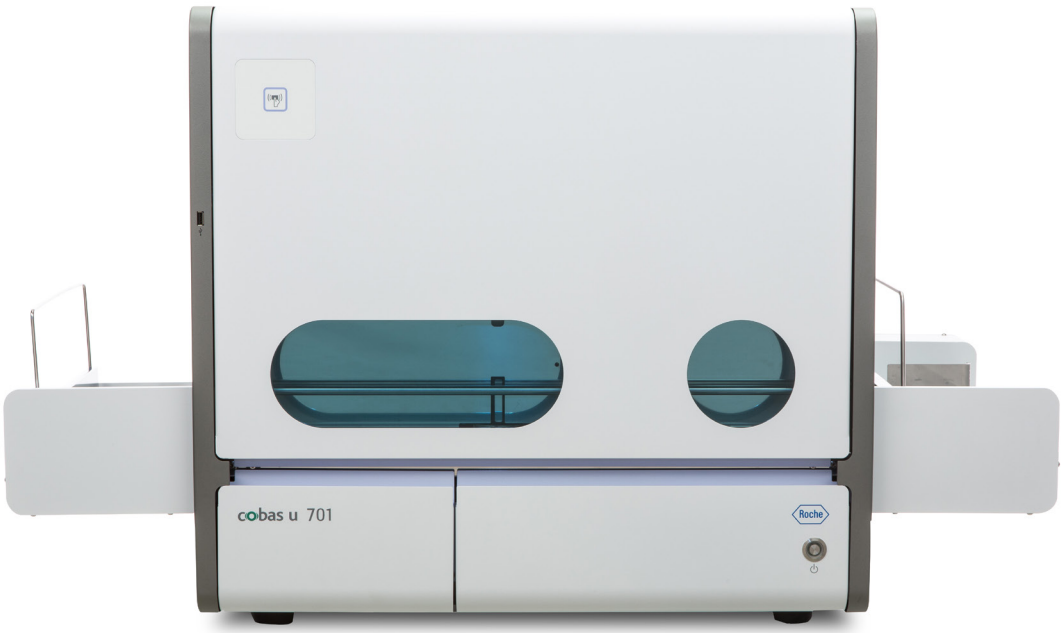
cobas u 701 microscopy analyzer

Performance Data (International)
1.3



Document information

Revision history

Publication version	Revision date	Change description
1.0	May 2014	First publication.
1.1	July 2016	Added limitations for amorphous urates.
1.2	February 2021	IVDR compliance.
1.3	April 2023	• Replaced: CE symbol. • Removed: Reference to (a) Compendium of Urinalysis, 2020, Roche deleted for the sentence "Do not add preservatives to the urine." • Added: Symbols labeled on the instrument box. • Added: Intended population. • Added: Expected values for BAC, NEC, SEC, HYA, PAT, CRY, YEA, MUC, SPRM. • Added: Additional information regarding expected values for WBC, RBC, BAC, NEC, SEC, HYA, PAT, CRY, YEA, MUC. • Rephrased: Text in table "Semi-quantitative parameters (BAC, NEC, SEC, HYA)" section "Intermediate Precision" and "Precision repeatability". • Added: Table "Qualitative parameters (PAT, CRY, YEA, MUC, SPRM)" section "Threshold".

Revision history

Edition notice

This publication is intended for operators and administrators of the **cobas u** 701 microscopy analyzer.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

General attention

To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instrument in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

Incident reporting

- Inform your Roche representative and your local competent authority about any serious incidents which may occur when using this product.

Trademarks

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Feedback

Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

Approvals

The **cobas u** 701 microscopy analyzer meets the requirements laid down in:

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Compliance with the applicable directives is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

IVD

For *in vitro* diagnostic use.

CE 0123

Complies with the provisions of the applicable EU regulations.

EAC

Eurasian Conformity. Demonstrates that the product meets the Eurasian Economic Union (EAEU)'s regulations and standards for customs clearance and trading.

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'Laboratory Equipment' is the product identifier as shown on the type plate.

