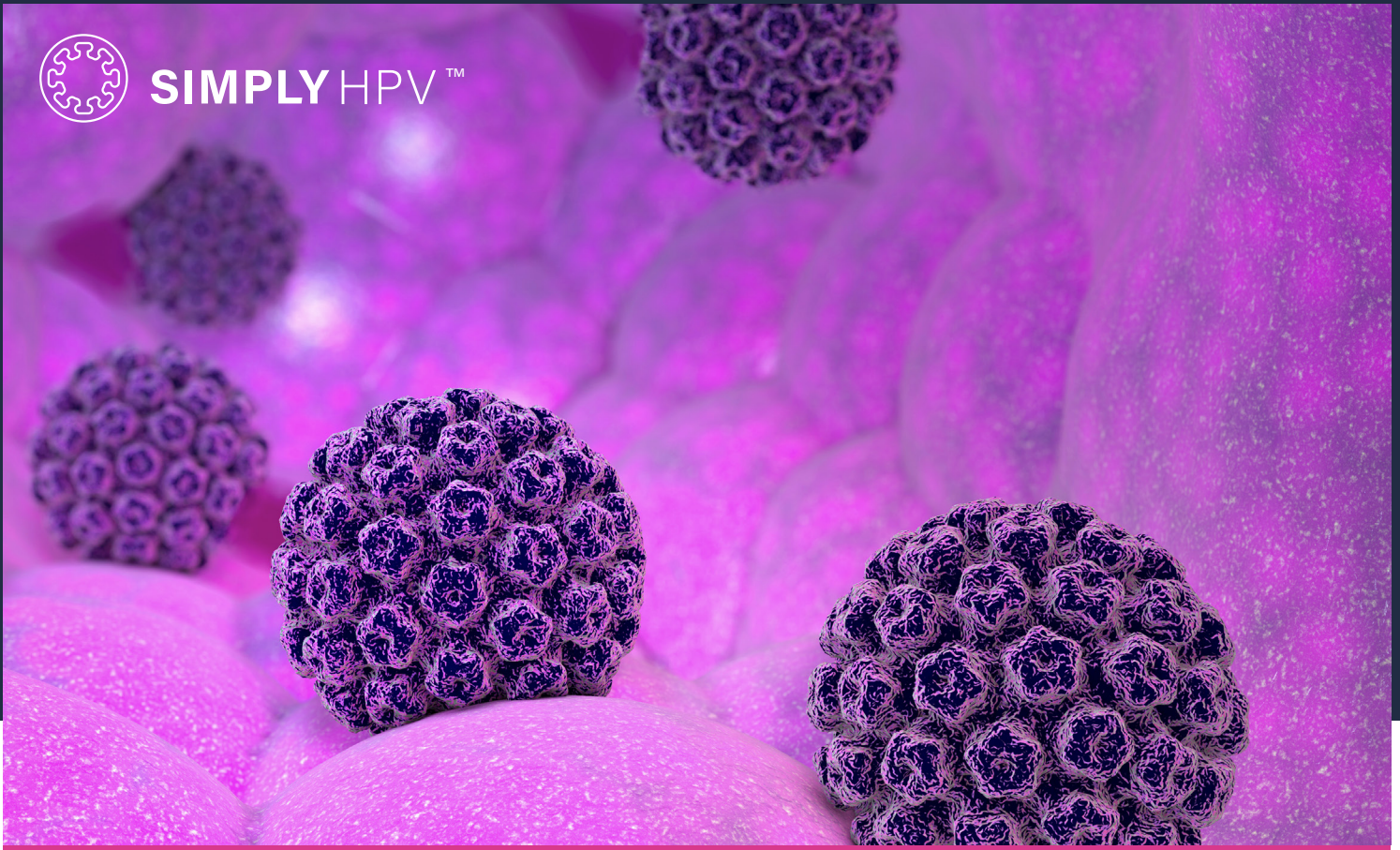
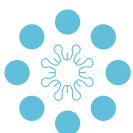


