

HumaCombilyzer & HumaCombina urine test strips

Kerstin Brunnhuber, 24.03.2025



HumaCombilyzer

Semi-automated urine strip reader

HumaCombilyzer is the ideal new and modern semi-automated urine test strip reader for

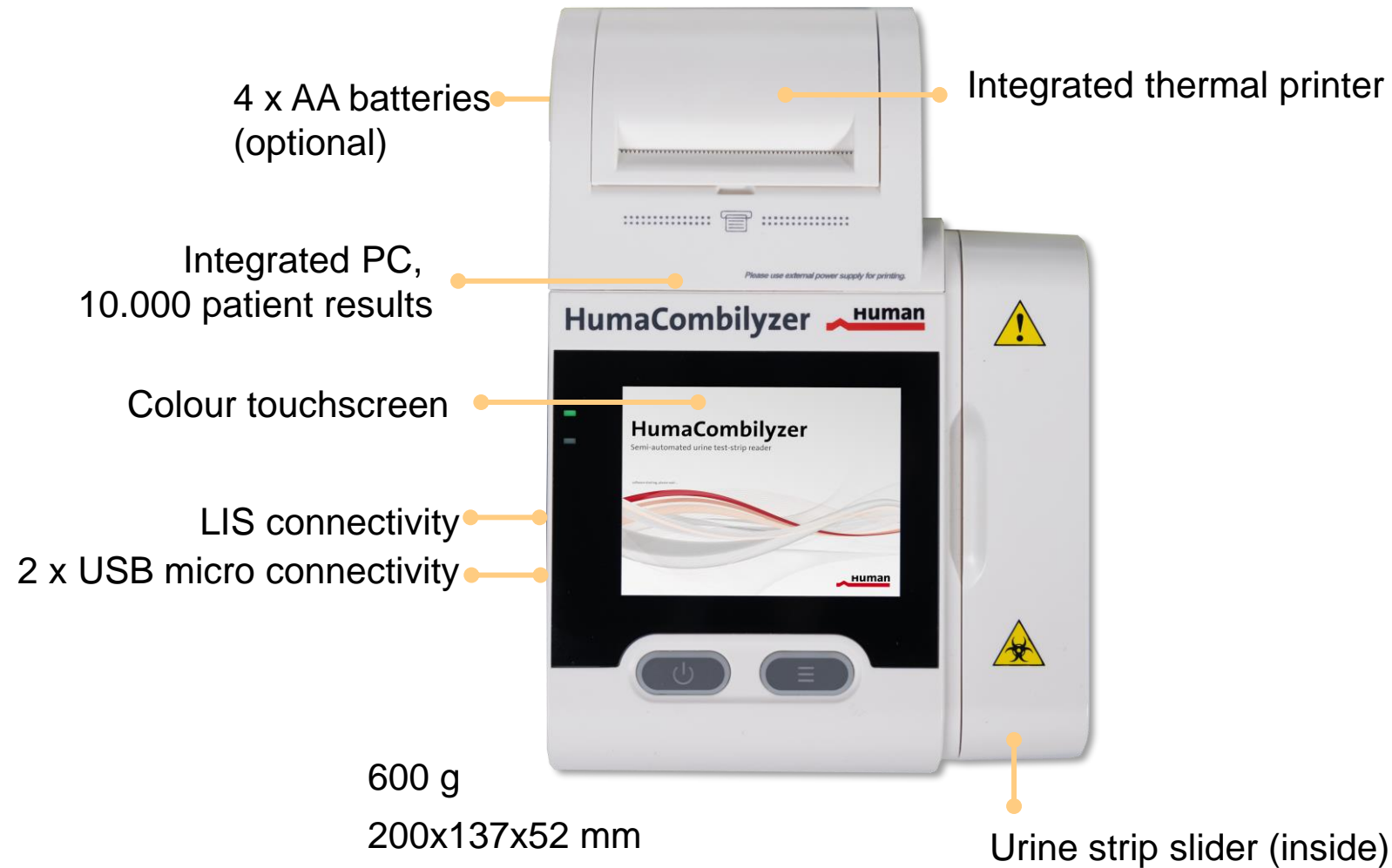
- standardized incubation,
- automated strip reading,
- immediate result interpretation,
- optional on-the-spot printing, with
- very large data storage.



