

State of Idaho
Bureau of Laboratories
2220 Old Penitentiary Rd
Boise, ID 83712-8249

Phone: 208-334-2235

Fax: 208-334-4067

E-mail: statelab@dhw.idaho.gov

Inside this issue:

Zika Virus Testing Process for Idaho 1

Timing Matters: Zika Virus Testing of Idahoans 1

Test Your Flu I.Q.! 4

Ask the CLIA Auditor 5

Influenza Submission Request 6

HIV Testing Algorithm Updates 7

Upcoming Webinars 8

Idaho Bureau of Laboratories Clinical Forum

Volume 9, Issue 3

Fall 2016

Zika Virus Testing Process for Idaho

Wendy Loumeau

From December 2015 to October 5, 2016, Idaho Bureau of Laboratories (IBL) has facilitated the testing of over 200 samples for Zika virus. As state testing capability and guidance from the Centers for Disease Control and Prevention (CDC) have evolved, state guidance to sentinel labs and providers has also changed. This article outlines Idaho's current processes and recommendations for Zika virus testing.

Zika Virus Suspected: When a patient is suspected of having Zika virus, the provider first must ensure testing is appropriate. Providers are advised to consult the current Idaho Public Health Guidance for Zika Virus Testing document located at www.epi.idaho.gov. This document details indications for testing

both persons reporting symptoms consistent with Zika virus and persons not reporting symptoms consistent with Zika virus. If testing is deemed appropriate, providers are to notify their local Public Health District or state epidemiologists.

Specimen Collection: Next, providers must collect the appropriate specimen for testing. Zika virus RNA may be detected in urine longer than serum, and new guidelines recommend that at least 1.0 mL urine and at least 1.0 mL of serum be collected for all patients for Zika virus testing.¹ Samples should be kept cold, not frozen.

Shipment to IBL: Samples must be accompanied by a completed CDC Form 50.34 for

(Continued on page 2)

Timing Matters: Zika Virus Testing of Idahoans

Idaho Division of Public Health

During December 31, 2015–August 2, 2016 the Idaho Bureau of Laboratories (IBL), Division of Public Health, logged in specimens from 127 persons for Zika virus testing. Among these persons, 81 (64%) were asymptomatic, 109 (87%) were female, and 84 (77%) of females were reported to be pregnant. As of September 26, 2016, three cases of Zika virus infection, all associated with travel to areas of active transmission outside the United States, have been reported in Idaho. Two of the cases were detected by IBL, and one

was determined positive by the Centers for Disease Control and Prevention (CDC).

In mid-April 2016, IBL implemented use of the Trioplex Real-time reverse transcriptase polymerase chain reaction (rRT-PCR) RNA amplification assay for the identification of Zika, dengue, and chikungunya viruses in serum and Zika virus in urine and amniotic

(Continued on page 2)



IDAHO DEPARTMENT OF HEALTH & WELFARE
DIVISION OF PUBLIC HEALTH

Clinical Forum
Editorial Staff

Dr. Christopher Ball
Robert Voermans
Wendy Loumeau
Amanda Bruesch
Matthew Burns
Vonnita Barton
Erin Peterson
Liz Parent

Zika Virus Testing Process for Idaho

(Continued from page 1)

Idaho, found at www.statelab.idaho.gov on the Clinical Testing page. Instructions for completing the form are also posted on the website. Samples with incomplete information on submittal forms will not be shipped for testing. Send the sample with the completed CDC Form 50.34 for Idaho to IBL (Attention: Virology Laboratory) as a Category B package in an insulated cooler with ice packs. Call 208-334-0589 to notify IBL when the shipment will arrive.

