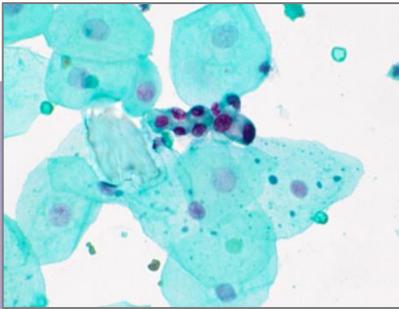


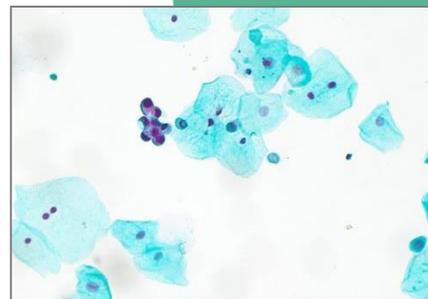


CellDetect®

Cytology



Reference
Atlas



ZCTIQ
A CANCER DIAGNOSTIC COMPANY

Introduction

CellDetect® is an innovative staining technology combining color and morphology to distinguish between normal and neoplastic cells in urine specimens. The color is used for highlighting in red/purple the nucleus of cells suspicious for malignancy.

The CellDetect® Staining Kit provides differential color-based staining while preserving the morphology of the cell. Color differentiation relies on the biochemical activity of a proprietary plant extract and the specific affinity of generic dyes to the various cell types and components.

The following document summarizes the recommended guidelines for interpretation of urine smears stained with the CellDetect® Staining Kit.

Procedure for Analysis

Assess Specimen Quality (based on the Bethesda system):

Use a microscope to scan the entire slide at x10-20 magnification.

Accept slides with an adequate number of well-preserved cells.

Reject slide if cellularity is too low or too high (overlapping cells).

In case that slide was rejected, prepare an additional slide. Dilute/concentrate cell pellet if necessary.

Reject specimens with >75% of cells obscured, unless abnormal cells are present.

Diagnosis is made based on single epithelial cells or clusters without nuclear overlapping.

Assess Staining Quality:

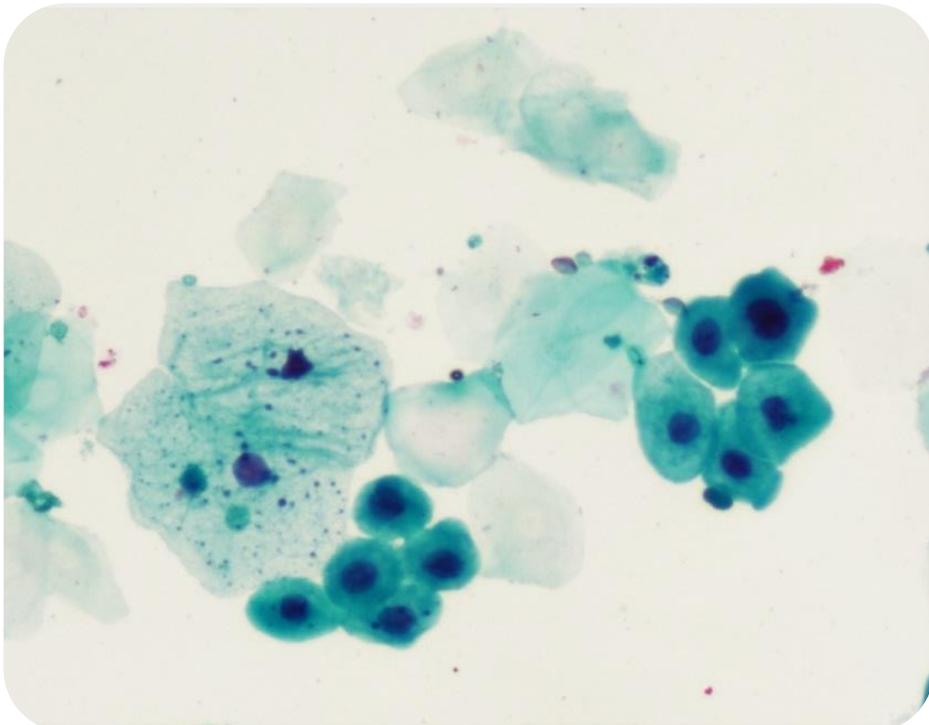
Before starting the analysis, evaluate the adequacy of the slide and the quality of the stain as detailed below.

- Evaluate color shade of normal epithelial cells. Ignore cells that are located in the margins and in patches of unclear or vague staining.
- Stain is accepted if the nuclei of most of the normal epithelial cells are green or purple and the cytoplasm is green. Slide containing >5% normal epithelial cells with red nucleus and/or pink cytoplasm should be termed unsatisfactory unless abnormal cells are present. Umbrella cells often have pinkish nuclei which is acceptable.
- If slide does not pass the above indications, perform staining of an additional slide. Otherwise, proceed to analyzing the slide.

