

# Outline and Features of Automated Urine Particle Digital Imaging Device UD-10

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## INTRODUCTION

The Automated Urine Particle Digital Imaging Device UD-10 (Sysmex Corporation, Kobe, Japan, hereinafter 'UD-10') captures images of particles such as RBC, WBC, and epithelial cells in an uncentrifuged urine sample, by using fully automated processing. The imaging results are stored in the UD-10, then transmitted and stored in the Urinalysis Work Area Information Management System U-WAM (or UDM, Sysmex Corporation, Kobe, Japan, hereinafter 'U-WAM'). The U-WAM supports on-screen classification of cells in conjunction with results from the fully automated urine particle analyzer UF-5000, 4000\* or 3000\* (Sysmex

Corporation, Kobe, Japan, hereinafter 'UF-5000').

This instrument can streamline the urinalysis process and increase the clinical value of the results.

\*Note: Depending on the region, those models may not be available.

## MAIN SPECIFICATIONS

### 1. External appearance of the analyzer

UD-10 consists of an analysis section (main unit), a sampler unit, a pneumatic unit and an IPU (instrument-processing unit for data processing) (**Fig. 1**).



**Fig. 1** External appearance of UD-10 (connected to UF-5000 and U-WAM)

Notes: This article is based on current regulatory requirements in Japan. (as of Mar. 2018)

The specifications, performances and functions described here may be different depending on the regions or the countries due to the regulatory affairs, legal matters or local guidelines. For more details, please contact your regional affiliates or distributors.

Depending on the region, some of the applications may not be available due to regulatory issues.

Functions described here are based on U-WAM ver. 10.

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## 2. Instrument specifications

The main specifications of the instrument are given below (**Table 1**).

To perform a measurement, place the sample tubes containing native (unspun) urine into sample racks and conduct sampler analysis, or place a sample tube or sample cup containing the urine into the STAT sample holder and conduct STAT analysis.

Samples aspirated by the aspiration pipette in the instrument are loaded to the imaging cell and whole-field images are captured. Individual particle images are extracted from the

whole-field images and then automatically grouped into [Class1] to [Class8] based on the size of the particles in the images.

The whole-field and individual cell images are automatically transmitted to U-WAM via the IPU of UD-10 for manual identification of the particles by the operator. In the U-WAM screen, the whole-field images and cropped pictures can be checked in more detail.

Moreover, quality control functions to check the number of particles or focus of the inner camera are applied. For these QC functions, UF-CONTROL™ is used, the same control material that is utilized for UF-5000.

**Table 1** Specifications of UD-10

<b>Name</b>	Automated Urine Particle Digital Imaging Device UD-10
<b>Principle of measurement</b>	Stage scanning image analysis
<b>Analysis targets</b>	Human urine
<b>Number of captured images</b>	40 whole-field captured images/sample (normal mode)
	80 whole-field captured images/sample (precise mode)
<b>Analyzed urine volume</b>	Approx. 1 µL (normal mode)
	Approx. 2 µL (precise mode)
<b>Throughput</b>	50 samples/hour (normal mode)
	30 samples/hour (precise mode)
<b>Aspirated sample volume</b>	0.3 mL in all modes
<b>Required sample volume</b>	Sampler analysis 1.6 mL, STAT analysis 0.6 mL
<b>Data storage capacity*</b>	Maximum 400 samples (including captured image and extracted particle image information)
	QC files: 3 files/analyzer (120 plots/file)
<b>Dimensions (mm)</b>	Analyzer (including the sampler (CV-11)): approx. 640 (W) × approx. 900 (D) × approx. 872 (H) mm
	Pneumatic unit: approx. 280 (W) × approx. 355 (D) × approx. 400 (H) mm
<b>Weight</b>	Analyzer (including the sampler (CV-11)): approx. 89 kg
	Pneumatic unit: approx. 17 kg
<b>Power source</b>	Analyzer: 100 to 240 V AC, 50/60 Hz
	Pneumatic unit: 100 to 117 V AC, 220 to 240 V AC, 50/60 Hz
<b>Power consumption</b>	Analyzer: 300 VA or less
	Pneumatic unit: 50 Hz: 230 VA or less (100 to 117 V), 220 VA or less (220 to 240 V) 60 Hz: 280 VA or less (100 to 117 V), 250 VA or less (220 to 240 V)

\*In the U-WAM, particle images can be stored for 7 days or up to a total of 1,000 images and 300 plots × 50 files of QC data.