Testing: If sample type and onset date are appropriate, IBL will perform PCR testing on the sample and may forward the sample to CDC for serology (e.g., IgM antibody, PRNT)

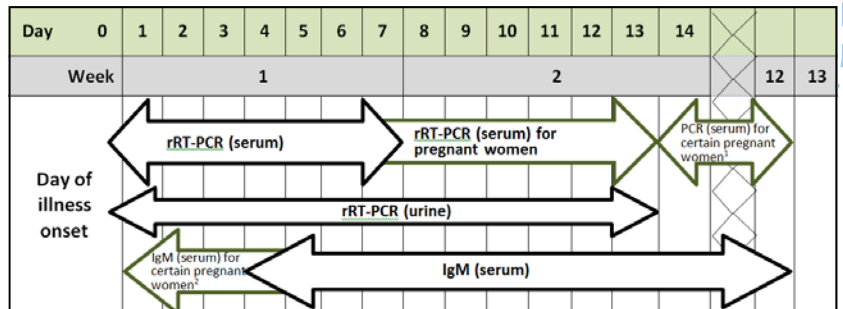
testing (Figures 1 and 2). There is currently no charge for testing by CDC or IBL. Final results are expected to be reported to the submitter listed on the submittal form within 4 weeks after specimen receipt at CDC. PCR results by IBL will be reported with a shorter turnaround time.

IBL thank its partners for continued collaboration and response with emerging diseases. This partnership maintains preparedness throughout the state.

References

¹Centers for Disease Control and Prevention. (2016). Diagnostic Tests for Zika Virus. Retrieved from <http://www.cdc.gov/zika/hc-providers/types-of-tests.html>

Figure 1. Timing of appropriate tests for Zika virus infection in persons who had compatible illness.



Timing Matters: Zika Virus Testing of Idahoans

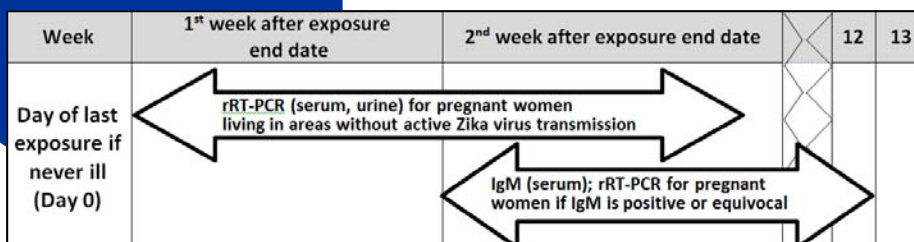
(Continued from page 1)

fluid, under an emergency use authorization (EUA) from the US Food and Drug Administration (FDA). RNA amplification assays should be requested for potentially exposed persons experiencing symptoms of Zika virus infection within the last two weeks (Figure 1). Recommendations for use of RNA

amplification assays in pregnant women were expanded on July 25.¹ Under the EUA for the Trioplex rRT-PCR, any urine sample submitted for testing MUST be accompanied by a patient-matched serum sample.² Positive results are indicative of current infection. Negative results do not rule out dengue, chikungunya, or Zika virus infections, but must be combined with clinical observation, patient history, and epidemiological information for patient management decisions. Specimens from symptomatic patients with travel history to an area with active transmission that

(Continued on page 3)

Figure 2. Timing of appropriate tests for Zika virus infection in persons with no history of acute illness.



Timing Matters: Zika Virus Testing of Idahoans

(Continued from page 2)

are negative for Zika virus by an RNA amplification assay should undergo antibody testing for Zika virus and other flaviviruses to which the patient might have been exposed³; however, because few commercial laboratories offer Zika antibody testing, the CDC has recommended ordering that the laboratory draw an additional amount of blood and retain an aliquot of the original specimen for submission to IBL for Zika antibody testing.⁴ Collection of additional samples for Zika antibody testing should be considered. Note that some commercial laboratories have initiated Zika IgM testing and are sending specimens from Idaho residents directly to CDC if additional testing is indicated per CDC testing algorithms. Please check with your commercial laboratory to determine if retained aliquots are needed.

