

cobas u 701 microscopy analyzer

Automation of the Gold Standard

References

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- 2 Cho, E.-J., Ko, D.-H. (2018). The efficient workflow to decrease the manual microscopic examination of urine sediment using on-screen review of images. *Clinical Biochemistry*. <https://doi.org/10.1016/j.clinbiochem.2018.04.008>
- 3 Roche Diagnostics (2018). *cobas 6500 urine analyzer series performance evaluation: Study report from a multicenter evaluation of the cobas u 601, cobas u 701, and cobas 6500 systems.* Switzerland: Roche Diagnostics International Ltd.
- 4 Wesarachkitti, B. & Khejonit, V. (2016) Performance Evaluation and Comparison of the Fully Automated Urinalysis Analyzers UX-2000 and Cobas 6500. *Laboratory Medicine*, 42(2), pp. 124-133

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cobas u 701 microscopy analyzer

Automation of the Gold Standard¹



The **cobas u 701** urine analyzer automates manual microscopy which is the gold-standard¹ in urine microscopy by standardization and automation of all manual steps, removing operator variability, significantly reducing operator intervention and increasing efficiency.² With a throughput of 116 samples/hour, it is suitable for laboratories with a workload of 100 to 500 urine samples per day.

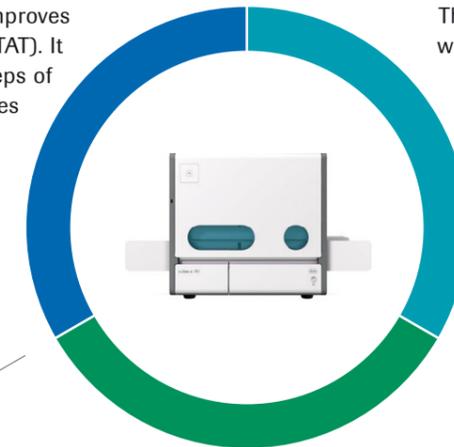
Full automation and standardization of microscopy⁴

The **cobas u 701** urine analyzer automates manual microscopy and therefore minimizes operator intervention and improves turn around time (TAT). It standardizes all steps of the analyses, creates digital images and provides objective results

Excellent counting performance³

The **cobas u 701** urine analyzer detects 11 different particle types of the sediment by analyzing the images with a neural network based algorithm.

This algorithm is trained with 1.5 million particles and is therefore able to produce reliable counting results



Storage of digital images

Images are stored and can be retained for later reference or training. Analysis of advance parameters can be done directly on the images via the user interface with automatic calculation of the results

cobas u 701 microscopy analyzer

At a glance



1 cobas u 701 user interface

- Operated on 19" touch screen, designed for ease of use
- Intuitive user interface allows for effective operation with minimal training, assisting staff management
- Convenient QC management by consolidation of QC data and results

2 RFID reader for QC

- Built-in RFID reader on the analyzer
- Scanning the RFID card, provided with the Bio-Rad Liquichek Urinalysis Controls, automatically transfers all QC information to the analyzer:
 - QC level
 - Target range
 - Lot number
 - Expiry date

3 cobas u 701 module

- Fully automated urine sediment analysis
- Throughput of up to 116 samples/hour
- Takes, retains and reports 15 images/sample
- Reagent-free design, only uses disposable cuvettes (cobas u cuvette) as consumables
- cobas u cuvette: 400 cuvette/cassette with RFID labeling
- Manual classification allows the operator to assess advanced parameters and reclassify particles as required