Procedure for Analysis

CellDetect® negative cells:

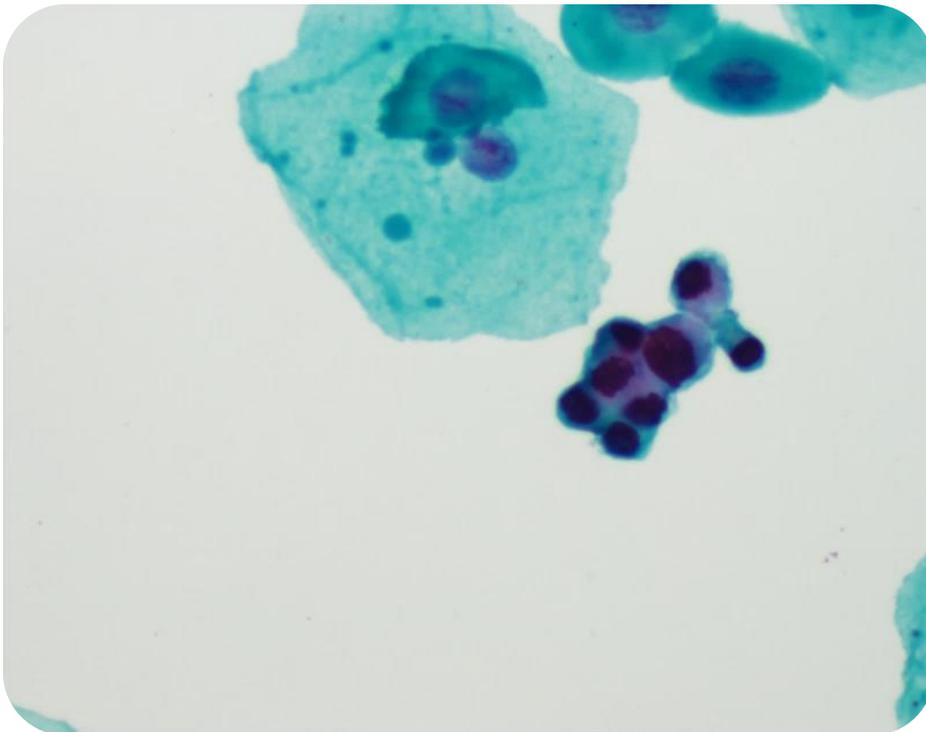
- Nuclei of epithelial cells are stained in either green, blue or faint pink, and usually do not show hyperchromasia (with the exception of the pycnotic nuclei of superficial cells). Umbrella or reactive cells may exhibit a pinkish staining of the nucleus. Inflammatory cells are stained in purple-red and erythrocytes are stained in green.
- Nuclei do not present morphological features of malignancy (e.g., nuclear/cytoplasm ratio is low; nucleus has round or oval shape with smooth nuclear membrane).
- Cytoplasm is green. Cell clusters may absorb non-specific staining thus would appear pink.



Procedure for Analysis

CellDetect® positive cells:

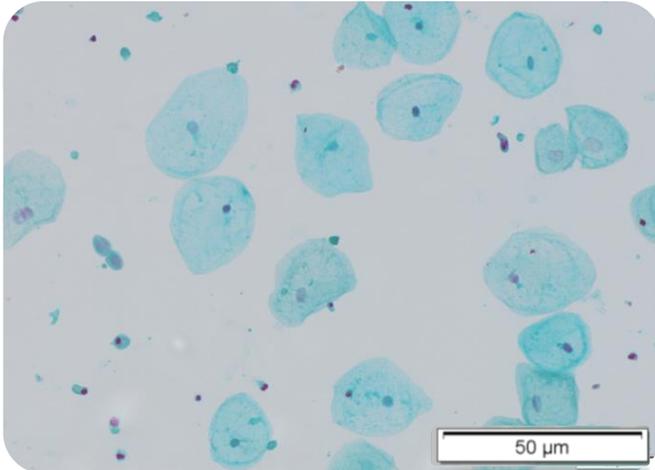
- Nuclei are usually stained in intense red/violet color and show hyperchromasia. Chromatin texture and structure are usually masked.
- Nuclei present morphological features of malignancy (e.g., high nuclear to cytoplasm ratio, irregular shape and irregular nuclear membrane).
- Cytoplasm may vary between green and pinkish color.



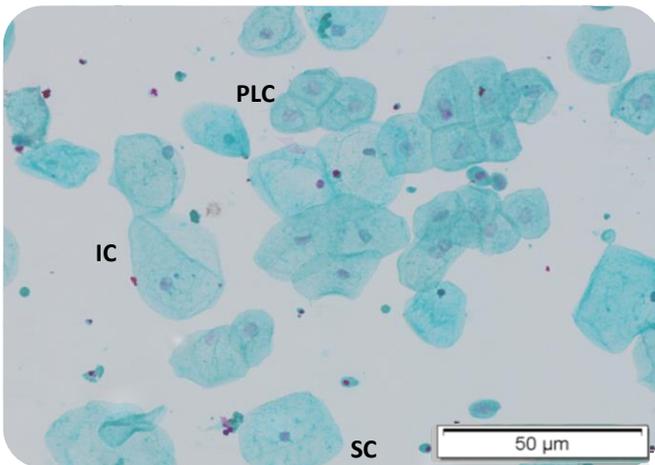
Atlas of Images

Biopsy Confirmed

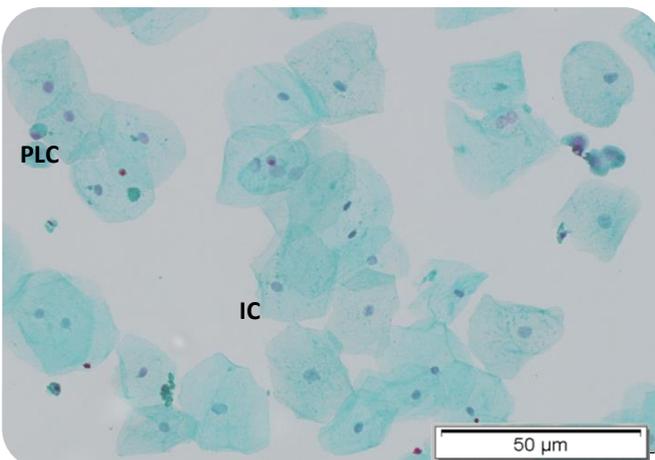
Negative Urothelial Cells



Negative urine samples confirmed by cystoscopy. Benign cell's nuclei are usually green or purple and cytoplasm is green.

