# Market Consultation

## Questionnaire Cervical Cancer screening

Name company

*If you have any questions about the questionnaire please submission questions through the module 'berichten' in TenderNed (see market consultation 5.2) . The closing date for handing in questions is on November 26th 2019 at 4 p.m.*

| Number | Question | | |
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| **1** | In 2023, the first HPV-vaccinated women are eligible for an invitation to the cervical cancer screening program. RIVM-CvB must ensure a responsible influx.<br><br>**Questions:**<br><br>**a.** To what extent are HPV tests, based on test characteristics, suitable for screening a (partially) vaccinated population and how has this been tested?<br>**b.** Has your HPV test been clinically validated for testing samples of a (partially) vaccinated population and how has that been included in the package insert of the tests? | **a.** | |
| | | **b.** | |
| **2** | The current screening algorithm of the program is based on primary HPV screening with cytology triage. All HPV positive women with ASCUS+ are referred to the gynecologist. CIN2 + is considered as a clinically relevant abnormality.<br><br>**Question:**<br><br>Which alternative screening algorithms would be possible based on HPV testing with your HPV test (and cytology as triage), whereby specificity increases without a substantial loss of sensitivity? | | |
| **3** | RIVM-CvB is exploring options for reducing the number of unnecessary referrals.<br>**Questions:**<br><br>**a.** What possibilities do you see (have available), for example in additional methods, to increase the specificity of cytology? | **a.** | |

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| | **b.** Do you expect that (in the short term) alternative methods will become available for the triage of women after a HPV positive result within a screening setting? If yes, which one(s)? | **b.** | |
| **4** | With an increasing of the use of the self-sampling device within the screening program, it is important that the outcome of the screening result remains guaranteed.<br><br>**Questions:**<br><br>**a.** To what extent are HPV tests clinically validated for the use of self-samples and (how) has this been included in the package insert of the tests?<br>**b.** If so, to which combinations of devices and media does the clinical validation apply and what criteria have been applied?<br>**c.** If not, what options do you see in the short term for the clinical validation of HPV tests on samples taken with a self-sampling device? | **a.** | |
| | | **b.** | |
| | | **c.** | |

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| **5** | Currently hrHPV genotyping is not applied in the Dutch population screening for cervical cancer. For primary HPV screening, however, genotyping of high risk types is becoming increasingly important.<br><br>**Questions:**<br><br>**a.** To what extent has your (clinically validated) HPV test the possibility of (partial) genotyping and for which hrHPV types?<br>**b.** How could genotyping (with your HPV test) contribute to the optimization of the Dutch population screening program? | **a.** | |
| | | **b.** | |
| **6** | No cytology can be performed on samples taken with a self-sampling device. If hrHPV is found, it is therefore necessary for the woman to have a smear taken for cytological evaluation. This increases the chance of loss-to-follow-up.<br><br>**Question:**<br><br>Do you expect methods to become available (on the short term) that will allow HPV analysis and triage both to be performed on the same self-sample? If yes which one(s)? | | |

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| **7** | On April the 5th 2017, the European Parliament adopted a regulation for medical devices and a regulation for in vitro diagnostics: the Medical Device Regulations (MDR) and the In Vitro Diagnostic Medical Device Regulations (IVDR). This means that medical devices (self-sampling devices) from May 26th 2020 and in-vitro diagnostics (HPV tests) must comply with new European rules from May 26th 2022. Existing certificates are still valid until May 2024.<br><br>**Question:**<br><br>To what extent have you prepared yourself for these new regulations and what is your planning / plan of action? | | |
| **8** | The HPV analysis of collected material (smears and ZAS) takes place in a limited number of screening laboratories. The HPV analysis must contribute to the timeliness of the total screening program.<br><br>**Questions:**<br><br>**a.** Is your (clinically validated) HPV test suitable for automated high throughput screening with low labor intensity?<br>**b.** What is the capacity in terms of numbers of samples that can be processed per day and what are the assay turnaround times? | **a.** | |
| | | **b.** | |

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| **9** | An important point of attention in increasing of the use of the self-sampling device is the processing of larger numbers in the screening laboratories. The current pre-analytical process is labor-intensive and requires many manual actions, thereby increasing the chance of sample exchange.<br><br>**Questions:**<br><br>**a.** What possibilities do you see for (the development of) pre-analytical automation for the processing of self-sampling sets within the screening laboratories?<br>**b.** Do you see possibilities for full tracking and tracing of the sample?<br>**c.** Do you have suggestions for the optimization of self-sampling devices to simplify the pre-analytical processing?<br>**d.** What options do you have / expect for an integrated solution consisting of automated pre-analytical processing of self-samples in combination with a clinically validated hrHPV screening solution? | **a.** | |
| | | **b.** | |
| | | **c.** | |
| | | **d.** | |

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| **10** | **Open question:**<br><br>Do you have any points of interest that you would like to provide to RIVM-CvB to take in account when developing scenarios and strategies for program optimization? | | |