

# Marketing & Sales Guide

## HumaVision System

**Executive  
Summary**

**Product  
Information**

**Market /  
Positioning**

**Competition**

**Objection  
Handling /  
Key Selling  
Arguments**

**Supporting  
Material**

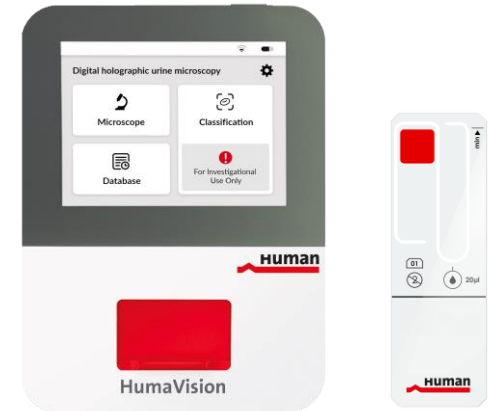
# K Executive Summary



## Product Introduction

### HumaVision

- Is an innovative AI-based urine microscope with unique Digital Holographic Imaging Technology.
- The smallest most comfortable microscope on the market, supporting native urine.
- Provides On-The-Spot results.
- It is intended to acquire holographic images of different cell types and particles in human urine samples for the quantitative human urine examination.
- It is used as an aid to diagnosis of the general health status.
- HumaVision is intended to be used with the specified Urine sample carrier (REF 17661).
- Determines quantitative urine sediment parameters (for investigational use only, IUO).
- Replaces many of manually done urine microscopies.



## Market

- Urinalysis plays a pivotal role in preventative healthcare, disease management, and substance screening.
- The need for easy-to-use small analyzers is ongoing, if quality of results is adequate and comparable to user dependent microscopy (high interobserver variability), with no digital result documentation.
- Accurate and timely diagnosis is crucial for appropriate therapies.
- The availability of easy-to-use instruments that provide fast on-the-spot results reduces pre-analytical steps and eliminates the need for sample transportation to a central lab, enabling faster patient management.
- Global Urinalysis market = 3.6 Billion USD in 2022, with a growing CAGR of ~4.1% (Clin.Chem. ~13 Billion USD in 2022)
- Fastest growing market: Asian Pacific



# Executive Summary



## Positioning and targeted customers

### Market segment

- Diagnosis of the general health status (basic diagnostic)
- No laboratory, no lab space needed
- Need for results on-the-spot

### Target customer

- Small to medium sized lab
- Hospital wards
- Doctors' office, health post
- Dialysis centers
- Elderly people home

### Customer segment

- Small to medium volume labs with 1-40 urine-sediment samples per day



# Executive Summary

## Key Selling Arguments, to replace many manual microcopies

- **Save time without compromising quality**

It saves time while maintaining objective AI-based high-quality results, DHM has additional phase information at a bigger field-of-view, runs on native urine and provides standardized results.

- **Portable precision for all environments**

The device provides precise, portable measurements suitable for any environment.

**Unique selling point: Together with HumaCombilyzer it is the only system offering urine dry chem. and sediment analysis on a mobile solution (battery driven) on native urine.**

- **Efficient digital result documentation**

Ensures efficient digital documentation of results for easy tracking.

- **Minimize costs and complexity: Less manual steps, no reagents or calibrators, higher throughput**

Reduces costs and complexity by reducing manual microscopy by a well-trained lab-technicians, reducing manual preparation steps and eliminating the need for reagents or calibrators.

# K Executive Summary

## Pricing Strategy, semi-automated system

### Investment

- Instrument price is in the price range of a digital microscope (plus PC). Closed system, requires use of Urine-Sample-Carrier HumaVision.
- Much lower investment cost than a fully or semi-automated urine-analyzers. Chance to enter the market at a much lower market entry barrier as automated systems.

### Consumables

- Sample carrier, the costs include the access to the AI-based technology and automated reading.
- Cleaning sticks (maintenance of optics).