WHITE PAPER

THE IMPORTANCE OF HPV SCREENING



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SPECTRUM
SIMPLYTEST™

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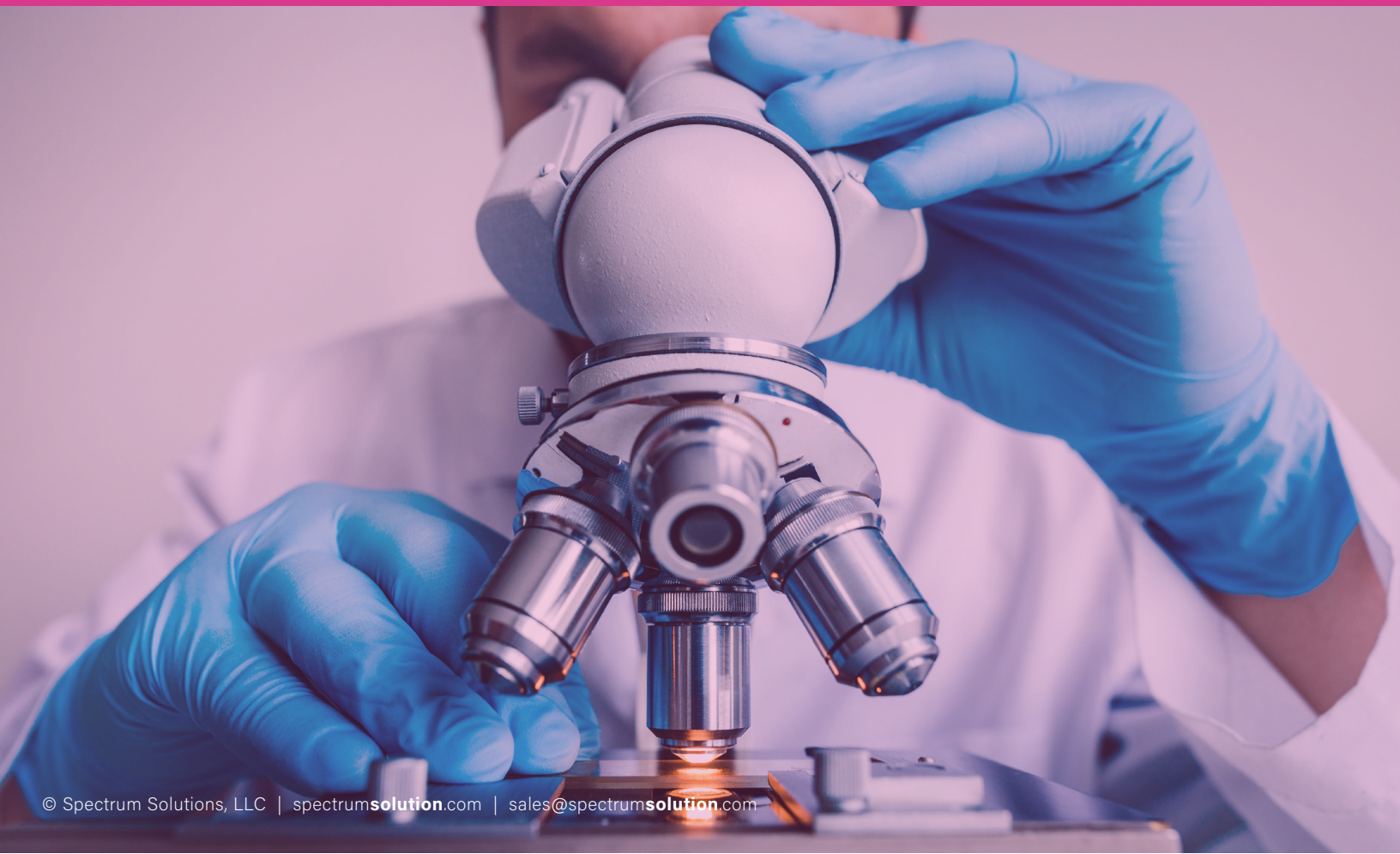
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1

EXECUTIVE SUMMARY

Early detection of high-risk HPV can lead to improved management and possible prevention of HPV related cancers. SimplyHPV™ looks for the presence of high-risk HPV strains that are associated with the development of cervical, vaginal, penile, anal or head/neck cancer.