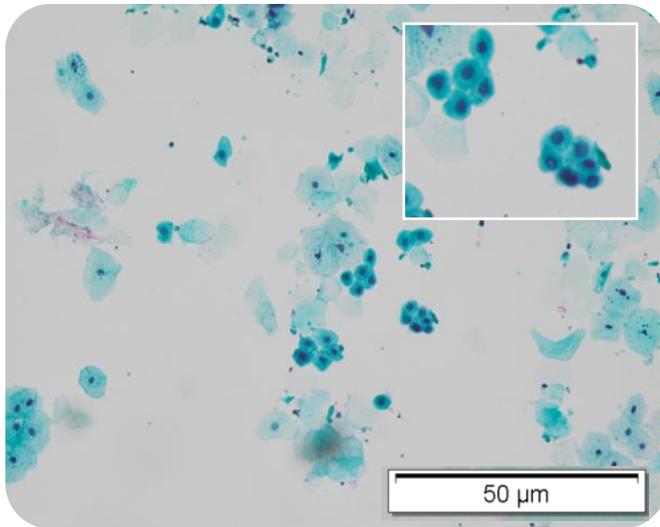


Different types of urothelial and squamous cells are shown. Cells' cytoplasm and nucleus are green. Superficial cells (SC), intermediate cells (IC) and para-basal like cells (PLC).



Different types of urothelial and squamous cells are shown. Cells' cytoplasm and nucleus are green. Superficial cells (SC), intermediate cells (IC) and para-basal like cells (PLC).

Different Cell Types

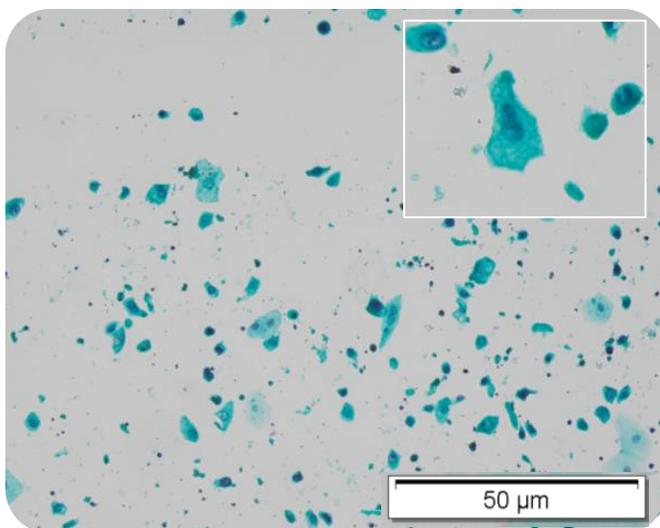


Reactive cells

Reactive cells are larger than normal urothelial cells and have a more abundant cytoplasm. Nucleus is enlarged. These cells are stained purple but considered benign. Reactive cell usual morphology:

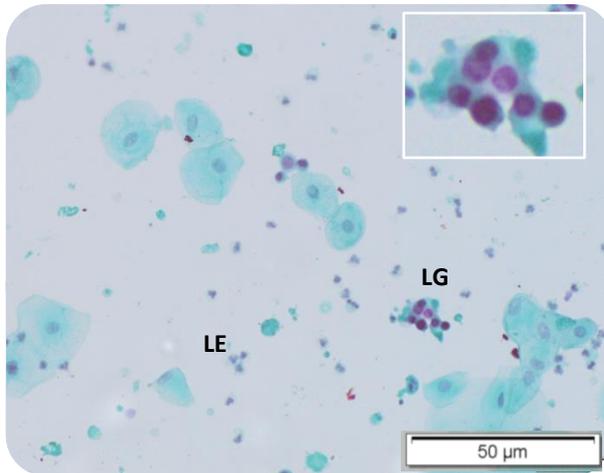
- Intact, smooth nuclear membrane
- Often focal cytoplasmic vacuolization
- Small conspicuous nucleolus

Umbrella cells



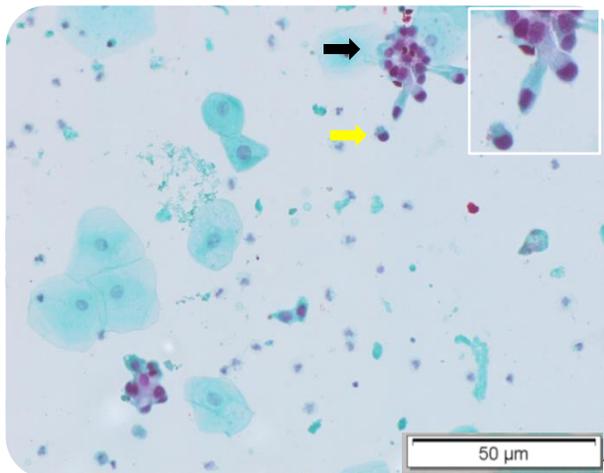
Umbrella cells are of unique and variable shape. They are large cells with abundant cytoplasm. They are often binuclear and contain prominent nucleoli. They stain as normal cells – green cytoplasm with light purple nucleus.

