



# QUALITY UPDATE

A regular publication providing information and updates to CompuNet Clients  
Mission: To provide excellence in medical laboratory testing to our community.

Volume 15. Issue 1    Editor: Mark Shearer (937) 297-8236 [mark.l.shearer@questdiagnostics.com](mailto:mark.l.shearer@questdiagnostics.com)    January 2008

## In this Issue

Virology Advancements	1
HPV Testing	2
Website Redesigned	3
Samples and Cold weather	4

## *Important Advances in Virology Department*

As the clinical importance for a rapid viral diagnosis grows, our virology lab has adapted to meet the needs of our clients. This season, CompuNet has instituted major changes that will benefit physicians seeking to determine etiology of disease and initiate a patient's treatment within a shorter window of time.

Prior to this season, CompuNet used conventional cell culture techniques, which required up to 14 (and sometimes 20) days of incubation before a final result could be reported. This fall, CompuNet has elected to adapt newer methodologies that will result in faster turn-around-times, while ensuring a high degree of sensitivity and specificity. As a result:

- *Final culture result can be reported in as little as 48 hours, as opposed to 14 days.*
- *Clients will receive 1) a preliminary report and 2) a final report, thereby eliminating extra charting.*
- Collection and ordering of specimens does not change, however, the specimen source must be stated on the requisition, or specimens cannot be processed. Including the specimen source will eliminate the need for us to call to your practice.

As an ongoing process, CompuNet Clinical Laboratories strives to better serve our clients and communities. Our goal is to continuously offer you, our client, the latest advances in laboratory medicine and help to ensure the health of your patients.

Your CompuNet sales representative can discuss the recent Virology changes and advantages or you may contact:  
Ted Schutzbank, Ph.D., (937) 290-7326 or  
Charlene Jarvis, Technical Specialist Virology (937) 297-8338.

## ***Human Papillomavirus Testing at CompuNet – An Update***

***by Ted Schutzbank, Ph.D.***

The family of viruses known as Human Papillomavirus (HPV) consists of more than 100 types. Those that have been shown to be causative agents of cervical cancer are referred to as “high-risk” strains. Current guidelines recommend testing women with a cytological diagnosis of atypical squamous cells of undetermined significance (ASCUS) for infection by high-risk types of HPV (1,2). In addition, HPV testing has been found to have higher sensitivity than PAP testing for detecting high-grade cervical intraepithelial neoplasia (CIN) (3, 4). Based on these studies, high-risk HPV testing is now often performed in women over 30 years of age in addition to PAP tests. To date, only the Digene Hybrid Capture-2 assay (HC-2) has been available to clinical diagnostic laboratories, such as CompuNet, for the detection of high-risk strains of HPV, as an ASCUS triage for referral to colposcopy, and in conjunction with cervical cytology as a primary screen for cervical cancer. This past year, the Molecular Diagnostics Laboratory at CompuNet conducted a study comparing an HPV detection methodology, based on proprietary Invader® technology from Third Wave Technologies Inc. (TWT), with the Digene HC-2 assay. We performed both HPV detection assays on a total of 87 cervical brushings in Cytoc ThinPrep media, obtained from women with cytological findings of ASCUS. The results were as follows: 37 patients tested positive by both the HC-2 and the TWT methods. There were 15 patients that had positive results with the HC-2 assay but were negative for HPV using the TWT method. Lastly one patient tested positive by the TWT assay, which was negative by HC-2. In order to sort out the discordant results, samples of the ThinPrep fluid corresponding to those patients were submitted to a referee laboratory for analysis by Polymerase Chain Reaction

(PCR) amplification analysis. Each sample was tested using PCR targeted to different segments of the HPV DNA genome; both PCR reactions had to be positive for a specimen to be considered positive. Additionally, the HPV DNA molecules resulting from the PCR analysis were sequenced to determine if the detected virus was a high-risk versus a low-risk type. Only 12 of the 16 discordant samples had sufficient material remaining for this analysis; the results are shown in Table 1.

The sole TWT positive, HC-2 negative result was confirmed as positive, and was typed as a high-risk, HPV type 51. All of the remaining samples that were TWT negative, but HC-2 positive turned out to either be negative by both PCR tests (4/11), or found to be positive with low-risk types of HPV (7/11). The high degree of cross reactivity of the Digene HC-2 assay with low-risk HPV types has been demonstrated in several studies conducted over the past several years (6).

