both the <u>number positive</u> and the <u>number tested</u> weekly. **Send Flu A unsubtypable specimens when subtyping for both 2009 H1N1 and seasonal H3 were attempted (Ct<35).



Laboratory-based Surveillance

All Clinical Laboratories performing influenza diagnostic testing

All Labs:

•Send those with international travel histories •Sampling of influenza-related hospitalizations •Unusual presentations/results •Contact with swine/ sick or dead poultry •Antiviral treatment failure

Other Pathogens of Public Health Importance to Report



- B. pertussis/ parapertussis RSV
- Non-influenza respiratory viruses
- Grp A Strep
- VZV

Rotavirus

NEW! Gastropathogen PCR

Gastrointestinal Pathogens PCR Testing

Please report the number of specimens tested and the number positive.

| | Number Tested | Number Positive |
|---|---------------|-----------------|
| Aeromonas | | |
| Campylobacter | | |
| Clostridium difficile (Toxin A/B) | | |
| E. coli O157 | | |
| Enteroaggregative E. coli (EAEC) | | |
| Enteropathogenic E. coli (EPEC) | | |
| Enterotoxigenic E. coli (ETEC) | | |
| Plesiomonas shigelloides | | |
| Salmonella | | |
| Shiga-like toxin-producing E. coli (STEC) | | |
| Shigella | | |
| Shigella/Enteroinvasive E. coli (EIEC) | | |
| Vibrio | | |
| Vibrio cholerae | | |
| Yersinia enterocolitica | | |
| Adenovirus 40/41 | | |
| Astrovirus | | |
| Norovirus GI/GII | | |
| Rotavirus A | | |
| Sapovirus | | |
| Cryptosporidium | | |
| Cyclospora cayetanensis | | |
| Entamoeba histolytica | | |
| Giardia lamblia | | |



Reporting Lab Results

There are two options.....

1. Web-based reporting



Select the method below to enter data; you must also select "Next".

Antigen Detection

O PCR

Culture

2. FAX

| | Back | Next | | | | | | | |
|-------------------|------|---|--------------|-------------|------------------|-----------|------|-------|--|
| | 759 | 6 | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | ~ | Please FAX by noon Wednesday of each | week to: | | | | | | |
| $(\Theta \cap O)$ | Q | Erik Reisdorf or Mary Wedig, Wisconsin State Laboratory of Hygiene at 608-265-9091 | | | | | | | |
| cporting | 5 | Contact Mary Wedig (608-890-0353) or Erik Reisdorf (608-262-1021) with questions. Please report the number of specimens tested and the number of specimens positive for each <u>Sunday</u> through Saturday week throughout the year even if no specimens were tested | | | | | | | |
| | | WISCONS | SIN TESTIN | G FAX RE | PORT | | | | |
| | | Identification Number: Your Instituti | on's Name, A | ddress & Te | lephone Num | her: | | | |
| | | Tour insulation s name, Address & Telephone Number. | | | | | | | |
| | | | | | | | | | |
| | | Change of Institution Address: | | | | | | | |
| | | change of institution Address. | | | | | | | |
| | | Report For Week (Sunday through S | aturday) Er | ding: | | | | | |
| | | | Number | | Numbe | er Positi | /e | | |
| | | Rapid Testing - Virus / Bacteria | Tested | A E | uenza 3 A & B | RSV | Rota | Strep | |
| | | Influenza A and B (Differentiated) | | | | | | | |
| | | 1 result for A & 1 result for B | | | | | | | |
| | | Influenza (Type Not Known) | | | Unknown | | | | |
| | | Testing provides Tresuit, could be A or B | | | - | | | | |
| | | Dev/ | | | | | | | |
| | | RSV | | | _ | | | | |
| | | RSV Rotavirus | | | | | | | |



What is the WSLH able to provide to support participating labs?

- Specimen collection supplies.
- Specimen shippers & packaging supplies.
- NO cost specimen transport.
- Influenza confirmatory testing.
- Influenza PCR validation specimen panel.
- Weekly updated surveillance data (*B. pertussis*, *Influenza*, *RSV* & others).
- Laboratory Surveillance Reports



Laboratory-Based Surveillance Plan 2015-2016



Information, Forms and Instructions



Educational Opportunities

WCLN Regional Meeting (2015)

- Laboratory preparedness and biosafety
- P.A.C.E® approved.

LocationsDate• Rice Lake, WIOct. 13• Kimberly, WIOct. 14• Wisconsin Dells, WIOct. 16

THANK

Your participation in the Wisconsin surveillance system is **vital** to monitor for emerging novel strains with pandemic potential and other pathogens that impact community health.



WSLH Surveillance Coordinators

- Erik Reisdorf Virology Lab-Team Lead Ph: 608-262-1021
 erik.reisdorf@slh.wisc.edu
- Mary Wedig Electronic Reporting Coordinator Ph: 608-890-0353 <u>mary.wedig@slh.wisc.edu</u>