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Technical Bulletin April 18, 2008

Hepatitis C Investigation Update #1

Current situation

The Southern Nevada Health District (SNHD) is still recommending testing for hepatitis C, hepatitis B, and HIV for patients who received injected anesthesia medication at the Endoscopy Center of Southern Nevada (700 Shadow Lane, Suite 165B) between March of 2004 and January 11, 2008. At this time, the health district is not recommending testing of patients who have had procedures at other clinics. As of April 18, 2008, SNHD has not been able to access records from other clinics to determine if further notifications are warranted.

Since February 27, 2008, over 20,000 samples have been analyzed for Southern Nevada residents who may have been exposed to hepatitis C virus (HCV), hepatitis B virus (HBV) or HIV due to unsafe injection practices at the Endoscopy Center of Southern Nevada. Testing of large numbers of asymptomatic persons may result in false positive test results. The initial testing algorithm outlined in the technical bulletin distributed on February 27th (http://www.southernnevadahealthdistrict.org/physician/download/tb-hepc-022708.pdf), was recommended by the CDC and SNHD for investigational purposes in order to minimize the number of false positive test results and to allow laboratories to rapidly screen a large number of samples using an initial three (3) test panel. The testing algorithm is intended to identify persons who have been exposed to hepatitis B, hepatitis C and/or HIV. Persons with positive tests will need to follow-up with their primary care provider for any additional diagnostic testing needed

The current HBV serologic testing algorithm was developed to meet the urgent and fast-breaking needs of the southern Nevada outbreak investigation. This algorithm will identify individuals with current acute and chronic infections. It also will identify individuals infected in the past, but with resolved infections of no clinical significance. However, it will not yield information about the timing or source of infection for individuals previously infected, but with resolved infections.

NOTE: this testing algorithm differs from current CDC guidelines, which is to first test with HBsAg, with follow-up testing as indicated. [See *"A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults"* at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5516a1.htm?s_cid=rr5516a1_e

Test Ordering

Many physicians are following the recommended testing algorithm and ordering the custom panel of tests provided by LabCorp, Quest, or Clinical Pathology Laboratories. However, the laboratories are receiving significant numbers of test orders that do not follow the testing algorithm. 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

Table 1 lists the initial recommended testing panel, while Tables 2-4 list the corresponding LabCorp, Quest and Clinical Pathology Laboratories test codes.

To assist with testing follow-up, and to ensure appropriate reflex testing occurs, LabCorp (Table 2), Quest (Table 3) and Clinical Pathology Laboratories (Table 4) will provide custom panels and tests for clients located in Nevada.

Hepatitis C Serology Interpretations

The "Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus" published by CDC in MMWR, February 7, 2003, 52 (RR03):1-16 provides recommendations for use of the signal-to-cutoff ratio (s/co) of positive HCV screening test results to identify samples which would require additional supplemental testing. The recommended s/co

Table 1 Initial and reflex laboratory testing

Test Name	Description	Synonyms	Reflex testing for positives
HBcAb, 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.	Hepatitis B Core Antibody, Total; Anti-HBc (total); HBV Core Total Antibody	Positives reflex to Hepatitis B core antibody, IgM and Hepatitis B surface antigen
HCV Ab	Antibody to Hepatitis C Virus. Screening immunoassay method with signal-to-cutoff ratio (s/co) reported	Hepatitis C Antibody; Anti-HCV; HCV; Hep C	Positives with low s/co ratio reflex to RIBA, anti HCV
HIV 1 or HIV 1/2	Antibody to Human Immunodeficiency Virus. Immunoassay method with reflex to Western Blot for all positives	HIV 1/2 EIA Antibody Screen; HIV-1; HIV-1/O/2	Positives reflex to HIV-1 Western Blot

Table 2. Labcorp Test Codes

Order the panel below which will include both initial and reflex testing

Labcorp Panel code	Initial testing includes	Reflex testing
344053	Hepatitis B Core Antibody, total (006718) Hepatitis C Antibody (143991) HIV-1/O/2 (083824)	Reflex testing for positives will automatically occur based on the tests listed in Table 1