# Product Information



Intended use



Product overview



Digital semi-automated urine microscope



Benefits of main aspects



# HumaVision



## Intended use

- The instrument **HumaVision** is a digital semi-automated urine microscope for mobile use.
- The urine-sediment analyzer determines quantitative urine-sediment-parameters (for investigational use only IUO) on native urine, in a defined volume.
- For professional use.





# HumaVision System

## Components



### HumaVision instrument

Digital semi-automated urine microscope

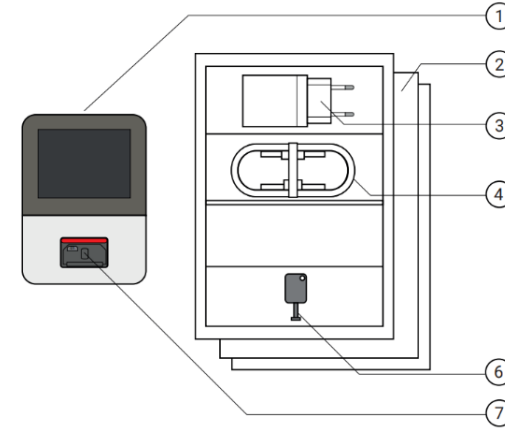
REF 17660



### Urine sample carrier

20  $\mu$ l native urine sample carrier (glass-slide)

REF 17661

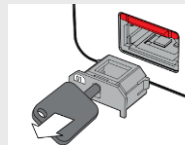


### Charger & cable

- > Battery run time 2-5 hrs
- > USB battery charger
- > USB-C cable

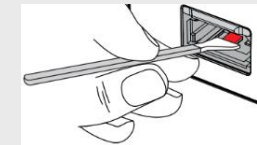
### Sample carrier holder

Sample carrier holder key



### Cleaning set

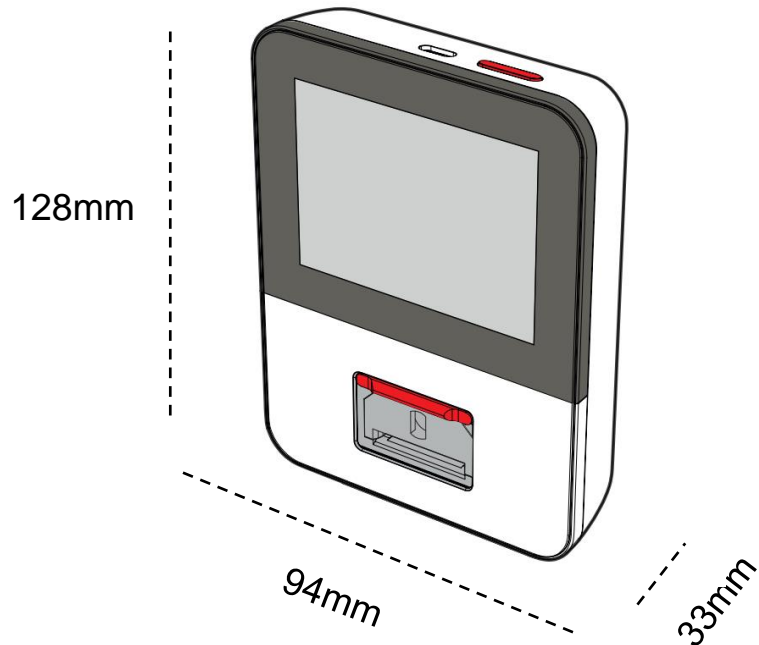
Cleaning swabs



REF 17662

# HumaVision System

## Technical specifications



<b>Type</b>	Single cartridge analyzer
<b>Touch screen</b>	3.5" color touch screen
<b>Technology</b>	Digital holographic image with automated AI-based urine particle analysis
<b>Battery</b>	Battery run time 2-5 hours
<b>Time-to-result</b>	2-7 minutes (batch mode possibility)
<b>Sample types</b>	Native urine
<b>Sample volume</b>	20 $\mu$ l
<b>Storage</b>	Storage of 300 results and images