## PRINCIPLE OF MEASUREMENT

### 1. Analysis principles

**Fig. 2** shows the basic alignment of the devices in the instrument.

### 2. Introduction of the sample into the imaging cell

The urine sample is aspirated using an aspiration pipette and is introduced into an imaging cell.

The imaging cell has a flat prismatic shape and the aspirated urine is allowed to sit for approx. 2 min. in order to let the particles in the sample settle to the bottom of the imaging cell.

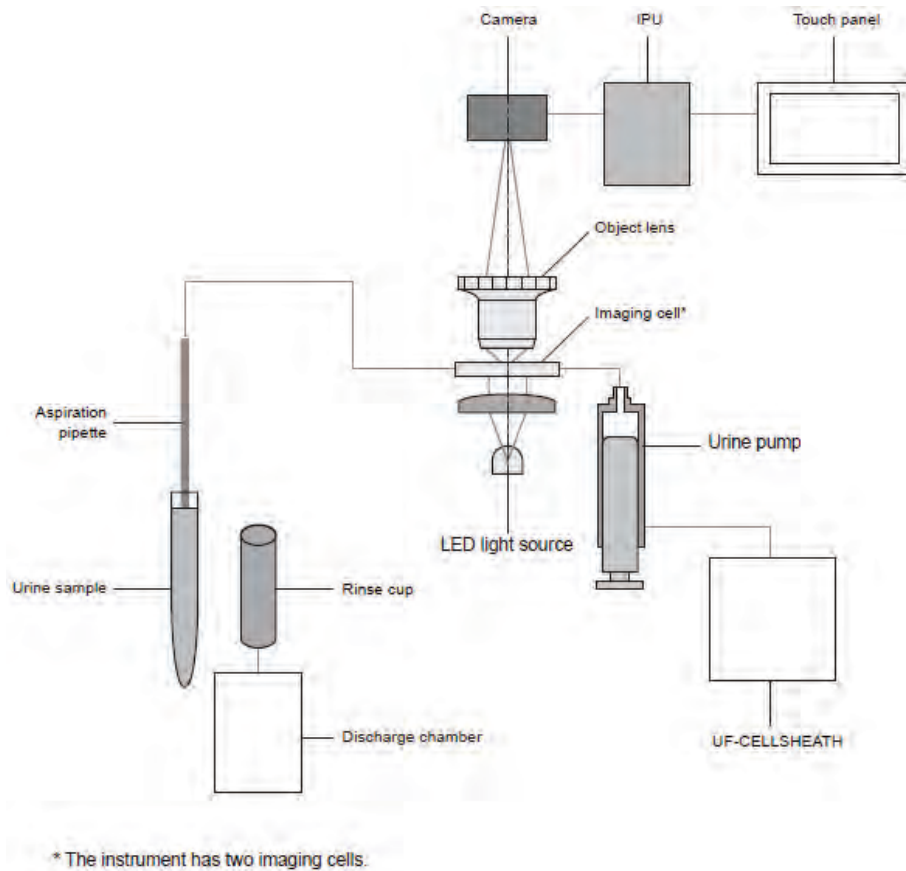
The urine volume capacity of the cell is approx. 20 $\mu$ L, but only 1 $\mu$ L of the 20 $\mu$ L of urine in the cell is actually used for image capturing (normal mode).

There are two imaging cells in the instrument and those are used in turn in order to accelerate the throughput. Forty images are captured and used for analysis in the normal mode in order to shorten the image analysis. In the precise mode, 80 images are used for the image analysis.

### 3. Image capture

After the settling process, black-and-white image capturing by a CCD camera is conducted. There is no staining of the particles in the UD-10. The green LED located under the imaging cell emits pulses of light, and the CCD camera captures images via its objective lens using a magnification of 15x.

While the imaging cell gently moves underneath the camera, 40 images per each imaging cell are captured with the camera. The captured images are analyzed by the IPU of the UD-10 and displayed on the U-WAM screen.



**Fig. 2** Basic alignment of the devices in the instrument. Aspirated urine is introduced into the imaging cell and the images are captured.

