ADVERTORIAL

HOLOGIC®

Towards a definitive diagnosis in HPV testing.
It starts with mRNA testing.

Cervical cancer diagnostic technology has advanced over the years, with different diagnostic approaches available to support HPV primary screening programmes that include improved specificity and sensitivity compared to conventional cytology.[1,2,3,4]

mRNA and DNA are two types of tests available and approved for the detection of high-risk human papillomavirus (HR-HPV) testing in the UK[5]. HPV DNA detects the presence of acute and chronic HPV infection that could be a transient HPV infection[7]. In contrast HPV mRNA tests target E6/E7 mRNA that indicate activity of HPV oncogenes that are essential for progression to cancer[6,7]. Both tests have a similar high sensitivity, meaning that there are few false negatives[7]. However, the mRNA HPV test has a higher specificity than DNA tests, which ensues a 24% reduction in false positives compared to an HPV DNA test[8]. With this in mind, the use of mRNA HPV testing may help to improve diagnosis, efficiencies, and patient experience.[9]

Improving diagnosis in HPV screening

With the current burden on services, improved identification of high-risk HPV patients is an important first step. To improve diagnostic standards and ensure most patients receive a definitive diagnosis, it is crucial that you can rely on the accuracy of the HPV test results.[10]

A specific and sensitive HPV mRNA test provides improved specificity, detecting only high-risk HPV infections that are more likely to progress to cancer, minimising false positive results, and reducing the burden on patients and services such as colposcopy.[1,2,3,4]

Over a 3 year period in a population of 2.25 million women screened using Aptima HPV mRNA instead of a HPV DNA based test, results showed: *

- 28,009 colposcopies averted[9]
- 3.7% reduction in unnecessary HPV tests performed[9]
- 42.6% reduction in unnecessary cytology tests performed[9]

Improving efficiencies in HPV screening

Cervical Screening Programmes (CPS) are met with challenges when it comes to meeting coverage targets and the risk of inaccurate results (false positives and negatives). Improving efficiencies in cervical cancer screening from diagnosis to treatment is urgently needed to ease pressure on a stretched workforce, tackle patient backlog, and manage unnecessary referrals to colposcopy services.[8]

With many women waiting far longer than they should for a referral after a cytology result, HPV primary screening must be run as efficiently and effectively as possible so that the right women are seen at the right time.[11]

Alleviating colposcopy burden in Cervical Screening Programmes (CSP)

Colposcopy is a vital stage on the patient pathway, where women get the answers they need. Between 2021 - 2022, over 235,223 women were referred to colposcopy in England[12], compared to almost 125,000 women between 2004 - 2005. The use of mRNA HPV testing would reduce this pressure on capacity, resources and yield costs due to averted unnecessary colposcopies.[9] Unnecessary referrals to colposcopy plays a big part in the burden on colposcopy services and overall efficiencies of HPV screening services. Seven percent of women aged 25–29 years are referred for colposcopy with a low-risk HPV genotype lesion.[13]

To help alleviate the colposcopy burden, it is important that accurate results delivered in a timely manner.

mRNA testing can save the NHS a £15.4 million, while reducing the number of unnecessary colposcopies by 29%.[9]

Improving patient experience in HPV screening

With mRNA HPV testing you are putting the patient at the centre of care by reducing the impact on the patient from receiving false positive results, unnecessary colposcopy procedures, overtreatment, and psychosocial burden[6,14,15]. These are all factors that can impact the patient pathway in HPV screening, affecting decision making in attending either routine invitation or recall screening.