❖ **Portable precision for all environments**

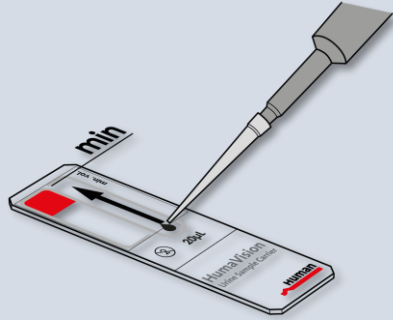
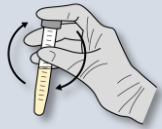
# HumaVision System

Simplified workflow by using native urine and AI-based particle differentiation and quantification

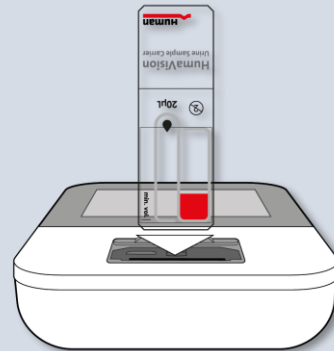
## HumaVision



Native urine



Pipette 20µl to sample carrier



Insert sample carrier, for reading

### Digital PDF Report

Overview			
BC	RBC/µl 18	WBC/µl 1	>
EC	SEC/µl 0 - 21	nSEC/µl 0 - 21	>
CRY	COD/µl 0-11	STR/µl 0 - 21	UNCC/µl 0 - 21 >
CAS	HYC/µl 0 - 23	nHYC/µl 0 - 23	>
BAC	Suspected presence >		

**2-7 min.**

Automated, quantitative digital results

## 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

### Digital Report



### Paper Report

Patient Name: \_\_\_\_\_ Age: \_\_\_\_\_ Sex:  M  F  
 Physician's Name: \_\_\_\_\_ Test Date: \_\_\_\_\_ Tester's Initials: \_\_\_\_\_  
 Collection Date: \_\_\_\_\_

**Physical Characteristics:**  
 Color:  colorless  yellow  orange  red  
 Appearance:  clear  hazy  cloudy  turbid

**Chemical Measurements:** (units as indicated)  
 osmolality (mOsm) normal 2 4 8  
 glucose (mg/dl) mg 50 100 200 300 400  
 ketone (mg/dl) mg 0.5 1 2 3 4 5 6 7 8 9 10  
 bilirubin (mg/dl) mg 0.2 0.4 0.6 0.8 1.0 1.2 1.4 1.6 1.8 2.0  
 nitrite mg pos (any pink color is considered positive)  
 leukocytes mg 0 1 2 3 4 5 6 7 8 9  
 blood mg 0 1 2 3 4 5 6 7 8 9  
 pH 5 6 7 8 9  
 specific gravity 1.000 1.005 1.010 1.015 1.020 1.025 1.030

**Microscopic Examination:**  
 WBC: \_\_\_\_\_ Count: \_\_\_\_\_  
 RBC: \_\_\_\_\_ Count: \_\_\_\_\_  
 Crystals: \_\_\_\_\_  
 Epithelial Cells: \_\_\_\_\_  
 Other: \_\_\_\_\_