Testing for IgM antibody to Zika virus may be offered for persons who experienced symptoms of Zika virus disease and for those who never became ill (Figures 1 and 2). If the Zika IgM enzyme-linked immunosorbent assay (ELISA) result is positive or equivocal, confirmatory testing will be done using plaque reduction neutralization (PRNT). Zika virus antibody testing for Idaho has been performed by the CDC. Because of shipping time and a high volume of samples, it can take up to 50 days for results from CDC to be finalized. IBL may be performing the Zika IgM ELISA soon; however, specimens will still be sent to CDC for PRNT. Note that as of September 26, 2016, the FDA has not issued an EUA for a test for IgG to Zika virus and CDC has not issued guidance on interpretation of Zika virus IgG test results.

In an initial evaluation of specimens received from December 31, 2015 – July 24, 2016, we observed that 34.5% of specimens submitted by Idaho healthcare providers for Zika virus testing in returning travelers were collected outside the time frames then recommended by CDC. Failure to collect specimens within the recom-

mended time frame severely diminishes the ability of the tests to detect evidence of Zika virus infection.⁵ IBL also continues to receive specimens collected from persons for whom testing is not indicated by CDC. CDC may refuse to test inappropriately collected specimens. Please consult Figures 1 and 2 and “Idaho Public Health Guidance for Zika Virus Testing” at www.epi.idaho.gov before collecting and submitting specimens for Zika virus testing. Because this document is updated as CDC guidance changes, please check to be sure you are referencing the most recent version posted online.

IBL continues to receive incomplete Zika test request forms (CDC Form 50.34 for Idaho) with patient specimens. If the test request form is incomplete, specimens will NOT be processed for testing until missing information is obtained. A local Public Health District epidemiologist will contact the provider’s office to obtain the required information, and test results will be delayed. Please ensure that staff follows instructions posted at www.epi.idaho.gov and on the IBL website www.statelab.idaho.gov to complete the Zika test request form. Required information most commonly missing is characterization of patient as asymptomatic, pregnancy status, a description of symptoms and onset date if the patient was symptomatic, history of previous flavivirus infection, and travel dates and locations.

If you have Zika testing questions, please contact IBL at (208) 334-0589, your local Public Health District, or the Bureau of Communicable Disease Prevention Epidemiology Program. See <https://www.cdc.gov/zika/hc-providers/index.html> for more information.

References

¹CDC. Update: Interim Guidance for Health Care Providers Caring for Pregnant Women with Possible Zika Virus Exposure — United States, July 2016. *MMWR Morb Mortal Wkly Rep* 2016;65:739-744. DOI: <http://dx.doi.org/10.15585/>

(Continued on page 4)

Timing Matters: Zika Virus Testing of Idahoans

(Continued from page 3)

[mmwr.mm6529e1](#).

²CDC. Diagnostic Testing of Urine Specimens for Suspected Zika Virus Infection. Distributed via the CDC Health Alert Network, May 25, 2016. CDCHAN-00389. <http://emergency.cdc.gov/han/han00389.asp>

³CDC. Revised diagnostic testing for Zika, chikungunya, and dengue viruses in US Public Health Laboratories. Memo from CDC, Division of Vector-Borne Diseases, February 7, 2016. <http://www.cdc.gov/zika/pdfs/denvchikvzikk-testing-algorithm.pdf>

⁴CDC. CDC Recommendations for Subsequent Zika IgM Antibody Testing. Distributed via the CDC Health Alert Network, June 21, 2016. CDCHAN-00392. <http://emergency.cdc.gov/han/han00392.asp>

⁵Rabe IB, Staples JE, Villanueva J, et al. Interim Guidance for Interpretation of Zika Virus Antibody Test Results. MMWR Morb Mortal Wkly Rep 2016;65. DOI: <http://dx.doi.org/10.15585/mmwr.mm6521e1>.