Low Grade Urothelial Carcinoma



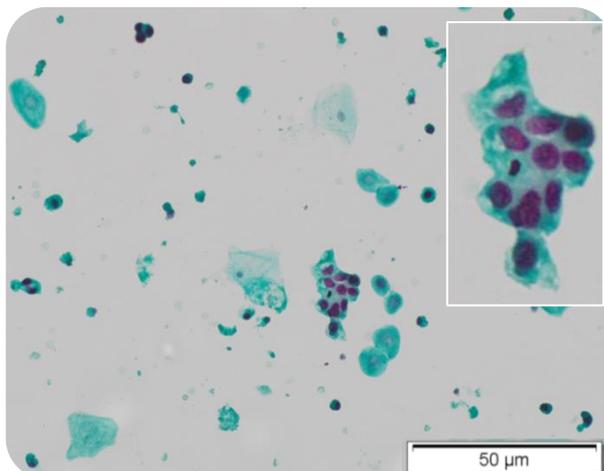
Low grade (LG) urothelial carcinoma confirmed by biopsy.

Samples may contain inflammatory cells, leukocytes (LE), which may feature purple-red nuclei.



Nuclei of LG cells are purple-red and cytoplasm is green.

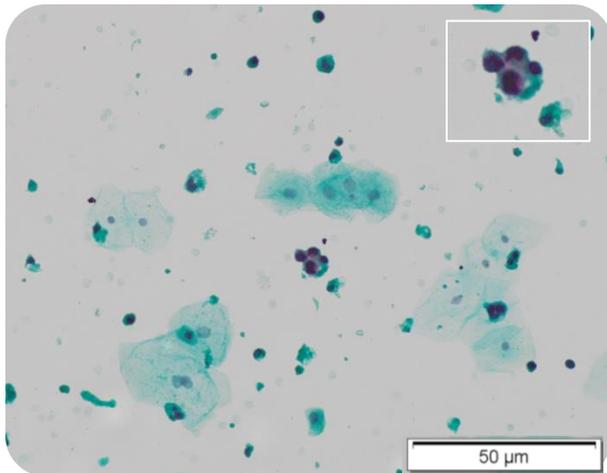
LG cells may be found as single cells (yellow arrow) or in small groups (black arrow).



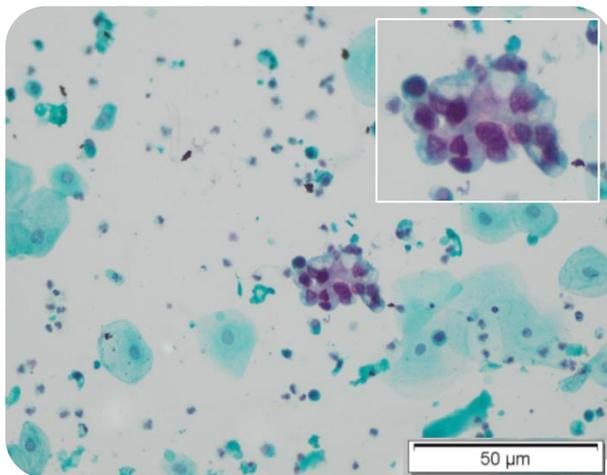
Nuclei of LG cells are purple-red and cytoplasm is green.

The clusters in LG urothelial carcinoma may or may not be papillary.

Low Grade Urothelial Carcinoma

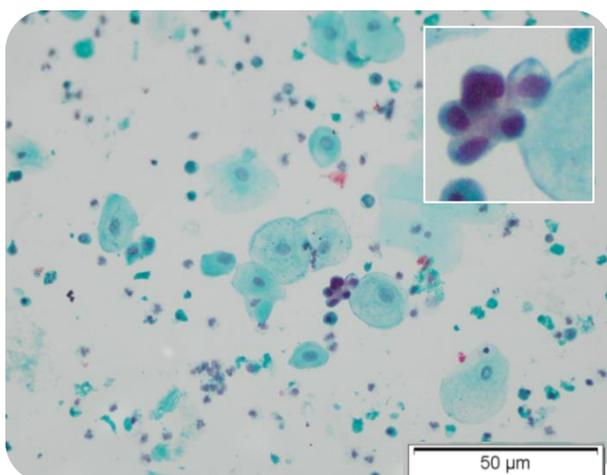


LG urothelial carcinoma confirmed by biopsy. Nuclei of LG cells are usually stained in intense red/violet color and show hyperchromasia. Chromatin texture and structure are usually masked.



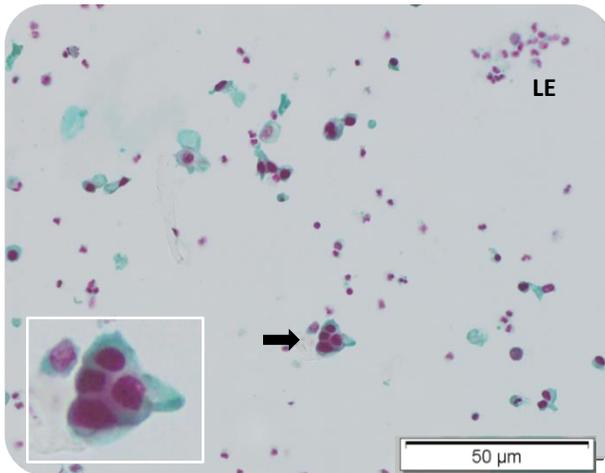
Nuclei of LG cells are purple-red and cytoplasm is green.