- ✓ Lightweight, handheld device, allowing for on-the spot testing.
- ✓ Optionally battery-powered, ideal for flexible use also in more rural areas.
- ✓ Coloured touch screen, further supporting the easy-to-use intuitive user interface.
- ✓ Microalbumin-to-creatinine ratio, allowing for state-of-the-art diagnostics.
- ✓ LIS capability, eliminating patient result mix-up and ensuring patient testing refund.

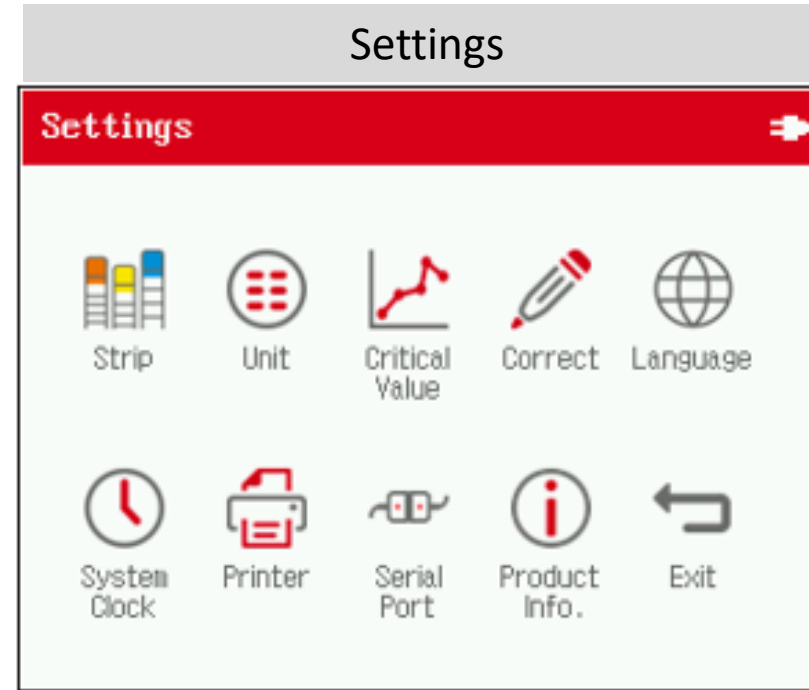
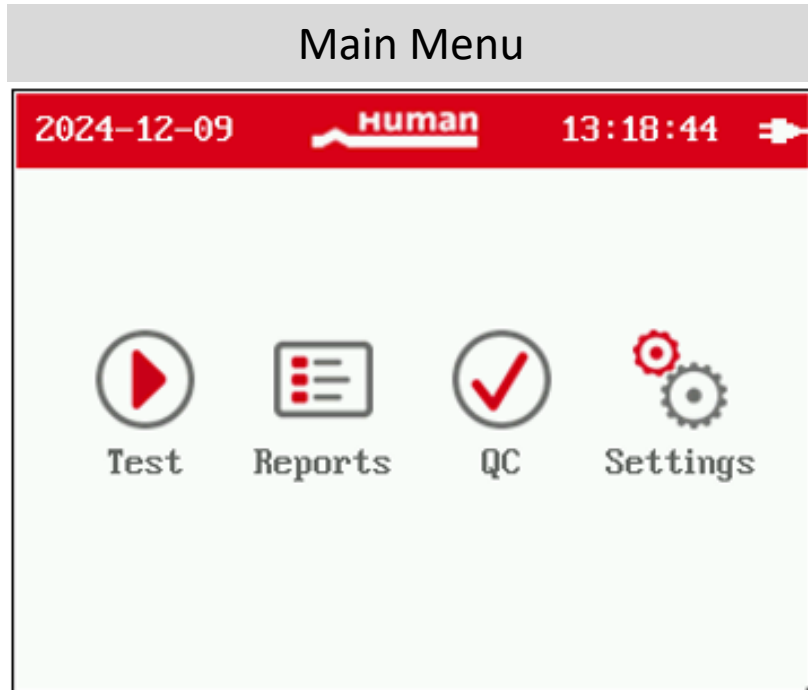
HumaCombilyzer

Semi-automated urine strip reader



HumaCombilyzer

Main User Interface Screens





HumaCombilyzer & HumaCombina

Components developed to fit each other



HumaCombilyzer instrument
REF 17630

Semi-automated urine strip reader

HumaCombina 13 strips
REF 22130

100 strips/vial for testing of 13 analytes

Bilirubin, blood, glucose, ketones, leukocytes,, nitrite, pH, protein, specific gravity, urobilinogen, **ascorbic acid**, **creatinine**, microalbumin