1. True/False: A flu vaccine can't give you the flu.
2. True/False: The "stomach flu" and influenza are the same thing.
3. True/False: Getting a flu vaccine in December or later is not too late.
4. True/False: Flu viruses change constantly which requires a new flu vaccine to be produced each year.
5. True/False: Washing your hands is the best thing you can do to protect against the flu.
6. True/False: The flu vaccine protects against three strains of flu.
7. True/False: The flu is typically spread through coughs and/or sneezes.
8. True/False: The flu is not a serious illness.
9. True/False: The flu vaccine is available as a shot or a nasal spray.
10. True/False: You can spread the flu to others before you have symptoms.

Test your Flu I.Q.!

answers on page 8

To be added or removed
from the Clinical Forum
email list:

statelab@dhw.idaho.gov

Congratulations!

Lindsey Catlin, Microbiologist Senior at Idaho Bureau of Laboratories, has been accepted into the Idaho State University School of Pharmacy. We wish her well on her new endeavors!



Ask the CLIA Auditor: Proficiency Test Referral and Satellite Facilities

Elizabeth Parent, MLS(ASCP), CG

In recent years, a number of hospital laboratories have been opening satellite laboratories or ancillary testing sites; this has resulted in the ability to provide better access to laboratory testing to patients and expansion of services. However, we have identified a compliance issue related to this change where satellite laboratories use their main laboratory's proficiency testing (PT) samples as their own. This is an unacceptable practice and can lead to regulators shutting down not only the satellite laboratory, but also the hospital or main laboratory.

Ask the Auditor will be an ongoing column for 2016 Clinical Forum issues. Email LabImprovement@dhw.idaho.gov to submit a question to the CLIA auditor. Responses may be made in a future issue of the Clinical Forum or directly to the submitter.

Brochure #8 on the Center for Medicaid and Medicare Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) website (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html) clearly spells out the rules for proficiency testing (Figure 1). First and foremost, each laboratory with a CLIA certificate and CLIA number must subscribe to and perform their own proficiency testing. Laboratories are not to share PTs between laboratories or compare results.

The confusion with the ancillary laboratories using the main laboratory's PT stems from the fact that the laboratories involved viewed their two laboratories as part of the same overall lab and continued PT testing as such. However, the laboratories are viewed by CMS and the CLIA program as two separate and distinct entities with separate CLIA ID numbers, and both must be enrolled under their separate CLIA numbers to avoid the situation presenting itself as PT referral.

The important message here is that if you manage separate laboratories with separate CLIA numbers, you must make sure that each laboratory has signed up for their own proficiency testing under their own CLIA numbers, take care regarding where the PT samples

are being shipped, and use extreme caution involving any communication about the testing or results prior to the proficiency testing deadlines.

For more information regarding proficiency testing under CLIA, access the following resources:

- 42 CFR Part 493.801 (<http://www.cdc.gov/clia/Regulatory/default.aspx>)

- CLIA Regulations on Proficiency Testing: Online Training Course, accessed at the State Lab website (www.statelab.idaho.gov), Training page, under Announcements (Figure 2)

