Urologic Pathology Approved Protocol Selections

INFORM DIAGNOSTICS
A FULGENT GENETICS COMPANY

Practice Name	Account Number

At my request, I hereby authorize Inform Diagnostics to perform the Approved Protocols, as individually selected below, that I believe to be medically appropriate for the diagnosis and/or treatment of my patients, on specimens that I send to Inform Diagnostics for diagnostic testing.

It is Inform Diagnostics' responsibility to emphasize clinician choice, proper disclosure, client/clinician education, and to facilitate the ability of a client/clinician to order any testing that he/she believes to be medically appropriate* for the diagnosis and/or treatment of his/her patients.

TEST REFLEX TO	REFLEX CRITERIA & MEDICAL RATIONALE (check all that apply)
Prolaris®	**31 cell cycle gene analysis to measure the cancer aggressiveness and predict individual's risk of disease progression within 10 years**[1] ☐ All Gleason Scores ☐ 3+3 ☐ 3+4 ☐ 4+3 ☐ ≥8 **For Medicare Beneficiaries**: By ordering Prolaris, I certify that I have completed requisite training and have enrolled in the Prolaris CTR Program (www.ProlarisCTR.com)
Genomic Prostate Score® (GPS) (formerly oncotype DX)	**GPS predicts disease aggressiveness for low, intermediate, and high-risk localized prostate cancers**[2] Gleason Scores ☐ 3+3 ☐ 3+4 ☐ 4+3 ☐ ≥8 **Ineligible for NCCN very-high-risk prostate cancers: T3b-T4, or primary Gleason pattern 5, or >4 cores with Grade group 4 or 5, or ≥ 2 high-risk features (T3a, Grade group 4 or 5, PSA >20 ng/mL).*
Decipher®	**Decipher prostate cancer genomic test to predict adverse pathology for localized disease** ☐ All Gleason Scores ☐ 3+3 ☐ 3+4 ☐ 4+3 ☐ ≥8
ConfirmMDx® for Prostate Cancer	**An epigenetic assay to address false-negative biopsy concerns**[3] ☐ Negative-prostate Bx — All cores are tested ☐ HGPIN-prostate Bx — All cores are tested ☐ Atypical small acinar proliferation (ASAP) — All cores are tested
PTEN & ERG IHC	**To improve prostate cancer risk stratification**[4,5] ☐ All Gleason Scores ☐ 3+3 ☐ 3+4 ☐ 4+3 ☐ ≥8 *†Inform Diagnostics will determine which cores to select based on protocol described below when multiple cancer cores are present and Gleason score is not uniform across cancer sites:* *1. Core with the highest Gleason score* *2. Core with highest percentage tumor involvement (If the same core has both the highest Gleason score and highest percentage of tumor involvement, we will use core with the second highest percentage involvement.)* *3. In some cases, a third core may also be selected to represent bilaterality or other case characteristics.*
PINgenius®	☐ **Upon diagnosis of HGPIN, to help predict the risk of prostate cancer at re-biopsy**[6,7,8]
UroVysion®	**To improve bladder and urinary tract cancer detection complementing urine cytology**[9] ☐ Negative cytology ☐ Atypical/suspicious cytology ☐ Positive cytology ☐ UroVysion® only

Document ID: _____

Your selections will be implemented upon receipt in our lab.

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By signing below, I am aware of the test components, the CPT† codes for the components, and the Medicare reimbursement rates for the tests ordered. I am also aware that the use of a blanket order may result in the ordering of tests which are not covered, reasonable or necessary. I understand the potential implications of signing a blanket order. I also understand that I have the ability to "Opt Out" of the blanket order protocol for each patient by writing "Opt Out" on the individual test requisition, or for all my patients by contacting Inform Diagnostics' Client Services at 866.588.3280.

I confirm that informed consent will be obtained, if required by state law. I certify that I will discuss with each patient their results and how their results inform treatment recommendations. I attest that the clinician name listed below is authorized by law in the relevant jurisdiction to order the test(s) requested herein. I confirm that I maintain on file each patient's assignment of benefits authorizing insurance benefits to be paid to ancillary healthcare service providers.

Clinician Name _____ Signature _____ Date _____

Clinician Name _____ Signature _____ Date _____

Clinician Name _____ Signature _____ Date _____

Clinician Name _____ Signature _____ Date _____

Clinician Name _____ Signature _____ Date _____

Please return the signed form to Inform Diagnostics

Fax 866.688.3280
OR **Email** clientservices@informdx.com

References

1. https://prolaris.com/publications/ Clinical Validation, Clinical Utility and Analytical Validation Publications
2. A 17-gene Panel for Prediction of Adverse Prostate Cancer Pathologic Features: Prospective Clinical Validation and Utility. Eggener S, Karsh LI, Richardson T, Shindel AW, Lu R, Rosenberg S, Goldfischer E, Korman H, Bennett J, Newmark J9, Denes BS. *Urology*. 2019 Apr; 126:76–82.
3. Predicting Cancer Following a Diagnosis of High-Grade Prostatic Intraepithelial Neoplasia on Needle Biopsy: Data on Men With More Than One Follow-Up Biopsy, Kronz J, Allan C, Shaikh A, Epstein J, *Am J Surg Pathol.* 2001 Aug 25(8):1079–85.
4. ERG overexpression and multifocality predict prostate cancer in subsequent biopsy for patients with high-grade prostatic intraepithelial neoplasia. Shah RB, Li J, Dhanani N, Mendrinos S. *Urol Oncol.* 2015 Nov 13 Epub ahead of print.
5. Fluorescence in situ hybridization study shows association of PTEN deletion with ERG rearrangement during prostate cancer progression. Han B, Mehra R, Lonigro RJ, Wang L, Suleman K, Menon A, Palanisamy N, Tomlins SA, Chinnaiyan AM, Shah RB. *Mod Path.* (2009) 1–11
6. TMPRSS2:ERG Gene Fusion Predicts Subsequent Detection of Prostate Cancer in Patients with High-grade Prostatic Intraepithelial Neoplasia. Park K, Dalton JT, Narayanan R, Barbieri CE, Hancock ML, Bostwick DG, Steiner MS, Rubin MA. *Journal of Clin Oncology*, 2013
7. Clinical Application of Novel ERG immunohistochemistry in Prostate Cancer Diagnosis and Management. Review. Shah RB. *Adv Anat Pathol*, 20(2): 117–24, 2013
8. ERG oncoprotein expression in prostate cancer: clonal progression of ERG-positive tumor cells and potential for ERG-based stratification. *Prostate Cancer Prostatic Dis* 2010;13:228–37.
9. A comparison of cytology and fluorescence in situ hybridization for the detection of urothelial carcinoma. Halling C, King W, Sokolova IA, Meyer RG, Burkhardt HM, Halling AC, Cheville JC, Sebo TJ, Ramakumar S, Stewart CS, Pankratz S, O'Kane DJ, Seelig SA, Lieber MM, Jenkins RB. *J Urol.* 2000 Nov. 164, 1768–1775.

***MEDICAL NECESSITY**

The Centers for Medicare and Medicaid Services (CMS) is responsible for administering Medicare and other federally mandated healthcare programs throughout the United States. Medicare laws prohibit payment for services and items deemed by local Medicare Carriers as not medically reasonable and necessary for the diagnosis or treatment of an illness or injury. In such cases, documentation of "medical necessity" is required before a claim may be paid. Medicare, with a few exceptions, will not pay for routine checkups or screening tests, defined as "diagnostic procedures performed in the absence of signs or symptoms."

†CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.