CLINICAL VALIDATION OF THE CLART4S HPV ASSAY ON SUREPATH AND THINPREP SAMPLES BY INTERNATIONAL GUIDELINES FOR HPV TESTS IN CERVICAL SCREENING

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Disclosure

Camilla Lagheden has nothing to declare

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Background

- Novel HPV assays for cervical screening use must be evaluated by International guidelines for HPV test requirements for cervical cancer screening (Meijer et al. 2009)

- The CLART HPV4S assay (Genomica, Madrid, Spain) is a PCR based microarray assay targeting the L1 region, detecting 13 oncogenic HPV individually

- We validated CLART 4S on both ThinPrep and SurePath screening samples, using MGP-PCR (Modified general primers (GP5+/6+)) and Luminex as comparator
The International guidelines

- The clinical **specificity** for a new HPV test has to be $\geq 0.98$ of the clinical specificity of the reference test
  (Standard: $\geq 800$ women with $<\text{CIN2}$ histological follow-up)

- The clinical **sensitivity** for a new HPV test has to be $\geq 0.90$ of the clinical sensitivity of the reference assay
  (Standard: $\geq 60$ women with histological confirmed $\geq\text{CIN2}$)

- Lower confidence bound for **intra** and **interlaboratory reproducibility** has to be 87% in a population of $\geq500$ sample where at least 30% are HPV positive
  (A minimum of 150 positive samples (30%) and 350 negative samples were required)
Sample collection, LBC

- ThinPrep - collected from Swedish women participating in the Swedish cervical screening program, Karolinska University Hospital, Stockholm

- SurePath - collected from Danish women participating in the Danish cervical cancer screening program at Copenhagen University hospital, Hvidovre
Project group

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Thank you!

Guidelines for human papillomavirus DNA test requirements for primary cervical cancer screening in women 30 years and older.
Meijer et al, Int J Cancer. 2009

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