HumaCombina 10 strips
REF 22100

100 strips/vial for testing of 10 analytes

Bilirubin, blood, glucose, ketones, leukocytes,, nitrite, pH, protein, specific gravity, urobilinogen

HumaCombina urine testing strips

Your choice

HumaCombina multianalyte urine strips support the diagnostics of diseases like

- Urogenital disorders
- Renal insufficiency
- Diabetes
- Liver diseases
- Tumour diagnostics

HumaCombina 13	HumaCombina 10
Urobilinogen	Urobilinogen
Bilirubin	Bilirubin
Ketones	Ketones
Creatinine	--
Blood	Blood
Protein	Protein
Microalbumin	--
Nitrite	Nitrite
Leukocytes	Leukocytes
Glucose	Glucose
Specific gravity	Specific gravity
pH	pH
Ascorbic acid	--



HumaCombina 10 and HumaCombina 13

General Information

Test strips / bottle

100 strips

Stability

Shelf-life 24 months
In-use 30 days

Storage temperature

2 - 30 °C
Not in refrigerator.

Analytes on strips

10: URO, BIL, KET, Blood, PRO, NIT, LEU, GLU, SG, pH
13: 10 + CREA + MALB + VC + MALB:CREA-ratio

Testing temperature

20 - 30 °C

Incubation time

60 seconds
Do not interpret coloration after > 2 min. after immersion.



Instrument Applications

10: HumaCombilyzer
13: HumaCombilyzer
13: Combilyzer¹³



HumaCombilyzer & HumaCombina

Products made to fit each other



Visual reading

HumaCombina 10
REF 22100



HumaCombina 13
REF 22130



HumaCombilyzer NEW



Combilyzer¹³

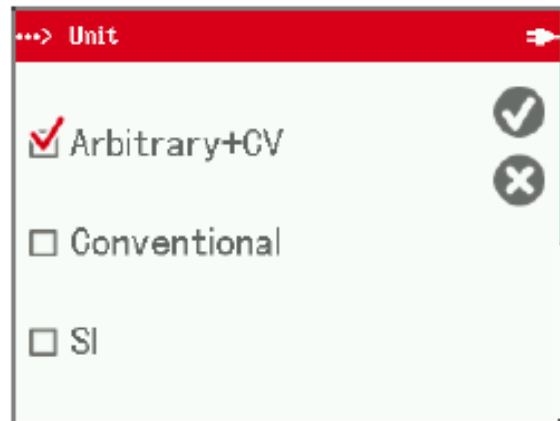


HumaCombilyzer / HumaCombina

Alternative Result Units

Instrument Screen / Print out "Unit"

Select "Unit"  in the setting menu:



User Manual

11. GRADIENT TABLE

	Arbitrary	International (SI)	Conventional
UBG	Normal	3.4 $\mu\text{mol/L}$	0.2 mg/dL
	Normal	17 $\mu\text{mol/L}$	1 mg/dL
	1+	34 $\mu\text{mol/L}$	2 mg/dL
	2+	68 $\mu\text{mol/L}$	4 mg/dL
	3+	$\geq 135 \mu\text{mol/L}$	$\geq 8 \text{ mg/dL}$
BIL	Neg.	Neg.	Neg.
	1+	17 $\mu\text{mol/L}$	1 mg/dL
	2+	51 $\mu\text{mol/L}$	3 mg/dL
	3+	$\geq 103 \mu\text{mol/L}$	$\geq 6 \text{ mg/dL}$