#### 4. Image analysis

The captured images are analyzed by the IPU of the UD-10 and individual particle images are extracted and classified into [Class1] to [Class8] according to the particles' size. In the IPU, all these images are initially stored and the number of extracted images is counted. If the number of extracted images exceeds the number of displayed images (see **Table 2** below), a representative sample of extracted images is selected according to the following procedure.

- 1) In classes 2 to 5, a representative sample of extracted images is selected, which reflects a proportion of different particle types that is similar to that of the whole-field captured images. The selected images are then displayed (please refer to **Fig. 3** below).
- 2) For the other classes, the extracted images are displayed according to the order in which they were detected.

The extracted images that were not selected are not stored, and only the total number of extracted images identified is recorded for each individual class. The captured images and

the extracted particle images are transmitted to and stored in the U-WAM.

The maximum number of particle images stored/ displayed by U-WAM are shown in **Table 2** (from [Class1] to [Class8], respectively). **Fig. 3** shows the [Overview] screen in U-WAM.

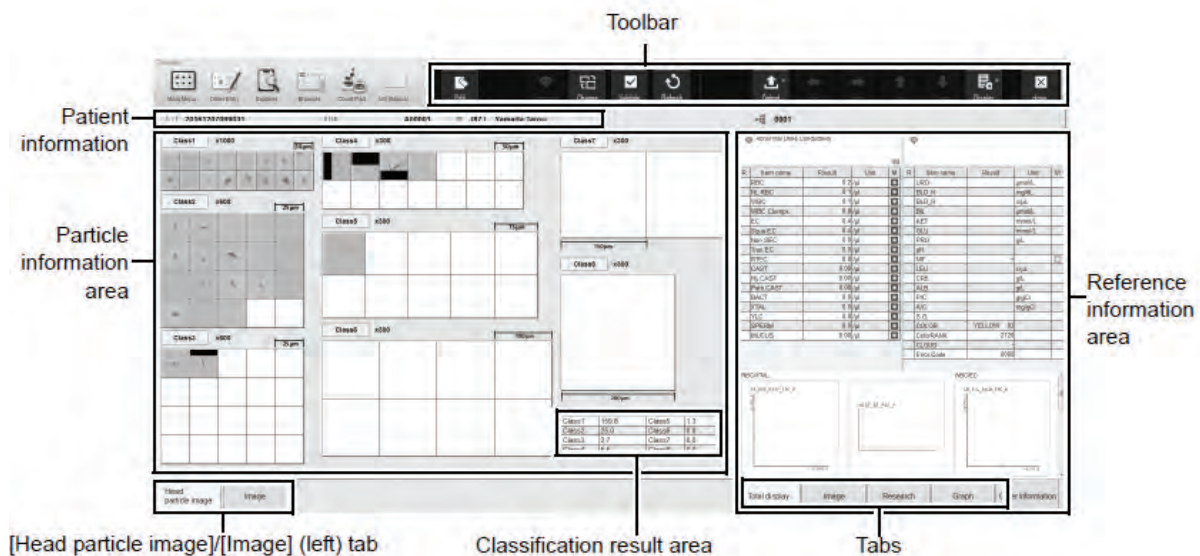
#### 5. [Overview] screen (**Fig. 3**)

The obtained particle images are displayed in the [Overview] screen in U-WAM.

In this [Overview] screen, quantitative results, scattergrams and histograms from UF-5000, results from the UC-3500 (urine test strip examination) and individual particle images by UD-10 can be displayed simultaneously. If those images from the UD-10 are comparable to the results from UF-5000, detailed identification or individual particle counting by examining those images is not required. Here, the images may be used just for verification of the UF results. Only in such cases in which significant differences were observed

