New Approaches in the Evaluation for High-Risk Human Papillomavirus Nucleic Acid Detection Devices

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Microbiology Devices Panel Meeting

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Welcome!

Thank you for your public service!!

Today's Meeting:

What will be discussed at today's meeting are new approaches to the development and evaluation of devices intended for the detection of High Risk HPV that might allow for advances and innovation for HPV diagnostics and reduced burden to device manufacturers.

FDA's Mission:

- **Protect public health**
- **Promote public health**

FDA is also responsible for advancing the public health by facilitating to speed innovation that make devices more effective, safer, and more affordable and by helping the public to get the accurate, science-base information they need to use devices to maintain and improve their health.

Why Now?
Accumulated Knowledge!

Scientific:

- A negative HR HPV device result is associated with a <1% risk of developing CIN3+ over the course of 5 years (Gage 2016)
- About 50% of CIN2 lesions regress spontaneously in 2 years (Tainio 2018)

Device Safety & Effectiveness:

- FDA approved 5 devices of this type; 2 based on clinical studies that enrolled 30,000-45,000 women
- FDA has evaluated device performance using multiple collection devices (i.e. broom, brush) and liquid based cytology media (i.e., PreservCyt, SurePath)

Vaccination and Clinical Trial:

- Prevalence of vaccine-targeted HPV types decreased 60-70% within 8 years of vaccine introduction (Oliver 2017)
- CIN2+ lesions caused by vaccine targeted types decreased by ~ 8% between 2008 and 2014 (McClung 2019)

Meeting Goals:

Discussion & panel recommendation:

- Outlined issues with current clinical study design for HPV device evaluation
- Data analysis approaches for performance evaluation of HR HPV devices
- FDA's proposals addressing other outlined issues such as 'intended use'

Agenda:

- Morning: Presentations and Open Public Hearing
- Afternoon: Questions to the Panel and Deliberation


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