

## WG4 Molecular Markers for Histopathology - Public Comments

### February 6, 2012 – February 12, 2012

Practice Type		
Clinician	8	36%
Pathologist	11	50%
Other, please specify	3	14%

Years of Experience		
More than 20 years	11	48%
11-20 years	9	39%
10 years or less	3	13%
Currently a resident/student	0	0%

Practice Setting		
Academic	6	32%
Community/Private Practice	10	53%
Government	1	5%
Industry	1	5%
Insurance/Payers	0	0%
*Other, please specify	1	5%
*Community/academic		

## Clinician Public Comments

**Question 1: Were any published articles omitted from consideration (please refer to Work Group scope/key questions and inclusion/exclusion criteria links above)? How would these articles impact the Work Group's conclusions?**

No

no

no

no

**Question 2: Do you think there are any significant misrepresentations or biases in the draft recommendations?**

No

no

**Question 3: Do you have any disagreements with the main conclusions and/or evaluations of the literature?**

No

no

**Question 4: What topics/gaps for future research/guidelines should be priorities?**

Guidelines specific to Groups: Low & High Risk

**Question 5: Other comments (including, if applicable, support for the recommendations):**

HPV alone not a risk need dysplasia changes or HPV lesions before action can be taken.

I fully support recommendations I fully support this method of solidifying support for the recommendations. Well done.

## **Pathologist Public Comments**

**Question 1: Were any published articles omitted from consideration (please refer to Work Group scope/key questions and inclusion/exclusion criteria links above)? How would these articles impact the Work Group's conclusions?**

Need to evaluate the company bias, such as the company (that made p16) and its financed articles vs truly scientific and large blinded research data.

no

Agree with the recommendations. Source of the p16 IHC antibody is variable. Statement of use in CIN 1 lesions is a little ambiguous. The description of the p16 staining concerning CIN 1 lesions is ambiguous.

Not that I know of

No

Not sure

No

**Question 2: Do you think there are any significant misrepresentations or biases in the draft recommendations?**

Do not know. But recommendation should be based on sound scientific data and whether those recommendations will make a difference in term of clinical managements (such as CIN II and p16 negative pts on biopsy, should they have cervical cone biopsy? what are long term outcome if the cervical cone biopsy not performed on those CIN2? and what are most cost effective approaches?)

no

No.

No

Possibly

No

**Question 3: Do you have any disagreements with the main conclusions and/or evaluations of the literature?**

Need some statistics in your analysis summary to be sure one way or the other. From pathologists perspets, many recommendations proposed in the past few years have biases (largely benefits the companies that pushed for it) and never evaluate the cost effectiveness!!!!

no

No.

No

Yes

No

**Question 4: What topics/gaps for future research/guidelines should be priorities?**

Risk of p16 positive CIN1

Agreement from OB/GYN physicians on implementation.

Molecular markers for CIN-1/low grade lesion

I believe thee role of KI-67 not as a marker for HSIL or HPV, but as marker of exclusion should be looked at more carefully. It owuld be rare to have an intra-epithelial lesion in KI-67 negative biopses, and Ki-67 should be used as a marker of exclusion in cases where clarity is needed with reactive changes. This will reduce false positive results or unambiguous results. Ofocurse if Ki-67 is positive then the diagnosis shoudl go to morphologic and/or P-16 as suggested.

Continued review of molecular markers for Neoplasia

**Question 5: Other comments (including, if applicable, support for the recommendations):**

Like the limited p16 use.

None

## Other

<b>Practice Type</b>
Director cytotechnologist

**Question 1: Were any published articles omitted from consideration (please refer to Work Group scope/key questions and inclusion/exclusion criteria links above)? How would these articles impact the Work Group’s conclusions?**

KQ 1&2 Recommendation #1: Throughout the document “Block Positive” is used and is not well defined. This is not common terminology used in Pathology text books (versus “diffuse stain”) and should be defined early in the document. (reference: R. J. Kurman, L.H. Ellenson and B.M. Ronnett (Eds.) Blaustein’s Pathology of the Female Genital Tract, Sixth Edition, Springer, 2011; Chapter 5: Precancerous Lesions of the Cervix In the most recent text books and scientific publications “diffuse” is commonly used to describe the staining pattern of a positive p16 result and therefore replacement of “block Positive” with “diffuse” may reduce misunderstanding and draw a stronger correlation between the Guidelines and the most recent literature. KQ7 : Add to the end of the paragraph “Refer to KQ4 recommendation #4 “ P16 should be used as an adjunctive test as recommended in #4: Reference: Ordi J, Garcia S, del Pino M, et al. p16INK4a Immunostaining Identifies Occult CIN Lesions in HPV-positive Women. Int J Gynecol Pathol; 2009;28:90–7.

no

**Question 2: Do you think there are any significant misrepresentations or biases in the draft recommendations?**

No

**Question 3: Do you have any disagreements with the main conclusions and/or evaluations of the literature?**

No

**Question 4: What topics/gaps for future research/guidelines should be priorities?**

None at this printing but should be reviewed annually.

**Question 5: Other comments (including, if applicable, support for the recommendations):**

None