- HPV is the most common sexually transmitted infection, with most sexually active individuals becoming positive at some point in their lives.
- HPV is the leading cause of cervical cancer, making early screening programs vital to preventative treatments, administer vaccines, and control transmission.
- SimplyHPV's™ kit includes devices for self-collection, which is critical to adoption and ongoing retention for screening and care.
- SimplyHPV™ is a PCR-based test for 14 high-risk HPV strains with an industry-leading 100% specificity and sensitivity assay.

2

INTRODUCTION

Human papillomavirus (HPV) is the most common sexually transmitted infection (STI). It is transmitted through sexual and close skin-to-skin contact. In 2018, there were a reported 43 million infections in the US, many of which were mostly young adults in their early 20s and late teens. Most people recover within two years of infection, but 10% of reported cases develop health issues such as genital warts and cancer. About 19,400 women experience cancers caused by HPV every year; however, there remains approximately 1.5 billion women that have never been screened.¹

Accumulated evidence supports the use of HPV-based tests for the detection of precancerous lesions as a preferred test for primary screening.²

3

SYMPTOMS OF HPV INFECTION

HPV infection does not usually cause any symptoms. Most people who have it do not realize that they have the infection and experience very few problems. But sometimes the virus can cause painless growths or lumps around the vagina, penis or anus (genital warts). Because most HPV infections are asymptomatic there is significant importance in periodic screening for infection or for consideration of HPV vaccine.

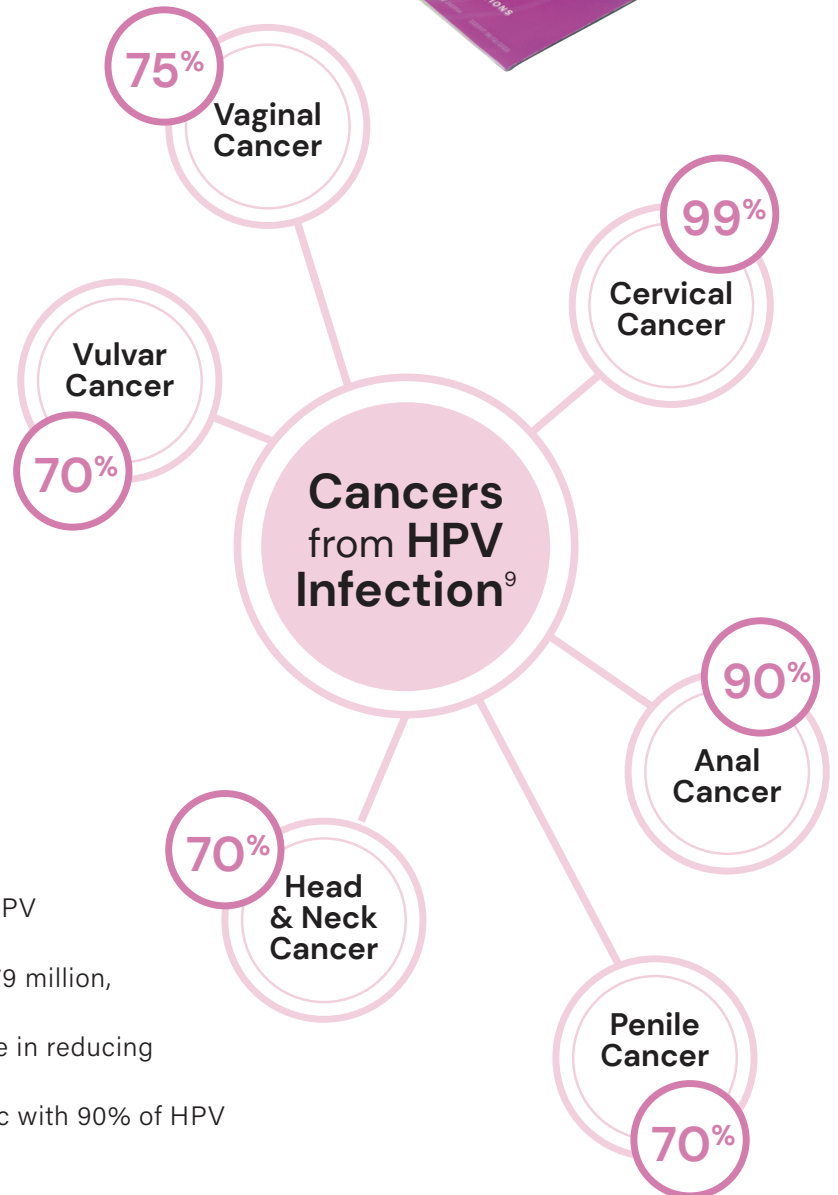
Using an HPV DNA NAAT as the primary screening test prevents more cervical cancers and saves more lives than using visual inspection with acetic acid (VIA) or cytology (conventional Pap smear and liquid-based cytology) as the primary screening test.³



