CLINICAL COMPANION & SAMPLE REPORT

Curated Clinical Case and Sample Report

How the Integrated Prostate Cytomolecular Report adds clinical value

A short physician-facing companion to a single demonstration case — followed by the full sample Integrated Prostate Cytomolecular Report.

DOCUMENT
CCR-IPCT-002

ISSUED
April 2026

PAGES
9 (incl. 5-page sample report)

01 / WHY THIS CASE · CLINICAL SUMMARY

A case of persistent suspicion despite a prior negative biopsy.

A 68-year-old man with rising PSA, abnormal digital rectal examination, and a dominant left anterior PI-RADS 4 lesion — in whom a prior biopsy returned negative. This sample case was selected because it illustrates the clinical value of BioVantra's Integrated Prostate Cytomolecular Report in a patient with persistent suspicion for clinically significant prostate cancer despite a prior negative biopsy. The clinical picture — a rising PSA of 9.4 ng/mL, an abnormal DRE, and a dominant left anterior PI-RADS 4 lesion on multiparametric MRI — sets up the kind of integrative read the report is designed to support.

The integrated report combines prostate fine-needle aspiration (FNA) cytology, TMPRSS2–ERG fluorescence in situ hybridization (FISH), whole-gland sector mapping, and the Genetic Complexity Score (GCS) into a single clinically actionable report — moving the case from persistent uncertainty toward a more coherent, gland-level interpretation.

AGE	PSA	DRE	MRI	PRIOR BX
68 yr	9.4 ng/mL	T2a	PI-RADS 4 (L ant)	Negative

Imaging & biochemistry

Dominant left anterior PI-RADS 4 lesion on multiparametric MRI; PSA 9.4 ng/mL; DRE abnormal at clinical stage T2a.

Prior workup

One prior systematic biopsy returned negative, leaving persistent diagnostic uncertainty in the face of clinical and imaging concern.

Question for the integrated report

Confirm or refute clinically significant disease in the dominant lesion, and characterize the rest of the gland — focality, laterality, and biologic complexity.

Why this case

The mismatch between strong imaging signal and a negative prior biopsy is exactly the scenario the integrated report is designed to resolve.

DEMONSTRATION NOTE

This document is a demonstration sample for educational purposes. All patient, physician, accession, and institutional identifiers in the appended report have been fictionalized for publication and teaching use. The appended report is not an issued clinical document.

02 / WHY THIS REPORT ADDS VALUE · HOW TO READ IT

An integrated, whole-gland read — not a collection of isolated specimens.

In this case, the integrated report confirmed the dominant MRI-visible lesion as cytologically overt prostatic carcinoma (Grade 2/3) with concordant TMPRSS2–ERG positivity and a high Genetic Complexity Score, identified adjacent left-anterior extension, and revealed additional molecularly abnormal sectors — including contralateral right-sided findings — demonstrating disease more extensive than imaging or cytology alone would suggest.

WHY IT ADDS VALUE

Improved correlation with imaging

Confirms the dominant MRI-visible lesion and refines interpretation through specimen-level cytologic grading, molecular confirmation, and sector-based localization.

Whole-gland localization

Sector-based mapping visualizes the spatial distribution of concordant, discordant, indeterminate, and negative findings across the prostate.

Biologic context through GCS

The Genetic Complexity Score adds molecular interpretation by incorporating rearrangement type, abnormal cell count, abnormality heterogeneity, and copy-number change — helping identify the biologically more significant components of disease.

More informed treatment planning

Integrating MRI, cytology, molecular findings, and GCS gives a more complete picture of focality, laterality, and biologic complexity — useful when weighing targeted biopsy, focal therapy, hemi-ablation, or definitive treatment.

HOW TO READ THE REPORT

Concordant sectors

Cytology and molecular results agree — the strongest read. The dominant left-anterior carcinoma sector is concordant: Grade 2/3 cytology, TMPRSS2–ERG positive, GCS 100.

Discordant sectors

Cytology and molecular results disagree — usually a benign cytology paired with a positive or indeterminate molecular signal. These sectors raise the possibility of cytologic undersampling near a molecularly active focus.

