

# The ExoDx™ Prostate Test and mpMRI Independent but Complementary

mpMRI is a powerful imaging technology that provides additional insight into which tumors may be clinically significant, along with information for biopsy targeting.

However, all risk assessment methods, including mpMRI or biomarkers, have strengths and limitations. The key to more informed clinical decision-making is to understand each technology's limitations and consider the appropriate integration of complementary methods.

## 1. Reader Variability/Subjectivity

Subjective visual assessment of mpMRI imaging is driven by experience and expertise.<sup>4,6,23,52</sup>

## 2. Tumor Visibility

Multiple factors affect tumor visibility such as size, location and architecture. Tumors that are not visible on mpMRI are one aspect of the mpMRI false negative rate for HGPCa. 16-24% of all HGPCa (≥GG2) are not visible on mpMRI.<sup>28,56,57</sup>



## 3. False Negatives

Guidelines reflect published data emphasizing that, by itself, a negative mpMRI does not omit the possibility of high-grade cancer and clinicians should consider biomarkers when looking to defer a biopsy in a patient with a negative mpMRI.<sup>3, 56, 57</sup>



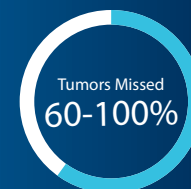
## 4. Multifocality / Disease Heterogeneity

Stabile *et. al.* followed fusion biopsy with TRUS biopsy and found 30% HGPCa outside of the index lesion.<sup>5,34</sup>



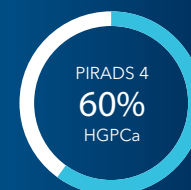
## 5. Tumor Size

60-100% of HGPCa tumors less than 1 cm are missed by mpMRI.<sup>39-42,44</sup>



## 6. PIRADS Variation

PIRADS categories have a diverse range of HGPCa levels, low-risk cancer (GG1), and benign tissue, and the distribution varies depending on the PIRADS category. For example, PIRADS 4 has 60%, 9% and 31% HGPCa, low-risk cancer and benign tissue, respectively.<sup>23</sup>



## 7. False Positives

Numerous conditions can cause false positive MRI readings. False positive rates vary depending on the PIRADS category, and range from 17-40% for PIRADS 4 & 5, respectively.<sup>23,36</sup>




**Areas for  
 Enhancement**

**Find more information  
 and references in our  
 Whitepaper entitled, The ExoDx  
 Prostate Test and mpMRI -  
 A Complementary Approach**



## Complementary Testing with The ExoDx™ Prostate Test

The ExoDx Prostate Test is a noninvasive urine-based biomarker assay recognized in the NCCN guidelines as a risk stratification for HGPCa. Available as an At-

Home Collection Kit, it provides greater accessibility for patients while integrating seamlessly with in-office procedures.

### The ExoDx Prostate Test

- Objective score
- Independent of clinical features
- Easy at-home collection, and quick reporting
- Effective for HGPCa risk stratification (NPV=91.3%)
- mpMRI and the ExoDx Prostate Test provide complementary information

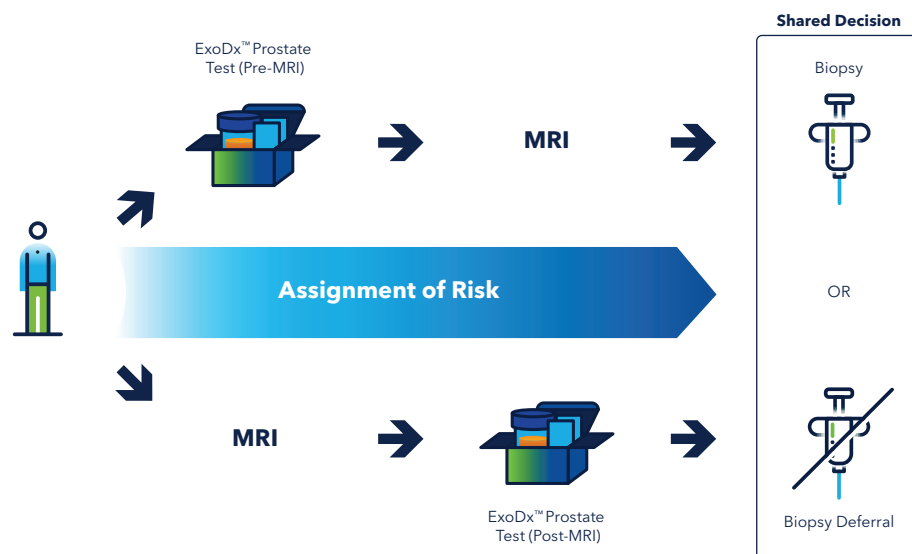


Figure 1 Potential clinical strategies for combining the ExoDx Prostate Test and multiparametric magnetic resonance imaging (mpMRI). Using the ExoDx Test either before or after mpMRI are possible approaches for integrated risk assessment and more informed decision-making.<sup>79,82,83</sup>

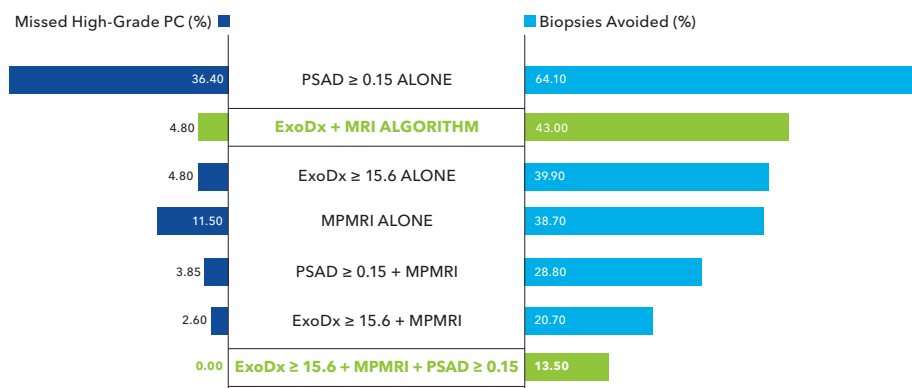


Figure 2 Figure recreated from de la Calle *et al* 2020. In this study, independent of Exosome Diagnostics involvement or sponsorship, synergy between the ExoDx Prostate Test and mpMRI was shown by de la Calle *et al*. The study compared PSAD alone, mpMRI alone, PSAD + mpMRI, ExoDx + mpMRI + PSAD and an ExoDx + mpMRI algorithm (defer mpMRI and Bx below the ExoDx cut point (15.6), but have mpMRI if the ExoDx result is between 15.9 and 19, but Bx only if the MRI is positive. If EPI >19, obtain mpMRI and Bx regardless of MRI results). Elevated PSA was considered <20 ng/mL.<sup>7,79</sup>



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