4

HPV INFECTION IN HEALTH AND DISEASE

- Cervical cancer is caused by persistent infection with high-risk human papillomaviruses.⁴
- Almost all sexually active individuals will acquire HPV at some point in their lives.⁵
- 40% overall and 25% of women are infected within 2 years of first sexual encounter.⁶
- 4 out of 10 cancer patients infected with HPV are men.
- Most head and neck cancer associated with HPV are diagnosed in men.
- In the United States, there are approximately 79 million, 14 million new, infections annually.
- Screening programs have been highly effective in reducing cervical cancers over the past 50 years.⁷
- Infection is usually transient and asymptomatic with 90% of HPV infections will clear within 2 years.⁸



5

LABORATORY PROCEDURES

The CDC recommends routine screening for unvaccinated women aged 21 to 65 years. Multiple state-run programs are pushing education in their communities with the expectation that will help increase awareness for early screening and preventative testing. In order to gain adoption and maintain compliance, self-collected specimens have now gain tremendous traction because the of ease of use, convenience, privacy, and physical and emotional comfort (including decreased embarrassment, anxiety, and pain).¹⁰

SimplyHPV™ test has been validated using a cervical brush that can self-administered by an individual in a setting that is conducive to their well-being.

SimplyHPV™ is a PCR based test that looks for 14 high-risk HPV strains (also called types). The test specifically identifies HPV-16 and HPV-18 while simultaneously detecting other high-risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68).

HPV-16 and HPV-18 are the most common HPV strains that cause genital cancer.^{11,12}

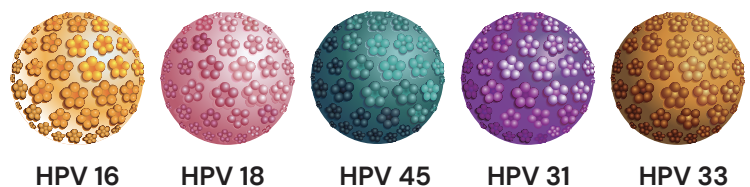
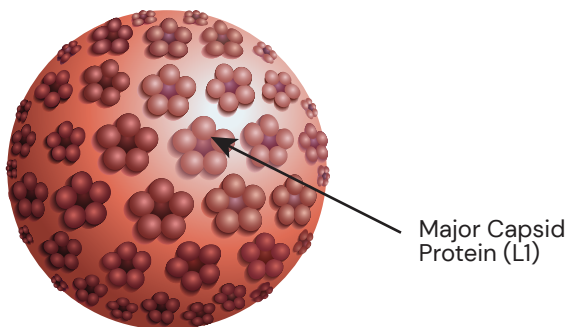
SimplyHPV™ does not detect types of HPV that are not considered high risk for cancer development.

6

ACCURACY OF RESULTS

Sensitivity (expected on-target amplification) was evaluated based on comparison to well-characterized, normalized genomic DNA, and multi-target synthetic DNA samples. While the FDA requirement is > 90%, the sensitivity of SimplyHPV across all assays and days was 100%.¹³

Specificity (off-target amplification) was analyzed by examining potential cross-reactivity with common microflora, related species, and cross-reactivity among targets within the panel, using well-characterized, normalized genomic DNA pools. No Template Controls (NTC) and negative extraction controls (NEC) were evaluated for specificity in the absence of microbial DNA targets. The specificity across all assays was 100%, once again exceeding the FDA requirements for primary HPV testing.