4 Input buffer

5 Output buffer

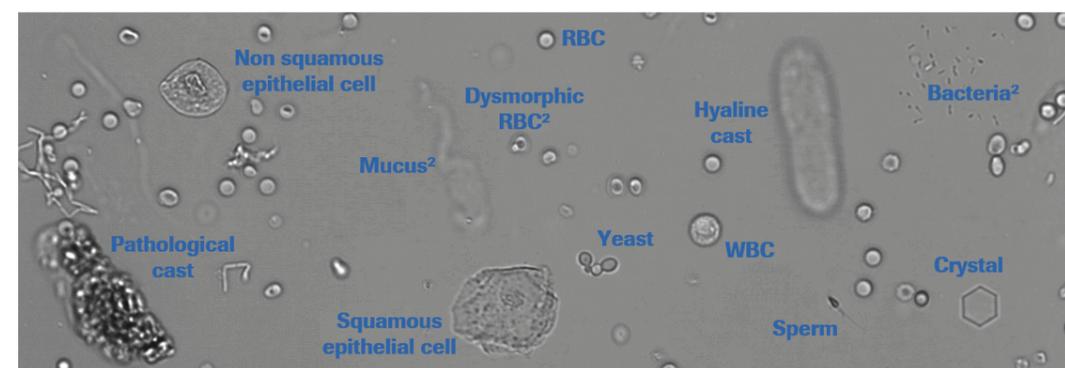
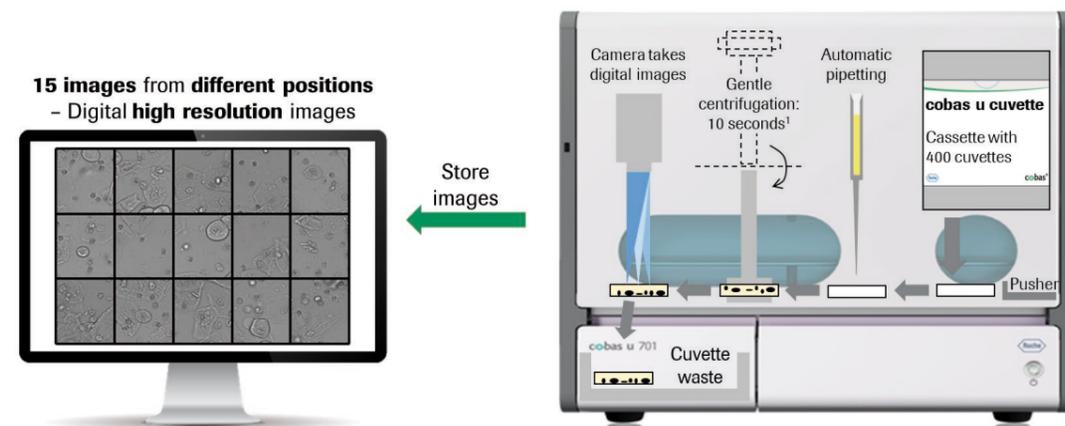
- Tray loading and unloading – One movement for full buffer exchange
- Loading capacity of 75 samples (15 racks/tray, 5 samples/rack)
- Continuous loading/unloading
- Automatically starts operation after sample loading



Full automation and standardization of microscopy

The **cobas u 701** microscopy analyzer provides objective and reliable results through a highly automated work process:

- The sample is automatically pipetted into a disposable cuvette (**cobas u** cuvette)
- A gentle centrifugation is performed on the cuvette for 10 seconds¹
- Digital high resolution images are taken and transferred to the GUI

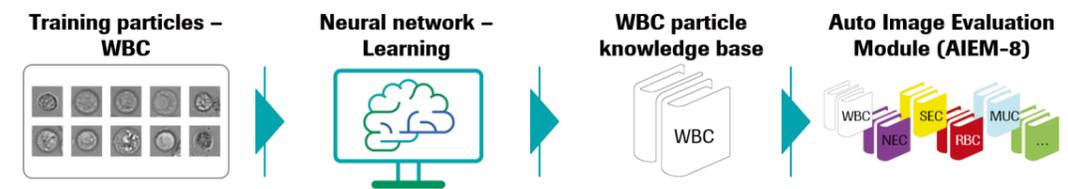


- The system generates digital high power field like images that show a magnification of $\times 400$
- A neural network based algorithm analyzes the particles in the images and labels them
- Manual reclassification of particles into user defined categories (e.g. dysmorphic RBC) is possible

1) Centrifugation force is 260 g 2) Not automatically labeled by the software

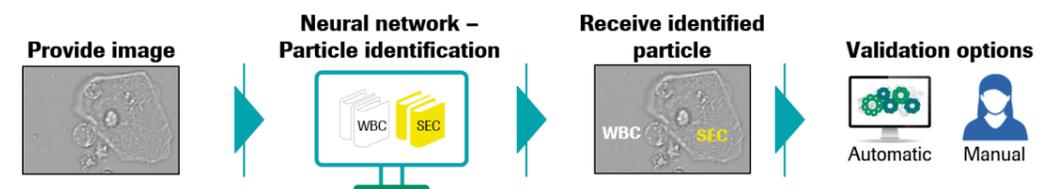
Reliable counting performance

Training



- Manually selected training particles are used to train the neural-network based algorithm
- The result of this learning is a knowledge base for each particle type
- The combination of these particle knowledge bases for all particle types is the "Auto Image Evaluation Module" (AIEM-8)
- The AIEM-8 is based on over 1.5 million training particles

