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# OPKO Lab Receives Accreditation From College of American Pathologists

***CAP Accreditation is Awarded to Clinical Laboratories Meeting the Highest Standards of Excellence in Quality Laboratory Practices***

NASHVILLE, Tenn. & MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) today announced that the College of American Pathologists (CAP) has awarded accreditation to the OPKO Lab in Nashville, Tennessee based on results of a recent on-site inspection. This accreditation is awarded to facilities that meet the highest standards of quality in laboratory services. With this recognition, OPKO Lab joins the prestigious ranks of some of the most prominent clinical laboratories in the world.

"We are extremely proud to receive CAP accreditation," stated David Okrongly, OPKO Lab's President. "This important milestone reflects our commitment to providing the highest quality standards for our clinicians and their patients."

The U.S. federal government recognizes the CAP Laboratory Accreditation Program, which began in the early 1960s, as being equal-to or more-stringent-than the government's own inspection program. During the CAP accreditation process, inspectors examine the laboratory's quality system, quality control program and quality records for the preceding two years. CAP inspectors also examine laboratory staff qualifications, validation of tests and systems, equipment, facilities, safety program and record, and overall management.

"The OPKO Lab team has always held the quality of the results we provide to our physicians and patients as central to our mission," said Dr. Vinita Mathur, Laboratory Director of OPKO Lab. "The College of American Pathology accreditation is recognition of our commitment to quality and makes us all very proud."

## **About OPKO Lab**

OPKO Lab, a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, as amended ("CLIA"), operates as a full-service medical laboratory with a urologic focus and serves as the commercial platform for the U.S. launch of the 4Kscore test®. OPKO Lab is a division of OPKO Health, Inc., a multi-national pharmaceutical and diagnostic company. OPKO Health, Inc. works to establish industry-leading positions in medical markets through discovery, development, and commercialization expertise and through novel technologies. OPKO's offerings include point-of-care diagnostics, novel molecular diagnostics, and proprietary pharmaceuticals and vaccines. For more information, visit <http://www.opko.com>.

## **About the 4Kscore Test**

The 4Kscore is the only blood test that accurately identifies risk for aggressive prostate cancer. The 4Kscore measures the blood plasma levels of four different prostate-derived

kallikrein proteins: Total PSA, Free PSA, Intact PSA and Human Kallikrein-2 (hK2). These biomarkers are combined with a patient's age, Digital Rectal Exam (DRE) status (nodule / no nodule), and prior negative biopsy status (yes / no) using a proprietary algorithm to calculate the risk (probability) of finding a Gleason Score 7 or higher prostate cancer. The four kallikrein panel of biomarkers utilized in the 4Kscore Test is based on over a decade of research conducted by scientists at Memorial Sloan-Kettering Cancer Center and leading European institutions. The 4Kscore Test provides individualized risk for the presence of aggressive prostate cancer and adds new information to the shared decision making discussion between Urologists and their patients.

## **About the College of American Pathologists**

The College of American Pathologists (CAP), celebrating 50 years as the gold standard in laboratory accreditation, is a medical society that serves more than 18,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. The College advocates accountable, high-quality, and cost-effective patient care. More information about the CAP can be found at [www.cap.org](http://www.cap.org).

## **SAFE HARBOR STATEMENT**

*This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding our ability to maintain CAP accreditation, expected benefits of the 4Kscore test, that the 4Kscore will accurately identify risk for aggressive prostate cancer, whether the test will bring great benefit to patients and the healthcare system by helping avoid the cost of unnecessary, sometimes harmful procedures, whether the test will accurately predict high-grade cancers, whether OPKO will successfully commercialize the 4Kscore, the market for and expected sales of 4Kscore, whether the test will be an important benefit for Urologists and their patients and will lead to lower overall healthcare costs, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.*

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Source: OPKO Health, Inc.