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Table of contents

Intended use

The **cobas u** 701 microscopy analyzer is a fully automated urine microscopy system intended for the in vitro quantitative determination of erythrocytes and leukocytes, the semi-quantitative determination of squamous and non-squamous epithelial cells, bacteria, and hyaline casts and the qualitative determination of pathological casts, crystals, yeasts, mucus, and sperm in urine.
These measurements are useful in the evaluation of kidney disease and urinary tract infections.
This system is intended to be used by trained operators in clinical laboratories.

Symbols and abbreviations

Visual cues are used to help locate and interpret information quickly. This section explains the conventions used for this purpose.

Symbols used in this publication

The following symbols are used:

Symbol	Explanation
•	List item.
	Table. Used in table titles and cross-references to tables.

Symbols used in this publication

Symbol	Comment
	Safety alert.

Symbols used for easy recognition of information

Symbols used on product

The following symbols are used:

Symbol	Explanation
REF	Catalogue number.
GTIN	Global Trade Item Number.
SN	Serial number.
	Date of manufacture.
	Manufacturer.
	Indicates that the equipment is suitable for alternating current only; to identify relevant terminals.
IVD	For *in vitro* diagnostic use.
UDI	Unique device identifier.
CE 0123	Complies with the provisions of the applicable EU regulations.
	Please consult instructions for use.
c UL us LISTED	Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.
EAC	Eurasian Conformity.
Equipment de Laboratoire / Laboratory Equipment	'Laboratory Equipment' is the product identifier as shown on the type plate.

Symbols used on product

Symbol	Explanation
	Temperature limit.
	Humidity limit.
	Air pressure limit.
	Fragile, handle with care.
	Keep dry.
	This way up.
	Stacking limit.

Symbols used on product

Abbreviations

The following abbreviations are used:

Abbreviation	Explanation
BAC	Bacteria
CLSI	Clinical and Laboratory Standards Institute
CRY	Crystals
CV	Coefficient of variation
EC	European Community
HYA	Hyaline casts
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation
LoB	Limit of Blank
LoD	Limit of Detection
LoQ	Limit of Quantitation
MUC	Mucus

Abbreviations

Abbreviation	Explanation
NEC	Non-squamous epithelial cells
PAT	Pathological casts
RBC	Red blood cells
SD	Standard deviation
SEC	Squamous epithelial cells
SPRM	Sperm
UL	Underwriters Laboratories Inc.
WBC	White blood cells
YEA	Yeasts

Abbreviations

Specific performance data for sediment parameters

Representative performance data on the analyzers are given below.

Results obtained in individual laboratories may differ.

Quantitative parameters (RBC, WBC)

Parameter	RBC				WBC			
Expected values		N	97.5th percentile	99th percentile		N	97.5th percentile	99th percentile
	Women	199	5.28 p/µL	7.04 p/µL	Women	199	6.16 p/µL	8.43 p/µL
	Men	196	3.52 p/µL	5.28 p/µL	Men	196	6.16 p/µL	8.8 p/µL
	Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.							
Additional information regarding expected values	**RBC**: Upper limits for erythrocytes range from 3 to 20/µL. Erythrocytes are found in small numbers (0–2 cells/hpf) in normal urine; more than 3 cells/hpf is considered abnormal.[a] **WBC:** Normal values for neutrophils vary from 5 to 30/µL. Typically, fewer than 5 leukocytes/hpf are seen in normal urine, although females not uncommonly will have somewhat higher quantities present. Increased numbers of leukocytes (principally neutrophils) in the urine constitute pyuria and indicate the presence of infection or inflammation in the urinary tract. When accompanied by leukocyte casts or mixed leukocyte–epithelial cell casts, increased urinary leukocytes are considered to be renal in origin.[a]							

Quantitative parameters (RBC, WBC)