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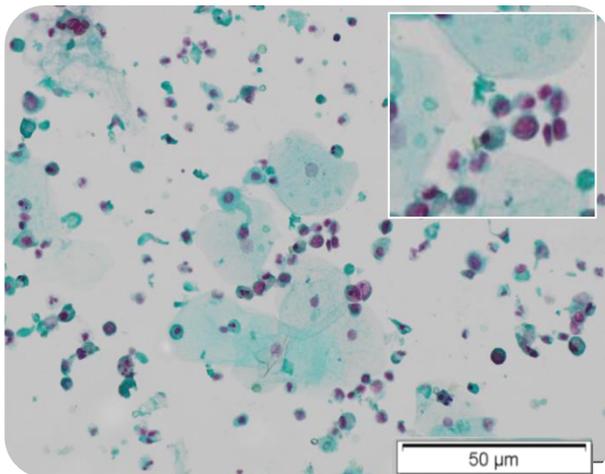


LG urothelial carcinoma confirmed by biopsy. Samples may contain inflammatory cells, leukocytes (LE), which may feature purple-red nuclei.

Low Grade Urothelial Carcinoma

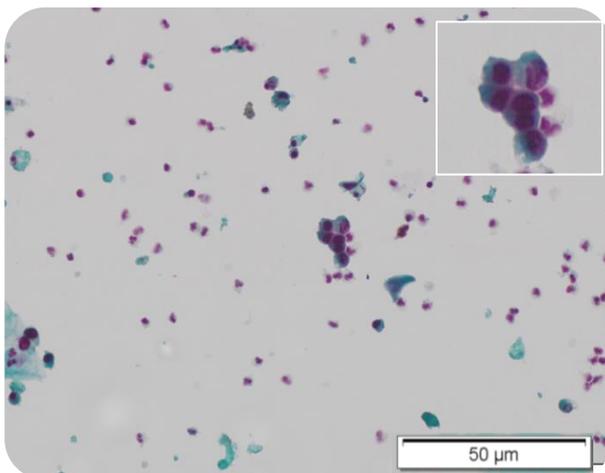


LG urothelial carcinoma confirmed by biopsy. Samples may contain inflammatory cells, leukocytes (LE), which may feature purple-red nuclei.



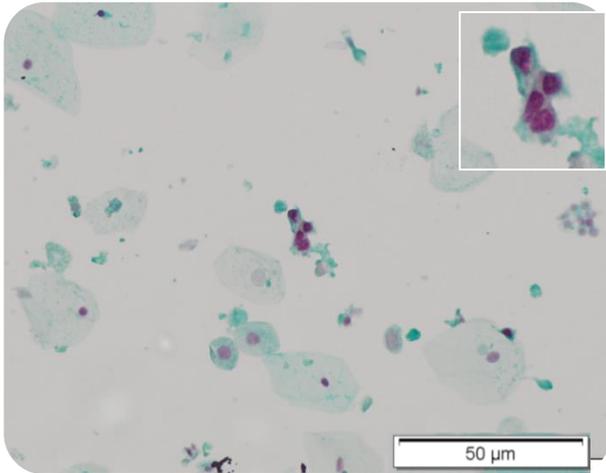
Nuclei of LG cells are purple-red and cytoplasm is green.

LG cells may be found as single or in small groups.

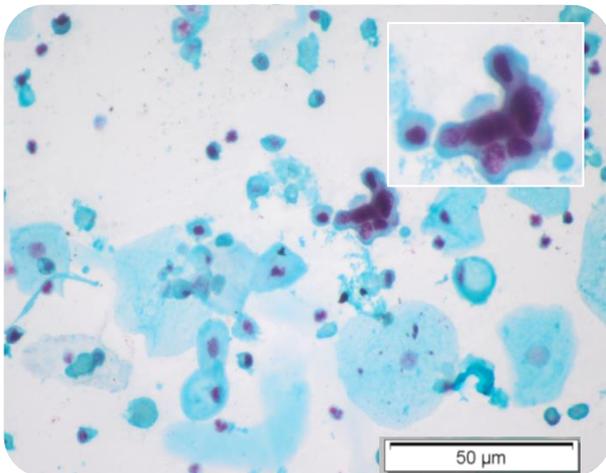


LG urothelial carcinoma confirmed by biopsy. Nuclei of LG cells are usually stained in intense red/violet color and show hyperchromasia. Chromatin texture and structure are usually masked.

Low Grade Urothelial Carcinoma



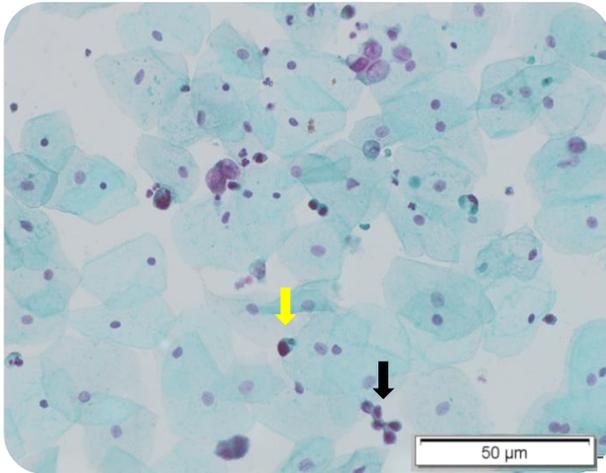
Nuclei of LG cells are purple-red and cytoplasm is green.



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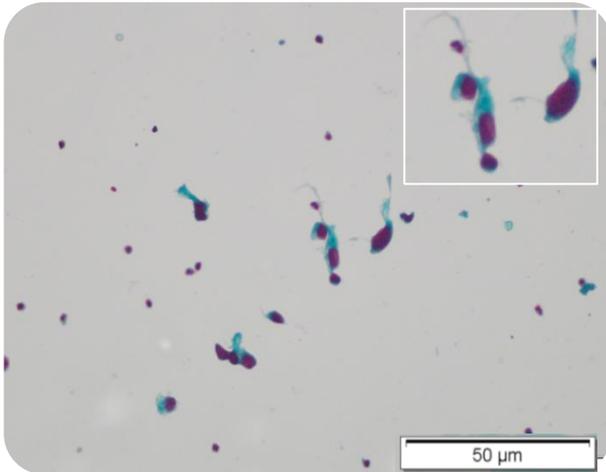
The clusters in LG urothelial carcinoma may be papillary.