As previously stated, the findings of several large-scale studies have clearly demonstrated that HPV testing is more sensitive for detecting high grade CIN than pap smears alone. Based on these studies, it has been proposed that HPV screening be performed on all women over the age of 30, in addition to PAP testing (5). Colposcopic examination is the standard follow-up for women with abnormal cytological findings, to include ASCUS combined with a positive HPV result. Based on the results from the Digene HC-2 testing, colposcopy would have been performed inappropriately on at least 11 of the 87 women included in this study. With most screening assays, (e.g., HIV and HCV testing), positive results are confirmed with a secondary method with high specificity. Unfortunately no such confirmatory assays are currently available for HPV testing. Therefore, if HPV DNA testing is to be performed as an addition to PAP testing,

*Continued on page 3*

*Continued from page 2*

the specificity of the HPV test becomes of critical importance to ensure that women are not subjected to a needless invasive procedure, in addition to being told erroneously that they have been infected with a sexually transmitted virus. Our results clearly demonstrate the TWT Invader® HPV methodology is suitable for use as a companion to PAP testing. In the limited number of patients tested utilizing this assay, there were no false positive or false negative results. These results have been published in the December, 2007 issue of the *Journal of Clinical Microbiology* (7).

CompuNet strongly believes that we must employ the most up-to-date technologies available to ensure the highest degree of accuracy of the test results that you use to treat and manage your patients. Therefore, we will be switching to the Third Wave Technologies HPV testing methodology, beginning February 1, 2008. We must point out that the TWT HPV assay has not yet been submitted to the Food and Drug Administration (FDA) for approval. It is expected that such a submission will happen in the early part of 2008; the review process for this type of test typically takes 9 – 12 months. However, CompuNet does not expect any issues with reimbursement by either Medicare or Medicaid, or by any of the private health insurance carriers. The TWT HPV method is now utilized by over 30 laboratories across the country, with no reported reimbursement issues. The same CPT code, **87621**, used for billing the Digene HC-2 assay, is also utilized for the TWT method. We recognize that representatives from Digene may be visiting your office to discuss our decision to switch HPV testing methods with you and your staff. Should you have any questions regarding their comments please feel free to contact me by telephone at (937) 290-7326, or by email at [ted.e.schutzbank@questdiagnostics.com](mailto:ted.e.schutzbank@questdiagnostics.com).

## ***CompuNet Launches Redesigned Website by Kim Stanforth, Marketing***

To better serve our clients and patients, CompuNet has launched a redesigned website, <http://www.compunetlab.com>. The new site, which went “live” in September, is a culmination of information and feedback gathered over the past year regarding what website features would be beneficial to our customers.

Some of the new features of the website include:

- Easier to navigate sections for physicians and patients
- A “search tests” function that quickly helps website visitors access *Directory of Services* information regarding a specific test’s specimen requirements, tube type, test code, and CPT code(s)
- In-depth resources for patients including:
  - how to prepare for laboratory testing
  - billing information
  - an updated and easy to read patient service center page
  - a confidential online patient satisfaction survey
- A Quality Update library so that clients can access past issues of Quality Updates
- Patient and Physician laboratory educational resources with printable PDF links

Our goal is to provide easily accessible information for our customers and some of the features from our former website were left intact. For example, popular links like the Care360™ log-in remain on the new website’s home page.

Our goal is to update content and make improvements so that our visitors stay informed of new developments at CompuNet. If you have suggestions for [www.compunetlab.com](http://www.compunetlab.com), you may email them to [kim.a.stanforth@questdiagnostics.com](mailto:kim.a.stanforth@questdiagnostics.com).



## **January 2008**

Virology Advancements	1
HPV Testing	2
Website Redesign	3
Samples and cold weather	4

## **Handling of Specimens in Cold Weather**

As the New Year has started, so has the cold weather. With the lowering of the temperatures some additional precautions need to be taken for specimens that are placed in CompuNet lockboxes that are located on the exterior of buildings.

- Bring the lockbox in the building when not in use. Having the box at room temperature when placed outside will provide additional time before the specimens might be compromised.
- Wrap the samples in newspaper or other insulating material. Again this will keep the samples protected from the freezing temperatures for a longer period of time.
- Place the lockbox outside at the very last minute. The less time the samples are exposed to the cold the better.

We make every effort to pick samples up from the lockboxes as quickly as possible; however the snow, ice and cold weather can make it difficult to get around the Miami Valley as quickly as we might like. These simple precautions will go a long way to ensure the quality of the samples and thus the quality of the results obtained from them.