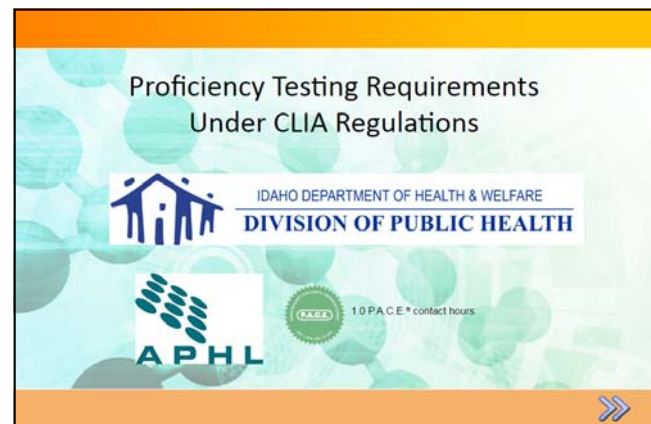
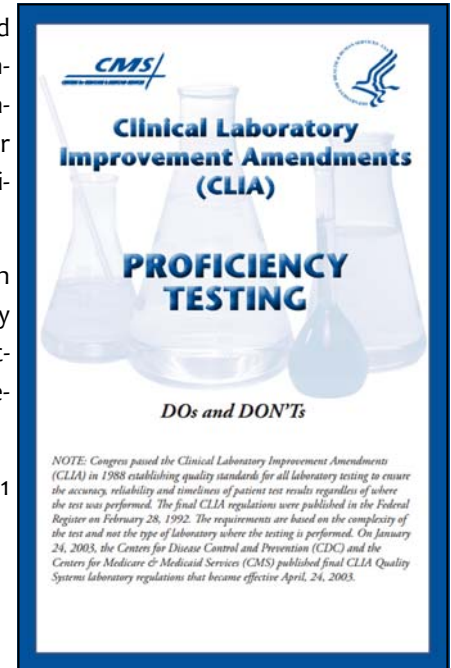


Figure 2. Idaho Bureau of Laboratories, in cooperation with the Association for Public Health Laboratories (APHL), developed an online training module on proficiency testing requirements for CLIA.

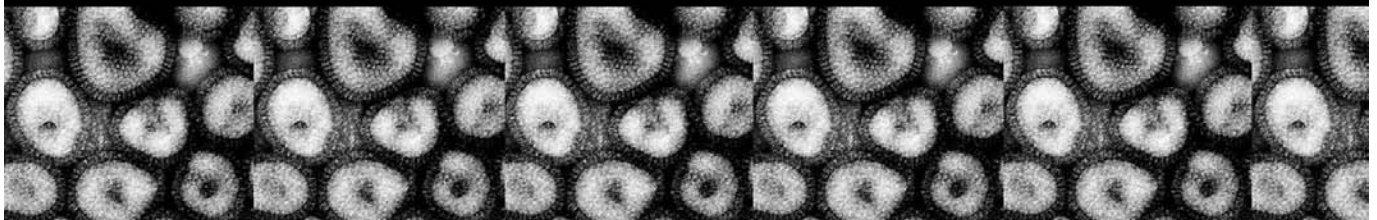
WANTED

INFLUENZA RESPIRATORY SAMPLES



REWARDS

- Partner with the Idaho Bureau of Labs to serve as a WHO influenza collaborating lab
 - Discover the Influenza A subtype or Influenza B lineage
 - Antiviral resistance testing
 - Negative Samples are further tested for other possible viruses
 - Surveillance helps formulate the vaccine



Testing is free of charge. FedEx account number available upon request.
Visit www.statelab.idaho.gov for submittal forms. Questions? 208.334.0594

HIV Testing Algorithm Updates

Vonnita Barton

In June 2014, The Centers for Disease Control and Prevention (CDC) published updated recommendations for Laboratory Testing for the Diagnosis of HIV Infection (<http://www.cdc.gov/hiv/pdf/hivtestingalgorithmrecommendation-final.pdf>), providing a recommended laboratory testing algorithm for human immunodeficiency virus (HIV). While the algorithm has not changed, diagnostic tests have evolved.

One such evolution pertains to the HIV antibody differentiation immunoassay. Currently, this assay has been performed by Idaho Bureau of Laboratories (IBL) using the Bio-Rad HIV Multispot kit for differentiation testing on samples that were repeatedly reactive by the HIV-1/HIV-2 antigen/antibody combination immunoassay (HIV Ag/Ab Combo), but this kit will be discontinued in October 2016. The HIV Multispot will be replaced by the Bio-Rad Geenius assay, a more automated and sensitive test, yet also more expensive.

