



**UMassMemorial**

*Laboratories*

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# ***Lab Updates***

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## **December 2006/January 2007**

### **CHANGES IN HCV GENOTYPING TESTING**

As of January, 10, 2007, the HCV Genotype assay will be performed in the UMass Memorial Molecular Diagnostics Laboratory. The methodology is VERSANT HCV Genotype 2.0 Assay (LiPA). Two regions, 5' UTR and core region of HCV RNA which are specific for different genotypes are amplified by Reverse Transcriptase Polymerase Chain Reaction (RT-PCR). Biotinylated products hybridize to oligonucleotide probes which are immobilized to a nitrocellulose strip. The banding pattern is developed by chromogenic reaction and analyzed using LiPA Scan software.

Genotyping and subtyping: Genotypes and subtypes of Hepatitis C Virus that can be detected by this method include: 1, 1a, 1b, 2, 2a, 2b, 2c, 3, 3a, 3b, 3c, 3k, 4, 4a/4c/4d, 4b, 4e, 4f, 4h, 5a, and 6a/6b. The assay will be performed once a week and turnaround time will be 5-8 days. The look of the reports will change slightly and will indicate that the testing was performed using VERSANT HCV Genotype 2.0 Assay (LiPA), Bayer HealthCare, Diagnostics Division.

If you have further questions please contact:

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### **REFERENCE RANGE CHANGES**

Effective December 13, 2006, please note the following changes:

<b>Test</b>	<b>Current Reference Range</b>	<b>New Reference Range</b>
Protein C	70 – 180%	70 – 140%
Factor VIII	60 – 150%	70 – 150%

## LABORATORY CONFIRMATION OF PERTUSSIS INFECTION

In an effort to clarify for clinicians the best testing approach for the diagnosis of Pertussis infection we are providing the following summary. Please note that the Massachusetts State lab does not accept serology testing from other laboratories as a confirmation of disease.

*Bordetella pertussis* infection (Pertussis, Whooping Cough) is an acute, highly contagious disease. It is characterized clinically by a severe and prolonged cough. Coughing fits may be paroxysmal and, usually in infants, followed by an inspirational “whoop”. Because of the contagiousness of the infection, specific laboratory testing may be needed to confirm the diagnosis when pertussis is suspected clinically.

The CDC currently recognizes three tests for the confirmation of clinical cases of pertussis (See: MMWR Dec 23, 2005/Vol. 54/No. 50.): 1) Isolation of *B. pertussis* by culture; 2) a positive result in a *B. pertussis* specific PCR testing; 3) a positive serology result performed by the Massachusetts State Laboratory. (**Note:** Neither the CDC nor the Massachusetts Department of Public Health recognize *B. pertussis* serological test results from other laboratories as confirmatory for pertussis infection.) The choice of assay for confirmatory testing depends on the age of the patient and the phase of illness as described below.

**Culture:** Isolation of *B. pertussis* by culture of nasopharyngeal secretions is diagnostic of pertussis because of its high specificity. Negative cultures, however, are common. The sensitivity of culture decreases with the increasing time after onset of symptoms and the yield of culture is very low after two weeks of symptoms. Special *B. pertussis* cultures are performed by the UMass Memorial Microbiology Laboratory; collection kits are available from the lab. *B. pertussis* culture is recommended for confirmation of pertussis infection for patients with symptoms < 2 weeks.

**PCR:** *B. pertussis* specific PCR is also confirmatory for patients with a clinical case definition of pertussis. *B. pertussis* PCR is performed by the Massachusetts State Laboratory. Testing requires completion of the State Lab Specimen Submission Form (available through Customer Service). The collection kit for pertussis culture also has materials and instructions for the PCR test. *B. pertussis* PCR is recommended for confirmation of pertussis infection for patients with symptoms < 2 weeks.

**Serology:** There are as yet no FDA approved serologic test kits available for pertussis. However, the Massachusetts State Laboratory offers a single-specimen serology test to confirm pertussis that is accepted by the CDC. The assay measures IgG antibody to pertussis toxin. The test results are not interpretable in children younger than 11 years old because of interference due to persistent antibody formed by childhood vaccination. In individuals older than 11 years, however, a positive result for the State Laboratory *B. pertussis* Serology test indicates acute or recent pertussis. Antibody levels do not exceed the high threshold of the assay until at least two weeks after the onset of symptoms. A State Lab Specimen Submission Form is required for testing. *B. pertussis* serology testing, performed at the State Laboratory, is recommended in patients older than 11 years with onset of symptoms < 2 weeks prior to specimen collection.

**Note:** Neither IgA nor IgM antibodies have been shown to be protective against *Bordetella pertussis*. UMass Memorial Laboratories does not recommend ordering these assays to confirm a clinical diagnosis of pertussis or to assess for susceptibility/immunity to pertussis.

For any further questions or comments, please contact:  
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