Introducing mRNA HPV testing into screening pathways may help to promote overall efficiency to meet coverage targets, reduce delays to diagnosis, and improve the patient experience. One thing that is key to all of this, is a definitive HPV diagnosis. And the key to a definitive diagnosis, is mRNA.[9]

For more information visit https://hologic.co.uk/hpvmrna

¥ Specifically, the Aptima HPV mRNA test
* Compared to no screening
** Based on a probabilities HPV+ for year 1: DNA – 0.2026, mRNA – 0.1232; year 2: DNA (for women with normal reflex cytology in year 1): DNA – 0.6486, mRNA – 0.5505; and year 3 (for women with normal reflex cytology in year 2): DNA – 0.4283, mRNA – 0.3153. **The cost of screening was estimated using a micro-costing approach and validated by clinicians, the cost of colposcopy was based on the NHS National Tariff, treatment costs are not included. †Based on statistical calculation.

REFERENCES

1. Tjalma WA, Depuydt CE. Cervical cancer screening : which HPV test should be used—L1 or E6/E7? Eur J Obstet Gynecol Reprod Biol. 2013 Sept; 170(1):45-6. DOI: 10.1016/j.ejogrb.2013.06.027. Epub 2013 Aug 6. PMID: 23932300
2. Saslow D, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology Screening Guidelines for the Prevention and early Detection of Cervical Cancer. Am J Clin Pathol 2012;137:516–42.
3. Tinelli A, Leo G, Pisanò M et al. HPV viral activity by mRNA-HPV molecular analysis to screen the transforming infections in precancer cervical lesions. Curr Pharm Biotechnol. 2009;10(8):767-71
4. Cuschieri KS, Whitley MJ, Cubie HA. Human papillomavirus type specific DNA and RNA persistence--implications for cervical disease progression and monitoring. J Med Virol. 2004;73(1):65-70.
5. AQUARIUS POPULATION HEALTH - Using an mRNA versus DNA test in the English cervical screening programme can save £15m annually and reduce unnecessary testing. Accessed at: https://aquariusph.com/news/mrna-hpv-test-cost-saving/ (Accessed on 05 October 2023)
6. Aptima HPV assay [package insert, AW-22202-001 Rev 001 (EN), San Diego, CA; Hologic, Inc., 2023
7. Iftner T, Haedicke J. A review of the clinical performance of the Aptima HPV assay J Clin Virology. 2016
8. Strang T H.R, Gottschlich A, Cook D A, Smith L W. Long-term cervical precancer outcomes after a negative DNA- or RNA-based human papillomavirus result. Am J Obstet Gynecol. 2021 November; 225(5):511.e1–511.e7. doi:10.1016/j.ajog.2021.05.038. Page 16. Table 3. (2021)
9. Weston, G. et al. (2020) Use of the APTIMA mrna high-risk human papillomavirus (HR-HPV) assay compared to a DNA hr-HPV assay in the English cervical screening programme: A decision tree model based economic evaluation, BMJ Open. Available at: https://bmjopen.bmj.com/content/10/3/e031303 (Accessed: 29 August 2023).
10. NCI - ACS's Updated Cervical Cancer Screening Guidelines Explained. 2020 Available at: https://www.cancer.gov/news-events/cancer-currents-blog/2020/cervical-cancer-screening-hpv-test-guideline (Accessed on 05 October 2023)
11. GOV.UK. Good working practices – Providing a quality colposcopy clinic. 2023 Available at: https://www.gov.uk/government/publications/cervical-screening-programme-and-colposcopy-management/3-providing-a-quality-colposcopy-clinic (Accessed: 05 October 2023)
12. About (2023) BSCCP. Available at: https://www.bsccp.org.uk/about (Accessed: 29 August 2023).
13. Sawaya GF, Kuppermann M. Identifying a "range of reasonable options" for cervical cancer screening. Obstet Gynecol. 2015;125(2):308-10.
14. McBride E, Marlow LAV, Forster AS et al. Anxiety and distress following receipt of results from routine HPV primary testing in cervical screening: The psychological impact of primary screening (PIPS) study. Int J Cancer. 2020;146(8):2113-21.
15. Liverani C. Reconsidering Primary HPV Testing in Cervical Cancer Screening. Journal of Life Sciences. 2015;10.

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