ABBOTT RECEIVES FDA APPROVAL FOR HPV TEST TO RUN ON ALINITY M, OFFERING PRIMARY HPV SCREENING AND ASSESSMENT OF HIGH-RISK CANCER-CAUSING TYPES OF HPV

- According to the U.S. Centers for Disease Control (CDC), most sexually active adults will experience HPV infections; new test detects those HPV genotypes that could lead to cancer
- Abbott's new HPV test uses molecular technology to provide genotype determination on the 14 high-risk, cancer-causing types of HPV
- The test is one of the few[i] HPV tests approved for use as a primary screen for cervical cancer as recommended by professional guidelines

ABBOTT PARK, Ill., Nov. 2, 2023 /PRNewswire/ -- Abbott (NYSE: ABT) has received U.S. Food and Drug Administration (FDA) approval for its molecular human papillomavirus or HPV screening solution, adding a powerful cancer screening tool for detecting high-risk HPV infections to the Alinity m family of diagnostic assays.

According to the U.S. Centers for Disease Control (CDC), HPV infection is extremely common – most sexually active adults will experience an HPV infection at some point in their lives. There are many different strains of HPV, each with a unique genetic signature or genotype. Specific genotypes of HPV can cause cancer, including cervical cancer in women. Historically, Pap tests were used to screen for cervical cancer, but today professional guidelines[ii] recommend testing for HPV infections, called primary screening, over Pap testing as the best way to screen for cervical cancer. However, some commonly used HPV tests are not approved for primary screening and only deliver limited information regarding which of the many different genotypes of HPV are present.

The Alinity m high risk (HR) HPV assay is approved as a test for HPV detection and for use in routine cervical cancer screening as per professional medical guidelines. The assay is also approved for use in combination with a Pap test, for patients and physicians who prefer to use both tests, called co-testing. Importantly, the Alinity m HR HPV assay delivers information on five risk groups covering the 14 different potentially cancer-causing genotypes of the virus, helping physicians identify not just if a patient has an HPV infection but whether that infection is caused by one (or more) of the types that may cause cancer.

"Professional guidelines are clear in their recommendation to shift away from Pap tests in favor of clinically validated, primary HPV testing as the best way to detect risk of cervical precancer and cancer," said Mark H. Stoler, M.D., professor (emeritus) of pathology and clinical gynecology at the University of Virginia. "As more women are vaccinated against the highest risk strains of the virus, it continues to be important to screen women for other HPV strains that have the potential to cause cancer. Extended genotyping enables us to improve risk assessment and tailor follow up for patients so we can minimize unnecessary treatment while still guarding against cancer development."

"HPV testing is a powerful tool for detecting HPV infections that can lead to certain cancers, including cervical cancer and illustrates the power of molecular diagnostics in infectious disease," said Keith Cienkus, vice president of Abbott's molecular business. "The Alinity m HR HPV assay was carefully designed to support patient care and streamline HPV testing."

The Abbott Alinity m HR HPV assay will be available for use on Abbott's Alinity m laboratory instrument, Abbott's most advanced molecular PCR platform which provides fast results in high volumes. Assays available for use on the Alinity m system in the U.S. include: SARS-CoV-2 (Emergency Use Authorization), Resp-4-Plex (Emergency Use Authorization), HCV (Hepatitis C), HBV (Hepatitis B), HIV-1 (Human Immunodeficiency Virus type 1), STI (CT/NG/TV/MG), CMV (Cytomegalovirus) and EBV (Epstein–Barr virus).

About Alinity:
Abbott's Alinity family of harmonized solutions is unprecedented in the diagnostics industry, working together to address the challenges of using multiple diagnostic platforms and simplifying diagnostic testing. Alinity systems are designed to be efficient – with the goal of running more tests in less space, generating test results faster, and minimizing human errors – while continuing to provide quality results. The availability of the Alinity systems and tests varies by geography. More information is available at alinity.com.

About Abbott:
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 115,000 colleagues serve people in more than 160 countries.

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[i] U.S. Food and Drug Administration. See www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm

[ii] The American College of Obstetricians and Gynecologists (ACOG), the Society of Gynecologic Oncology (SGO)

and the American Society for Colposcopy and Cervical Pathology (ASCCP) all endorse the U.S. Preventative Services Task Force (USPSTF) cervical cancer screening recommendations. See ACOG Updated Cervical Cancer Screening Guidelines reaffirmed April 2023. https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/04/updated-cervical-cancer-screening-guidelines

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