Parameter	RBC	WBC
Method comparison Method comparison acc. to CLSI EP9-A3. Method comparison against manual microscopy with KOVA chamber counting with human urine samples.	Passing-Bablok regression • y = 0.89x -2.3 Pearson's r = 0.95 Tested measurement range: • 1.76 p/µL - 1479 p/µL Number of samples measured: • n = 378	Passing-Bablok regression • y = 0.96x + 0.75 Pearson's r = 0.96 Tested measurement range: • 1.32 p/µL - 770 p/µL Number of samples measured: • n = 501
Precision acc. to CLSI EP5-A2. Measured over 21 days with 2 aliquots per control with 2 replicates each, total n=84. For low concentration SD is calculated as precision value. For medium and high concentrations the CV is calculated instead.	**Repeatability**: Control 1: (Bio-Rad qUAntify Plus, Level 1) • Mean: 0.25 p/µL • Standard deviation = 0.41 p/µL Control 2: (Bio-Rad qUAntify Plus, Level 2) • Mean: 442 p/µL • CV = 6.9% **Intermediate**: Control 1: (Bio-Rad qUAntify Plus, Level 1) • Mean: 0.25 p/µL • Standard deviation = 0.61 p/µL Control 2: (Bio-Rad qUAntify Plus, Level 2) • Mean: 442 p/µL • CV = 8.2%	**Repeatability**: Control 1: (Bio-Rad qUAntify Plus, Level 1) • Mean: 0.0 p/µL • Standard deviation = 0.0 p/µL Control 2: (Bio-Rad qUAntify Plus, Level 2) • Mean: 250 p/µL • CV = 8.1% **Intermediate**: Control 1: (Bio-Rad qUAntify Plus, Level 1) • Mean: 0.0 p/µL • Standard deviation = 0.0 p/µL Control 2: (Bio-Rad qUAntify Plus, Level 2) • Mean: 250 p/µL • CV = 9.3%
Precision repeatability 21 replicates per sample, measured in one run.	Human urine sample 1: • Mean: 0.3 p/µL • Standard deviation = 0.7 p/µL Human urine sample 2: • Mean: 27.6 p/µL • Standard deviation = 8.0 p/µL Human urine sample 3: • Mean: 1367 p/µL • CV = 12.8%	Human urine sample 1: • Mean: 1.0 p/µL • Standard deviation = 0.7p/µL Human urine sample 2: • Mean: 13.5 p/µL • Standard deviation = 3.8 p/µL Human urine sample 3: • Mean: 318 p/µL • CV = 8.4%

Quantitative parameters (RBC, WBC)

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Limits and ranges

Measuring range

Parameter	RBC	WBC
Measuring range	1 p/µL - 1800 p/µL	1 p/µL - 900 p/µL

Measuring ranges for quantitative parameters (RBC, WBC)

Lower Limits of measurement

Parameter	RBC	WBC
Lower Limit of measurement acc. to CLSI EP17-A2.	LoB ≤ 1 p/µL LoD ≤ 5 p/µL LoQ ≤ 5 p/µL (with CV ≤ 60%)	LoB ≤ 1 p/µL LoD ≤ 5 p/µL LoQ ≤ 5 p/µL (with CV ≤ 60%)

Limits and ranges for quantitative parameters (RBC, WBC)

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95%.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples. The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95%).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a coefficient of variation (CV) of 60%.

Values below the Limit of Blank will be reported as Value < LoB.

Semi-quantitative parameters (BAC, NEC, SEC, HYA)

Parameter	BAC		NEC	
Expected values	N	97.5th percentile	N	97.5th percentile
	395	neg	395	neg
	Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.			
Additional information regarding expected values	**BAC**: Finding bacteria in urine may or may not be significant depending on the method of urine collection and how soon after collection of the specimen the examination takes place.[(a)] The threshold for asymptomatic bacteriuria from a clean-catch voided urine specimen is isolation of a single organism in quantitative counts ≥105 colony-forming units (CFU)/mL (105 /mL corresponds 100 p/µL).[(b)] **NEC**: A few urothelial cells are present in normal urine, reflecting normal desquamination. Renal tubular cells: small numbers of cells may be seen in normal urine, reflecting the normal sloughing of aging cells.[(a)]			

Semi-quantitative parameters (BAC, NEC)

