

WHO TO BIOPSY

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TEST	INDICATION	SCIENCE	RESULTS	COST
Prostate Health Index Beckman Coulter	Blood based test for patients with a PSA between 2-10ng/ml (4-10ng/ml FDA) <ul style="list-style-type: none"> Reduces negative biopsies Calculates risk of finding prostate cancer on biopsy 	FDA approved index of proteins in the blood that combines the concentrations of PSA, freePSA and pro2PSA in a formula that produces the PHI Score, which has three time the specificity for prostate cancer compared to PSA alone.	<ul style="list-style-type: none"> PHI results fall into four categories of risk that prostate cancer may be found on biopsy. 	<ul style="list-style-type: none"> \$499 Medicare: Currently not covered Financial assistance: Available by PCLS 866-725-7522 (PCLS)/855-420-7140 (IDL) Prostatehealthindex.us
4Kscore® OPKO	Indicated for men with an abnormal PSA or DRE as a reflex blood test combined with clinical information to determine an individual patient's risk for high-grade prostate cancer on biopsy <ul style="list-style-type: none"> For patients who are considering a first biopsy or who have had a prior negative biopsy 	Laboratory test measuring 4 kallikreins in the blood (Total PSA, Free PSA, Intact PSA and hK2) and combined with the patient's clinical information in an algorithm to predict the individual patient's risk of having high-grade prostate cancer versus indolent or no cancer.	<ul style="list-style-type: none"> 4K results provide percent probability (positive predictive value) of an individual patient's risk of having high-grade prostate cancer on biopsy. 	<ul style="list-style-type: none"> \$1,185 Medicare: Currently not covered Financial assistance: Contact billing office for issues 800-883-7999 Clinical.opko.com
ConfirmMDx™ MDxHealth	Biopsy tissue based test for patients who are repeat biopsy candidates <ul style="list-style-type: none"> Provides risk stratification on decision for repeat biopsy Eligibility: Patients with a prior negative or HGPIN biopsy result in past 24 months 	Three-gene methylation assay to detect an epigenetic field effect associated with the cancerization process at the DNA level.	<ul style="list-style-type: none"> Negative ConfirmMDx result: Avoid repeat biopsy and monitor with routine screening. Positive ConfirmMDx result: Suspicious areas marked as positive providing repeat biopsy guidance on a prostate map. 	<ul style="list-style-type: none"> \$3,300 Medicare: Covered (LCD#35368) Financial assistance: Available for out of pocket expenses 866-259-5644 Mdxhealth.com
Progenesa® PCA3 Assay Hologic Inc.	Urine-based test, post DRE, which adds useful info when PSA or DRE is inconclusive <ul style="list-style-type: none"> For patients who are considering first or repeat biopsy FDA approved for use in conjunction with other patient info to aid in the decision for repeat biopsy in men ≥ 50 years 	Test detects PCA3 gene that is highly specific for prostate cancer. Measures concentration of prostate cancer gene3(PCA3) and prostate specific antigen (PSA) RNA in post-DRE urine and calculates ratio of PCA3 molecules to PSA molecules to produce the PCA3 score.	<ul style="list-style-type: none"> As the PCA3 score increases, the likelihood for positive biopsy increases. As the PCA3 score decreases, the likelihood for a positive biopsy decreases The greatest diagnostic utility occurs at a cutoff score of 25 	<ul style="list-style-type: none"> \$300-500 Medicare: Covered (CPT Code: 81313) 800-523-5001 Pca3.org
Oncotype DX® Genomic Health	Biopsy tissue based test to help determine how aggressive cancer is by providing a likelihood of favorable pathology. <ul style="list-style-type: none"> For patients that are NCCN Very Low, Low & Intermediate Risk Provides personalized Risk Assessment, aids in the decision for active surveillance or immediate treatment 	Assay looks at 17 genes within 4 pathways (androgen signaling, stromal response, cellular organization, proliferation) to assess tumor aggressiveness.	<ul style="list-style-type: none"> Genomic Prostate Score (GPS) from 0 to 100. Likelihood of freedom from high grade and/or non-organ-confined disease. GPS is reflective of the biology of the tumor at the time of biopsy. 	<ul style="list-style-type: none"> \$4,180 Medicare: Covered Financial assistance: Available for out of pocket expenses 866-662-6897 Oncotypedx.com