HumaCombina

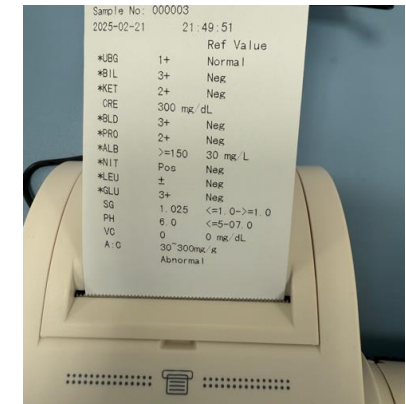
Printout on HumaCombilyzer

Arbitrary values

Conventional values

International (SI) values

Sample No:	08012007	08012007	08012007
Date:	2025-03-05	2025-03-05	2025-03-05
Time:	11:04:07	11:04:07	11:04:07
Ref Value			
UBG	Normal	Normal	Normal
BIL	Neg	Neg	Neg.
KET	Neg	Neg	Neg.
CRE	200 mg/dL	200 mg/dL	17.7 mmol/L
*BLD	3+	Neg	>=200Ery/ μ L
*PRO	1+	Neg	30 mg/dL
*ALB	>=150	30 mg/L	>=150 mg/L
*NIT	Pos	Neg	Pos
LEU	Neg	Neg	Neg.
*GLU	1+	Neg	100 mg/dL
SG	1.020	<=1.0->=1.0	1.020
PH	6.0	<=5-07.0	6.0
VC	0	0 mg/dL	0 mg/dL
A:C	30~300mg/g	Abnormal	3.4~33.9mg/mmol Abnormal





Method Comparison to non-HUMAN devices

HumaCombina 10 & 13

n = 340 samples each for every analyte distributed throughout the whole measuring range (concentrations).		HumaCombina 13/HumaCombilyzer vs. DIRUI R14Ca/Dirui N600		HumaCombina 10/HumaCombilyzer vs. DIRUI R14Ca/Dirui N600	
Analyte	Unit	% overall concentration levels exact match	%-agreement (± one colour pad)	% overall concentration levels exact match	%-agreement (± one colour pad)
Urobilinogen	µmol/L	95.59 %	100 %	96.76 %	100 %
Bilirubin	µmol/L	99.41 %	100 %	99.41 %	100 %
Ketone	mmol/L	95.29 %	100 %	97.06 %	100 %
Creatinine	mmol/L	95.00 %	100 %	-	-
Blood	Ery/µL	95.59 %	100 %	96.76 %	100 %
Protein	g/L	97.94 %	100 %	97.65 %	100 %
Microalbumin	mg/L	96.76 %	100 %	-	-
Nitrite	Neg. / Pos.	99.71 %	100 %	99.41 %	100 %
Leukocytes	Leu/µL	96.76 %	100 %	97.65 %	100 %
Glucose	mmol/L	98.24 %	100 %	98.82 %	100 %
Specific Gravity	-	80.00 %	99.12 %	85.00%	100 %
Ascorbic Acid	mmol/L	100.00 %	100 %	-	-
pH	-	95.00 %	100 %	97.35 %	100 %
Microalbumin-to-creatinine ratio	mg/g	89.12 %	na	-	-

Method Comparison to HUMAN Combilyzer¹³

HumaCombina 13

n = 100 samples each for every analyte distributed throughout the whole measuring range (concentrations).

HumaCombina 13/HumaCombilyzer vs. HumaCombina 13/Combilyzer¹³

Analyte	Unit	% overall concentration levels exact match	%-agreement (± one colour pad)
Urobilinogen	µmol/L	94.00 %	100 %
Bilirubin	µmol/L	99.00 %	100 %
Ketone	mmol/L	94.00 %	100 %
Creatinine	mmol/L	93.00 %	100 %
Blood	Ery/µL	94.00 %	100 %
Protein	g/L	96.00 %	100 %
Microalbumin	mg/L	96.00 %	100 %
Nitrite	Neg. / Pos.	99.00 %	100 %
Leukocytes	Leu/µL	95.00 %	100 %
Glucose	mmol/L	97.00 %	100 %
Specific Gravity	-	80.00 %	99.12 %
Ascorbic Acid	mmol/L	100.00 %	100 %
pH	-	91.00 %	100 %

HumaCombilyzer

Third party control material

BioRad Liquichek Urinalysis Control

- HUMAN Target values / Target value ranges
- Lot 98050 and higher
- On HUMAN website