Table 3. Quest test codes

Order the individual Hepatitis custom codes and HIV test code listed below. The Hepatitis custom codes must be written on the test requisition form to ensure the appropriate reflex testing occurs

Quest test code	Description	Reflex testing
7040E	Hepatitis B Core Antibody, Total	Reflex testing for positives will automatically occur based on the tests listed in Table 1, only if custom test codes are ordered
1590E	Hepatitis C Antibody (HCV)	
3200	HIV1/2 EIA Antibody Screen with reflexes	

Table 4. Clinical Pathology Laboratories (CPL) Test Codes

CPL Panel code	Initial testing includes	Reflex testing
9327	Hepatitis B Core Antibody, total (2730) Hepatitis C Antibody (4647) HIV1 & 2 EIA Antibody Screen (3540)	Reflex testing for positives will automatically occur based on the tests listed in Table 1

ratio will vary depending on the testing equipment used. Contact the reference laboratory for details regarding the supplemental testing performed at their facility. If the custom panels and tests are ordered, the reflex testing for HCV will occur as recommended by CDC in the MMWR cited above. These recommendations include:

- HCV antibody positive screening test results with high s/co ratios can be considered anti-HCV positive without supplemental testing.
- HCV antibody positive screening test results with low s/co ratios should have supplemental testing performed, preferably by Recombinant Immunoblot Assay (RIBA) for HCV antibody.
- If Nucleic Acid Test (NAT) for HCV RNA is performed, CDC recommends RIBA follow up for a negative NAT.

Hepatitis B Serology Interpretations

The initial recommended test for HBV, total hepatitis B core antibody, is a non-specific marker of acute, chronic or resolved hepatitis B. If the custom panel or test codes are ordered, a positive test will reflex to hepatitis B core antibody IgM and hepatitis B surface antigen. These tests will assist the physician in distinguishing current from past infection and acute from chronic infection. Some physicians are ordering an additional test, Hepatitis B surface antibody (anti-HBs). This test is typically used to evaluate Hepatitis B immunity and may not provide useful information for this investigation.

Table 5, which provides guidance for interpretation of Hepatitis B panels is adapted from a CDC table. Reference: http://www.cdc.gov/ncidod/diseases/hepatitis/b/Bserology.htm

Definitions:

Hepatitis B Surface Antigen (HBsAg): A serologic marker on the surface of HBV. It can be detected in high levels in serum during acute or chronic hepatitis. The presence of HBsAg indicates that the person is infectious.

Hepatitis B Surface Antibody (anti-HBs): The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.

Total Hepatitis B Core Antibody (anti-HBc): Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus (HBV) in an undefined time frame.

IgM Antibody to Hepatitis B Core Antigen (IgM anti-HBc): This antibody appears during acute or recent HBV infection and is present for about 6 months.

Patient Resources

Individuals who have potentially been exposed as a result of the unsafe injection practices at the Endoscopy Center of Southern Nevada have many questions and needs that are outside the scope of the routine physician/patient relationship. To assist these residents, SNHD has developed a list of resources on the health district website at http://www.southernnevadahealthdistrict.org/outbreaks/hepc-patients.htm. Among the informational items included here are clinical and laboratory services, support groups, fact sheets, and a form for requesting medical records from the Endoscopy Center through the Las Vegas Metropolitan Police Department.

Table 5. Interpretation of the Hepatitis B Panel

Tests	Results	Interpretation	Action
HBsAg anti-HBc	negative negative	Not infected	No action
HBsAg anti-HBc IgM anti-HBc	negative positive negative	Previous infection at undefined time	No action
HBsAg anti-HBc IgM anti-HBc	positive positive positive	Acutely Infected	Report to SNHD Evaluation and follow up
HBsAg anti-HBc IgM anti-HBc	positive positive negative	Chronically infected	Report to SNHD Evaluation and follow up
Pathology consultation from the reference laboratory is available to assist with interpretation or follow-up testing.			