**Table 2** Number of displayed images and range of particle count

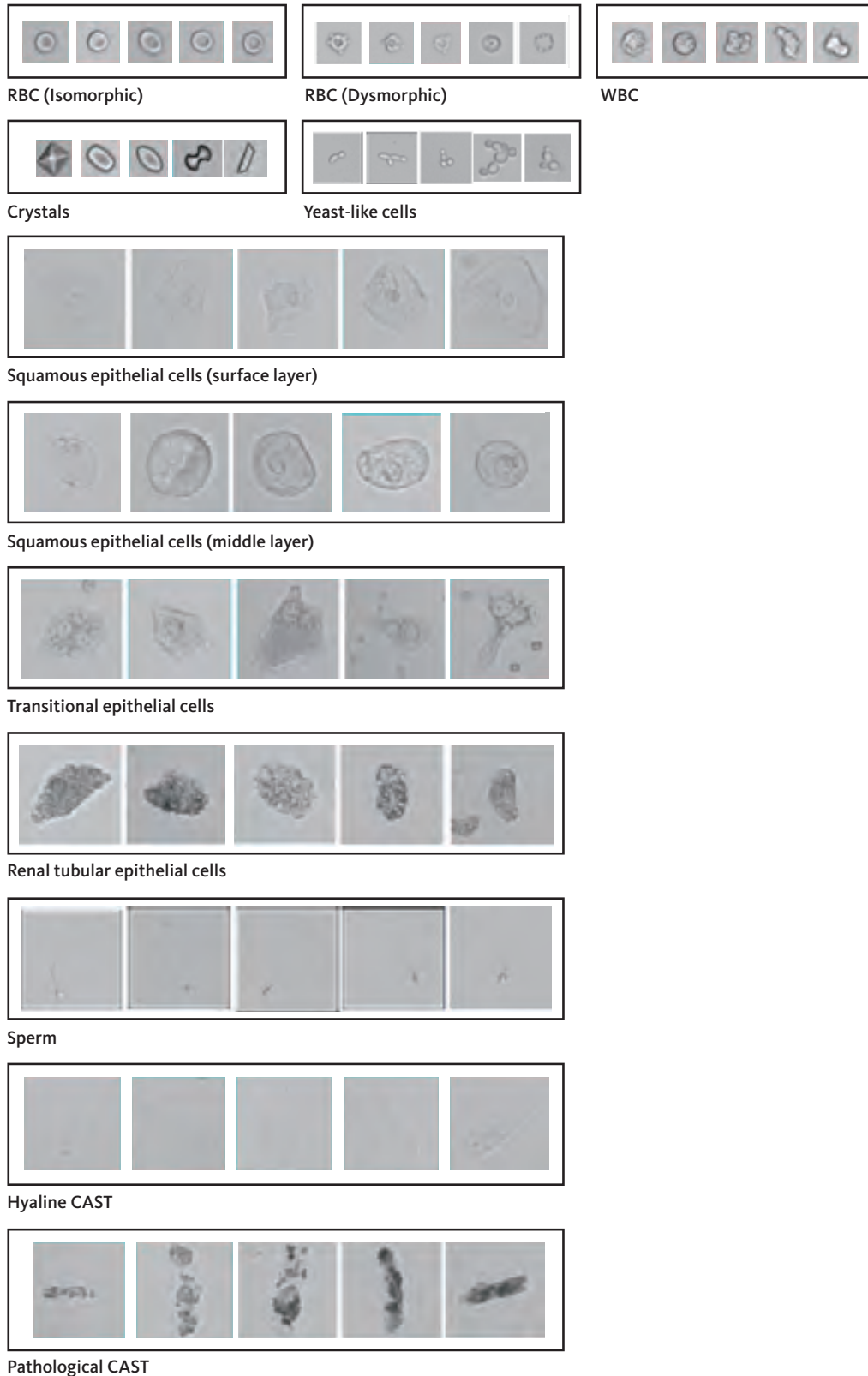
Class	size (μm)	Number of displayed images	Range of particle count
1	2 ~ 6	100	0.0 ~ 99,999.9
2	6 ~ 10	100	0.0 ~ 99,999.9
3	10 ~ 16	100	0.0 ~ 99,999.9
4	16 ~ 36	50	0.0 ~ 99,999.9
5	36 ~ 71	50	0.0 ~ 99,999.9
6	71 ~ 101	20	0.0 ~ 99,999.9
7	101 ~ 151	20	0.0 ~ 99,999.9
8	151 ~	20	0.0 ~ 99,999.9



**Fig. 3** [Overview] screen in U-WAM

between results from UF-series and UD-10, particle identification by UD-10 is to be conducted. By applying this kind of workflow, a more efficient and effective urine screening procedure may be realized. Examples of obtained

particle images are shown in **Fig. 4**. These particle images are not automatically classified by UD-10/U-WAM but manually specified based on the obtained images.