Due to the higher cost of the supplemental assay and the low volume of HIV differentiation testing at IBL, IBL plans to refer samples to North Dakota's Division of Laboratory Services to provide the differentiation testing at a set fee per test. Result turnaround time may increase by one day to account for sample transit to North Dakota. Only samples that are HIV Ag/Ab Combo repeatedly reactive (i.e., positive) will be forwarded for the HIV-1/HIV-2 antibody differentiation immunoassay (Figure 1). IBL anticipates sending approximately 25 samples per year to North Dakota for antibody differentiation.

Samples that are negative or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay will be referred to the New York Department of Health, Wadsworth Center for HIV Nucleic Acid Amplification Testing (NAAT). In addition, if HIV-1 RNA is not detected, the sample is automatically reflexed to HIV-2 NAAT (not shown in Figure 1).

Please consult the HIV Sampling and Submission Guide at www.statelab.dhw.idaho.gov for details on acceptable sample types. Contact IBL at 208-334-0589 for more information about Idaho's updated HIV testing algorithm.

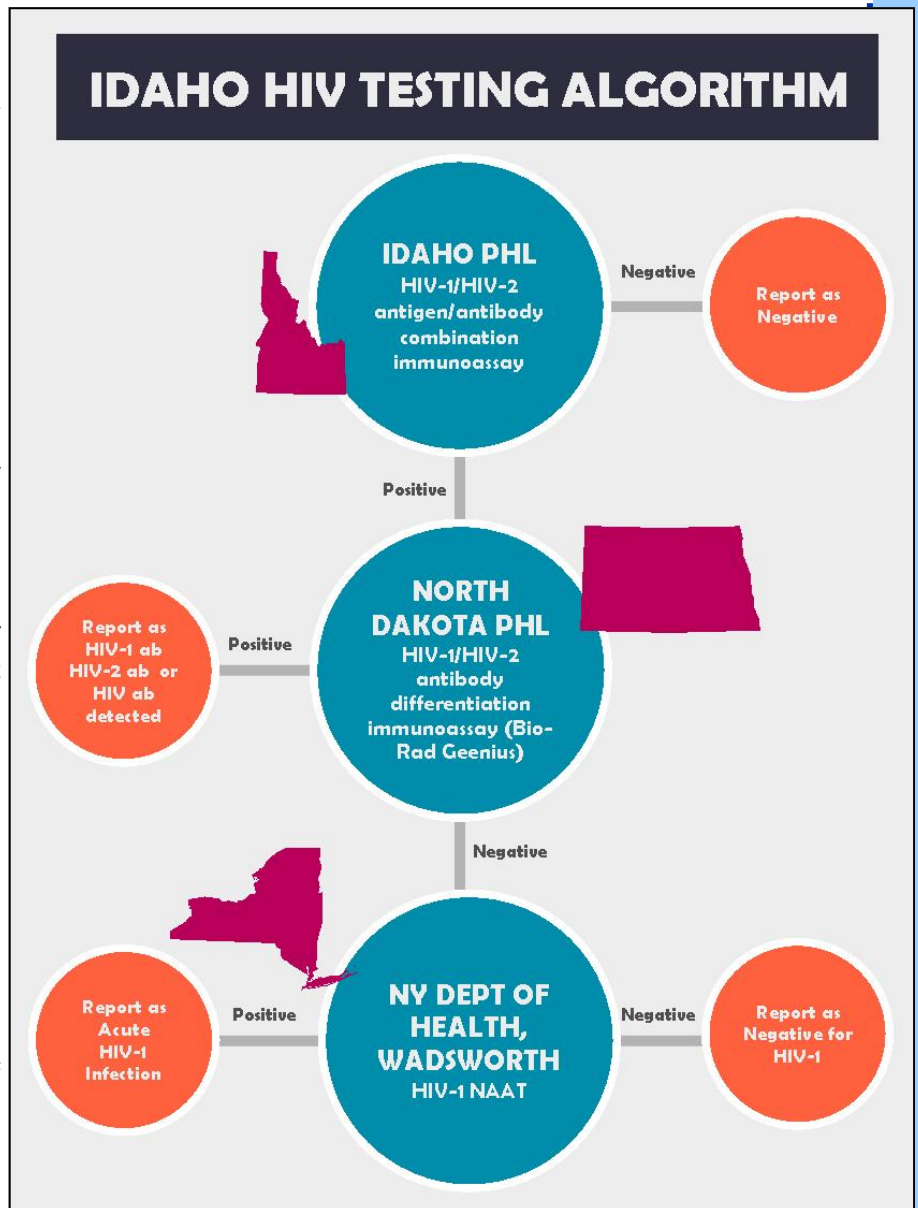


Figure 1. HIV Testing Algorithm for Idaho (PHL-Public Health Laboratory).

Answers to Test Your Flu I.Q.!

1. TRUE: The flu vaccine cannot cause flu illness. The viruses in the vaccine are either killed (flu shot) or weakened (nasal spray vaccine), which means they cannot cause infection.
2. FALSE: The flu is a respiratory (lung) disease, not a stomach or intestinal disease. The main symptoms of the flu are fever (usually high), headache, extreme tiredness, dry cough, sore throat and muscle aches. Stomach symptoms also can occur but are more common in children than adults.
3. TRUE: CDC recommends that people get vaccinated as soon as the vaccine becomes available and that vaccination continue into December, January and beyond. Influenza activity usually peaks in February most years, but disease can occur as late as May.
4. TRUE: The viruses in the vaccine change each year based on worldwide monitoring of influenza viruses.
