IMPORTANT TEST UPDATES
TEST UPDATE 697

NOTICE DATE: December 27, 2019
EFFECTIVE DATE: January 1, 2020

TEST CHANGE

MIPS
Order code MIPS
CPT Code 0113U

Effective January 1, 2020, we are writing to provide some exciting updates regarding the Mi-Prostate Score (MiPS) urine test for prostate cancer. Based on additional clinical data and expanded discussion with clinicians, we have made significant changes to the test and the clinical report provided to you and your patients. Given the complex landscape of prostate cancer detection, our aim is to provide a clear, maximally-useful report that will best support you in guiding your patients through the decision-making process. We have summarized these updates below:

1. Introducing MyProstateScore: To reflect the individual-specific nature of our test, which is based upon three patient-specific measurements (Serum PSA, Urine PCA3 and Urine TMPRSS2:ERG), we have changed the name of the test to MyProstateScore (MPS).

2. Focus on high-grade (Gleason score ≥7) prostate cancer: Based on the body of literature establishing the non-metastatic, non-lethal nature of low-grade (Gleason score 6) cancer1,2 and universal endorsement of active monitoring strategies for low-grade disease, MPS is intended for use in predicting risk of aggressive (Gleason score ≥7) cancers, which are most likely to benefit from early detection and treatment. On the new report, there is only one score provided, which reflects the probability of detecting high-grade cancer upon biopsy.

3. Clear, practical approach to test interpretation: Consistent with our previous approach, MPS values range from 0 to 100, and higher scores indicate an increased risk of high-grade cancer. To facilitate ease of interpreting MPS results, we will now provide clearly-defined risk categories along with each score report. These categories were developed in our clinical training cohort (n=733) and validated in a large external cohort (n=1198).3 MPS risk categories and associated probabilities of high-grade cancer are listed in the table.

Table: Validation Cohort Findings

<table>
<thead>
<tr>
<th>MPS</th>
<th>% Population</th>
<th>Probability GS≥7</th>
<th>MPS Risk Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 9</td>
<td>25%</td>
<td>1.4%</td>
<td>Low</td>
</tr>
<tr>
<td>10 – 28</td>
<td>40%</td>
<td>14%</td>
<td>Intermediate</td>
</tr>
<tr>
<td>29 – 100</td>
<td>35%</td>
<td>32%</td>
<td>High</td>
</tr>
</tbody>
</table>

In men referred for prostate biopsy, a low-risk MPS ruled out the likelihood of high-grade cancer on biopsy with a 98.6% negative predictive value (98.1% sensitivity). MPS testing would have enabled one-quarter of patients (25%) to forego biopsy, with only 0.3% of patients (4 of 1198) having a diagnosis of high-grade cancer delayed.
By contrast, nearly one-third of men with MPS ≥9 harbored high-grade cancer; such patients are most likely to benefit from immediate biopsy with or without additional testing.

4. New commercial partner: The MyProstateScore which was originally developed by Hologic/Gen-Probe has now been exclusively licensed to LynxDx, a Michigan Medicine spin-off company focused on the commercialization and further development of MyProstateScore. Representatives from LynxDx may engage your practice to understand how the test is utilized and how MyProstateScore can better serve patients and physicians.

Again, we are hopeful that these updates will help to provide maximal clinical benefit to you and your patients. If you have further questions in regards to MyProstateScore, feel free to contact Michigan Medicine Laboratories (MLabs) at 800.862.7284

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**EFFECTIVE DATE:** January 21, 2020

**TEST DELAY**

**pH, Pleural Fluid Panel**
Order Code: FPH
CPT Code: 83986

Effective January 21, 2020, MLabs will offer Pleural Fluid Panel (FPH) testing. The test was originally scheduled to go live December 17, 2019 but has been delayed.

Collection Instructions: Collect a minimum of 0.3 mL of fluid in a blood gas syringe. Ship the specimen refrigerated within 24 hours of collection.

Analytic Time: Daily, 24 Hrs.