**Fig. 4** Representative particle images obtained by UD-10

## 6. [Edit] screen (Fig. 5)

In the U-WAM connected with UD-10, the extracted particle images can be displayed. The images are displayed by group (classes 1 to 8), according to the size of the particles shown in the images. Manual identification and enumeration of individual images can be performed using three different procedures (in U-WAM ver. 10), as listed below. The operator performs these procedures manually; the UD-10 does not perform any automated classification of the images.

- 1) Touch the individual images one by one and assign each image to the appropriate classification such as RBC, WBC, etc.
- 2) Review all extracted particle images and/or captured images obtained by UD-10, assign the particle types and enter the appropriate value for each item.
- 3) Load the results from UF-5000 to the UD-10 using the 'Apply UF Values' icon, and then edit the results based on the UD-10 images using either of the procedures mentioned above.

We will describe in more detail several options of applying the UD-10 for a more efficient urine screening. The optimized workflow is to be designed depending on the expectations for urine screening results from clinicians, workflow efficiencies for the laboratory and cost-effectiveness in the laboratory or actual analytical performance of the results. It is essential to make a comprehensive consideration and employ the most appropriate features of the entire system (UC + UF + UD) to align with the needs of each

individual laboratory in the hospital, clinic or commercial laboratory system.

- 1) Touch the individual images one by one and assign each image to the appropriate classification such as RBC, WBC, etc.

In the [Overview] screen in U-WAM, touch the icon indicating the class to be edited (e.g. [Class2]); then the [Edit] screen of the defined class is displayed. Touch an extracted particle image to highlight it and select the 'Rough Classification' icon in the lower left corner of the screen that corresponds to the cell type, then select the 'Fine Classification' icon to assign the identification. Repeat the process for each individual image or group of images. The result (#/HPF, etc.) is calculated and displayed in the classification result list. This calculation (conversion) is done automatically.

If the number of the extracted particle images is larger than the number of displayed images shown in **Table 2**, only the displayed images are used for classification. This image processing is done independently for each class. For example, even if the numbers of particle images in classes 2 and 3 exceed their respective upper limits of 100 displayed images, all large-sized particle images (i.e. particle images categorized in [Class6]) can still be displayed on the screen as long as their number is below the upper limit of displayed images defined for this class. Accordingly, even in this situation, the total analysis urine volume remains 1 $\mu$ L (normal mode) for those large-sized particles.

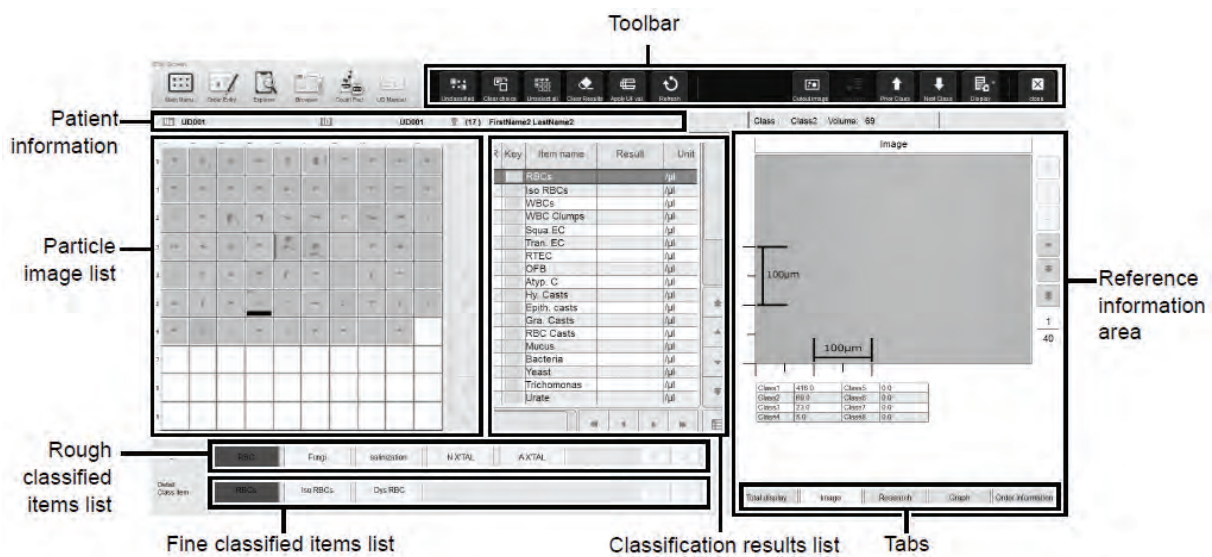


Fig. 5 [Edit] screen in U-WAM

- 2) Review all extracted particle images and/or captured images obtained by UD-10, and enter the appropriate value for each item (e.g. RBC: 1-4/HPF; WBC: 10-19/HPF).

