

## Quality Control of HPV Test

Alameda F<sup>1</sup>, Carrasco MA<sup>2</sup>, Tressera F<sup>3</sup>, Muset M<sup>1</sup>, Bellosillo B<sup>1</sup>, Kopsteva I<sup>2</sup> and Lloveras B<sup>1</sup>

<sup>1</sup>Department of Pathology, Hospital Del Mar, Barcelona, Spain

<sup>2</sup>Department of Pathology, General Hospital of Catalunya, Barcelona, Spain

<sup>3</sup>Department of Pathology, Dexeus University Hospital, Barcelona, Spain

\*Corresponding author: Alameda F, Department of Pathology, Hospital Del Mar, Passeig Maritim 25-29, 08003 Barcelona, Spain, Tel: +34932483919; E-mail: 86780@hospitaldelmar.cat

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### To the Editor

The HPV test shows high sensitivity for CIN2+ and is therefore a useful tool for cervical cancer screening. The Cobas 4800 system is an FDA approved HPV test that has been validated with established criteria [1-3]. The Cobas 4800 involves real-time PCR for the detection of high-risk HPV and also informs about HPV 16, HPV 18 and high-risk HPV other than 16 and 18. The cervical cancer screening guidelines recommend performing external quality assurance of the laboratories using HPV test [4,5], that is to say inter laboratory agreement studies (IAS).

IAS can be performed by sending all the participants samples from the same cases or by swapping cases between participants. We have performed an IAS of the Cobas 4800 in which a number of cases were swapped between the participating centers. Three hospitals participated in this study (HM, HD, HGC). All three tested 30 cases independently of cytological diagnosis (Table 1).

|     | GLO   | RE-T    | 16    | RE-T    | 18      | RE-T  | O     | RE-T    |
|-----|-------|---------|-------|---------|---------|-------|-------|---------|
| NEG | N= 30 | N= 29   | N= 30 | N= 30   | N= 30   | N= 30 | N= 30 | N= 29   |
|     | P=0   | P= (a)  | P=0   | P=0     | P=0     | P=0   | P=0   | P=1 (f) |
| PA  | P=30  | P=30    | P=20  | P=20    | P=4     | P=4   | P=27  | P=27    |
|     | N=0   | N=0     | N=10  | N=10    | N=26    | N=26  | N=3   | N=3     |
| PB  | P=29  | P=24    | P=13  | P=11    | P=2     | P=2   | P=25  | P=19    |
|     | -     | N=5 (b) | -     | N=2 (c) | N=27    | N=27  | -     | N=6 (d) |
|     | N=0   | -       | N=16  | N=15    | P=1 (e) | -     | N=4   | N=4     |

**Table 1:** Agreement and disagreement cases [NEG: Negative cases; PA: Positive cases before the cycle 35; PB: Positive cases after the cycle 35; GLO: Global initial results; RE-T: Re-test results; 16: HPV 16; 18: HPV 18; O: HPV high-risk others than 16 or 18; (a,f): Cycle 38,6; (b,d): Cycles 36.5 to 39.7; (c): Cycles 38.4 and 40; (e): cycle 37.8].

Of these 30 cases: 10 had to be HPV positive before cycle 35 (PA), 10 cases positive between cycles 36 and 40 (PB); and ten cases negative (N). The three hospitals swapped these cases, thus facilitating comparison of results between two hospitals (HD-HGC, HGC-HM and HM-HD). In total, 30 negative and 60 positive cases (30 PA and 30 PB) were re-tested. The laboratories that re-tested the cases were blind to the first result obtained.

The agreement for negative cases was 96.7%. One of the initially negative cases was found to be positive in cycle 38.6 of the re-test (a). There was 100% agreement for positive PA cases and 82.8% agreement for PB cases. One of the cases in the PB group was not valid three times in the re-test and 5 cases that were initially positive between cycles 36.5 and 39.7 were negative in the re-test (b).

Regarding the results for HPV 16, there was 100% agreement for negative and for positive PA cases. The agreement for positive PB cases was 89.7%. Two cases that were positive in the cycles 38.4 and 40 resulted negative in the re-test (c). A third case, which was negative, was positive in cycle 37.8 of the re-test (e).

The results for HPV 18 showed 100% agreement for negative, positive PA and positive PB cases. The agreement for high-risk HPV other than 16 and 18 was 96.7% in negative cases. One case that was negative resulted positive in cycle 38.6 of the re-test (f). The agreement for PA positive cases was 100% and for PB positive cases was 76%.

All the cases that were positive between cycles 36.5 and 39.7 were found to be negative in the re-test (d).

We conclude that the results of Cobas 4800 show very good inter laboratory agreement, especially for negative and positive HPV 16 and HPV 18 cases. The cases with disagreement were positive in the cycles over 35.

### References

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