

BSCC Abstract Template

Lecture Title:	Hologic™ Cervista™ HR HPV Test – An Overview
Lecturer Name:	Jo Frost
Lecturer Biography:	Account Executive/Cytology Applications Specialist, Hologic UK Ltd
Abstract	<p>Hologic™ Cervista™ HR HPV Test – An Overview</p> <p>The Cervista™ HPV High Risk test was CE marked and FDA approved in early 2009 for the detection of the 14 high risk HPV types. Cervista HPV HR provides 100% detection of CIN3+^{1,2}, no cross-reactivity with common low risk HPV types and an internal control to ensure adequate sample DNA to deliver consistent, reliable results.</p> <p>Cervista HPV HR uses patented Invader® chemistry which directly detects specific nucleic acid sequences through two simultaneous isothermal reactions and fluorescence detection.</p> <p>This technology offers a flexible, scalable laboratory solution with four hours of hands free time while the test is processing.</p> <p>¹100% CIN3 Detection in ASC-US: 95% CI (85.1% - 100%) ² Consult Cervista package insert for full clinical details</p>
Take home message(s)	<p>Hologic™ announces Cervista™ - a new CE marked and FDA approved High Risk HPV Test. Features of the test are:</p> <ul style="list-style-type: none"> • 14 High risk HPV types detected • 100% detection of CIN3+ • No cross reactivity with common low risk HPV types • Internal control confirms sample contains adequate DNA

References	Cervista™ multicentre clinical trail, 2006-2008, data on file Hologic Inc Cervista™ HPV HR package insert #15-3053, 2009
Declaration of interest	Jo Frost is a Hologic employee

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Lecture Title:	Potential Benefits of the No Further Review Category
Lecturer Name:	Wilma Anderson
Lecturer Biography:	<p>I am the Healthcare Senior Technical Manager at Source BioScience plc who is the exclusive UK distributor of the BD SurePath™ LBC and FocalPoint™ GS Imaging technology. I have been with the company since 2001 having previously commenced my cytology career at Monklands General Hospital in Scotland where I gained my LBC certificate in 2001. I have experience of both LBC technologies as my initial conversion from conventional cytology to Liquid Based Cytology was on ThinPrep preparations. One of my responsibilities is to provide support and expertise on the many projects that we undertake in conjunction with the laboratories particularly with regards to Automated Imaging. I also oversee both the technical and customer support to the labs that are using the BD SurePath™ technology. Source BioScience also provides additional services to the NHS, pharma/biotech and academic institutions such as both general pathology and molecular pathology.</p> <p>I regularly attend cytology meetings both internationally and within the UK representing Source BioScience but also for personal and continual education.</p>
Abstract	<p>The BD FocalPoint™ screens up to 400 slides a day and uses standard BD SurePath™ PAP stain. It then selects up to 25% of these slides, which it considers to have no abnormalities which are placed into a “No further Review” [NFR] category.</p> <p>The results of the MAVERIC study presented at the ICC meeting in Edinburgh demonstrated that the BD FocalPoint™ “No Further Review” mode had 99.7% sensitivity for detecting high grade disease which exceeds the 95% sensitivity accepted by the NHSCSP for manual screening. This sensitivity was not improved by rapid review of these slides</p> <p>The BD FocalPoint™ therefore enables the laboratory to reduce by up to 25% the number of slides that require a manual screen.</p> <p>Further recent studies at both Derby City Hospital and Wales have demonstrated similar results with a NFR sensitivity of 99.7% in Derby and a NFR sensitivity of 97.3% in Wales.</p> <p>The NFR mode is unique to the BD FocalPoint™ and is a true example of the potential for Automated Imaging.</p> <p>Together with future lab configuration, HPV triage and HPV vaccination the BD FocalPoint™ will greatly reduce the number of slides which have to be manually screened whilst maintaining the high standards required in the service.</p> <p>Further cost benefit analysis of the NFR category is being considered by the HTA. The final report is expected late 2010 early 2011</p>

Take home message(s)	The benefits of using the No Further Review Category 'NFR' within the screening programme in light of the proposed changes to the current service and what impact this could have within your own laboratory.
References	
Declaration of interest	I am a full time employee with Source BioScience