Parameter	BAC	NEC
Method comparison Method comparison acc. to CLSI EP9-A3 Method comparison against manual microscopy with KOVA chamber counting with human urine samples.	78% of all negative results are negative 89.3% of all positive results are positive Number of samples measured: n = 564	82.4% of all negative results are negative 73.8% of all positive results are positive Number of samples measured: n = 564
Intermediate Precision (1 day x 5 runs x 4 replicates, total n=20)	Human urine sample 1: • Semi-quantitative category: neg • 100% of results are negative Human urine sample 2: • Semi-quantitative category: 500 p/µL • 100% of results are within 2 adjacent concentration blocks with 60% of results at 500 p/µL and 40% of results are 150 p/µL Human urine sample 3: • Semi-quantitative category: 1000 p/µL • 100% of results provided exact agreement	Human urine sample 1: • Semi-quantitative category: neg • 100% of results are negative Human urine sample 2: • Semi-quantitative category: 5 p/µL • 100% of results are within 2 adjacent concentration blocks with 95% of results at 5 p/µL and 5% of results are 15 p/µL Human urine sample 3: • Semi-quantitative category: 15 p/µL • 100% of results provided exact agreement
Precision repeatability One run with 21 replicates for all defined samples.	Human urine sample 1: • Semi-quantitative category: neg • 100% of results are negative Human urine sample 2: • Semi-quantitative category: 150 p/µL • 100% of results are within 2 adjacent concentration blocks with 95.2% of results at 150 p/µL and 4.8% of results are negative Human urine sample 3: • Semi-quantitative category: 1000 p/µL • 100% of results provided exact agreement	Human urine sample 1: • Semi-quantitative category: neg • 100% of results are negative Human urine sample 2: • Semi-quantitative category: 5 p/µL • 100% of results provided exact agreement Human urine sample 3: • Semi-quantitative category: 15 p/µL • 100% of results are within 2 adjacent concentration blocks with 85.7% of results at 15 p/µL and 14.3% of results are 5 p/µL

Semi-quantitative parameters (BAC, NEC)

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(b) Nicolle LE, Gupta K, Bradley SF, et al. Clinical Practice Guideline for the Management of Asymptomatic Bacteriuria: 2019 Update by the Infectious Diseases. Society of America. Clin Infect Dis 2019; 68:e83.

Parameter	SEC		HYA	
Expected values	N	97.5th percentile	N	97.5th percentile
	395	neg	395	neg
	Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.			
Additional information regarding expected values	**SEC**: SEC (squamous epithelial cells) are the most frequent epithel cells seen in normal urine and are the least significant.[(a)] **HYA**: In the normal person, very few casts are seen in the urinary sediment. Hyaline casts are the most frequently observed casts. Zero to two hyaline casts per low-power field is considered normal. Increased numbers are seen with renal diseases and transiently with exercise, heat exposure, dehydration, fever, congestive heart failure, and diuretic therapy.[(a)]			

Semi-quantitative parameters (SEC, HYA)

Parameter	SEC	HYA
Method comparison Method comparison acc. to CLSI EP9-A3 Method comparison against manual microscopy with KOVA chamber counting with human urine samples.	91.2% of all negative results are negative 91.9% of all positive results are positive Number of samples measured: n = 564	96.6% of all negative results are negative 82% of all positive results are positive Number of samples measured: n = 564
Intermediate Precision (1 day x 5 runs x 4 replicates, total n=20)	Human urine sample 1: • Semi-quantitative category: neg • 100% of results are negative Human urine sample 2: • Semi-quantitative category: 40 p/µL • 100% of results are within 2 adjacent concentration blocks with 60% of results at 40 p/µL and 40% of results are 15 p/µL Human urine sample 3: • Semi-quantitative category: 75 p/µL • 100% of results are within 2 adjacent concentration blocks with 55% of results at 75 p/µL and 45% of results are 40 p/µL	Human urine sample 1: • Semi-quantitative category: neg • 100% of results are negative Human urine sample 2: • Semi-quantitative category: 5 p/µL • 100% of results are within 2 adjacent concentration blocks with 70% of results at 5 p/µL and 30% of results are 15 p/µL Human urine sample 3: • Semi-quantitative category: 15 p/µL • 100% of results provided exact agreement
Precision repeatability One run with 21 replicates for all defined samples.	Human urine sample 1: • Semi-quantitative category: neg • 100% of results are negative Human urine sample 2: • Semi-quantitative category: 15 p/µL • 100% of results are within 2 adjacent concentration blocks with 66.7% of results at 15 p/µL and 33.3% of results are negative Human urine sample 3: • Semi-quantitative category: 75 p/µL • 100% of results provided exact agreement	Human urine sample 1: • Semi-quantitative category: neg • 100% of results are negative Human urine sample 2: • Semi-quantitative category: 5 p/µL • 100% of results are within 2 adjacent concentration blocks with 66.7% of results at 5 p/µL and 33.3% of results are 15 p/µL Human urine sample 3: • Semi-quantitative category: 15 p/µL • 100% of results provided exact agreement