High Grade Urothelial Carcinoma

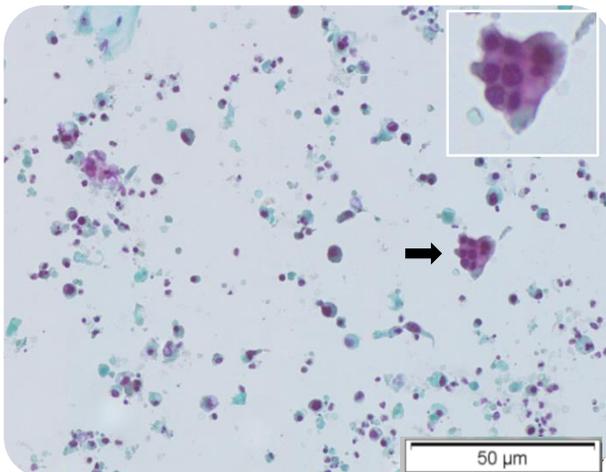


High grade (HG) urothelial carcinoma confirmed by biopsy.

HG cells may be found as single cells (yellow arrow) or clusters (black arrow). Normal cells feature green or purple nucleus and green cytoplasm.

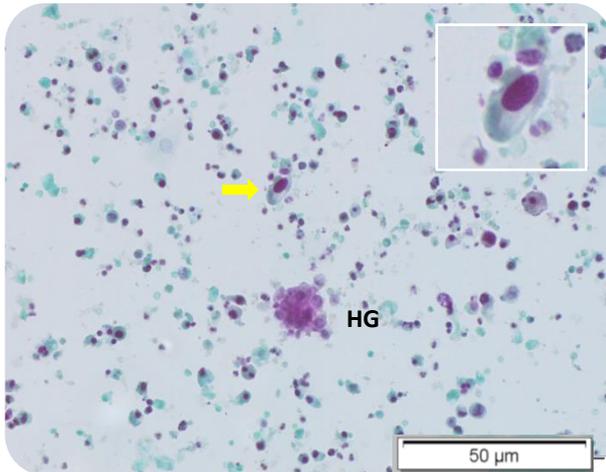


HG cells display high nucleus-to-cytoplasm ratio. The cytoplasm can be seen only focally in some cases. Nuclei appear purple-red and cytoplasm is usually green.



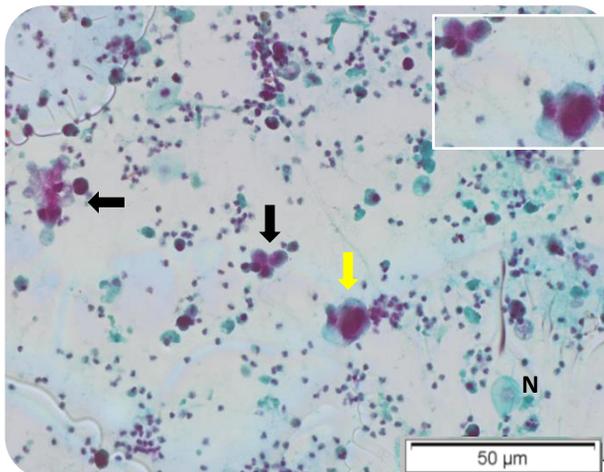
In some cases, cytoplasm is also stained in pinkish color.

High Grade Urothelial Carcinoma

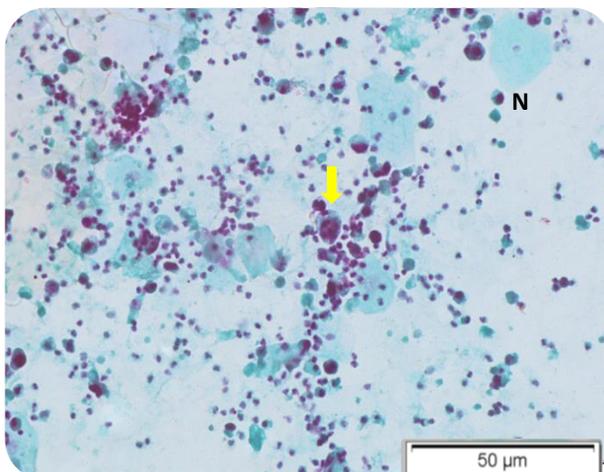


HG urothelial carcinoma confirmed by biopsy.

HG cells are pleomorphic and nuclei may contain a prominent, irregular nucleus.



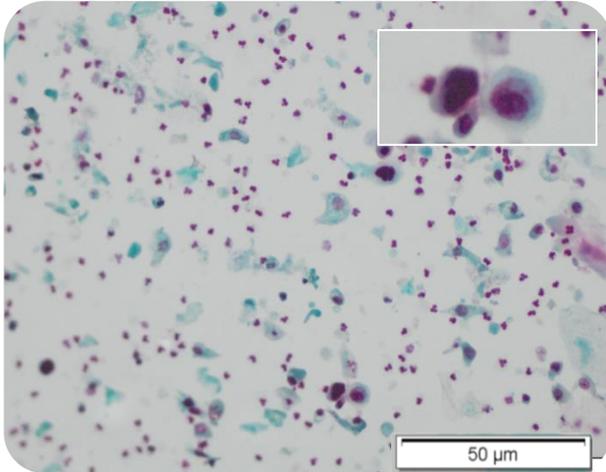
HG cells display high nucleus-to-cytoplasm ratio. The cytoplasm can be seen only focally in some cases. Nuclei appear purple-red and cytoplasm may vary between green and pinkish.



