



# STATE OF NEW YORK DEPARTMENT OF HEALTH

Wadsworth Center

The Governor Nelson A. Rockefeller Empire State Plaza

P.O. Box 509

Albany, New York 12201-0509

Richard F. Daines, M.D.  
*Commissioner*

James W. Clyne, Jr.  
*Executive Deputy Commissioner*

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Dear Laboratory Director:

This is the summary and evaluation of the graded New York State Proficiency Test for human papilloma virus (HPV) determination. Five vials (HPV021 – HPV025) containing cervical cells in PreservCyt® medium were sent out to every participating laboratory on October 19th, 2009, and the due date for the test result was November 9, 2009. Each correct answer received 20 points, and an incorrect one zero points. Passing the test required a sum of 80 points (80 percent) for the entire test event. Answers could be provided in two categories, positive (pos), negative (neg), or indeterminate (ind) for high risk HPV screening, and for those laboratories performing genotyping, the genotype(s) present.

### Results

In this mailing, 66 test sets were sent out, and valid answers were received from 64 laboratories by the due date. Fifty-one laboratories (80 %) used the Hybrid Capture® method, eight (12 %) Cervista® (Invader technology), four (6 %) polymerase chain reaction, and one (2 %) in situ hybridization. The results are shown in Table 1. Regardless of the methods used, the consensus was in general excellent. Among the 255 responses obtained by the Hybrid Capture® method there was not a single discrepancy. The results of the Cervista® method were almost as good since among 40 responses only 1 (2.5 %) was discrepant, one single negative result instead of the consensus positive. Among the 20 results provided by polymerase chain reaction methods, there were 3 errors, resulting in one laboratory failure. Finally, this time the only laboratory that uses in situ hybridization for determining HPV DNA also was discrepant.

Table 1. Results obtained using Hybrid Capture®, Cervista, PCR or Ventana ISH methods:

	HPV021	HPV022	HPV023	HPV024	HPV025
<b>Hybrid Capture</b>					
Total	51	51	51	51	51
Negative	0	0	0	0	51
Positive	51	51	51	51	0
Indeterminate	0	0	0	0	0
% Negative	0.0%	0.0%	0.0%	0.0%	100.0%
% Positive	100.0%	100.0%	100.0%	100.0%	0.0%
% Indeterminate	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Consensus</b>	<b>POS</b>	<b>POS</b>	<b>POS</b>	<b>POS</b>	<b>NEG</b>

<b>Cervista</b>					
Total	8	8	8	8	8
Negative	1	0	0	0	8
Positive	7	8	8	8	0
Indeterminate	0	0	0	0	0
% Negative	12.5%	0.0%	0.0%	0.0%	100.0%
% Positive	87.5%	100.0%	100.0%	100.0%	0.0%
<b>Consensus</b>	<b>POS</b>	<b>POS</b>	<b>POS</b>	<b>POS</b>	<b>NEG</b>
<b>PCR</b>					
Total	4	4	4	4	4
Negative	0	0	0	1	2
Positive	4	4	4	3	1
Indeterminate	0	0	0	0	1
% Negative	0.0%	0.0%	0.0%	25.0%	50.0%
% Positive	100.0%	100.0%	100.0%	75.0%	25.0%
% Indeterminate	0.0%	0.0%	0.0%	0.0%	25.0%
<b>Consensus</b>	<b>POS</b>	<b>POS</b>	<b>POS</b>	<b>POS</b>	<b>-</b>
<b>Ventana</b>					
	NEG	POS	NEG	POS	NEG

## Genotyping

Laboratories that do determine HPV genotypes were also asked to submit those results (“genotyping”). The methods used for genotyping were diverse, and since the number of laboratories doing it was small, the genotyping results were assessed only but not graded. In other words, no penalties were imposed because of potential errors in genotyping. A few laboratories did genotyping after the Hybrid Capture method provided positive HPV DNA results.

Since the methods for genotyping are not standardized, it is understandable that the results were widely divergent. The cancerogenic type 16 was found most frequently, followed by types 18 and 58.

Table 2 summarizes the genotyping results.

Table 2. Genotyping results, 11 laboratories:

Method	HPV021	HPV022	HPV023	HPV024	HPV025
INV	16,18	16,18	16	16,18	NA
INV	16	16,18		16	NA
INV	16	16,18	16	16,18	NA
INV		16,18	16,18	16,18	NA
PCR	16,18,31	16,18,31	16,18 (weak),31 (weak)	16,18 (weak),31	NA
PCR	16,35/68,52/58	16,31,39/56,51/59	16,18,52/58	16,31,35/68,39/56,51/59	NA
PCR	16,18,68	16,18,45,51,59	16,18,59	16,18,51,68	NA
PCR	16,18,52,56,58	16,18,35,39,45,51,52,56,58,68	16,18,52,56,58,59	16,18,35,39,45,51,52,56,58,68	NA
RFLP	58,84	31,53,58	58,84	18,31,45,53,58	NA
RFLP	58,CP6108,82,UNK	31,32,58	UNK	31,16, LVX160	NA
RFLP	16,52	31,52,58			31,58

NA = not applicable, UNK = unknown, INV = Cervista, PCR = polymerase chain reaction, RFLP = PCR followed by restriction fragment length polymorphism determination

### Low risk types

It should be noted that only the determination of high risk types of HPV has clinical implications. Testing for low risk types has little clinical value and laboratories were not asked to provide such results. According to a questionnaire sent out previously, the laboratories that furnish information about the low risk HPV types do it only if clinicians explicitly request it.

### Conclusion

In general, the results of this HPV DNA proficiency testing are very satisfactory.

Tentative schedule for the 2010 New York State HPV proficiency tests:

#### Mail-out Dates

March 30, 2010

July 13, 2010

October 19, 2010

#### Due Dates

April 19, 2010

August 2, 2010

November 8, 2010

Correspondence:

George K. Nagy, M.D.  
Wadsworth Center, Room D206,  
Empire State Plaza,  
Albany, NY 12201 – 0509.

If you have questions, call or e-mail:

George K. Nagy, M.D., 518-474-3190, [gkn02@health.state.ny.us](mailto:gkn02@health.state.ny.us)  
Halyna Logan, 518-473-8715, [hll01@health.state.ny.us](mailto:hll01@health.state.ny.us)  
Helen Ling, 518-474-0036, [hxl01@health.state.ny.us](mailto:hxl01@health.state.ny.us)