HumaVision

Innovative, AI-based urine microscopy

with unique Digital Holographic Microscopy technology

from native urine

Speaker: Alfons Krug

Need of on-the-spot results

Brings medical diagnosis to the patient

Requirements for POCT urine diagnostic

- Small and easy to use
- Battery driven
- Automated determination of results
- No need for a laboratory specialist
- Native Urine
- No centrifugation, no waiting time for sedimentation (no lab needed)
- Small sample vol. (20µl)
- No reagents or calibrators

Present solutions, by manual microscopy

or by fully automated

expensive systems,

are no feasible option

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Simplified workflow

Manual microscopy

Native urine

Fill 12 ml of urine into tube, to prepare sediment

ID on tube label

Centrifugation

Wait for **sedimentation**

Pipette to glass slider or to counting chamber

No defined volume, no quantitative results

Quantitative, but costly counting chamber

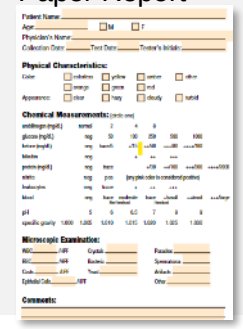
Manual microscopy by **experienced** lab technician

Type in of results

30 min.

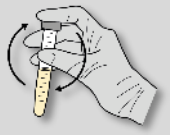
Digital Report

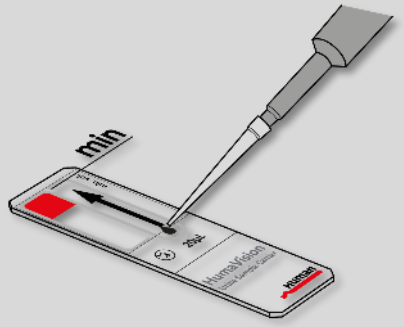
Paper Report



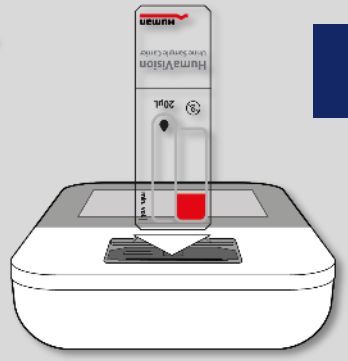
HumaVision

Native urine





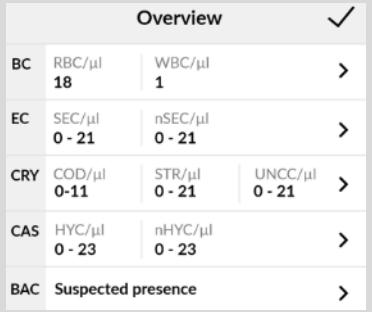
Pipette 20µl to sample carrier



Insert sample carrier, for reading

2-7 min.

Digital PDF Report



Automated, quantitative digital results

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Simplified workflow

Tony Petzold

Application

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Causes of diagnostic errors

Potential loss of erythrocytes, leukocytes and epithelia cells

No defined volumes, so no quantitative result

Typing errors 1-5 % wrong results

Interobserver variability[1]

- Good agreement on broad and fatty casts (79%)
- Poorest on dysmorphic RBC and WBC (31%)
- Kappa = 0.54 on squamous
- Kappa
- **Co** achieved slight to mo agreement in the identification of structures that are commonly observed in the urine sediment

Poor standardisation, a kidney disease or infection could be missed,

(1) R. Wald: doi: 10.2215/CJN.05331008. Epub 2009 Mar 4.

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Smallest, most comfortable urine microscope on the market

Battery run time 2-5 hours

USB-C charger

3.5” color touch screen

Integrated PC, **powerful AI**

Storage of 300 results and images

LIS connectivity

WIFI, Hotspot

Only 240g

128x94x33 mm

Closed system

Sample carrier for 20µl native urine absolute results/µl

Second examination with a microscope

➢ At any time possible

➢ **Portable precision for all environments**

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Advantage Native Urine vs. Urine Sed.

