LifeLabs Medical Laboratory Services

Physicians' Lab Update

June 2011

LifeLabs to offer HPV Test

As of 6 June 2011, LifeLabs will be offering Human Papillomavirus (HPV) testing by a Health Canada approved PCR kit (Roche). The test detects 13 HPV types that pose a high risk for the development of cervical cancer. Since this test is not funded by the Medical Services Plan (MSP), it will be offered on a patient pay basis at $90.

Biology and Epidemiology

HPV is a small DNA virus. More than 100 types have been identified of which more than 40 types are sexually transmitted and affect the anogenital region.[1] Some types are considered low-risk and can cause warts on the anus, vagina, vulva, penis and thighs, whereas other types are considered high-risk and can cause precancerous lesions and can lead to cancer of the cervix, anus and other genital areas.[1]

Humans are the only reservoir for HPV. Data based on a study of women attending for Pap smear screening in Ontario, Canada, showed that the overall prevalence of HPV of any type was 13.3% and the overall prevalence of oncogenic types was 9.6%.[2] The infection rate with oncogenic HPV types varied by age and was the highest among women 20-24 years old (see table below).[2] In a British Columbia population-based study, 17% of women were infected with high- and/or low-risk HPV types, 14% with high-risk types and 6% with low-risk types.[1]

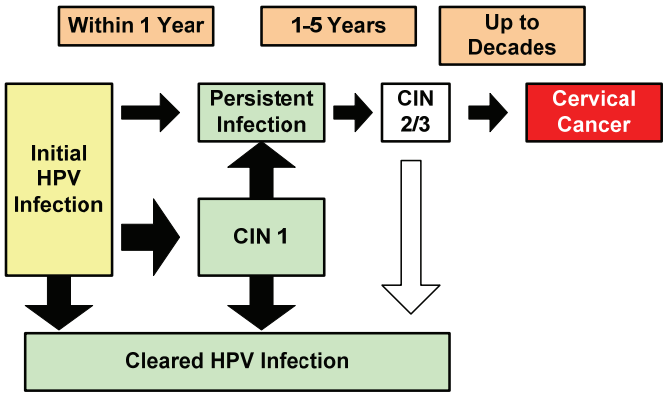
Infection rate for Oncogenic HPV types according to Age					
Age group (years)	**15 - 19**	**20 - 24**	**25 - 29**	**40 - 44**	**45 - 49**
Infection rate	15.7%	24%	16.4%	8.3%	3.4%

Clinical Disease

Most HPV infections are asymptomatic and result in no clinical disease. Clinical manifestations of HPV infection include:

- Anogenital warts
- Recurrent respiratory papillomatosis
- Cervical cancer precursors (cervical intraepithelial neoplasia – CIN)
- Cancer (cervical, anal, vaginal, vulvar, penile and some head and neck cancers).[1]

The natural history of HPV is shown in the diagram below.



Screening for HPV

Screening for HPV infection is the most sensitive method for detection of women at risk for developing cervical cancer. Since 1977, the cervical cancer rate in Canada has declined by 50%, and the cervical cancer mortality rate has declined by 60%. This has largely been attributed to the Pap smear.

The HPV Test is a molecular screening method for detection of 13 high-risk HPV types that are associated with cervical cancer. Although the HPV Test is far more sensitive (95% vs 55% for traditional Pap) for cancer screening, the Pap test is more specific (97% vs 94% for the HPV Test).[3] Therefore, using both tests together provides the best accuracy for cervical cancer risk detection.

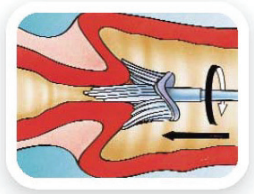
The HPV Test does not replace Cytology. The HPV Test can help physicians decide how soon screening should be done again, and what (if any) other tests are needed (*see References on next page for more detailed information*).[1,4,5]

The HPV Test is not recommended for women under 30 years of age as most infections in this age group clear up on their own.[1,4,5]

Results will be available within two weeks of receipt of a specimen at LifeLabs. Results will be reported as positive, negative or indeterminate for high-risk HPV. Indeterminate results may be due to inadequate specimen collection and/or the presence of inhibitory substances in the sample.

Testing requires cervical sampling into a liquid based cytology collection vial. Collection instructions are indicated below and are also included in the collection kit.

Collection kit

1. Collect	2. Transfer	3. Close	4. Label
			
Insert central bristles of broom-like device into endocervical canal deep enough to allow shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a **clockwise direction 5 times**. ***Note*:** *Use of lubricants is not recommended during testing.*	Rinse broom as quickly as possible into PreservCyt® Solution vial by **pushing broom 10 times** into the bottom of vial, forcing the bristles apart. As a final step, **swirl the broom** vigorously to further release material. Discard collection device.	Tighten cap so that **torque line** on cap passes torque line on vial.	Ensure **patient's name, date of birth, PHN and sample collection date** are on the vial. Record patient information and medical history on requisition form.

If you have any questions, please contact one of the LifeLabs Medical Microbiologists: Dr. Michael Kelly, Dr. Colette Pienaar, Dr. Romina Reyes or Dr. Luis Martinez.

References:

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Burnaby Reference Laboratory
3680 Gilmore Way, Burnaby, BC, V5G 4V8
Victoria Reference Laboratory
#3201 – 4464 Markham Street, Victoria, BC, V8Z 7X8

LifeLabs Medical Laboratory Services

1-800-431-7206
www.lifelabs.com
Editor-in-Chief: Dr. Colette Pienaar
Associate Editor: Dr. Jan Palaty

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SCC Accredited Medical Laboratory ISO 15189:2007

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