Review the entire class/group of extracted particle images obtained by UD-10, and then double-click the analysis parameter you want to enter in the classification result list in the center of the screen. Enter the result of the item directly by choosing an appropriate value from the pre-defined result value list in the drop-down menu (1-4 / HPF, etc.) that appears on the screen. The total number of extracted particle images is also displayed on the upper right of the [Edit] screen for the corresponding class. Respective values are given for each class. This number indicates the total number of particles categorized in a class (class 1, 2, etc.) in 1µL of urine (normal mode). Therefore, that number can also be helpful for choosing the appropriate rank value for an individual item.

- 3) Load the results from UF-5000 to the UD-10 using the 'Apply UF Values' icon, and then edit the results based on the UD-10 images using either of the procedures mentioned above.

In the tool bar that appears on the top of the [Edit] screen, there is an 'Apply UF values' icon. By clicking the icon, the results from UF-5000 are copied into the classification result list in the center of the screen. If there is no indication that the UD results are different from the UF values, the UF results can be reported as the results of UD-10.

## 7. Others

Reagents used for this instrument are shown in **Table 3**. There is no staining solution. Native (unspun) urine is directly introduced into the imaging cell and the images

are captured; then the urine is discarded and transferred to the waste by flushing with UF-CELLSHEATH™. CELLCLEAN U™ is used for the automated rinsing of the analysis line, imaging cell and pipette as a part of routine maintenance. This rinsing is also one of the processes during shutdown.

## CONCLUSION

The healthcare environment has become more constrained in terms of cost pressure, higher clinical demand for accuracy and reliability of the test results, effectiveness and efficiency of laboratory work, etc. From a diagnostic point of view, depending on the actual patient's symptoms or clinician's diagnostic assumption, the required clinical information<sup>1)</sup> from the laboratory is also variable in the respect of accuracy, examination procedure or items and degree of details.

From a laboratory management point of view, the clinical examination should be implemented efficiently and effectively, and the results should be provided in a timely manner to the clinicians. The pressure to keep costs down is also quite high.

It is quite important to consider the clinical needs and actual laboratory workflow management to design an optimized examination process for urine screening. Computerization of the examination of laboratory data has been expanding and the clinical examination ordered by clinicians can be increasingly flexible<sup>2)</sup> to reflect the individual patient's needs. In these environments, we continue to develop an optimized and most streamlined clinical examination by applying the UD-10 as a part of a complete urine screening system and in order to make the best proposal for an improved laboratory workflow.

**Table 3** Reagents and control material

Reagents	Name	UF-CELLSHEATH
	Components	Tris buffer 0.14%
	Functions	System fluid for sample aspiration and as a washing fluid
	Name	CELLCLEAN U
	Components	Sodium hypochlorite (Effective chlorine concentration 5.0%)
	Functions	Rinse solution to clean the fluid system
Control material	Name	UF-CONTROL
	Components	UF-CONTROL-H Control particles 0.4% UF-CONTROL-L Control particles 0.1%
	Functions	Control material for use in the quality control measurement procedure of the Sysmex Fully Automated Urine Particle Analyzers and the Sysmex Fully Automated Urine Particle Digital Imaging Device
	Others	Contains latex particles

**References**

- 1) Yuno T. Report format for urinalysis (Japanese). *Journal of Clinical Laboratory Medicine*. 2017; 61(1): 76-85.
- 2) Ohtsuka R, et al. Efficient urine sediment examination by using fully automated urine particle analyzer UF-5000 (Japanese). *Japanese Journal of Clinical Laboratory Automation*. 2017; 42(4): 448. (JACLaS EXPO 2017 abstracts)