European guideline recommends:

“ A quantitative result for urine particles is **more reliable** obtained by direct counting of **uncentrifuged specimens**…than after centrifugation.” (2)

Native Urine used on HumaVision or in flow cytometers 	**Urine Sediment** used in manual microscopy, or in fully automated systems 
No loss of erythrocytes, leukocytes and epithelia cells by centrifugation (1), (3)	Centrifugation, loss of (20–80%) of erythrocytes and leukocytes, **difficult quantification** (1)
No potential crystal increase by pH or temperature changes during storage of urine(4)	Storage can cause crystal formations
Reduced hands-on time	Centrifugation, various pipetting steps…

(1) Delanghe, J., & Speeckaert, M. (2014). Preanalytical requirements of urinalysis. Biochemia Medica, 89-104.
(2) Kouri, T., Pestel-Caron, M. (2023). The EFLM European Urinalysis Guideline
(3) https://pmc.ncbi.nlm.nih.gov/articles/PMC5806615/
(4) https://pubmed.ncbi.nlm.nih.gov/12555980/

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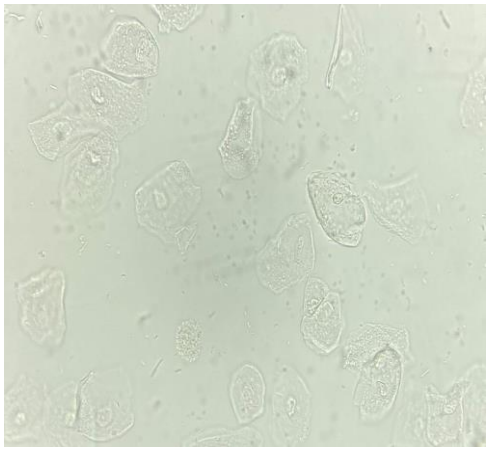
Digital Holographic Microscopy (DHM)

Unique technology – phase information

Microscopy field of view only 0.2 mm²



Particle differentiation

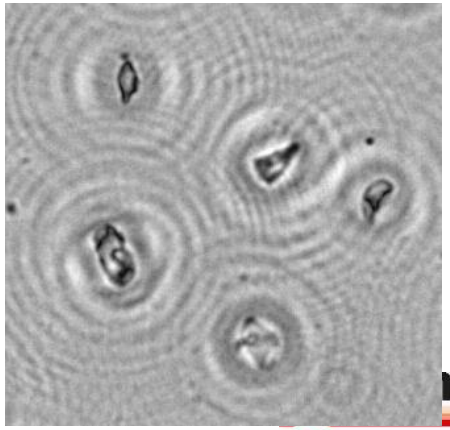
At **microscopy by eye**

- **Size / Shape (2D)**
- User experience
- In a corresponding native **urine volume** of **0.041 mm³**
- **Semi-quant.-count *no defined volume***

With **Digital Holographic Microscopy** and **AI**

- **3D cell / shape volume**
- **Data-base of >1 Mio. particles (AI)**
- Measure of **phase-information**
  by a holographic image (based on refractive index, geometry/topography)
- **13 times bigger observed volume of 0.525 mm³**
- **Absolute counts *particles/µl***

