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***Title*** Detection of high-risk human papilloma virus (HPV) RNA as part of primary prevention of cervical cancer

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**Aim**

The Directorate-General for Health has asked HAS to determine whether HPV RNA can be detected in the same way as HPV DNA, as part of primary screening of precancerous conditions of the cervix, in women age 30 to 65.
Three assessment subjects were selected to answer to this request:

- Subject 1: Is the diagnostic validity of the RNA HPV test different from the diagnostic validity of the DNA HPV test approved for the detection of precancerous conditions of the cervix as part of primary screening?
- Subject 2: What is the long-term performance of the RNA HPV test compared to that of the DNA HPV test?
- Subject 3: Is the diagnostic validity of an RNA HPV test on a self sample (SPV) equivalent to the RNA HPV test on a cervical sample collected by a professional (i.e. physician-collected)?

**Conclusions and results**

The data collected during this assessment can be used to consider that, despite the few studies available, their methodological weaknesses and heterogeneity of their results, the diagnostic performances of the RNA HPV test, where it is carried out on a physician-collected sample, are today considered not to be different to those of the DNA HPV test, and justify its use for the primary screening of cervical cancer, like the DNA HPV test, on the condition that three procedure-related requirements are met, namely:

- an internal cellular control is present;
- sample transport and storage media compatible with most tests available on the market (RNA and DNA) are used;
- sample transport and storage media for carrying out a reflex test are used.

The conclusion of this report can be reviewed in order to take account of any future long-term data, and thus confirm the similar long-term diagnostic performances of the two HPV tests.
For SPV, the RNA HPV test is not recommended and broad access to the DNA HPV test should be ensured so as not to compromise SPV screening strategies in the populations concerned.

**Methods**

The conclusions of this report are based on:

- critical analysis of data from the literature identified after a systematic literature search and selection on the basis of explicit criteria, having led to meta-analyses;
- the position of a multidisciplinary group of individual experts;
- collection of the collective viewpoint of bodies of professionals and patients' associations, questioned as stakeholders.

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