SERVICE OVERVIEW

Integrated Urothelial Cytomolecular Testing.

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

This document provides an overview of BioVantra's Integrated Urothelial Cytomolecular Testing service and the structured report it generates by combining urine cytology, multi-target FISH, and case-level interpretation into a single physician-facing diagnostic document.

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01 / WHAT THIS SERVICE IS

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

BioVantra's Integrated Urothelial Cytomolecular Testing service combines urine cytology, multi-target fluorescence in situ hybridization (FISH), and structured interpretive reporting into one integrated diagnostic workflow.

Rather than reporting cytology and molecular findings as disconnected results, the service brings them together in a case-level framework that clarifies whether urothelial abnormality is supported by morphology alone, molecular findings alone, or by concordant combined evidence.

The service is intended for patients undergoing evaluation or surveillance for urothelial carcinoma, particularly when cytologic findings are atypical, suspicious, or otherwise insufficient to fully resolve the clinical question.

Inputs and integrated output

INPUTS

- Urine cytology
- Multi-target FISH
- Clinical history and surveillance context
- Cystoscopic correlation
- Structured case-level interpretation

INTEGRATED OUTPUT

- Case-level integrated diagnosis
- Cytology + FISH correlation
- Molecular abnormality pattern recognition
- Structured interpretive comment
- Physician-facing integrated report

This service is intended to move interpretation beyond isolated urine cytology or molecular results toward a more clinically useful integrated read.

02 / WHAT THE REPORT DELIVERS

A structured report designed to support diagnostic refinement and surveillance interpretation.

The Integrated Urothelial Cytomolecular Report is organized to deliver both test-level detail and case-level synthesis. It is intended to help the physician understand not only the cytologic and molecular findings themselves, but how those findings fit together in clinical context.

01 **Case diagnosis and interpretation**

A concise integrated diagnosis combines cytology and FISH into a single physician-facing interpretive statement.

02 **Cytology result**

The report identifies the morphologic category of the urine specimen, ranging from negative or atypical to suspicious or positive for high-grade urothelial carcinoma.

03 **Multi-target FISH result**

The report classifies FISH findings as positive, negative, or uninformative and describes the specific abnormality pattern identified.

04 **Integrated interpretive comment**

The report explains what the combined findings mean clinically, especially when molecular evidence adds significance to atypical or equivocal morphology.

05 **Methodology and interpretive framework**

The report includes specimen description, FISH criteria, interpretive thresholds, test description, and references so the clinical basis and limitations are clear.

The report is intended to function as an integrated diagnostic document rather than a simple pairing of separate cytology and FISH results.

03 / WHY IT ADDS CLINICAL VALUE

Additional diagnostic clarity in surveillance and equivocal urinary cytology.

The clinical value of the integrated report lies in its ability to correlate urine cytology and multi-target FISH in settings where morphology alone does not fully define the level of concern, particularly in surveillance patients or cases with atypical cytologic findings.

Clarification of atypical cytology

When urine cytology is atypical rather than definitively malignant, multi-target FISH may provide additional evidence of urothelial abnormality not fully captured by morphology alone.

Better surveillance interpretation

In patients with prior bladder cancer and recent non-confirmatory cystoscopy, integrated cytology plus FISH may help refine the level of concern and support follow-up planning.

Added biologic context

FISH abnormality patterns provide more interpretive depth than a simple positive/negative label by identifying chromosomal gains or 9p21 loss associated with urothelial neoplasia.

More useful case-level reporting

The integrated report gives the physician one structured conclusion rather than requiring them to reconcile cytology and molecular results independently.

Support for clinical correlation

The report is designed to be interpreted alongside cystoscopy, clinical history, and other available pathologic data, helping frame the significance of combined findings in context.

HOW TO READ THE INTEGRATED RESULT

- **Concordant abnormal findings** — Cytology and FISH both support urothelial abnormality, strengthening the overall interpretation.
- **Atypical cytology with supportive FISH** — Morphology is not definitive, but molecular findings increase concern for urothelial neoplasia not fully captured by cytology alone.
- **Negative or non-supportive FISH** — A negative FISH result may reduce concern but does not exclude urothelial neoplasia when clinical suspicion remains.
- **Uninformative results** — Interpretation may be limited when specimen quality or cellularity is insufficient for reliable molecular analysis.

04 / WHEN TO CONSIDER THIS REPORT

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

This service may be most useful when integrated interpretation is needed rather than another isolated cytology or FISH result.

SCENARIO 01 **Surveillance after prior urothelial carcinoma**	A patient with prior bladder cancer undergoes follow-up testing, and integrated cytology plus FISH may help refine the significance of current urinary findings.
SCENARIO 02 **Atypical urine cytology**	Morphology alone is not definitive, and molecular findings may help clarify whether the specimen raises greater concern for urothelial neoplasia.
SCENARIO 03 **Recent negative or non-confirmatory cystoscopy with ongoing concern**	Integrated reporting may be useful when recent cystoscopic findings do not fully explain persistent clinical concern.
SCENARIO 04 **Cases needing stronger interpretive correlation**	The report is especially useful when cytology, FISH, clinical history, and surveillance context need to be understood together rather than separately.
SCENARIO 05 **Follow-up planning after equivocal findings**	Combined results may help support decisions about repeat evaluation, closer surveillance, or correlation with other clinical findings.

The Integrated Urothelial Cytomolecular Report is intended for clinicians who want a more structured understanding of urinary cytology and molecular findings by combining morphology, multi-target FISH, and case-level interpretation into one physician-facing diagnostic document.

SERVICE OVERVIEW ONLY — FULL SAMPLE REPORT AVAILABLE SEPARATELY.