Suspicious / indeterminate

Cytology suggests atypia or suspicion without confirming carcinoma; molecular results may support, refute, or remain indeterminate. The map encodes this as supportive but not confirmatory evidence.

Negative sectors

Benign cytology with negative molecular result — the cleanest true-negative read, and an important counterweight to the positive findings in the rest of the gland.

QUICK KEY FOR THIS CASE

- **Integrated diagnosis**
  Benign · Atypia · Suspicious · Carcinoma.
- **TMPRSS2–ERG (T2E)**
  neg · ind · pos.
- **GCS risk group**
  ≤36.4 Low · >36.4–75.8 Mod · >75.8 High.

APPENDIX · PAGES 05 – 09

Sample Integrated Prostate Cytomolecular Report

Demonstration exhibit for educational purposes.

All patient, physician, accession, and institutional identifiers have been fictionalized for publication and teaching use.

BioVantra

Patient: Bennett, Michael R

DOB: 3/14/1958 | Accession #: C26-00124

Integrated Prostate Cytomolecular Report

PATIENT DETAILS

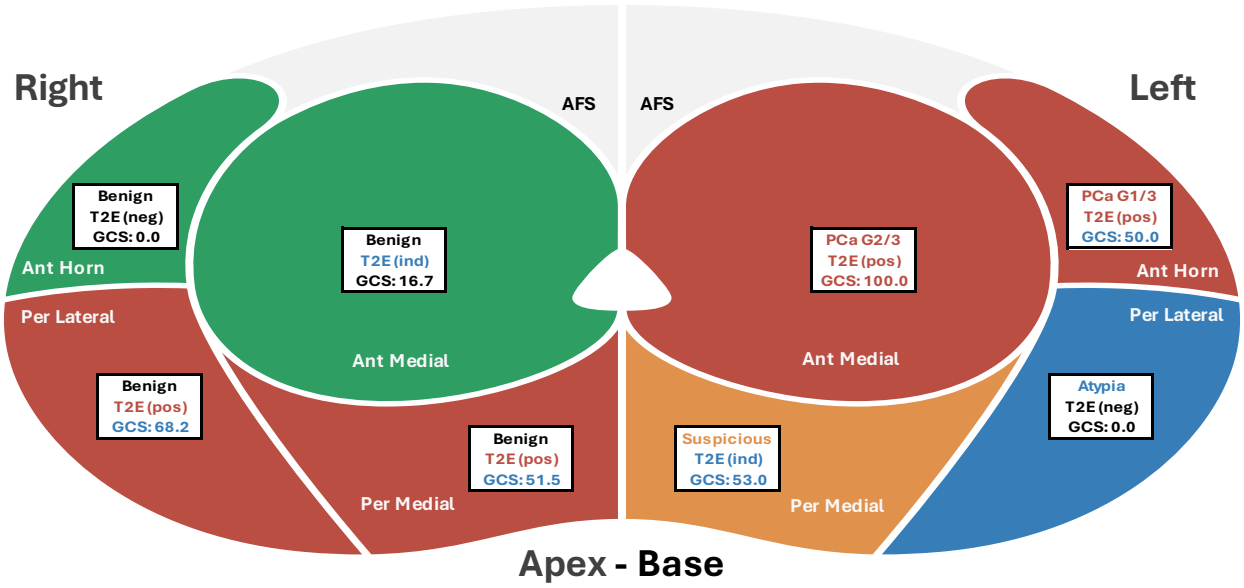
PATIENT	PHYSICIAN	CLINICAL DETAILS	SPECIMEN
Name: **Bennett, Michael R**	Name: **Andrew Collins, M.D.**	PSA: **9.4 ng/mL (3/3/26)**	Collected: **4/8/2026**
DOB (Age): **3/14/1958 (68 y)**	Clinic: **Urology Associates**	DRE: **T2a (≤ 50% 1 lobe)**	Received: **4/9/2026**
Patient ID: **MB25031467**	Add'l Recip.: **Sarah Whitman, M.D.**	MRI: **PI-RADS 4 (2/18/26)**	Reported: **4/15/2026**
Diagnosis: **R97.2**		Prior Bx: **Negative (10/2/24)**	Accession No: **C26-00124**

CASE DIAGNOSIS AND INTERPRETATION

Prostatic adenocarcinoma identified, including Grade 2/3 (intermediate-grade) cytology.