HumaVision field of view 5.25 mm²



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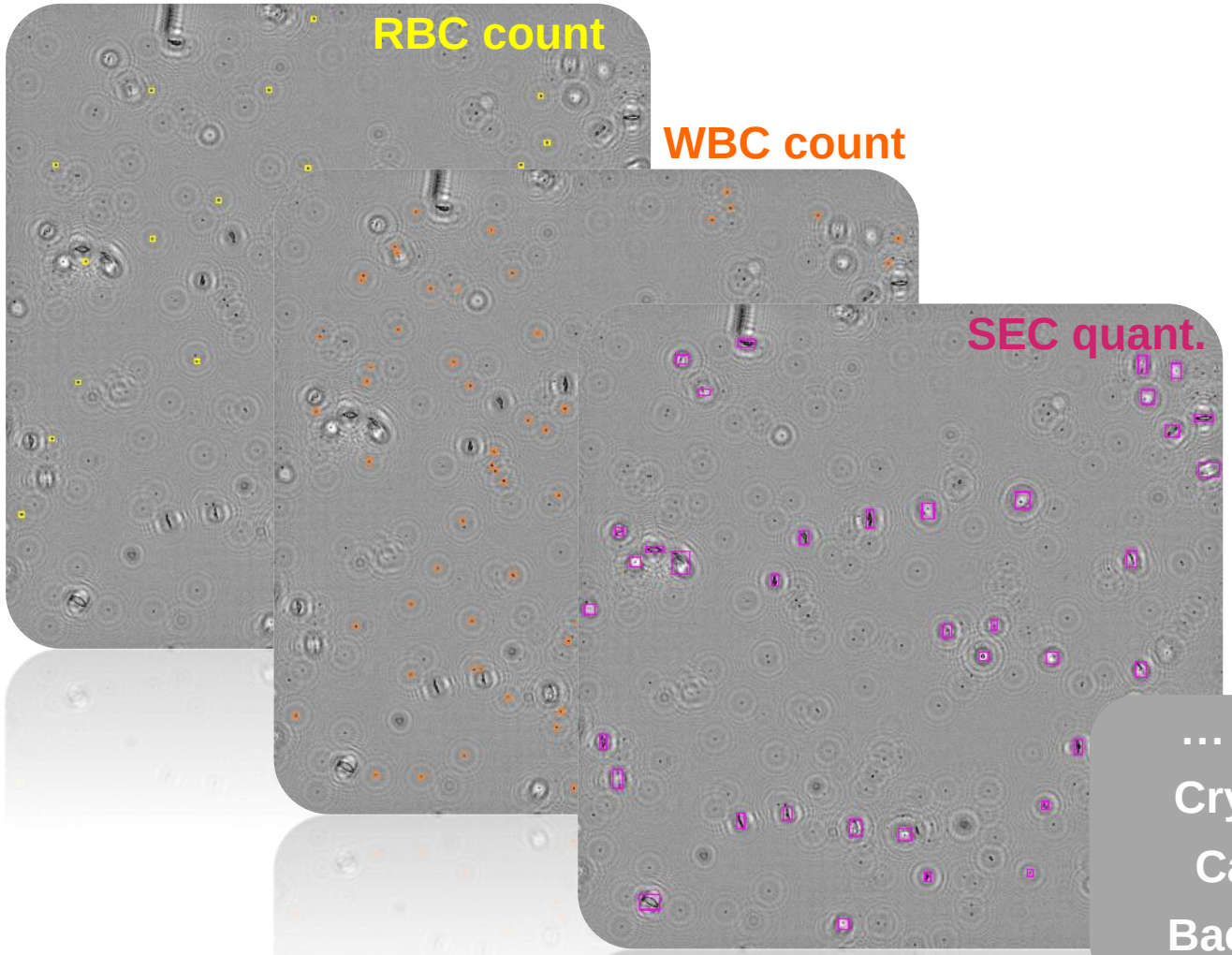
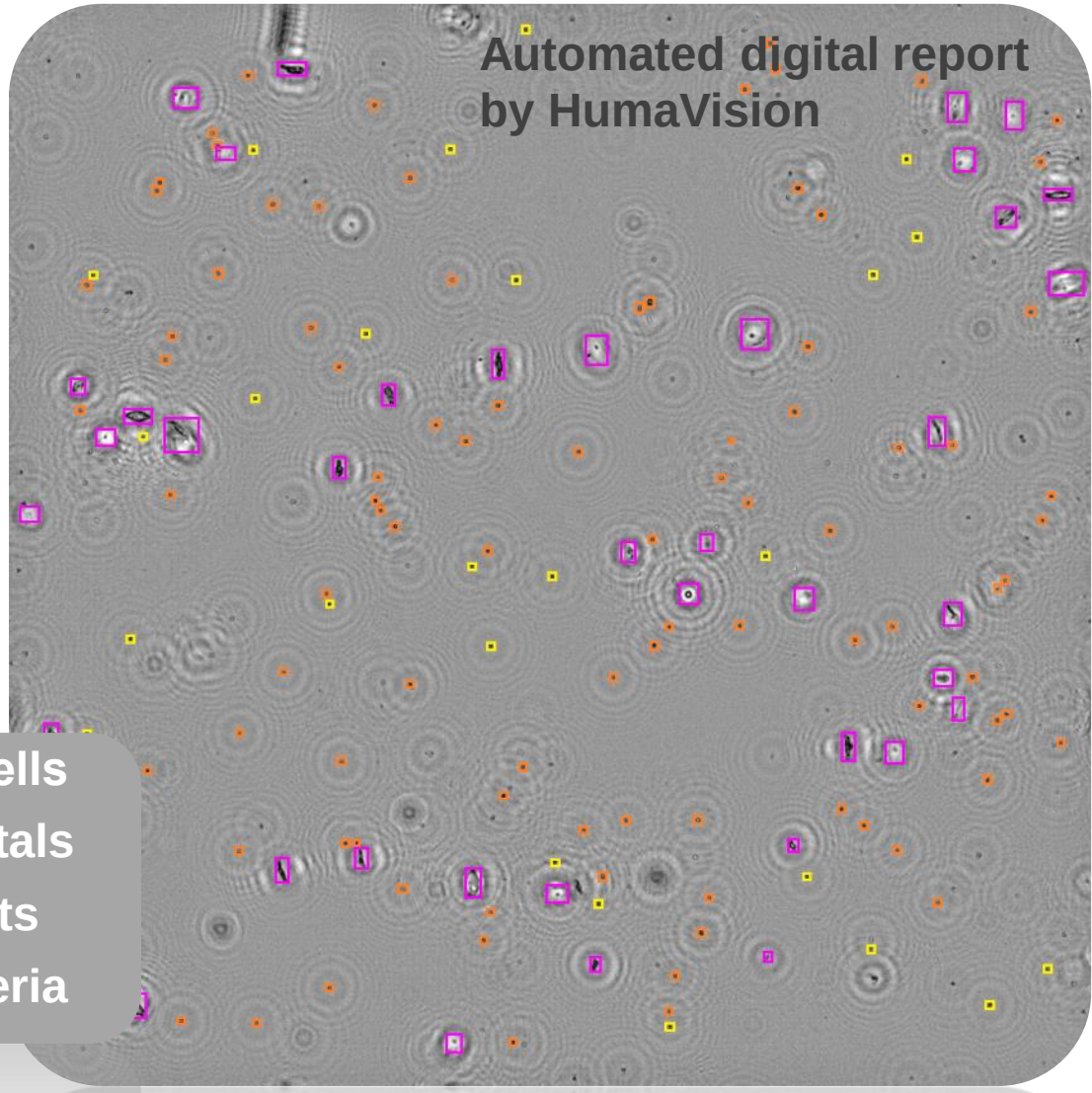
AI-based differentiation and counting