Evaluation

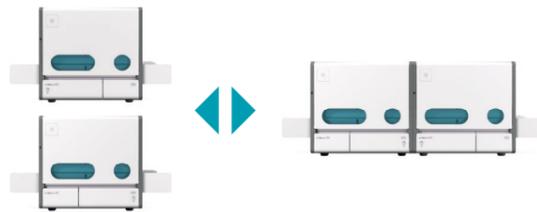


- During the evolution process, the AIEM-8 is used to detect the particles in the images
- The AIEM-8 uses its knowledge base to search for the individual particles types in the image
- These detected particles are then labeled in the image
- The provided result can be validated automatically or manually

*The **cobas u 701** microscopy analyzer from Roche Diagnostics with its standardized microscopy technology provides objective and reliable results while minimizing operator intervention through highly automated work processes.*

Full automation of urine microscopy for optimized overall laboratory workflow

- Loading and unloading of 75 samples on one tray with 5-position Roche standard racks that can be used on other Roche systems. Operation starts automatically after sample loading
- Urine samples are well mixed, pipetted into a cuvette and centrifuged to create a monolayer of particles providing a high level of standardization compared to normal manual slide analysis
- Easy loading of **cobas u** cuvette: cassette containing 400 disposable cuvettes and which are automatically transferred to the waste area after use to avoid carry over. RFID labeled cassettes reduce operator intervention and ensure the correct transfer of lot specific information
- The modular concept of the **cobas u** 701 allows the flexibility to use the analyzer as a standalone system or connected to the **cobas u** 601 forming the **cobas**® 6500 urine analyzer series



Automated QC data input for simplified workflow

- Built-in RFID reader on the analyzer
- Scanning the RFID card, provided with the Bio-Rad Liquichek Urinalysis Control package, automatically transfers all QC information to the analyzer:
 - QC level
 - Target ranges
 - Lot number
 - Expiry date



Simple QC management

- Convenience by consolidation of QC data and results on a single platform

Roche is able to connect the **cobas** 6500 urine analyzer series with a complete test profile, including urine strip and sediment testing in a fully automated lab workflow solution.



Figure 1: **cobas** connection module (CCM) connected to two **cobas**® 8000 modular analyzer series, two **cobas p** 612 pre-analytical systems, a **cobas p** 501 post-analytical unit, a **cobas** 6500 and a **cobas u** 601

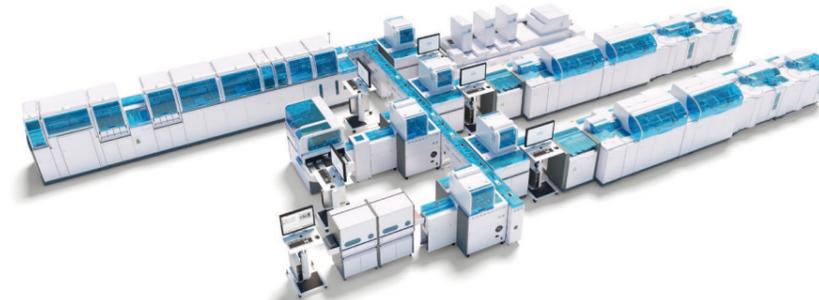


Figure 2: **cobas**® 8100 automated workflow series connected to two **cobas** 8000 modular analyzer series, a **cobas** 6500, a **cobas t** 711 and a hematology line

Roche with its strong commitment to innovate in the diagnostic field is not only continuously developing new products, but also integrating them into the entire portfolio to provide a valuable solution addressing the challenges in today's laboratories.