The overall findings support prostatic adenocarcinoma. TMPRSS2-ERG rearrangement provides confirmatory molecular evidence in involved sectors. The findings suggest a multifocal process. These findings support whole-gland diagnostic mapping and may assist clinical interpretation and treatment planning.

CYTOMOLECULAR DIAGNOSTIC MAP



INTEGRATED DIAGNOSIS*	TMPRSS2-ERG (T2E)	GCS RISK GROUP
Benign	**neg:** Negative	**≤ 36.4:** Low
Atypia	**ind:** Indeterminate	**> 36.4 and ≤ 75.8:** Moderate
Suspicious	**pos:** Positive	**> 75.8:** High
Carcinoma		
Unsatisfactory		

*Sector colors reflect the integrated cytomorphologic and TMPRSS2-ERG molecular interpretation for each sampled region.

Integrated Prostate Cytomolecular Report

DIAGNOSIS AND RESULTS

A. Left Per Med ROI

Suspicious for carcinoma; molecular abnormality present (supportive).

Cytology: Suspicious for malignancy

T2E: Indeterminate. Copy number gain detected without rearrangement, below positivity threshold [1, 5].

GCS: 53.0 (Moderate)

B. Left Per Lat ROI

Atypical cytology, favor benign; no molecular evidence of carcinoma.

Cytology: Atypical, favor benign

T2E: Negative. No rearrangement or copy number changes were detected in the TMPRSS2-ERG region [5].

GCS: 0.0 (Low)

C. Left Ant Med

Prostatic carcinoma (cytologic diagnosis) with molecular confirmation (T2E-positive).

Cytology: **Prostatic Carcinoma, Grade 2/3 (Intermediate-grade)**

T2E: Positive. Copy number gain detected without rearrangement [1, 5].

GCS: 100.0 (High)

D. Left Ant Horn

Prostatic carcinoma (cytologic diagnosis) with molecular confirmation (T2E-positive).

Cytology: Prostatic Carcinoma, Grade 1/3 (Low-grade)

T2E: Positive. Copy number gain detected without rearrangement [1, 5].

GCS: 50.0 (Moderate)

E. Right Per Med

Prostatic carcinoma, molecularly confirmed (T2E-positive), despite benign cytology.

Cytology: No cytological evidence of malignancy

T2E: Positive. ERG-based rearrangement with multiple copies of the derivative allele detected [4].

GCS: 51.5 (Moderate)

Note: *Discordant cytology and molecular findings. Cytologic undersampling or sparse tumor cells may contribute to an apparently benign result.*

Integrated Prostate Cytomolecular Report

DIAGNOSIS AND RESULTS (Continued)

F. Right Per Lat

Prostatic carcinoma, molecularly confirmed (T2E-positive), despite benign cytology.

Cytology: No cytological evidence of malignancy

T2E: Positive. Copy number gain detected without rearrangement [1, 5].

GCS: 68.2 (Moderate)

Note: *Discordant cytology and molecular findings. Cytologic undersampling or sparse tumor cells may contribute to an apparently benign result.*

G. Right Ant Med ROI

Benign with low-level molecular abnormality (non-diagnostic).

Cytology: No cytological evidence of malignancy

T2E: Indeterminate. Low-level ERG-based TMPRSS2-ERG rearrangement detected, below the threshold for positivity [3].

GCS: 16.7 (Low)

H. Right Ant Horn

Benign; no molecular evidence of carcinoma.

Cytology: No cytological evidence of malignancy

T2E: Negative. No rearrangement or copy number changes were detected in the TMPRSS2-ERG region [5].

GCS: 0.0 (Low)

ENUMERATION SUMMARY

Fluorescence in situ hybridization (FISH) assay for detection of TMPRSS2-ERG rearrangements and copy number located at 21q22.

