Quest Diagnostics®

More options for screening more patients

Our comprehensive cervical cancer screening portfolio empowers you to meet every unique patient need.

- **Co-testing with Pap and HPV**
- **Primary HPV screening, physician-collected**
- **HPV screening, patient self-collected**

Quest Diagnostics is committed to helping you **deliver best-in-class screening and testing.**

Every woman should have access to potentially life-saving screening

Ensuring routine cervical cancer screening remains a challenge[1]

4.4M fewer
American women received screening in 2021 versus 2019[2]

1.7% increase
in incidence of cervical cancer in women 30-44 years old[3]

Quest is committed to supporting you in providing the necessary testing for your patients. Our comprehensive array of screening options is designed to reduce barriers and empower you to tailor testing approaches to meet the unique needs of each patient.

Quest supports leading cervical cancer screening guidelines

	American College of Obstetricians and Gynecologists[4a]	US Preventive Services Task Force[5] (guidelines in process)	American Cancer Society[6]
Women younger than 21	No screening	No screening	No screening
Women ages 21-29	Pap alone every 3 years	Pap alone every 3 years	No screening ages 21-24
Women ages 30-65	• Pap alone every 3 years • Co-testing (per guidelines, Pap and HPV) every 5 years • Primary HPV screening every 5 years	• Pap alone every 3 years • Co-testing (Pap and HPV) every 5 years • Primary HPV screening every 5 years	**The following is for women 25-65 years of age:** • Primary HPV screening every 5 years **Alternative options if HPV primary not available:** • Pap alone every 3 years • Co-testing (Pap and HPV) every 5 years
Women older than 65	Screening should be discontinued if patient has had adequate negative prior screening results and no history of CIN 2+. Recommend continuing age-based screening for ≥20 years in those patients with a history of CIN 2, CIN 3, or adenocarcinoma in situ. Adequate negative prior screening results is defined as 3 consecutive negative Paps or 2 consecutive negative co-tests within the past 10 years, with the most recent test occurring within the past 5 years.		
Women after hysterectomy with removal of the cervix and no history of high-grade precancer or cervical cancer	Do not screen	Do not screen. Applies to women without a cervix and without a history of CIN2 or a more severe diagnosis in the past 20 years or cervical cancer ever	Those who have had their cervix removed, such as from a hysterectomy, don't need screening as long as the surgery was done for reasons not related to cervical cancer or serious precancer
Women who have been vaccinated with the HPV vaccine	Follow age-specific recommendations (same as unvaccinated women)		

Note: The above table may not be inclusive of every cervical cancer screening option in these guidelines, including Pap with reflex to HPV scenarios. Clinicians should refer to health plan policy algorithms for coverage instructions on allowable screening and management of abnormal options and related coverage.

[a] Endorses the 2018 USPSTF guidelines.

Co-testing with Pap and HPV provides 2 levels of assurance

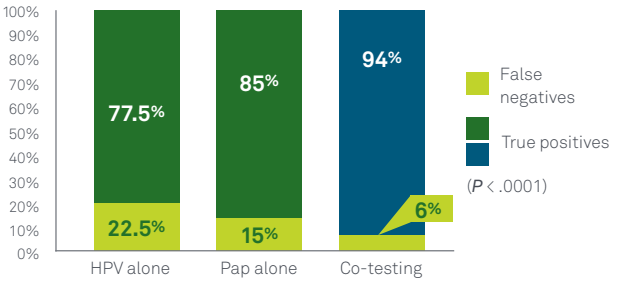
Co-testing with Pap and HPV together helps identify more cases of cancer and precancer than either test alone. In a recent Quest Diagnostics Health Trends® retrospective, longitudinal study, co-testing had a significant impact (see charts below).[7]

The Aptima® mRNA HPV assay targets E6/E7 mRNA and identifies high-risk infections that are both present and active, reducing the need for unnecessary patient call-backs and overtreatment. HPV types 16, 18, and 45 are associated with up to 80% of squamous cell carcinomas and up to 92% of HPV-related cervical adenocarcinomas.

Co-testing versus HPV alone

HPV was not detected in 1 in 5 cases of cervical cancer[7]

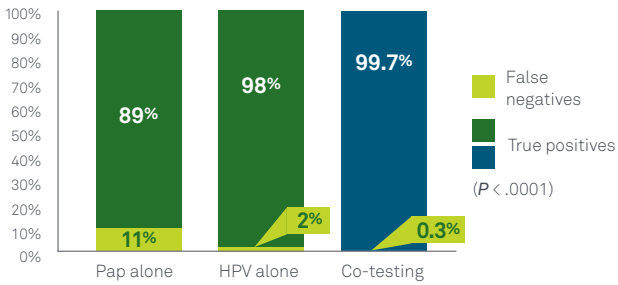
Data <12 months to cancer diagnosis



Co-testing versus Pap alone

Pap alone did not identify presence of a precancerous condition in 11% of patients[7]

Data <12 months to precancer diagnosis



Guidelines from leading organizations including ACOG,[a] USPSTF, and ASCCP endorse co-testing as a Grade A level screening option for women ages 30-65.

[a] Endorses the 2018 USPSTF guidelines.

Pap testing excellence and accuracy[b]

- Almost 1 in 5 Pap tests are reviewed a second time as part of routine quality control
- Our quality control standards meet, and often exceed, all state and federal requirements
- Our team of medical experts includes 400 anatomic and clinical pathologists—a significant number of whom have a gynecologic subspecialty—who meet frequently to discuss your most challenging cases
- We perform a higher volume of Pap and high-grade lesion evaluations than most other labs

[b] No lab test is 100% accurate due to multiple reasons. Quest has controls in place to reduce these conditions.