cobas u 701 microscopy analyzer

Technical specifications

cobas u 701

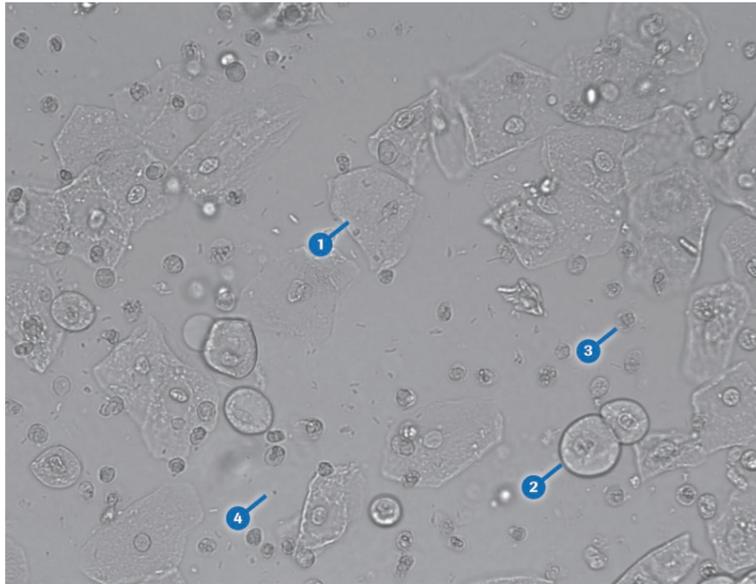
System	Modular, analytical system platform for urine sediment analysis, expandable and reconfigurable on site with cobas u 601 module to a urine work area																						
Types of module	cobas u 701 module: urine microscopy measuring unit																						
Module combinations	Stand-alone: <ul style="list-style-type: none"> • cobas u 701 urine analyzer with one cobas u 701 module • cobas u 701 can be connected to the cobas u 601 forming the cobas 6500 urine analyzer series 																						
Sample throughput	Up to 116 samples/hour																						
Test parameters	<table border="0"> <tr><td>RBC</td><td>Red blood cells</td></tr> <tr><td>WBC</td><td>White blood cells</td></tr> <tr><td>NEC</td><td>Non-squamous epithelial cells</td></tr> <tr><td>SEC</td><td>Squamous epithelial cells</td></tr> <tr><td>YEA</td><td>Yeasts</td></tr> <tr><td>CRY</td><td>Crystals</td></tr> <tr><td>BAC</td><td>Bacteria</td></tr> <tr><td>HYA</td><td>Hyaline casts</td></tr> <tr><td>SPRM</td><td>Sperm</td></tr> <tr><td>MUC</td><td>Mucus</td></tr> <tr><td>PAT</td><td>Pathological casts</td></tr> </table>	RBC	Red blood cells	WBC	White blood cells	NEC	Non-squamous epithelial cells	SEC	Squamous epithelial cells	YEA	Yeasts	CRY	Crystals	BAC	Bacteria	HYA	Hyaline casts	SPRM	Sperm	MUC	Mucus	PAT	Pathological casts
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SPRM	Sperm																						
MUC	Mucus																						
PAT	Pathological casts																						
Consumables	<ul style="list-style-type: none"> • cobas u cuvette: cassette with 400 cuvettes for urine microscopy analysis with RFID label 																						
Sample input/output	<ul style="list-style-type: none"> • Tray loading and unloading – One movement for full buffer exchange • Loading capacity of 75 samples (15 racks/tray, 5 samples/rack) • Continuous loading/unloading • Automatically starts operation after sample loading 																						
Sample tube types	<ul style="list-style-type: none"> • Length: 65 – 115 mm • Diameter: 13 – 16 mm • Bottom: round, conical or false 																						
Minimal sample volume	<ul style="list-style-type: none"> • 2.0 mL 																						
Measurement principles	<ul style="list-style-type: none"> • Automated microscopy • Automatic image evaluation 																						
Calibration	<ul style="list-style-type: none"> • Reference cuvette for the microscope check 																						