Source	# Cells	Abnormal	TMPRSS2-ERG Rearrangement and CNI Class	GCS
A. Left Per Med ROI	96	3 (3.1%)	CNI (1) | 2+Tsplit CNI (1) | 2+Tsplit (1)	53.0 (Moderate)
B. Left Per Lat ROI	88	0 (0.0%)	No TMPRSS2-ERG Rearrangement	0.0 (Low)
C. Left Ant Med	102	8 (7.8%)	CNI (5) | 2+Edel CNI (2) | 2+Tsplit CNI (1)	100.0 (High)
D. Left Ant Horn	78	5 (6.4%)	CNI (1) | Esplit (3) | Tsplit (1)	50.0 (Moderate)
E. Right Per Med	121	4 (3.3%)	2+Esplit (2) | Esplit (2)	51.5 (Moderate)
F. Right Per Lat	77	9 (11.7%)	CNI (1) | 2+Esplit (2) | Esplit (5) | Tsplit (1)	68.2 (Moderate)
G. Right Ant Med ROI	95	2 (2.1%)	Esplit (2)	16.7 (Low)
H. Right Ant Horn	84	0 (0.0%)	No TMPRSS2-ERG Rearrangement	0.0 (Low)
Totals	741	31 (4.2%)	CNI (8) | 2+Edel CNI (2) | 2+Tsplit CNI (2) | 2+Esplit (4) | 2+Ts	100.0 (High)

Integrated Prostate Cytomolecular Report

ENUMERATION SUMMARY (Continued)

TMPRSS2-ERG FISH PROBE DESCRIPTION AND INTERPRETATION CRITERIA

This three-color FISH assay detects TMPRSS2-ERG rearrangements involving chromosome 21q22, including deletions, translocations, and copy number increase (CNI).

REFERENCE RANGE

Positive: ≥4 cells with rearrangement and/or CNI

Indeterminate: 1–3 cells with rearrangement and/or CNI

Uninformative: Insufficient specimen quality, inadequate preparation, or fewer than 50 evaluable cells without detectable rearrangement and/or CNI

ABBREVIATION KEY

Esplit = ERG split rearrangement

Tsplit = TMPRSS2 split rearrangement

Edel = ERG deletion pattern

CNI = Copy number increase

2+ prefix = corresponding abnormality present with additional copy gain / increased genomic complexity

GENETIC COMPLEXITY SCORE (GCS)

The Genetic Complexity Score (GCS) is a composite measure derived from the type and distribution of TMPRSS2-ERG molecular abnormalities identified within a specimen. Higher scores reflect greater molecular complexity and may indicate increased biologic heterogeneity.

GCS CATEGORIES

Low: ≤36.4

Moderate: >36.4 to ≤75.8

High: >75.8

SPECIMEN DESCRIPTION

A. Left Per Med ROI: Received 20 mL of cloudy, pink fluid in cytology fixative labeled with patient's name and date of birth for ThinPrep processing, Papanicolaou stain, and TMPRSS2-ERG Fluorescence in situ hybridization (FISH) assay. Specimen is adequate for processing.

B. Left Per Lat ROI: Received 20 mL of cloudy, pink fluid in cytology fixative labeled with patient's name and date of birth for ThinPrep processing, Papanicolaou stain, and TMPRSS2-ERG Fluorescence in situ hybridization (FISH) assay. Specimen is adequate for processing.

C. Left Ant Med: Received 20 mL of cloudy, pink fluid in cytology fixative labeled with patient's name and date of birth for ThinPrep processing, Papanicolaou stain, and TMPRSS2-ERG Fluorescence in situ hybridization (FISH) assay. Specimen is adequate for processing.

D. Left Ant Horn: Received 20 mL of cloudy, pink fluid in cytology fixative labeled with patient's name and date of birth for ThinPrep processing, Papanicolaou stain, and TMPRSS2-ERG Fluorescence in situ hybridization (FISH) assay. Specimen is adequate for processing.

E. Right Per Med: Received 20 mL of cloudy, pink fluid in cytology fixative labeled with patient's name and date of birth for ThinPrep processing, Papanicolaou stain, and TMPRSS2-ERG Fluorescence in situ hybridization (FISH) assay. Specimen is adequate for processing.

