
 CLINICAL COMPANION & SAMPLE REPORT

Curated Clinical Case and Sample Report

How the Integrated Urothelial Cytomolecular Report adds clinical value.

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

DOCUMENT

CCR-IUCT-002

ISSUED

April 2026

PAGES

6 (incl. 2 -page sample
report)

A surveillance case with atypical cytology and supportive molecular findings.

A 68-year-old man with a history of low-grade Ta urothelial carcinoma treated by TURBT underwent surveillance evaluation following a recent negative cystoscopy. A follow-up voided urine specimen showed atypical urothelial cells, while multi-target FISH was positive. This sample case was selected because it illustrates the clinical value of the integrated report in a surveillance setting where morphology and recent cystoscopic findings do not fully resolve the clinical question.

AGE	HISTORY	THERAPY	CYSTO	SPECIMEN
68 yr	Prior Ta UC	TURBT	Negative	Voided urine

Clinical context

Prior low-grade non-muscle-invasive urothelial carcinoma under surveillance following TURBT.

Current urinary findings

Voided urine cytology showed atypical urothelial cells, while multi-target FISH was positive, providing additional evidence of urothelial abnormality.

Recent workup

Recent cystoscopy was negative, leaving current level of concern incompletely defined by direct evaluation alone.

Why this case

This is exactly the type of surveillance case in which integrated cytology and molecular interpretation may provide clinically useful refinement beyond morphology alone.

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 read of atypical morphology and supportive molecular evidence.

In this case, the integrated report shows how atypical urine cytology and positive multi-target FISH can be interpreted together in a surveillance patient with recent negative cystoscopy. Rather than leaving cytology and molecular findings as separate data points, the report provides a single case-level interpretation that raises concern for urothelial abnormality not fully captured by morphology alone.

WHY IT ADDS VALUE

Clarifies equivocal morphology

Atypical urothelial cells are not fully diagnostic on their own. The integrated report shows how supportive molecular findings may increase concern.

Improves surveillance interpretation

In a patient with prior urothelial carcinoma and recent negative cystoscopy, the report helps frame the significance of current urinary findings in context.

Brings cytology and FISH together

The report provides one integrated diagnosis and interpretive comment rather than requiring the clinician to reconcile separate results independently.

Supports follow-up planning

Combined findings may help support correlation with cystoscopy, surveillance planning, and further evaluation when appropriate.

HOW TO READ THE REPORT

Cytology

The specimen is categorized morphologically — here as Atypical Urothelial Cells.

FISH

The molecular component is classified as Positive, with abnormality pattern details described in the report.

Integrated diagnosis

The report combines morphology and molecular findings into a single physician-facing conclusion: *Atypical Urothelial Cells with Positive Multi-Target FISH.*

Interpretive comment

The final narrative explains the clinical meaning of the combined findings and recommends correlation with cystoscopic and clinical follow-up.

QUICK KEY FOR THIS CASE

■ Atypical cytology

Morphology is suggestive but not diagnostic on its own.

■ Positive FISH

Molecular evidence of urothelial abnormality.

■ Integrated interpretation

Combined cytologic and molecular read in one statement.

APPENDIX · PAGES 05 - 06

Sample Integrated Urothelial Cytomolecular Report

Demonstration exhibit for educational purposes.

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

Integrated Urothelial Cytomolecular Report

PATIENT DETAILS

PATIENT	PHYSICIAN	CLINICAL DETAILS	SPECIMEN
Name: Bennett, Michael R DOB (Age): 3/14/1958 (68y/M) Patient ID: MB25031467 Diagnosis: Z85.51	Name: Andrew Collins, M.D. Clinic: Urology Associates Add'l Recip.: Sarah Whitman, M.D.	Grade: Low grade Stage: Ta Prior Cysto: Negative (4/8/26) Therapy: TURBT	Collected: 4/8/2026 Received: 4/9/2026 Reported: 4/15/2026 Accession No: C26-00125

CASE DIAGNOSIS AND INTERPRETATION

Atypical Urothelial Cells with Positive Multi-Target FISH

The positive multi-target FISH findings provide additional evidence of urothelial abnormality in a specimen showing atypical urothelial cells. These combined findings raise concern for urothelial neoplasia not fully captured by morphology alone, and correlation with clinical and cystoscopic findings and follow-up evaluation is recommended. [2,5]