Tumor cell nuclei present morphological features of malignancy.

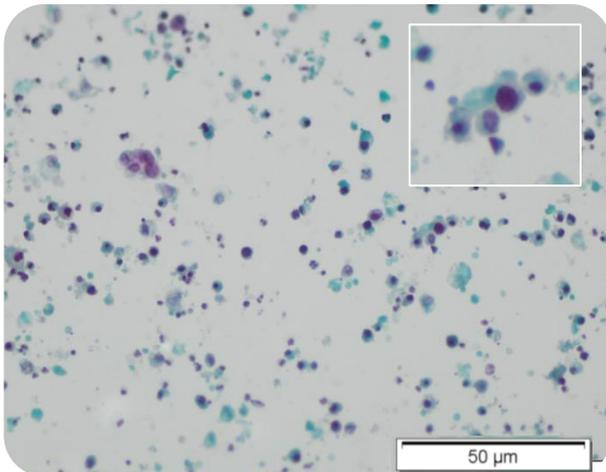
Tumor cell nuclei are usually stained in intense red/violet color and show hyperchromasia.

High Grade Urothelial Carcinoma

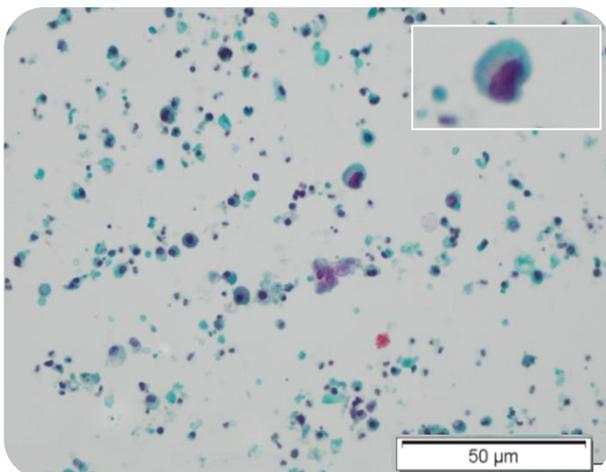


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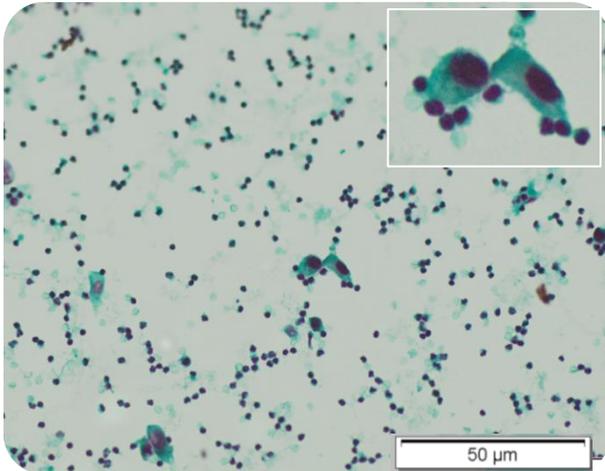


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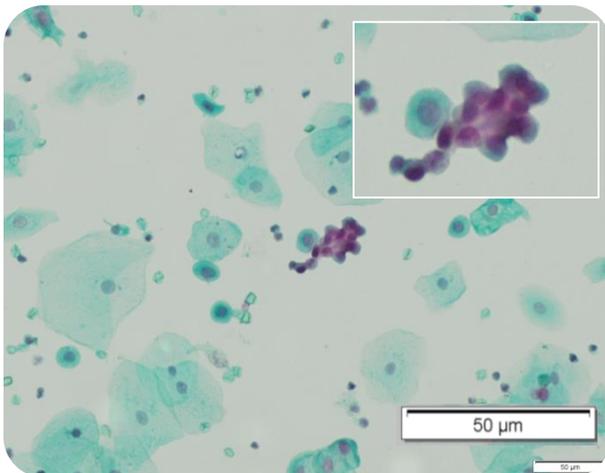
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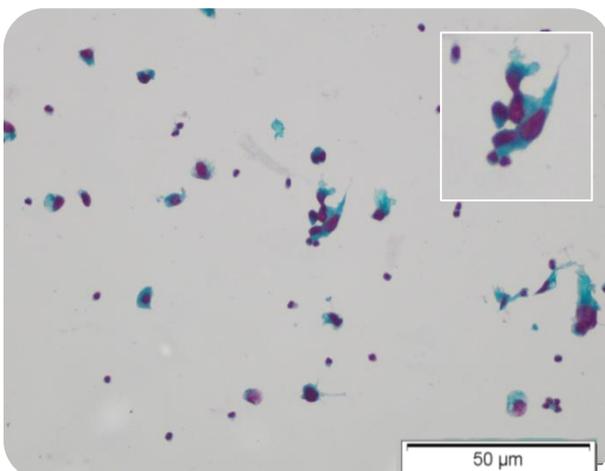


HG cells are pleomorphic and nuclei may contain a prominent, irregular nucleus.

Samples may contain inflammatory cells, leukocytes, which may feature purple-red nuclei.

