

## Investigation into Infection Control Breach at Physician's Office, Henderson, NV

### Current Situation

A recent investigation by the Nevada Board of Medical Examiners and the Food and Drug Administration Office of Criminal Investigation found that Dr. Michael Kaplan, urologist, reused endocavity needle guides, which are single-use-only medical devices, while performing some medical procedures to diagnose and treat prostate disease. Staff attempted to clean and disinfect the needle guides prior to reusing them, but these needle guides were not designed or intended to be reused. Patients who had the following procedures – prostate biopsy, VISICOIL™ implantable markers, or gold seed radiation implants between the dates of December 20, 2010 and March 11, 2011 at Dr. Kaplan's office located at 4 Sunset Way, Henderson, NV, may have been exposed to reused needle guides.

Based on the findings of the investigation, the Nevada Board of Medical Examiners suspended Dr. Kaplan's medical license indefinitely on March 14, and he is not able to practice medicine. The practice of reusing the needle guides at his office has stopped. However, the doctor's office is currently open for patients to gather their medical records. At this time we are not aware of any other procedures conducted by Dr. Kaplan that may have put patients at risk.

It is important to note that we have not identified any cases of disease related to this investigation. Based on similar incidents that have occurred in other states, the risk of contracting a disease is believed to be very low.

### Recommendations

As a precaution, we recommend that any patient who underwent any of these three procedures at Dr. Kaplan's office during this timeframe be tested for hepatitis C virus, hepatitis B virus, and human immunodeficiency virus (HIV). We are recommending that patients contact their personal physician to review their medical history for previous infection and arrange testing for the hepatitis B virus, the hepatitis C virus and the human immunodeficiency virus (HIV) as appropriate. We also recommend that patients get tested now and then get retested 6 months after the date of their medical procedure(s).

### Laboratory Testing

Testing for hepatitis C and hepatitis B and HIV is done through a simple blood test. For hepatitis C, an initial screening test is performed. If the initial test is positive, then, a second, more sensitive and accurate test is recommended. Depending on the testing laboratory, the second test may require that another sample of blood be collected and tested. The specific laboratory tests that need to be ordered by the physician are listed in the tables on page 2. Physicians should consult with the testing laboratory to identify appropriate test codes to use to ensure that positive test results are reflexed as recommended.

While physicians may order other test combinations, there are drawbacks to deviating from the recommended algorithm:

1. Ordering acute or comprehensive hepatitis panels on asymptomatic persons slows down the testing process, is more expensive, and does not include the HIV test.
2. Ordering individual tests on asymptomatic persons without custom coding or tests not in the algorithm may lead to false positive results or lack of reflex testing.

Updated technical bulletins will be provided as new information is received and/or the investigation finds the potential for wider exposure. Physicians also are recommended to review their office's infection control practices and ensure they follow current standards recommended by the Centers for Disease Control and Prevention (CDC) and other nationally recognized healthcare agencies and professional associations. Listed below are internet links to resources to assist you in your infection control and patient safety efforts:

Nevada State Needle Guide Technical Bulletin: [http://health.nv.gov/Epidemiology/2011-03\\_NeedleGuideTechnicalBulletin.pdf](http://health.nv.gov/Epidemiology/2011-03_NeedleGuideTechnicalBulletin.pdf)

One & Only Campaign: <http://www.oneandonlycampaign.org/media/default.aspx>

CDC Healthcare Associated Infections website: <http://www.cdc.gov/hai/>

Article on Needle Guides: <http://www.ncbi.nlm.nih.gov/pubmed/18400273>

**Table 1. Recommended Initial and reflex laboratory testing**

Test Name	Description	Synonyms	Reflex testing for positives
Hepatitis B surface antigen	Serologic marker on the surface of Hepatitis B virus. Presence indicates person is infectious.	HBsAg; HBV surface antigen	No reflex for positive
Hepatitis B surface antibody, qualitative	Antibody to Hepatitis B surface antigen. Presence indicates recovery and immunity from Hepatitis B infection.	Anti-HBs; HBV surface antibody	No reflex for positive
Hepatitis B Core Antibody, Total	Antibody to Hepatitis B core antigen, total IgG and IgM. Nonspecific marker of acute, chronic, or resolved Hepatitis B infection. It is not a marker of vaccine induced immunity	Anti-HBc(total); HBV Core Total Antibody; HBcAb, Total	Request that positives reflex to Hepatitis B Core antibody, IgM
Hepatitis C Antibody	Antibody to Hepatitis C virus. Screening immunoassay method.	HCV Ab; Anti-HCV; HCV; Hep C	Request that positives reflex to HCV RNA. Depending on the testing laboratory, this may require recollection of an additional sample for HCV RNA testing.
HIV 1 or HIV 1/2	Antibody to Human Immunodeficiency virus. Immunoassay method with reflex to Western Blot for all positives	HIV1/2 EIA Antibody screen; HIV-1; HIV-1/O/2	Request that positives reflex to HIV-1 Western Blot

**Table 2. Quest test codes**

Quest Diagnostics Laboratory has developed a custom panel for clients located in Nevada which will include all tests listed in the recommended initial and reflex testing table. The custom panel test code #9000E must be written on the test requisition form to ensure that the appropriate initial and reflex testing is performed.

Quest panel test code	Test Name	Reflex testing
9000E	Hepatitis B surface antigen Hepatitis B surface antibody, qualitative Hepatitis B Core Antibody, Total Hepatitis C Antibody HIV 1/2 EIA Antibody Screen with reflexes	Reflex testing for positives will automatically occur based on the tests listed in Table 1 if the panel test code is ordered initially. Follow up testing for HCV RNA will require recollection of an additional sample.