Tanta University
College of Pharmacy
Drug Information
and Poison Control
Center

Drug & Poison Information Bulletin

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Hepatitis C Virus Remains Infective for 6 Weeks on Fomites

Drops of hepatitis C virus (HCV) dry and remain infective for 6 weeks at room temperature . Therefore, fomites may be a source of nosocomial HCV infections. The persistence of the virus on fomites may also underlie the continued high incidence of HCV infection among people who inject drugs .

Source :www.medscape.

INSIDE THIS ISSUE:

Medical & Pharmaceutical News

Prostate Cancer Foundation announces new urine test for prostate

A new urine test for prostate cancer that measures minute fragments of RNA is now commercially available to men nationwide through the University of Michigan MLabs. The new test " ***Mi-Prostate Score (MiPS)*** " improves the utility of the PSA blood test, increases physicians' ability to pick out high-risk prostate tumors from low-risk tumors in patients, and may help men avoid unnecessary biopsies.

The ***MiPS*** test incorporates blood PSA levels and two molecular RNA markers specific for prostate cancer in one final score that provides men and their doctors with a personalized prostate-cancer risk assessment.

The PSA test is a non-specific test for prostate cancer. That is, non-cancerous conditions such as an enlarged or inflamed prostate can cause elevations in PSA levels and even when PSA levels rise above what has routinely been considered a trigger level (4.1 ng/ml in the blood) indicating the need for a needle biopsy to check prostate tissue for signs of cancer, less than half of those biopsies find cancerous cells.

The limited reliability of the PSA test, and its lack of specificity for prostate cancer has led to sharp disagreement over the use of the PSA test as a routine health screening measure for men of a certain age. To date there are no perfect biomarkers that identify only high-risk prostate cancer. But each year progress is made toward such a goal.

Today, the University of Michigan's Department of Pathology MLabs will begin offering the ***MiPS*** urine test that is ultra specific for prostate cancer. The ***MiPS*** test scans urine samples for two molecular markers that are distinct to prostate cancer. One marker is a snippet of RNA made from a gene ***(PCA3)*** that is overactive in 95 percent of all prostate cancers. The second marker is RNA that is made only when two genes ***(TMPRSS2 and ERG)*** abnormally fuse. The presence of this fusion RNA in a man's urine is ultra specific for prostate cancer.

A commercial urine test (PROGENSA PCA3) for ***PCA3***, developed and marketed by the California-based biotech company Gen-Probe, gained FDA approval in 2012 for use in men who are considering repeat biopsy after an initially negative result.

Source: www.breakthroughdigest.com. September, 2013

Medical Safety Updates

FDA issues warning on acetaminophen-associated skin reactions

The US Food and Drug Administration (FDA) issued a safety announcement in August 2013 advising that anyone who has a skin reaction, such as the development of a rash or blister, while taking Acetaminophen should stop using the drug and seek immediate medical care ; owing to the risk of 3 rare, but potentially fatal, skin disorders which are ***Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalized exanthematous pustulosis .***

The FDA issued its warning following a review of medical literature and of cases of adverse reactions reported to the FDA (Adverse Event Reporting System database) .

This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to choose other medications, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects which are potentially fatal.

Other drugs used to treat fever and pain, such as nonsteroidal anti-inflammatory drugs including Ibuprofen and Naproxen, already carry warnings about the risk of serious skin reactions.

FDA is requiring that a warning about these skin reactions be added to the labels of all prescription medicines containing Acetaminophen. FDA will work with manufacturers to get the warnings added to the labels of over-the-counter (OTC) medicines containing Acetaminophen.

Source : www. fda.gov. August, 2013

Taking Acid Inhibitors Long-term May Lead to B12 Deficiency

Use of acid-inhibiting medications for two or more years may lead to vitamin B_{12} deficiency, especially among women and younger individuals who take stronger doses, according to a study published in the December 11 issue of ***Journal of the American Medical Association*** *(JAMA).*

Vitamin B_{12} deficiency may lead to irreversible neurological damage and other complications if left untreated for a long period.