ProMark™ Metamark Genetics	Biopsy tissue based prognostic assay for patients with biopsy Gleason Scores 3+3 and 3+4 <ul style="list-style-type: none"> For patients who are deciding between active surveillance and treatment Provides a personalized risk score Can be used as stand-alone risk score or combined with NCCN risk categories 	Eight-protein signature predicts cancer aggressiveness (>4+3 and/or non-organ confined). Selected markers eliminate sampling variability, provides a direct analysis of cancerous regions of interest. Test requires 4 tissue sections.	<ul style="list-style-type: none"> ProMark Score gives a personalized % probability of aggressive cancer. Interpretation as stand-alone result and in combination with NCCN risk categories. Results delivered within an easy-to-interpret, personalized report. 	<ul style="list-style-type: none"> Cost: \$3,900 Medicare: Not currently covered Financial assistance: Available if out-of-pocket cost are greater than \$350 877-743-3338 Metamarkgenetics.com
Prolaris® Myriad Genetics	Biopsy tissue based test for patients who are Active Surveillance candidates. <ul style="list-style-type: none"> Available post-prostatectomy available to determine relative risk of BCR 	46-gene expression signature includes cell cycle progression genes selected based upon correlation with prostate tumor cell proliferation	<ul style="list-style-type: none"> Prolaris score Biopsy is < or = or > than AUA risk group and estimates. 10year mortality risk. Post-surgical results are similar but provide 10 year risk for BCR. 	<ul style="list-style-type: none"> \$3,400 Medicare: Covered Financial assistance: Available if estimated out-of-pocket costs are greater than \$375 800-469-7423 Prolaris.com
Decipher® GenomeDx Biosciences	Tissue based test for patients with adverse pathology post-surgery (radical prostatectomy) <ul style="list-style-type: none"> Provides metastatic risk stratification that can help guide post-operative treatment decisions For patients with pT3 or positive surgical margin or rising PSA Helps determine the need & optimal timing of radiation 	22 RNA biomarkers across multiple biological pathways associated with metastatic progression including cell cycle progression, immune system modulation and androgen signaling. Measures each patient tumor's metastatic risk. Based on the whole transcriptome analysis platform.	<ul style="list-style-type: none"> Decipher provides probability of metastasis at 5 years after surgery, and 3 years after detectable PSA Decipher high risk men may benefit from adjuvant radiation Decipher low risk men can be safely observed with PSA monitoring 	<ul style="list-style-type: none"> Cost: \$3,400 cash pay price Medicare: Covered Financial assistance: Available and patients pay no more than \$295 out-of-pocket Contact phone number for doctor: 1-888-972-1601 Genomedx.com

Specimen Provenance

Know Error® Strand Diagnostics	Oral swab and biopsy tissue based test provides DNA confirmation of specimen provenance <ul style="list-style-type: none"> Rules out undetected transposition or contamination of specimen among patients which could lead to misinterpretation of pathology or biomarker. Increases diagnostic accuracy 	Buccal swab in the clinic sent for DNA match to pathology specimen; may be used with all tissues. STR profiles assessed from multiplex panel of 16 genetic markers.	Results Confirm: <ul style="list-style-type: none"> DNA Match DNA Non-match Contamination 	<ul style="list-style-type: none"> \$1,780 Medicare: Currently not covered Financial assistance: Available and patients pay no more than \$295 out-of-pocket 888-924-6779 Ext. 2 Knowerror.com
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