F. Right Per Lat: Received 20 mL of cloudy, pink fluid in cytology fixative labeled with patient's name and date of birth for ThinPrep processing, Papanicolaou stain, and TMPRSS2-ERG Fluorescence in situ hybridization (FISH) assay. Specimen is adequate for processing.

G. Right Ant Med ROI: Received 20 mL of cloudy, pink fluid in cytology fixative labeled with patient's name and date of birth for ThinPrep processing, Papanicolaou stain, and TMPRSS2-ERG Fluorescence in situ hybridization (FISH) assay. Specimen is adequate for processing.

H. Right Ant Horn: Received 20 mL of cloudy, pink fluid in cytology fixative labeled with patient's name and date of birth for ThinPrep processing, Papanicolaou stain, and TMPRSS2-ERG Fluorescence in situ hybridization (FISH) assay. Specimen is adequate for processing.

Integrated Prostate Cytomolecular Report

CASE NOTES

Each specimen was submitted in a separate container from a distinct anatomic location and underwent independent multiplex in situ hybridization analysis with separate morphometric interpretation.

Test Description and Clinical Significance

This report integrates prostate fine-needle aspiration (FNA) cytology with TMPRSS2-ERG molecular testing to improve prostate cancer detection and characterization. FNA provides cellular morphologic assessment, while TMPRSS2-ERG fluorescence in situ hybridization (FISH) detects prostate cancer–associated gene rearrangements, providing complementary cytologic and molecular information.

FNA samples are obtained from multiple prostatic sectors to support spatial mapping. Cytologic findings are classified along a spectrum from benign to malignant, with malignant cases further stratified into low-, intermediate-, or high-grade categories that broadly correlate with conventional histopathologic grading systems. TMPRSS2-ERG rearrangements, when present, are highly specific for prostatic malignancy and define a molecular subtype with distinct biologic features.

TMPRSS2-ERG FISH results are categorized as positive, indeterminate, negative, or uninformative according to the number of abnormal cells identified. A Genetic Complexity Score (GCS) is calculated to further characterize molecular heterogeneity and tumor biology and is stratified as low, moderate, or high. When interpreted together with cytologic findings, this integrated cytomolecular approach may support diagnostic refinement, risk stratification, and therapeutic planning.

Interpretation should take into account potential limitations related to sample cellularity, tumor undersampling, and concurrent inflammatory changes. Absence of a TMPRSS2-ERG rearrangement does not exclude malignancy, and results should be interpreted in conjunction with the clinical history, imaging findings, and, when available, histopathologic data.

Selected References

1. Demichelis, F., Fall, K., Perner, S., et al. (2007). TMPRSS2:ERG gene fusion associated with lethal prostate cancer in a watchful waiting cohort. Oncogene, 26(31), 4596–4599.
2. Perner, S., Demichelis, F., Beroukhim, R., et al. (2006). TMPRSS2:ERG fusion-associated deletions provide insight into the heterogeneity of prostate cancer. Cancer Research, 66(17), 8337–8341.
3. Yoshimoto, M., Ludkovski, O., Bayani, J., et al. (2006). TMPRSS2:ERG gene fusions resulting from a novel mechanism involving complex genomic rearrangements. Cancer Research, 66(22), 10622–10629.
4. Weier, C., Haffner, M.C., Mosbruger, T., et al. (2013). Nucleotide resolution analysis of TMPRSS2 and ERG rearrangements in prostate cancer. The Journal of Pathology, 230(2), 174–183.
5. Attard, G., Clark, J., Ambroisine, L., et al. (2008). Duplication of the fusion of TMPRSS2 to ERG sequences identifies fatal human prostate cancer. Oncogene, 27(3), 253–263.

Joseph A. Migliozzi, M.D., Ph.D.
Laboratory Director

4/15/2026
Date

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

This test was developed and its performance characteristics were determined by BioVantra. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary for clinical use. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high-complexity testing. CLIA ID No. 10D1087213; CAP No. 7214934.