**Comments:**

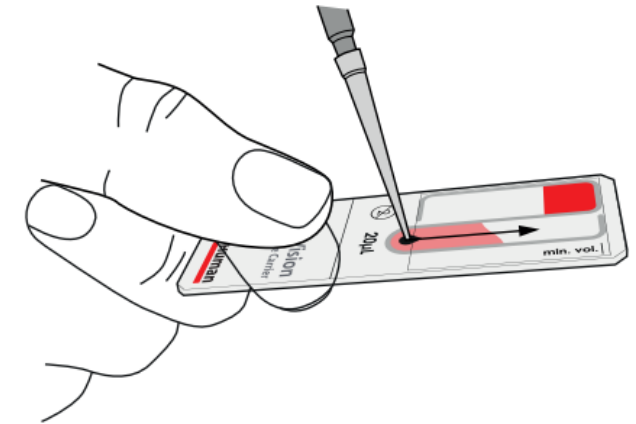
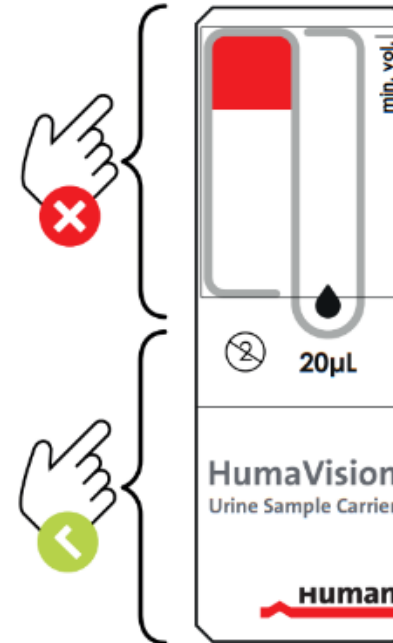
**30 min.**

# HumaVision – Urine Sample Carrier

High quality – test principle

## Sample carrier for 20µl native urine

- Absorbed by capillary action.
- Exact quantity.
- Holographic image, covers much more urine particles than a mono-layer (2-slides) microscopy.



❖ **Second examination with a microscope at any time possible**





# HumaVision – Urine Sample Carrier

## Advantage of using Native Urine instead of Urine Sediment

### European guideline recommends:

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

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

(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/>

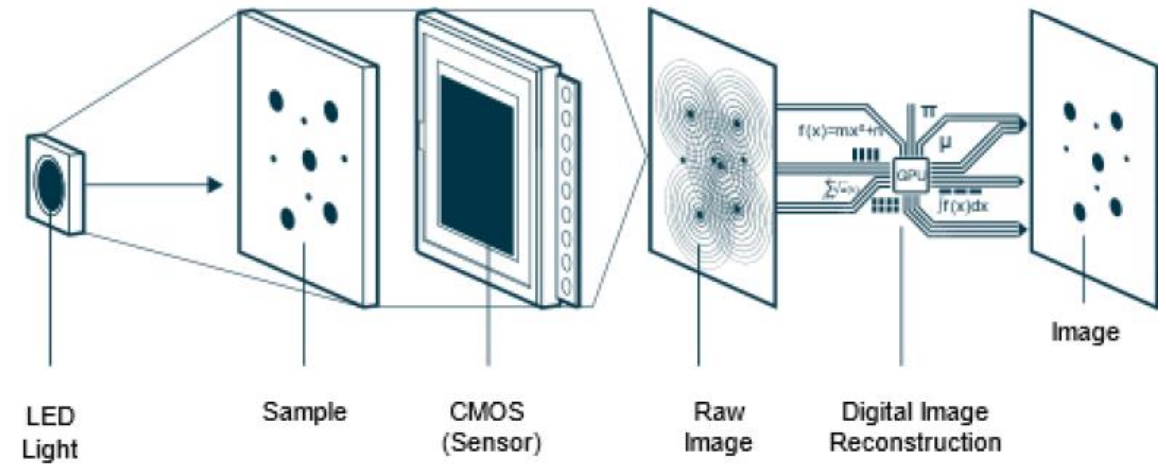
(4) <https://pubmed.ncbi.nlm.nih.gov/12555980/>

