

# Client Update

BioReference  
LABORATORIES

genpath

LABORATORIO  
Buena Salud

OPKO Health Companies

## November 2019 – 4Kscore LCD

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Test Name	Test Code	Effective Date
4Kscore® Local Coverage Determination	N/A	12/30/19

We are pleased to share exciting news about the 4Kscore® Test. OPKO Health, Inc. has been notified that Novitas Solutions, Inc. issued its final Local Coverage Determination (LCD) for the 4Kscore® test with defined coverage criteria, effective December 30, 2019. Full text of the final LCD can be found here <https://go.cms.gov/2Qm2l4l>.

The 4Kscore® test is used in men after an abnormal prostate-specific antigen (PSA) or digital rectal exam (DRE) result. It provides the risk of finding high-grade prostate cancer if biopsy were to be performed and has the potential to minimize avoidable biopsy procedures. Data from two prospective clinical studies involving approximately 1,500 patients in urology centers in the U.S. demonstrated that the 4Kscore® test had 94% sensitivity and 95% Negative Predictive Value for detecting aggressive prostate cancer. The 4Kscore® test has been used by more than 4,000 urologists, with more than 250,000 tests performed. The test has been included in the National Comprehensive Cancer Network Guidelines® (NCCN) since 2015, and European Association of Urology Prostate Cancer Guidelines since 2016. OPKO has offered the 4Kscore® test since 2014 in the U.S., Europe and elsewhere.

As stated by our Executive Chairman Jon R. Cohen, *“The 4Kscore® test is widely recognized by clinicians to be an important tool in the diagnostic paradigm for prostate cancer, and we are pleased with the final LCD by Novitas. This final determination is expected to significantly improve men’s access to the 4Kscore® test. We look forward to continuing to provide urologists with a test that accurately determines a man’s risk of aggressive prostate cancer.”*

For more information about the 4Kscore® test, please visit <https://4kscore.com/>, If you have any further questions, please call 4Kscore Customer Service at 833-4KSCORE (833-457-2673) or contact your dedicated sales account executive.