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Lecture Title:	Cobas® 4800 HPV test
Lecturer Name:	Josephine Blakebrough
Lecturer Biography:	Product Manager, Roche Diagnostics
Abstract	<p>The cobas® 4800 System is designed to deliver new standards in laboratory testing efficiency. By delivering a diagnostic test that identifies high-risk HPV types and specific genotyping for HPV type 16 and 18 in one reaction, physicians can identify women most at risk for developing cervical cancer and reduce unnecessary procedures. The system combines state-of-the-art sample preparation with Roche’s proprietary real-time PCR technology for amplification and detection. The intuitive, easy-to-use software integrates sample preparation, amplification and detection, and results management.</p> <p>The ATHENA (Addressing the Need for Advanced HPV Diagnostics) trial is a randomised, multicenter study, of over 47,000 women. Data from the trial has shown that cobas® 4800 HPV test meets the current standard of care in women with ASC-US cytology by performing comparably with current industry ‘gold standard’.¹</p> <p>Data from the ATHENA trial also showed that 1 in 10 women age 30-years and older who tested cobas® 4800 HPV 16 and/or 18 +ve had cervical pre-cancer, although their cytology test was normal. Women >30 years with ‘normal’ cytology were shown to have absolute risk of 11.4% and 9.8% for CIN2+ and CIN3+ respectively, which is comparable with that for high risk HPV +ve women with ASC-US cytology (equivocal cytology).²</p>
Take home message(s)	<ul style="list-style-type: none"> • cobas® 4800 is a high-throughput, automated solution for simultaneous detection of high-risk HPV and HPV 16/18 genotyping, requiring minimal hands on time and set up. • The cobas® 4800 HPV test has been proven to meet the current standard of care and is comparable to current industry ‘gold standard’.¹ • Screening using the cobas® 4800 for high risk HPV types 16 and 18, can identify those women with cervical pre-cancer missed by cytology and should be included to provide predictive information about a woman’s risk for having cervical pre-cancer or cancer.²

References	<ol style="list-style-type: none">1. Stoler M, <i>et al.</i> 26th International Papillomavirus Conference. Montreal, Canada, July 3-8, 2010; P-4172. Wright T Jr <i>et al.</i> 26th International Papillomavirus Conference. Montreal, Canada, July 3-8, 2010; P-417
Declaration of interest	None

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Lecture Title:	Automated solutions for diagnostic HPV testing to address changing volumes of testing
Lecturer Name:	Dr Geraldine Roeder
Lecturer Biography:	Dr Geraldine Roeder is Market Development Manager, Northern Europe for Women's Health products at QIAGEN. Prior to joining QIAGEN she held sales and marketing positions at 3M Health care and Gambro Renal Products. Her PhD thesis was titled "Gene Therapy for Cervical Cancer" and she has maintained an interest in the link between HPV and Cervical Cancer since that time.
Abstract	<p>As the Sentinel Sites project continues and the data supporting the use of Human Papillomavirus testing grows¹⁻³, it seems likely that HPV triage testing may be adopted in England in the near future.</p> <p>The <i>digene</i> HPV test from QIAGEN (Hybrid Capture 2) has been shown to have exquisite clinical sensitivity for high grade cervical disease in numerous large scale clinical studies and to reduce incidence and mortality from cervical cancer. Hybrid Capture 2 can be automated on the Rapid Capture System, and QIAGEN have recently developed the QIAensemble series of instruments, a cutting-edge next-generation diagnostic system for HPV. QIAensemble automates all steps including sample loading, target denature, probe hybridization, target capture, signal production, signal detection and assay result reporting. This automated system has been designed to generate up to 400 clinical results per 8 hr shift.</p> <p>The QIAensemble system runs the enhanced Hybrid Capture assay (eHC) which is designed to capitalise on the clinical sensitivity of Hybrid Capture 2 for high grade cervical disease, whilst creating a highly specific result . Here we present preliminary data on the eHC assay and the QIAensemble series of instruments.</p>
Take home message(s)	<ul style="list-style-type: none"> - HPV testing using HC2 can reduce the incidence and mortality from cervical cancer⁴. - HC2 is the gold standard HPV test and has been clinically validated in numerous randomized controlled trials¹⁻⁵. - The QIAensemble system is a fully automated, true walk-away system for HPV testing based on proven hybrid capture technology. - The throughput of the QIAensemble system is flexible, is cost effective from an average of 10+ samples per day and allows testing of up to 400 clinical specimens in an 8 hour shift. - Preliminary data shows that the eHC assay maintains the clinical sensitivity of Hybrid Capture 2 but shows enhanced specificity

<p style="text-align: center;">References</p>	<ol style="list-style-type: none"> 1. Moss, K., et al. (2006) Effect of testing for human papillomavirus as a triage during screening for cervical observational before and after study BMJ. 332, 83. 2. Legood, R., et al. (2006) Lifetime effects, costs and cost effectiveness of testing for human papillomavirus to manage low grade cytological abnormalities: results of the NHS pilot studies. BMJ. 332, 790. 3. Cuzick, J., et al. (2008) Long-term follow-up of cervical abnormalities among women screened by HPV testing and cytology - results from the Hammersmith study. Int. J. Cancer 122, 2294. 4. Sankaranarayanan R et al. (2009) HPV Screening for Cervical Cancer in India. NEJM 360,1385-1394 5. Meijer et al (2009) Guidelines for Human Papillomavirus DNA tes requirements for primary cervical screening in women 30 years and older. Int. J. Cancer 124, 516-520
<p style="text-align: center;">Declaration of interest</p>	<p>Dr Geraldine Roeder is employed by QIAGEN UK Ltd.</p>