cobas u 701

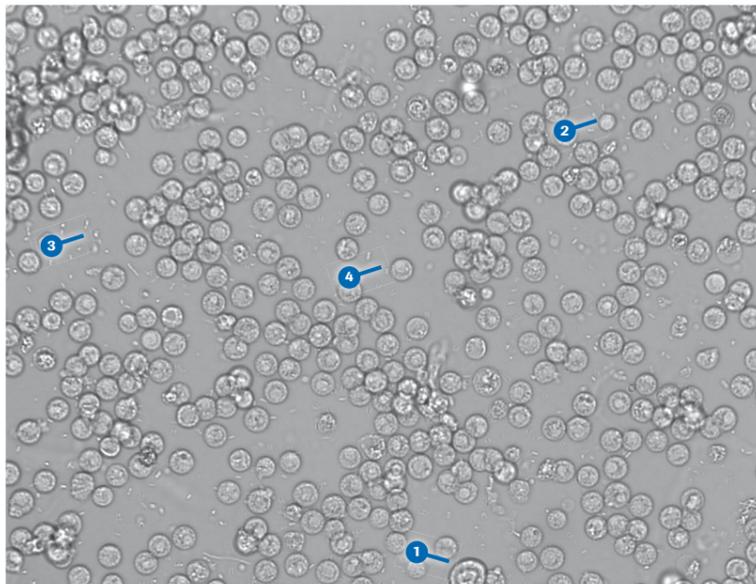
Storage capacity	<ul style="list-style-type: none"> • Up to 10,000 test results (including images) • QC and microscope check: up to 300 each • Operator can export all results on the analyzer, including QC and calibration results 						
Power requirements	<ul style="list-style-type: none"> • Line voltage: <ul style="list-style-type: none"> 100 – 125 VAC, permanent connection ($\pm 10\%$) 200 – 240 VAC, permanent connection ($\pm 10\%$) • Line frequency: <ul style="list-style-type: none"> 50 or 60 Hz ($\pm 5\%$) 						
Regulatory requirements	<p>The cobas u 701 urine analyzer meets the protection requirements defined in IVD Directive 98/79/EC. Furthermore, the instruments are manufactured and tested according to the following international standards:</p> <ul style="list-style-type: none"> • IEC 61010-1, 2nd Edition • IEC 61010-2-081, 1st Edition • IEC 61010-2-101, 1st Edition • CAN/CSA C22.2 No. 61010 2nd Edition • EN IEC 61326-1 1st Edition • EN IEC 61326-2-6 1st Edition • UL 61010-1, 2nd Edition 						
Certificates	CE, FDA, UL, CB						
Operating conditions	<ul style="list-style-type: none"> • Ambient room temperature: 18 – 32 °C • Relative humidity: 30% – 80%, non-condensing • Altitude and pressure: Max. 2,000 m above sea level, 80 - 106 kPa 						
Environmental impacts	<ul style="list-style-type: none"> • Noise: 61 dB • Heat: 125 W 						
Water and waste	<ul style="list-style-type: none"> • Water container: 5 L capacity = approx. 400 samples • Liquid waste container: 5 L capacity = approx. 400 samples • Direct water supply and direct liquid waste connection available 						
Physical dimensions	<table border="0"> <tr><td>• Width (with buffers)</td><td>107.9 cm</td></tr> <tr><td>• Depth</td><td>53.2 cm</td></tr> <tr><td>• Height</td><td>64.4 cm</td></tr> </table>	• Width (with buffers)	107.9 cm	• Depth	53.2 cm	• Height	64.4 cm
• Width (with buffers)	107.9 cm						
• Depth	53.2 cm						
• Height	64.4 cm						
Weight	<ul style="list-style-type: none"> • With buffers 88.8 kg 						
Connectivity	<p>Connection to Roche automation:</p> <ul style="list-style-type: none"> • cobas connection module (CCM) • cobas 8100 automated workflow series 						