HUMAN		
Target Values		
BioRad Liquichek™ Urinalysis Control		
[CC] 435 (Level 1) 12x12cm (30 per bottle) 435 (Level 2) 12x12cm 435X (Level 1+2) 24x24cm (10 per bottle)		[LOT] 98050 Level 1 98051 Level 2 98052 [IVD] N 1816-07-01 Link for latest version of target value sheet: https://www.human.de/urinalysis/target-value-sheet
REF		
Parameter / Analyte	Level 1 - 98031	Level 2 - 98032
HUMAN HumaCombina 13 TEST STRIP (REF 22130) / HumaCombilyzer 13 ANALYZER (REF 17500)	Bilirubin Negative Blood Negative Creatinine 20 - 200 mg/dL (4.4 - 17.7 mmol/L) Glucose Negative Ketones Negative Leukocytes Negative Microalbumin 10 mg/L Nitrite Negative pH 5.0 - 6.0 Protein, Total Negative Specific Gravity 1.005 - 1.020 Urobilinogen 0.2 mg/dL (3.4 μmol/L)	31 - 103 μmol/L (2+ - 3+) ca. 80 - 200 Ery/μL (2+ - 3+) 200 - 300 mg/dL (17.7 - 26.5 mmol/L) 200 - 300 mg/dL (14 - 28 mmol/L) 15 - 78 mg/dL (1.5 - 7.8 mmol/L) 70 - 125 Leuco/μL 80 - 150 mg/L Positive 5.0 - 6.0 300 - ≥2000 mg/dL (3.0 - ≥20.0 g/L) 1.015 - 1.025 2 - 8 mg/dL (34 - 132 μmol/L)
Parameter / Analyte	Level 1 - 98031	Level 2 - 98032
HUMAN HumaCombina 13 TEST STRIP (REF 22130) / Combilyzer 13 ANALYZER (REF 17500)	Bilirubin Negative Blood Negative Creatinine 20 - 200 mg/dL (4.4 - 17.7 mmol/L) Glucose Negative Ketones Negative Leukocytes Negative Microalbumin 10 mg/L Nitrite Negative pH 5.0 - 6.0 Protein, Total Negative Protein-to-Creatinine Ratio normal (30 mg/g (3.4 mg/mmol)) Specific Gravity 1.010 - 1.020 Urobilinogen 0.2 mg/dL (3.4 μmol/L) normal	31 - 103 μmol/L (2+ - 3+) ca. 80 - 200 Ery/μL (2+ - 3+) 200 - 300 mg/dL (17.7 - 26.5 mmol/L) 200 - 300 mg/dL (14 - 28 mmol/L) 15 - 78 mg/dL (1.5 - 7.8 mmol/L) 70 - 125 Leuco/μL 80 - 150 mg/L Positive 5.0 - 6.0 100 - 300mg/dL (1.0 - 3.0 g/L) Abnormal: 30 - 300 mg/g (3.4 - 33.9 mg/mmol) 1.020 - 1.030 2 - 8 mg/dL (34 - 132 μmol/L)
Parameter / Analyte	Level 1 - 98031	Level 2 - 98032
HUMAN HumaCombina 13 TEST STRIP (REF 22130) / HumaCombilyzer ANALYZER (REF 17500)	Bilirubin Negative Blood Negative Creatinine 20 - 200 mg/dL (4.4 - 17.7 mmol/L) Glucose Negative Ketones Negative Leukocytes Negative Microalbumin 10 mg/L Nitrite Negative pH 5.0 - 6.0 Protein, Total Negative Protein-to-Creatinine Ratio normal (30 mg/g (3.4 mg/mmol)) Specific Gravity 1.010 - 1.020 Urobilinogen 0.2 mg/dL (3.4 μmol/L) normal	31 - 103 μmol/L (2+ - 3+) ca. 80 - 200 Ery/μL (2+ - 3+) 200 - 300 mg/dL (17.7 - 26.5 mmol/L) 200 - 300 mg/dL (14 - 28 mmol/L) 15 - 78 mg/dL (1.5 - 7.8 mmol/L) 70 - 125 Leuco/μL 80 - 150 mg/L Positive 5.0 - 6.0 100 - 300mg/dL (1.0 - 3.0 g/L) Abnormal: 30 - 300 mg/g (3.4 - 33.9 mg/mmol) 1.020 - 1.030 2 - 8 mg/dL (34 - 132 μmol/L)
Rev. 011 valid of 10.12.2024 Human Gesellschaft für Biochemie und Diagnostica mbH Max-Planck-Ring 21 · 04625205 · Weidenhofen · Germany Tel.: +496122 99880 Fax: +496122 9988100 · e-mail: human@human.de		
DEUTSCH (1) Bei einigen Analyten kann eine atypische Farbe beobachtet werden. Ergebnisse basieren auf Reaktionsstärken. (2) Atypische Färbung beobachtet		
ENGLISH (1) Atypical color may be observed with some analytes. Results are based on reaction strengths. (2) Atypical coloration observed		
FRANÇAIS (1) Une couleur atypique peut être observée pour certains analytes. Les résultats sont basés sur les intensités de réaction. (2) Coloration atypique observée		
ESPAÑOL		



Thank you for your attention!

Any questions?

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