Semi-quantitative parameters (SEC, HYA)

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Lower Limits of measurement

Parameter	BAC	NEC	SEC	HYA
Lower Limit of measurement acc. to CLSI EP17-A2.	LoB ≤ 80 p/µL LoD ≤ 120 p/µL	LoB ≤ 1.0 p/µL LoD ≤ 2.0 p/µL	LoB ≤ 2.0 p/µL LoD ≤ 9.0 p/µL	LoB ≤ 0.05 p/µL LoD ≤ 1.6 p/µL

Limits for semi-quantitative parameters (BAC, NEC, SEC, HYA)

Limit of Blank (LoB) and Limit of Detection (LoD)

The Limit of Blank and Limit of Detection were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95%.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples. The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95%).

Qualitative parameters (PAT, CRY, YEA, MUC, SPRM)

Parameter	PAT		CRY	
Expected values	N	97.5th percentile	N	97.5th percentile
	395	neg	395	pos
	Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.			
Additional information regarding expected values	**PAT**: In the normal person, very few casts are seen in the urinary sediment. Quantitative counts: casts as few as 1 to 2/µL. In kidney diseases, they may appear in large numbers and in many forms. Casts may be classified according to their matrix, inclusions, pigments, and cells present, It is recommended to confirm the finding of pathological casts with cytopathologic examination.[a] **CRY**: Although most crystals in the urine are of limited clinical significance, proper identification is essential so as not to miss the relatively few abnormal crystals that are associated with various pathologic conditions. The presence of abnormal crystals should be confirmed chemically and correlated with the patients history.[a]			
Method comparison Method comparison acc. to CLSI EP9-A3. Method comparison against manual microscopy with KOVA chamber counting with human urine samples.	91% of all negative results are negative 83.6% of all positive results are positive Number of samples measured: n = 564		93% of all negative results are negative 83.8% of all positive results are positive Number of samples measured: n = 564	
Precision repeatability One run with 21 replicates for all defined samples.	**Agreement rate**: Human urine sample 1: • Neg = 100% of negative samples are found negative Human urine sample 2: • Pos = 100% of positive samples are found positive		**Agreement rate**: Human urine sample 1: • Neg = 100% of negative samples are found negative Human urine sample 2: • Pos = 100% of positive samples are found positive	

Qualitative parameters PAT, CRY

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Parameter	YEA		MUC	
Expected values	N	97.5th percentile	N	97.5th percentile
	395	neg	395	pos
	Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.			
Additional information regarding expected values	**YEA**: Yeasts (most commonly, Candida species) may be causative agents in UTIs (e.g., in diabetes mellitus), but yeasts are also common contaminants from the skin, the female genital tract, and the air.[a] **MUC**: Mucus is more frequently present in female urine specimens. It has no clinical significance when present in either female or male urine.[b] Mucus threads are reported as rare, few, moderate, or many per lpf. Mucus is more frequently present in female urine specimens. It has no clinical significance when present in either female or male urine.[b]			
Method comparison Method comparison acc. to CLSI EP9-A3. Method comparison against manual microscopy with KOVA chamber counting with human urine samples.	94.5% of all negative results are negative 86.5% of all positive results are positive Number of samples measured: n = 564		86.8% of all negative results are negative 69.5% of all positive results are positive Number of samples measured: n = 564	
Precision repeatability One run with 21 replicates for all defined samples.	**Agreement rate**: Human urine sample 1: • Neg = 100% of negative samples are found negative Human urine sample 2: • Pos = 100% of positive samples are found positive		**Agreement rate**: Human urine sample 1: • Neg = 100% of negative samples are found negative Human urine sample 2: • Pos = 100% of positive samples are found positive	

Qualitative parameters YEA, MUC

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(b) Susan King-Strasinger,DA; MLS (ASCP) Urinalysis and Body Fluids, 6 th Edition, 2014 ISBN 978-0-8036-3920-1 (pbk.: alk paper)

