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 SERVICE OVERVIEW

# Integrated Prostate Cytomolecular Testing.

A concise physician-facing overview of the integrated service, report structure, and clinical value.

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This document outlines BioVantra's integrated prostate diagnostic service and the structured report it produces, in which prostate FNA cytology, TMPRSS2-ERG molecular testing, whole-gland sector mapping, and the Genetic Complexity Score (GCS) are interpreted together as a single case-level read.

— 01 / WHAT THIS SERVICE IS

## An integrated prostate diagnostic service — not a collection of isolated tests.

BioVantra's Integrated Prostate Cytomolecular Testing service brings prostate fine-needle aspiration (FNA) cytology, TMPRSS2-ERG fluorescence in situ hybridization (FISH), sector-based whole-gland sampling, and the Genetic Complexity Score (GCS) together within a single interpretive workflow.

Rather than reporting cytology and molecular results as disconnected specimen-level findings, the service integrates them into a gland-level diagnostic framework. The result is a more coherent read of where clinically significant disease is present, where sectors are concordant, discordant, or indeterminate, and how molecular complexity may refine biologic understanding.

It is intended for prostate cancer diagnostic settings in which imaging, prior biopsy results, cytology, and molecular findings need to be correlated rather than reviewed in isolation.

### Inputs and integrated output

#### INPUTS

- Prostate FNA cytology
- TMPRSS2-ERG FISH
- Sector-based specimen localization
- Clinical context and imaging correlation
- Genetic Complexity Score (GCS)

#### INTEGRATED OUTPUT

- Case-level integrated diagnosis
- Sector-based whole-gland interpretation
- Cytology + molecular correlation
- GCS-informed biologic context
- Structured physician-facing report

*Designed to move interpretation from specimen-by-specimen reporting toward a more clinically useful whole-gland read.*

## A structured report designed to support gland-level interpretation.

The Integrated Prostate Cytomolecular Report is organized to deliver both sector-level detail and case-level synthesis. It is intended to help the physician understand not only what was found in each sampled region, but how those findings fit together across the gland.

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### 01 Integrated case diagnosis

A concise case-level synthesis that integrates cytologic findings, TMPRSS2-ERG status, sector distribution, and GCS patterns into one overall diagnostic interpretation.

### 02 Cytomolecular diagnostic map

A sector-based whole-gland visual that shows the spatial distribution of integrated findings, allowing rapid recognition of concordant, discordant, suspicious, and negative sectors.

### 03 Diagnosis and results by sector

For each sampled region, cytology, molecular result, GCS, and interpretive language are reported together, so individual sectors can be reviewed without losing the broader case context.

### 04 Enumeration and molecular detail

The underlying TMPRSS2-ERG enumeration summary and molecular abnormality patterns are included to support interpretation and GCS assignment.

### 05 Methodology and interpretive framework

Specimen description, assay criteria, GCS category definitions, and case notes are provided so the basis and limitations of interpretation are clear.

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*The report is intended to function as an integrated diagnostic document — not a simple collection of independent laboratory results.*

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## Additional diagnostic clarity in clinically ambiguous or high-stakes situations.

The clinical value of the integrated report lies in correlating cytology, molecular findings, and gland-level localization in situations where imaging, prior biopsy, or individual specimen reads do not fully resolve the clinical question.

### Improved correlation with imaging

Strengthens interpretation of MRI-visible lesions by placing cytologic grading, molecular support, and sector localization within a single framework.

### Clarification of discordant findings

Benign or limited cytology in the presence of molecular abnormality may indicate undersampling, adjacent disease, or biologically active tissue that warrants closer attention.

### Support for planning

By combining sector localization with biologic context, the report can inform targeted biopsy strategy, whole-gland assessment, focal therapy planning, hemi-ablation considerations, and broader treatment decisions.

### Whole-gland perspective

Sector-based mapping helps clarify whether abnormal findings are focal, multifocal, unilateral, bilateral, clustered, or more extensive than a single lesion might suggest.

### Biologic context through GCS

The Genetic Complexity Score adds interpretive depth by reflecting the type and distribution of TMPRSS2-ERG abnormalities, rather than treating molecular positivity as a binary signal alone.

#### HOW TO READ THE DIAGNOSTIC MAP

##### ■ Concordant sectors

Cytology and molecular findings agree; these are typically the strongest reads.

##### ■ Suspicious or indeterminate

Supportive but not definitive evidence; usually requires correlation with the rest of the gland and the broader clinical picture.

##### ■ Discordant sectors

Cytology and molecular findings do not fully agree, which may reflect undersampling or biologically relevant abnormality adjacent to the sampled area.

##### ■ Negative sectors

Negative cytology with negative molecular findings; helps define cleaner true-negative regions and provides contrast to involved sectors.

— 04 / WHEN TO CONSIDER THIS REPORT

## Clinical scenarios in which the integrated report may be particularly useful.

The service is most useful when a gland-level, multi-input interpretation is needed — rather than another isolated data point.

SCENARIO 01

**Persistent suspicion despite prior negative biopsy**

MRI, PSA, or examination findings remain concerning, yet prior tissue sampling did not adequately resolve the clinical question.

SCENARIO 02

**MRI-visible lesion requiring biologic clarification**

A lesion is present on imaging, and additional cytologic and molecular context may help refine interpretation and sector mapping.

SCENARIO 03

**Need for a clearer whole-gland understanding**

Laterality, multifocality, sector extension, or contralateral abnormality may meaningfully influence biopsy planning or treatment strategy.

SCENARIO 04

**Pre-focal-therapy or pre-hemi-ablation assessment**

A structured gland-level interpretation can help clarify whether disease appears sufficiently localized or whether broader involvement should be considered.

SCENARIO 05

**Cases with specimen-level ambiguity**

Discordant, suspicious, or indeterminate sector-level findings may benefit from integration into a single case-level report rather than isolated result review.

The Integrated Prostate Cytomolecular Report is intended for clinicians who want a more structured, gland-level understanding of prostate disease — one in which cytology, TMPRSS2-ERG molecular findings, sector localization, and GCS interpretation are brought together in a single physician-facing diagnostic document.

SERVICE OVERVIEW ONLY — FULL SAMPLE REPORT AVAILABLE SEPARATELY.