The researchers evaluated whether the long-term use of Proton pump inhibitors (PPIs) or Histamine 2 receptor antagonists (H_2RAs) was associated with vitamin B_{12} deficiency.

The study revealed that; the higher the dose, the stronger the association and this interaction diminished after PPIs were discontinued , and which lead them to the following conclusion: acid required to separate B_{12} from food protein, the first step in absorption, which takes place in the stomach. Once you knock off that acid, you have knocked off the essential first step required for B_{12} absorption.

Source : Journal of the American Medical Association JAMA. **2013;310:2435-2442. December, 2013**

Pharmaceutical Authoritised News

Sovaldi (sofosbuvir)

Company: Gilead Sciences

Approval status: Approved December 2013.

A new hepatitis C drug that can be taken as a pill once a day. **Sovaldi** is specifically indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. Sovaldi (sofosbuvir) is a nucleotide analog inhibitor of HCV NS5B polymerase. Sofosbuvir is a nucleotide prodrug that undergoes intracellular metabolism to form the pharmacologically active uridine analog triphosphate (GS-461203), which can be incorporated into HCV RNA by the NS5B polymerase and acts as a chain terminator.

Current treatments can take almost a year to beat back the virus, and involve weekly injections of the drug Interferon, which can cause diarrhea and flu-like symptoms, the FDA said. Only about 75 percent of patients are cured with current treatments. In clinical trials, Sovaldi cured close to 90 percent of patients in just 12 weeks, when combined with the standard treatment. Sovaldi is supplied as a tablet for oral administration. The recommended dose is one 400 mg tablet taken once daily with or without food.

Sovaldi should be used in combination with Ribavirin or in combination with Pegylated interferon and Ribavirin. Recommended combination therapy and duration is as follows:
Genotype 1 or 4: Sovaldi + Peginterferon alpha + Ribavirin for 12 weeks
Genotype 2: Sovaldi + Ribavirin for 12 weeks
Genotype 3: Sovaldi + Ribavirin for 24 weeks.

Source: U.S. Food and Drug Administration, news release. December, 2013.

Sitavig (acyclovir) buccal tablets

Company: BioAlliance Pharma

Approval Status: Approved April 2013

Sitavig (acyclovir) is an antiviral buccal tablet formulated on the company's proprietary Lauriad mucoadhesive technology. Sitavig is specifically indicated for the treatment of recurrent herpes labialis in immunocompetent adults. Sitavig is supplied as a tablet for oral administration. One Sitavig 50 mg buccal tablet should be applied as a single dose to the upper gum region and held in place with a slight pressure over the upper lip for 30 seconds to ensure adhesion. The tablet should be applied within one hour after the onset of symptoms and before the appearance of any signs of herpes labialis lesions.

Source: www.centerwatch.com.

New Research

New research reveals novel way to develop anti-diarrheal drugs

New gastroenterology research carried out by the RCSI (Royal College of Surgeons in Ireland) in conjunction with Trinity College Dublin and Johns Hopkins University in Baltimore, Maryland has uncovered a new route for the development of anti-diarrheal drugs. The research found that drugs which act on a protein called **Farnesoid X Receptor (FXR)** in the tissue of the intestine can stop water moving in to the gut. By switching off the water movement in to the gut, this can prevent diarrhea occurring, because of this they may have broader efficacy and fewer side effects than many anti-diarrheal currently available on the market.

Source: Royal College of Surgeons in Ireland . December, 2013

Upcoming Conferences

- Egyptian Society Of Cardiology 41st Annual Conference 2014 **24 Feb** 2014 to **27 Feb** 2014, Heliopolis.
- German Society of Dermatology Compact 2014 from **28 Feb** 2014 to **01 Mar** 2014, Hamburg.
- American Academy of Allergy, Asthma and Immunology Annual Meeting 2014 from **28 Feb** 2014 to **04 Mar** 2014, San Diego.
- Jeddah Dermatology and Cosmetics Conference 2014 from **03 Mar** 2014 to **06 Mar** 2014, Jeddah.
- 22nd European Congress of Psychiatry 2014 **01 Mar** 2014 to **04 Mar** 2014, Munich.

Editorial Board

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