Smallest urine particle analyzer on the market



… Cells
Crystals
Casts
Bacteria



Innovative urine microscopy

Replacing many manual microscopies

Red Blood Cells

White Blood Cells

Squamous Epithelial Cells

Non-Squamous Epithelial Cells

Calcium Oxalate - Dihydrate

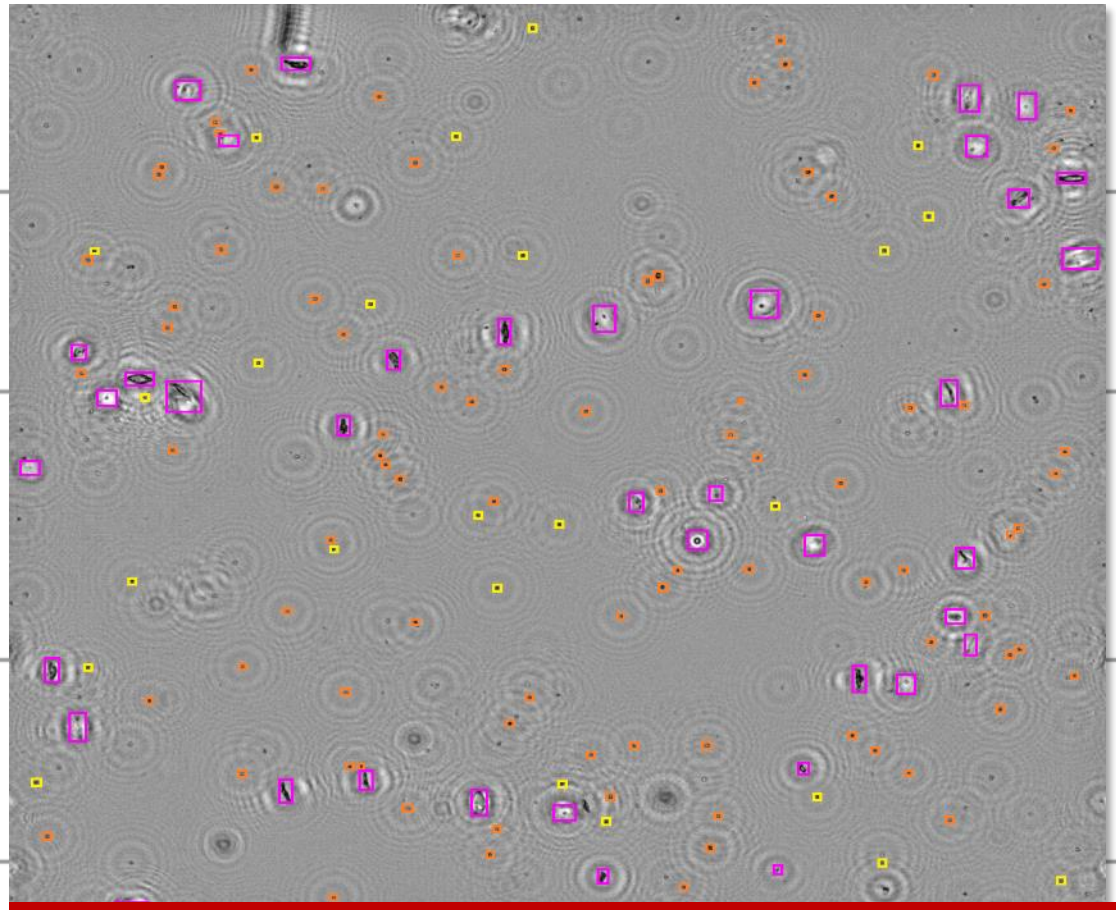
Triple Phosphate

Unclassified

Hyaline Casts

Non-Hyaline Casts

Bacteria



➢ **Saves time and complexity without compromising quality**

Where to use it?

On-the-spot digital results, operator independent

- **Small to medium sized general lab** – replacing many manual microscopies – improved standardization
- **Hospital wards** – mobile, on-the-spot results by unexperienced users – better patient care
- **Doctors' offices** – no laboratory needed – diagnosis-based therapy
- **Dialysis Centers** – immediate results on Crystals RBC, WBC – easy check of kidney, patient care
- **Elderly people homes** – mobile, check for urine infections – objective feedback on dement seniors
- **Health posts** – batch mode to collect samples: battery, solar driven – high-quality results in any environment

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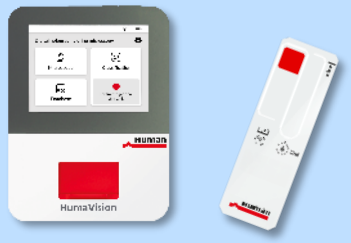
Competitors

Instrument	**HumaVision** (REF17660)	Manual microscopy	Semi-automated e.g UriSed Mini	Semi-automated e.g. US-500
Feature				
Native Urine	Yes, only 20µl	No, sediment	No, internal centrifuge	No, sediment
Digital holography	Yes, 13x higher field of view	No	No	No
Battery operation	**Yes**, 2-5 hours	No	No	No
Lab space required	**Non**, portable	Moderate	High	High
Automated results	Yes, AI, digital	No, no reporting, no second look	Yes, but focal plane adjustment	Yes
Operator skills	Low	Very high	Moderate	Moderate
Investment costs	**Low**	Low	High	High
Time to result	3-7 min.	~ 25 min.	2 min.	2 min.

➢ **Economical**

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Analytical Result Details (Customer North Mazedonia)

Running control materials, 20 repeated measurements of Urine-Sample Carrier HumaVision

Test Parameter	RBC	WBC	SEC	nSEC
Repeatability low concentrations (%)	6,30%	16%	3,50%	3,10%
Repeatability high concentrations (%)	5,30%	9,50%		4,70%