Are the five most frequent and aggressive HPV high-risk types involved in the development of precancerous lesions and cancers of various organs first and foremost cervical cancer.

7

CONCLUSION

The medical community alongside federal and state programs have laid an important foundation for the public to be more aware of HPV and its dangerous long-term pathology. While frequent screening continues to be a common theme, it has been challenging to meet the volume of testing required across billions. In addition, there is limited availability of self-administered kits with proper specificity and sensitivity assays. SimplyHPV™ provides an opportunity to reach a broader population, including underserved communities where individuals may have socioracial stigmas associated with healthcare. The effectiveness of the test ensures highly accurate, consistent results, which permits a chance for appropriate interventions when necessary.



Molecular Screening is an Important part of Prevention

The American Society for Clinical Pathologists (ASCP), recommend screening for all women starting at age 21 through 65.





REFERENCES

1. Sarah L. Bedell, MD and others, Cervical Cancer Screening: Past, Present, and Future, *Sexual Medicine Reviews*, Volume 8, Issue 1, January 2020, Pages 28–37, <https://doi.org/10.1016/j.sxmr.2019.09.005>
2. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin*. 2021;71:209–49.
3. Human papillomavirus (HPV) nucleic acid amplification tests (NAATs) to screen for cervical pre-cancer lesions and prevent cervical cancer: policy brief ISBN 978-92-4-004524-8 (electronic) ISBN 978-92-4-004525-5 (print)
4. Okunade KS: Human papillomavirus and cervical cancer. *J Obstet Gynaecol* 2019;1-7.
5. Chesson HW, Dunne EF, Hariri S, Markowitz LE: The estimated lifetime probability of acquiring human papillomavirus in the United States. *Sex Transm Dis* 2014, 41(11):660-664.
6. Castellsague X, Paavonen J, Jaisamrarn U, Wheeler CM, Skinner SR, Lehtinen M, Naud P, Chow SN, Del Rosario- Raymundo MR, Teixeira JC et al: Risk of first cervical HPV infection and pre-cancerous lesions after onset of sexual activity: analysis of women in the control arm of the randomized, controlled PATRICIA trial. *BMC Infect Dis* 2014, 14:551.
7. Yang DX, Soulos PR, Davis B, Gross CP, Yu JB: Impact of Widespread Cervical Cancer Screening: Number of Cancers Prevented and Changes in Race-specific Incidence. *Am J Clin Oncol* 2018, 41(3):289-294.
8. Huber J, Mueller A, Sailer M, Regidor PA: Human papillomavirus persistence or clearance after infection in reproductive age. What is the status? Review of the literature and new data of a vaginal gel containing silicate dioxide, citric acid, and selenite. *Womens Health (Lond)* 2021, 17:17455065211020702.
9. <https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-and-cancer>
10. Nishimura H, Yeh PT, Oguntade H, et al. HPV self- sampling for cervical cancer screening: a systematic review of values and preferences. *BMJ Global Health* 2021;6:e003743. doi:10.1136/ bmjgh-2020-003743
11. Burd EM: Human Papillomavirus Laboratory Testing: the Changing Paradigm. *Clin Microbiol Rev* 2016, 29(2):291- 319.
12. Burd EM, Dean CL: Human Papillomavirus. *Microbiol Spectr* 2016, 4(4).
13. Meijer CJ, Berkhof J, Castle PE, Hesselink AT, Franco EL, Ronco G, Arbyn M, Bosch FX, Cuzick J, Dillner J, Heideman DA, Snijders PJ. Guidelines for human papillomavirus DNA test requirements for primary cervical cancer screening in women 30 years and older. *Int J Cancer*. 2009 Feb 1;124(3):516-20. doi: 10.1002/ijc.24010. PMID: 18973271; PMCID: PMC2789446.