Parameter	SPRM	
Expected values	N	97.5th percentile
	395	neg
	Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.	
Method comparison Method comparison acc. to CLSI EP9-A3. Method comparison against manual microscopy with KOVA chamber counting with human urine samples.	96.3% of all negative results are negative 73.3% of all positive results are positive Number of samples measured: n = 564	
Precision repeatability One run with 21 replicates for all defined samples.	**Agreement rate**: Human urine sample 1: • Neg = 100% of negative samples are found negative Human urine sample 2: • Pos = 100% of positive samples are found positive	

Qualitative parameter SPRM

Parameter	PAT [p/µL]	CRY [p/µL]	YEA [p/µL]	MUC [p/µL]	SPRM [p/µL]
Threshold[a]	> 1.0	> 5.0	> 1.0	> 100.0	> 0.8

[a] The result is assigned to the positive range if it is above the specified value.

Qualitative parameter PAT, CRY, YEA, MUC, SPRM

Intended population

In general, urine testing can be performed for all patients where it is possible to collect a sample.[a]

Verification of the **cobas u** 701 microscopy analyzer was performed using adult patient samples, expected values for other patient populations would require further validation.

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.[b]

The specimen should be free of fecal contamination and contain no bathroom tissue or foreign materials.[c]

The preferred specimen, particularly for microscopy is well-mixed, un-centrifuged first morning urine. It will be most concentrated, which maximizes recovery of sediment elements.[c]

Perform the test within two hours after collection.[c]

If testing is delayed the specimen should be refrigerated, although amorphous urates and phosphates can precipitates.[c]

The longer the delay, the more likely are elements to lyse, especially when the urinary pH is alkaline and the relative density is low. The WBC counts may be questionable after 2-4 hours, even with refrigeration.[d]

Do not add preservatives to the urine.

(a) L.A. `t Hoen et al., Update of the EAU/ESPU guidelines on urinary tract infections in children; Journal of Pediatric Urology (2021)
(b) Compendium of Urinalysis, 2020, Roche
(c) GP16-A3 (Urinalysis; Approved Guideline – Third Edition)
(d) European Urinalysis Guidelines (Scand J Clin Lab Invest 2000; 60: 1 ± 96)

Limitations and interferences

Based on the technological characteristics of the manual microscopy method, when measuring the following sample types on the **cobas u** 701 microscopy analyzer there is a possibility that correct results may not be obtained.

Mucus and artifacts

Particles may be underrepresented in samples with high amounts of mucus.

Artifacts like fibres, hairs or dust may interfere the result. Therefore, clean sampling and storage is important. A wrong classification of these particles can lead to false positive results. Large artifacts may cause defocused particles, which will be misclassified or not detected.

Clumps, fragments, aggregations, and dysmorphic cells

Clumps of cells, clumps of cell fragments, cell fragments of particles and or aggregations of particles may lead to misclassification. Also dysmorphic cells may lead to a misclassification. Therefore the standard sample stability and sample storage conditions should be followed. The sample itself should be mixed gently before testing.

Shining particles

Shining particles sometimes may lead to misclassification.

Amorphous urates

Granules of amorphous urates with tendency to aggregate as coarse irregular dark masses may be detected as Bacteria (BAC). This depends on the size of the urates. Urates are a subclass of crystals (CRY) and should be identified as CRY within the image. If the crystals are really small they may be detected as BAC. BAC are not labeled in the images as the estimation for BAC is based on the ratio of occupied to non-occupied space.

Crowded samples

In cases of high positive samples like RBC, WBC, SEC, BAC, and CRY, where the images are crowded, the particles with high concentration may obscure those of lower concentration. This is due to the fact that the particles are centrifuged to a single layer, the focal plane. Such samples are not evaluated by the algorithm, they are marked with **U** and must be reviewed by the user. If the concentration of the quantitative parameters exceeds 1800 RBC/µL or 900 WBC/µL, the samples are marked with **O** (out of range).

Dilution

Dilution of samples may cause cell lysis. The degree of cell lysis depends on the osmotic pressure of the diluted sample. Dilution may cause misclassification due to changes in cell size or shape or the decrease in number of the cells.