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

Camilla Lagheden,

Ditte Møller Ejegod, Helle Pedersen, Kate Cuschieri, Ramya Bhatia, Joakim Dillner, Jesper Bonde

Disclosure

Camilla Lagheden has nothing to declare

The validation of CLART4S is sponsored by the manufacturer Genomica SAU, Madrid, Spain

The sponsor has no editorial rights on interpretation of data, publication or presentation of study data as per governing collaboration agreement

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 ***≥ 0.98 of the clinical specificity of the reference test***

  (Standard: ≥ 800 women with <CIN2 histological follow-up)

- The clinical **sensitivity** for a new HPV test has to be ***≥0.90 of the clinical sensitivity of the reference assay***

  (Standard: ≥ 60 women with histological confirmed ≥CIN2)

- Lower confidence bound for **intra** and **interlaboratory reproducibility** has to be ***87% in a population of ≥500 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

Ramya Bhatia
Elia Alcaniz Boada
Kate Cuschieri
Scottish HPV Reference Lab
Royal Infirmary of Edinburgh
Scotland

Camilla Lagheden
Joakim Dillner
Division of Laboratory Medicine
Karolinska Institute
Sweden

Ditte Møller Ejegod
Helle Pedersen
Jesper Bonde
Molecular Pathology Laboratory
Copenhagen University Hospital
Hvidovre Hospital, Denmark

Scientific advisors to the sponsor

F. Xavier Bosch Josë
Cancer Epidemiology Research Program,
Catalan Institute of Oncology, Barcelona, Spain

Javier Cortés
Spanish Society of Obstetrics and Gynecology,
Palma, Spain

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

Camilla.Lagheden@ki.se