cobas u 701 microscopy analyzer

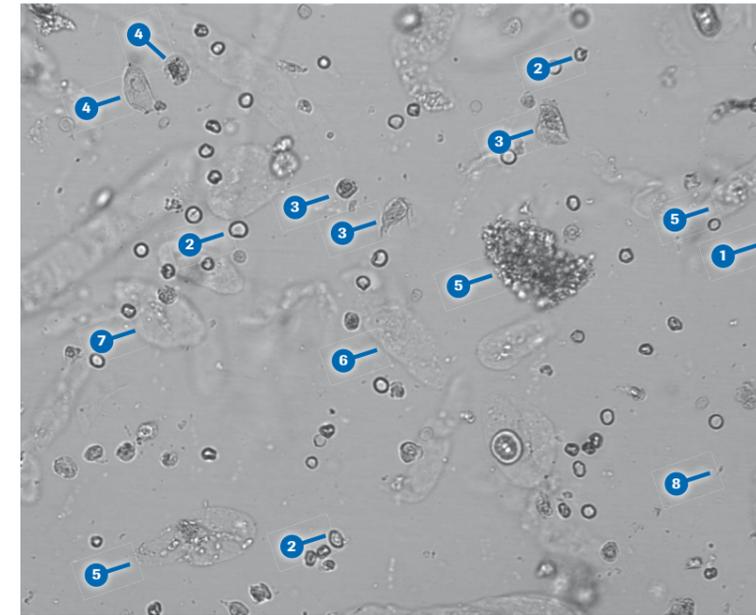
Digital microscopy images*



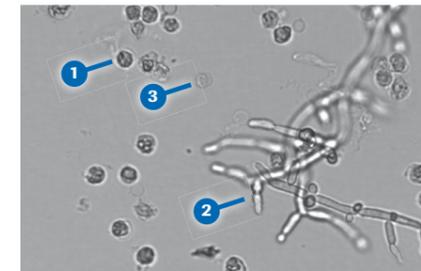
SEC, NEC, WBC and BAC: Squamous epithelial cells (SEC) (1), non-squamous epithelial cells (NEC) (2), white blood cells (WBC) (3) and bacteria (BAC) (4). This image shows characteristic features of acute or chronic urinary tract infection.



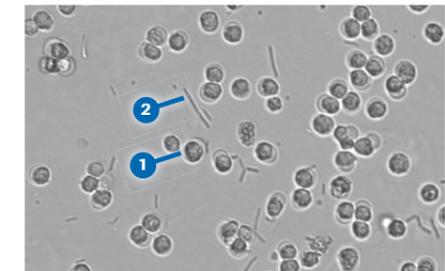
WBC, RBC, NEC and BAC: One non-squamous epithelial cell (NEC) (1), some red blood cells (RBC) (2) and some bacteria (BAC) (3) in addition to numerous white blood cells (WBC) (4). Polymorphonuclear neutrophils (12 - 15 µm) are easily recognized by their segmented, still visible nuclei. The WBCs are often dead and their nuclei degraded.



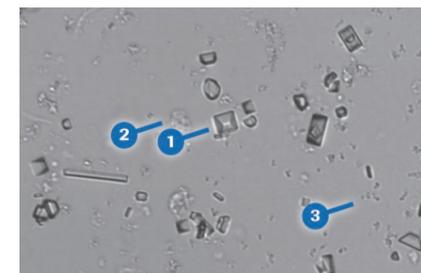
RBC, NEC, SEC, PAT, HYA, and BAC: Presence of isomorphic red blood cells (RBC) (1) as well as dysmorphic red blood cells (reported as RBC) (2), renal tubular cells (NEC) (3), transitional epithelial cells (NEC) (4), pathological casts (PAT) (5), hyaline casts (HYA) (6), squamous epithelial cells (SEC) (7) and some bacteria (BAC) (8). The overall picture is compatible with chronic glomerulonephritis.



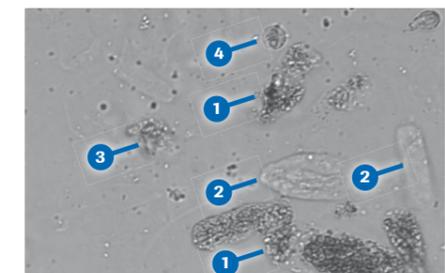
WBC, YEA and RBC: White blood cells (WBC) (1), yeast (YEA) (2) and red blood cell ghost (reported as RBC) (3). YEA and WBC are a frequent finding. In women *Candida* sp. often originate from the vulva and therefore can indicate yeast infection.



WBC and BAC: White blood cells (WBC) (1) with rod-shaped bacteria (BAC) (2). Note numerous rod-shaped bacteria. Clinical finding: acute pyelonephritis in patient with renal calculus.



CRY, WBC and BAC: Triple phosphate crystals (reported as CRY) (1), cell debris from white blood cells (WBC) (2) and bacteria (BAC) (3). Triple phosphate crystal ("coffin lids") are a frequent finding in infected alkaline urines; Their massive appearance in fresh urines may, however, indicate stasis in the lower urinary tract.



PAT, HYA, NEC, WBC, BAC and MUC: Granular casts (reported as PAT) (1), hyaline casts (HYA) (2), non-squamous epithelial cell (NEC) (3), white blood cell (WBC) (4), bacteria (BAC) (5) and mucus (MUC) (6). Granular casts are found in nearly all forms of specific renal disease. Their appearance should invariably prompt further tests of renal function. Clinical finding: chronic glomerulonephritis.

*The magnification of the images is ×400