DIAGNOSIS AND RESULTS

A. Left Per Med

Cytology: **Atypical Urothelial Cells**

FISH: **POSITIVE. Enumeration of 100 consecutive evaluable cells revealed non-tetrasomic polysomy involving at least two of chromosomes 3, 7, and 17 in 10 cells (10.0%).**

Note: *These FISH findings provide additional evidence of urothelial abnormality in a specimen showing atypical cytologic changes. Correlation with clinical and cystoscopic findings and follow-up evaluation is recommended.*

SPECIMEN DESCRIPTION

A. Urine, voided: Received 60 mL of clear, yellow fluid in cytology fixative labeled with patient's name and date of birth for ThinPrep processing, Papanicolaou stain, and chromosomes 3, 7, 17 and 9p21 locus multi-target FISH assay. Specimen is adequate for processing.

Integrated Urothelial Cytomolecular Report

Test Description and Clinical Significance

This report integrates urine cytology with multi-target fluorescence in situ hybridization (FISH) to improve detection and characterization of urothelial abnormalities. Urine cytology provides morphologic assessment of exfoliated urothelial cells, while multi-target FISH evaluates copy number abnormalities involving chromosomes 3, 7, and 17 and deletion of the 9p21 locus, providing complementary cytologic and molecular information.

Cytologic findings are interpreted along a spectrum from negative or atypical to suspicious or positive for high-grade urothelial carcinoma, while FISH is used to detect chromosomal abnormalities associated with urothelial neoplasia. The FISH component further characterizes abnormal hybridization patterns by identifying non-tetrasomic polysomy, tetrasomy/near-tetrasomy, isolated single-chromosome gain, and 9p21 loss. These categories provide additional biologic and interpretive context beyond a simple positive or negative result.

FISH results are classified as positive, negative, or uninformative according to established abnormal cell thresholds. A positive result is defined by one or more of the following: four or more non-tetrasomic cells showing gains in two or more of chromosomes 3, 7, and 17 within the same cell; ten or more cells showing tetrasomy/near-tetrasomy involving chromosomes 3, 7, and 17; ten or more cells showing isolated gain of a single chromosome 3, 7, or 17; or twelve or more cells showing homozygous loss of the 9p21 locus. A negative result indicates an adequate specimen with at least 25 evaluable cells and no findings meeting positive criteria. An uninformative result reflects insufficient specimen quality, inadequate slide preparation, or fewer than 25 evaluable cells.

When interpreted together, cytologic and molecular findings may support diagnostic refinement and risk assessment in patients undergoing evaluation or surveillance for urothelial carcinoma. Detection of chromosomal gains or 9p21 loss may identify urothelial abnormalities not fully captured by morphology alone, including cases with equivocal cytologic findings.

Interpretation should take into account potential limitations related to low cellularity, degenerative change, obscuring inflammation, and sampling variability. A negative FISH result does not exclude urothelial neoplasia, and abnormalities detected by FISH should be interpreted in conjunction with the cytologic findings, clinical history, cystoscopic findings, and other available pathologic data.

Selected References

1. Sarosdy, M.F., Kipp, B.R., Klos, K.S., Zarzour, H.W., Sheinfeld, J., Halling, K.C., and King, W. Clinical evaluation of a multi-target fluorescent in situ hybridization assay for detection of bladder cancer. *J Urol.* 2002;168(5):1950-1954.
2. Kipp, B.R., Karnes, R.J., Brankley, S.M., Harwood, A.R., Pankratz, V.S., Sebo, T.J., and Halling, K.C. Quantitative fluorescence in situ hybridization and its ability to predict bladder cancer recurrence and progression to muscle-invasive bladder cancer. *J Mol Diagn.* 2009;11(2):148-154.
3. Zellweger, T., Benz, G., Cathomas, G., Mihatsch, M.J., Sulser, T., and Gasser, T.C. Multi-target fluorescence in situ hybridization in bladder washings for prediction of recurrent bladder cancer. *Int J Cancer.* 2006;119(7):1660-1665.
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5. Yoder, B.J., Skacel, M., Hedgepeth, R., Babiarz, L., Ulchaker, J.C., Liou, L.S., Brainard, J.A., and Biscotti, C.V. Reflex UroVysion testing of bladder cancer surveillance patients with equivocal or negative urine cytology: a prospective study with focus on the natural history of anticipatory positive findings. *Am J Clin Pathol.* 2007;127(2):295-301.

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Laboratory Director

4/15/2026

Date



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.