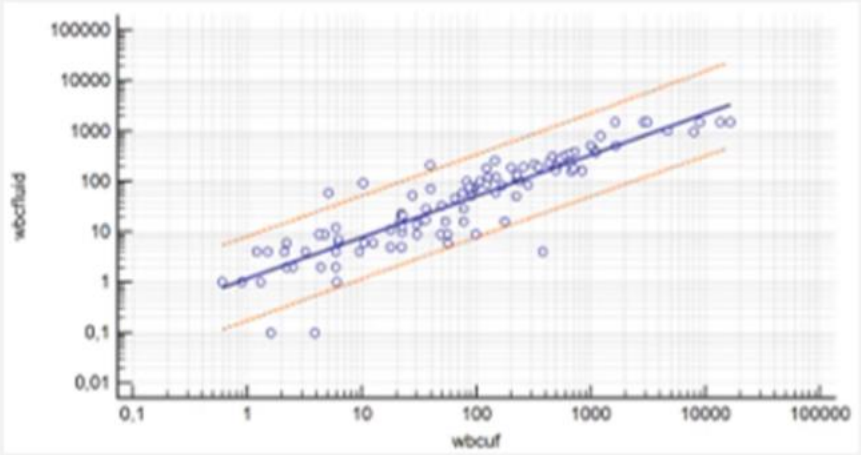
Excellent **reproducibility** (CV´s) on all parameters and all concentrations for HumaVision system