5. FALSE: CDC recommends a flu vaccine as the first and most important step in protecting against the flu. However, preventative actions like covering your cough and washing your hands often are important everyday steps that can help stop the spread of germs.
6. TRUE: While there are many different flu viruses, the flu vaccine protects against the three main flu strains that research indicates will cause the most illness during the flu season.
7. TRUE: Flu virus is mainly spread through droplets from coughs and sneezes.
8. FALSE: Each year in the United States, on average, more than 200,000 people are hospitalized from flu complications and 36,000 people die from flu.
9. TRUE/FALSE: Flu vaccine is also available as a nasal spray (brand name FluMist®). BUT, the nasal spray vaccine should not be used during the 2016-2017 season.
10. TRUE: Most healthy adults may be able to infect others beginning 1 day before symptoms develop and up to 5 days after becoming sick. That means that you may be able to pass on the flu to someone else before you know you are sick, as well as while you are sick.

Upcoming Webinars

- October 11, 2016; 11:00 am Mountain Time
“Rapid Diagnostics: Live Streaming for Bloodstream Infections”
- October 13, 2016; 11:00 am Mountain Time
“When Things Go Wrong: Lab Management of Nonconforming Events”
- October 20, 2016; 11:00 am Mountain Time
“Update on CDC’s Advanced Molecular Detection Initiative”
- October 25, 2016; 11:00 am Mountain Time
“2016 Influenza Update”
- November 1, 2016; 11:00 am Mountain Time
“New Drugs, New Tests, Practical Approaches in New Antimicrobials”
- November 9, 2016; 11:00 am Mountain Time
“MALDI-TOF and MicrobeNet: Enhancing the Clinical and Public Health Laboratory”
- November 10, 2016; 11:00 am Mountain Time
“Vaccine Preventable Diseases—Role of Prevention and Early Detection”

Contact Wendy Loumeau at
loumeauw@dhw.idaho.gov to register.

Questions for Test Your Flu I.Q.! from CDC’s Flu I.Q. widget: <http://www.cdc.gov/flu/fluiq.htm>. The Flu I.Q. widget is an interactive quiz to test your flu knowledge. Place the Flu I.Q. Widget on your Web site, portal home page or on your blog to help others raise their flu I.Q. too!