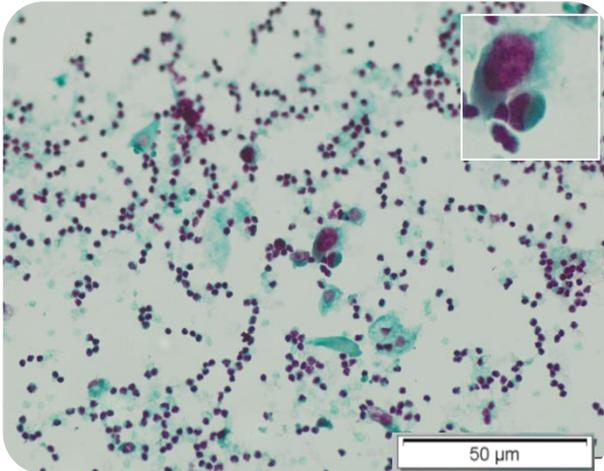


In some cases, cytoplasm is also stained in pinkish color.



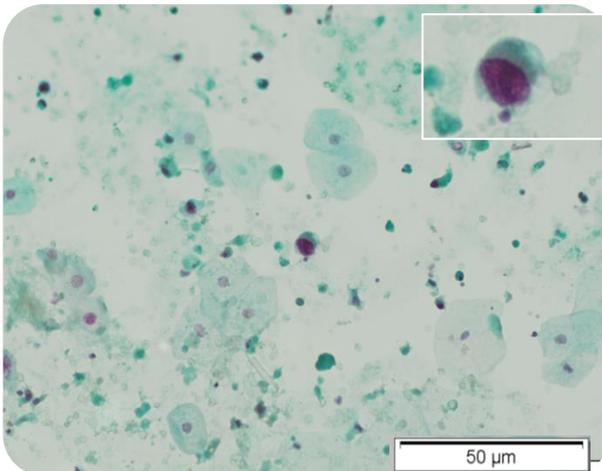
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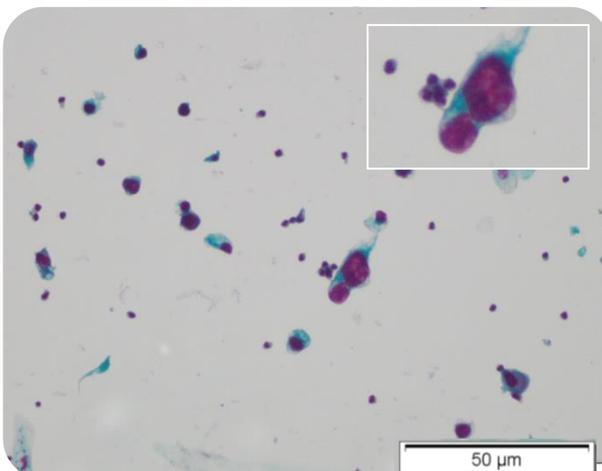


HG urothelial carcinoma confirmed by biopsy.

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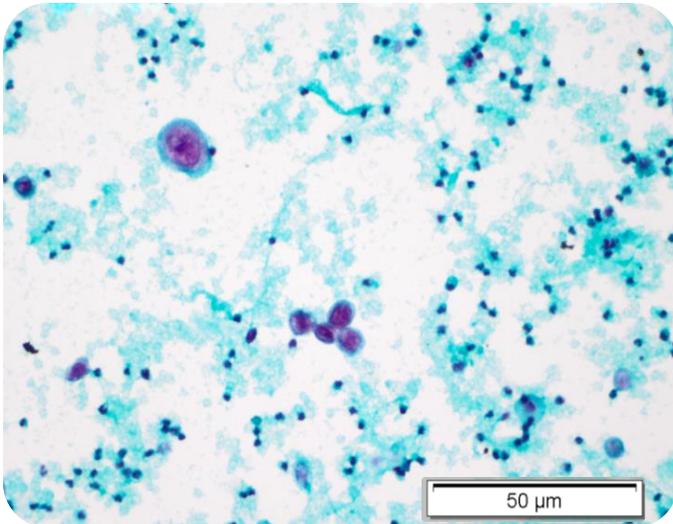
HG cells display high nucleus-to-cytoplasm ratio. The cytoplasm can be seen only focally in some cases. Nuclei appear purple-red and cytoplasm may vary between green and pinkish color.



HG cells are pleomorphic and nuclei may contain a prominent, irregular nucleus.

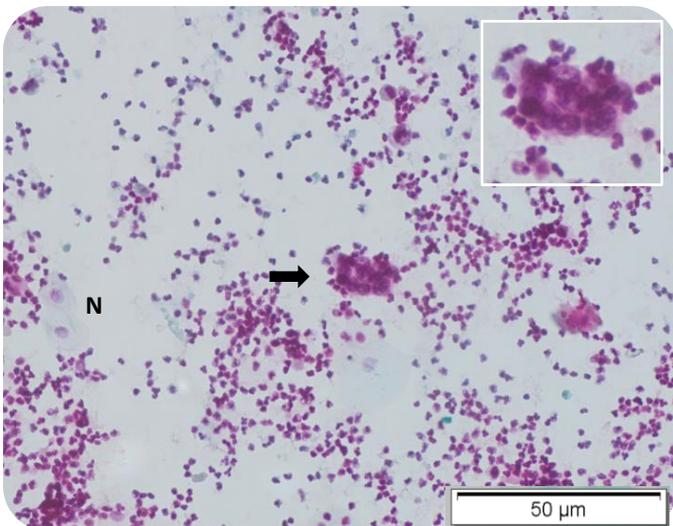
Nuclei of malignant cells are stained in red-purple.

Obscured Smears



HG with Hematuria

Red blood cells are stained in green by the CellDetect® stain and do not interfere with the interpretation.



HG with Inflammation

Occasionally, samples with numerous inflammatory cells may result in red background staining.



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Fax: 972-73-2753451

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