Confirmed by clinical samples

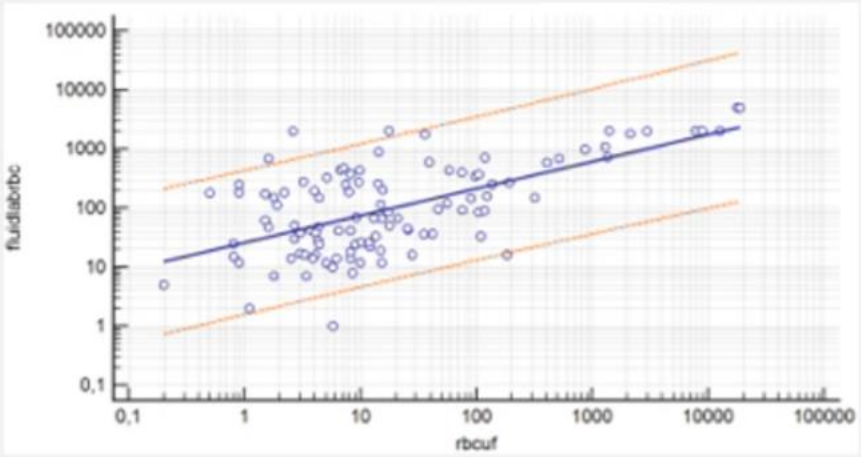
HumaVision – digital urine microscopy

Excellent correlation to fully automated systems

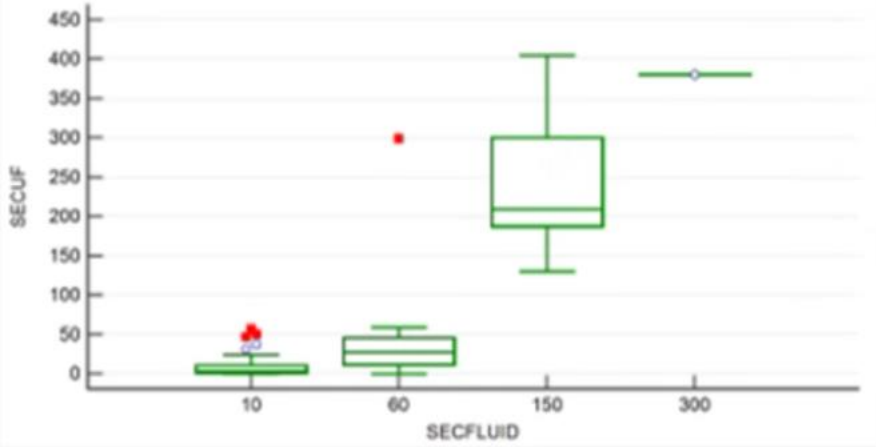
White Blood Cell Count, $R^2 = 0,8$



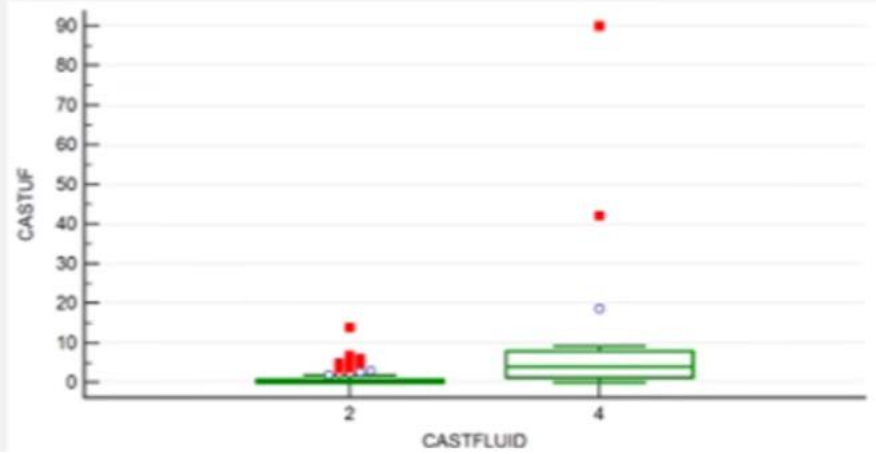
Red Blood Cell Count, $R^2 = 0,9$



Squamous Epithelial Cell Count



Hyaline Cast Count



"The HumaVision is on a performance level, which is comparable to the clinical standard flow cytometer (UF-4000)"

Prof. J. DeLanghe
Brussels, Belgium

Saves expenses without compromising quality

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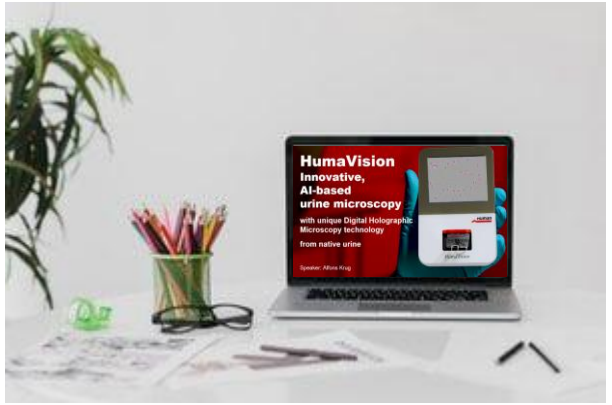
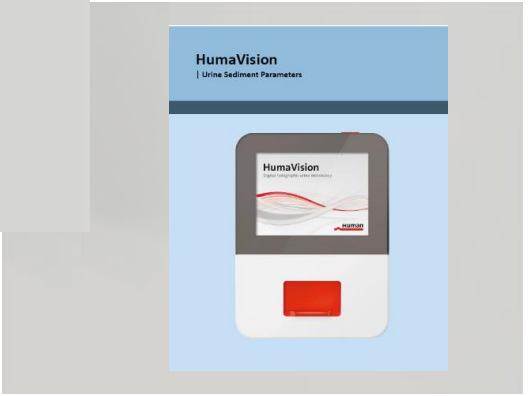
Support Material

- Urinalyis flyer (HumaVision, HumaCombilyzer)
- PowerPoint presentation (Customers)
- Teaser video,
- Application video (https://knowledge-center.human.de/ilp/pages/description.jsf?menuId=114230#/users/@self/catalogues/114930/courses/341025/description) please use your login.
- User manual on HumaVision Urine Sediment Parameters (instruction an evaluation data)
- Quick guide (application, dilution)





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Takeaway Points

HUMAN PARTNER SUMMIT
Advancing diagnostics together.

Opportunity

- Unique AI-based DHM technology
- Smallest urine microscopy on the market
- 80% faster than microscopy
- no interobserver variability

Positioning

- On-the-spot results
- Low investment cost
- Digital reporting
- No laboratory, no space needed

Target customer

- Small to medium sized lab
- Hospital wards
- Doctors´ office, health posts

MADE IN GERMANY

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HumaVision system

Components

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HumaVision (17660)

Digital Holographic Microscopy (DHM) technology, powerful AI
Integrated battery

Sample carrier (17661)

100 sample carrier in one box, (4-30°C storage)

Sensor cleaning stick (17662)

96 sample port cleaner per kit (4-30°C storage)

Thanks for your attention

Dr. Alfons Krug

a.krug@human.de

Power bank, solar panel

Mobil energy, ~ 8 h operation
Power bank 73 Wh,
Solar panel 36 W

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