Trust Quest to help elevate your patient care

We provide robust cytology testing and reporting in order to meet your cervical cancer screening needs.

Excellent performance
Tests that provide excellent clinical performance, specimen stability, and specimen availability[8,9]

Accurate results
Advanced technology that enhances the cytotechnologist's ability to interpret cells on the slide

Enhanced reporting
Talk to your representative about our enhanced report for Pap and HPV testing for integrated, streamlined results

Pap summary reports
Your Quest Diagnostics representative can also ensure that you receive electronic access to a comprehensive list of all Pap and HPV patient results organized in order of highest risk on a monthly basis

Primary HPV screening

As part of strategies to ensure every woman is tested, the USPSTF recommends primary HPV screening **in women 30-65 years old**[5]

With primary HPV screening, the high-risk HPV (hrHPV) test is used as the primary method to assess cervical cancer risk, with the Pap test reserved for follow-up when the hrHPV test identifies potential concerns. With traditional co-testing, both tests are performed simultaneously.

Screen for the types of HPV infection most likely to cause cancer

hrHPV causes virtually all cervical cancers.[10] In fact, 2 high-risk types—HPV 16 and HPV 18—cause 70% of cervical cancers worldwide.[10] HPV testing is recognized as providing the most clinically useful results for detecting cervical cancer risk in its earliest stages when treatment is likely to have the greatest impact.

Testing from Quest detects high-risk HPV strains

Primary HPV screening: cobas® HPV test
The cobas® HPV test is clinically validated and FDA-approved (with automatic reflex to cytology in high-risk positive results) to provide individual detection of HPV 16 and HPV 18 strains, as well as simultaneous pooled results for 12 other high-risk genotypes.[11]

HPV patient self-collected: cobas® DNA HPV assay
The cobas HPV assay utilizes DNA-based PCR technology for the simultaneous detection of HPV genotype 16, type 18 and 12 other high-risk pooled results (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68).[11]

Individual results	12 pooled hrHPV results		
HPV 16	31	33	35
HPV 18	39	45	51
	52	56	58
	59	66	68

> “Strategies that aim to ensure that all women are appropriately screened and receive adequate follow-up are most likely to succeed in further reducing cervical cancer incidence and mortality in the US.”[5]

Self-collect options can help overcome obstacles to traditional screening

A recent study shows that more than a quarter of US women are not up-to-date with cervical cancer screening,[12] and 50% of all new cervical cancers are in women who have never been screened or have not been screened in the previous 5 years.[13]

>25%
of women are not up-to-date with their screening[12]

50%
of new cervical cancers occur in women who have never been screened or who have not been screened in 5 years[13]

In many cases, noncompliance with screening guidelines can be attributed to lack of knowledge or access to appropriate care. There are also some women who delay testing because of the invasive nature of speculum-based specimen collection.

These may include

- Transgender individuals[14]
- Women with religious barriers to such procedures[15]
- Women with a history of physical trauma[16]

For these patients, self-collection provides a more discreet alternative.
In any healthcare setting, the patient can privately collect the specimen using a vaginal swab. Self-collect testing from Quest identifies the same hrHPV genotypes specified in guidelines with similar confidence levels as physician-collected tests, while complying with all major screening guidelines.

Some self-collected patient results may require follow-up.
While a primary self-collected test will fulfill patient screening requirements, a vaginally collected specimen is insufficient for reflex to cytology.

Consequently, patients who test positive or have inconclusive results will still need to undergo traditional cervical collection and, in some cases, may require colposcopy for further evaluation.

Two potential HPV-focused screening journeys

Guidelines continue to evolve, and Quest is committed to staying up-to-date with the most current algorithms.

1 Primary HPV screening

VISIT 1 Cervical collection—reflex to cytology if required		VISIT 2 (IF NEEDED) Colposcopy
Type 16/18 +		Colposcopy
12 other hrHPV+ reflex to cytology	≥ASC-US	Colposcopy
	NILM	Follow up in 12 months
Negative		Routine screening (5-year interval)

2 HPV self-collection[b]

VISIT 1 Vaginal collection	VISIT 2 (IF NEEDED) Cytology		VISIT 3 (IF NEEDED) Colposcopy
Type 16/18 +			Colposcopy
12 other hrHPV+	Bring patient back for cytology	≥ASC-US	Colposcopy
		NILM	Routine screening (5-year interval)
Negative			Routine screening (5-year interval)

[b] Hypothetical patient journey modeled after current guideline recommendations.

Together, we can remove barriers to cervical cancer screening

Self-collection provides patients with an effective, speculum-free HPV screening option

- Increase compliance among traditionally underserved populations
  - Transgender individuals
  - Victims of abuse
  - Those with religious or cultural objections
  - Anyone unable or unwilling to undergo a speculum exam

Part of our ongoing commitment to women's health

- Supported by advanced esoteric testing labs
- Testing options also include physician-collected co-testing with both Pap plus HPV or Pap alone, HPV primary screening, and HPV self-collection

The benefits of teaming with the largest provider of diagnostic services

- Guideline-based solutions
- Support from our nationwide team of medical and scientific experts
- Quanum® online lab services to simplify ordering with enhanced results, transparent pricing, and billing support on phone or laptop
- In-network access with most private insurance plans, Medicare, and Medicaid, which helps to minimize billing and reimbursement challenges
- Financial assistance programs where affordability is a barrier to appropriate care

Additional information can be found in the Quest test directory at **QuestDiagnostics.com/TestDirectory** or by contacting your **local Quest Diagnostics representative.**

References

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