# HumaVision – Innovative Technology

## Digital holographic microscopy (DHM)

### Digital holographic microscopy (DHM)

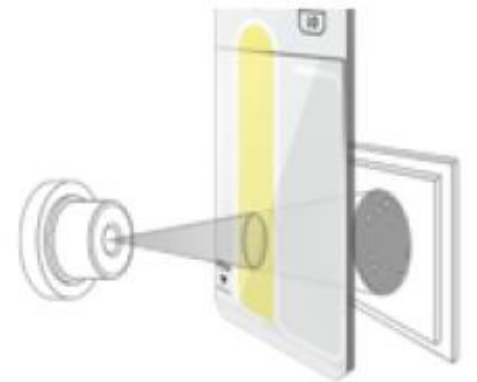
- An innovative combination of holography and microscopy, is revolutionizing urine microscopy analysis.
- The digital holographic imaging process begins with illuminating the urine sample with a light source.
- This light interacts with microscopic objects, resulting in complex interference patterns that form a hologram.
- The recorded hologram is then digitally reconstructed using advanced algorithms, producing a detailed image of the sample.



# HumaVision – Innovative Technology

## Digital holographic microscopy (DHM)

- The sample on the slide is illuminated with a LED which is characterized by having a constant phase relationship between its waves, resulting in a stable and predictable interference pattern when it interacts with the microscopic objects in the sample.
- As the coherent light passes through the urine sample, it interacts with the various microscopic objects present in the urine, such as cells, bacteria, crystals, and other cellular components. These microscopic objects diffract the light, causing it to change direction and create complex interference patterns.
- The interaction of the coherent light with the microscopic objects causes a phase shift in the light waves. The phase shift represents the variations in the optical path length caused by the presence of different objects in the sample.
- The phase-shifted light waves, along with the unaltered reference light (beam that does not interact with the sample), combine to form an interference pattern known as a hologram. This hologram is a complex pattern that contains information about both the amplitude and phase of the light waves at each point in the sample.

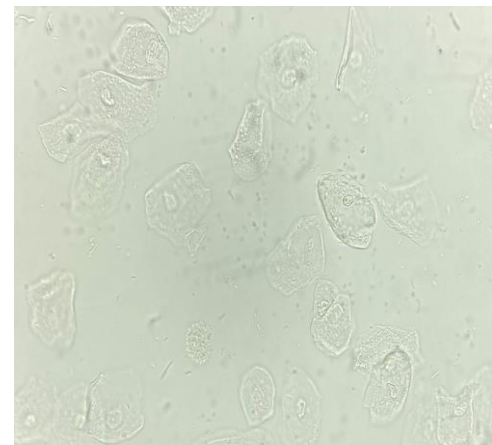


# HumaVision – Digital Holographic Microscopy (DHM)

Unique technology, with additional phase information, superior to manual microscopy



Microscopy field of view only  $0.2 \text{ mm}^2$



## Particle differentiation

### At microscopy by eye

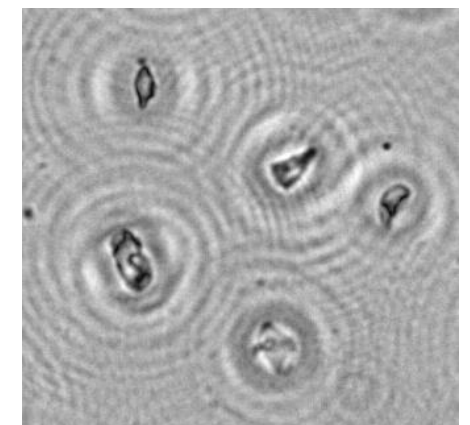
- Size / Shape (2D)
- User experience
- In a corresponding native urine volume of  $0.041 \text{ mm}^3$
- Semi-quant.-count *no defined volume*

### With Digital Holographic Microscopy and AI

- 3D cell / shape volume
- Data-base of  $>1 \text{ Mio.}$  particles (AI)
- Measure of **phase-information**  
by a holographic image (based on refractive index, geometry/topography)
- **13 times bigger observed volume of  $0.525 \text{ mm}^3$**
- **Absolute counts particles/ $\mu\text{l}$**



HumaVision field of view  $5.25 \text{ mm}^2$







# Parameters provided (PDF report)

Replacing many manual microscopies

Red Blood Cells

White Blood Cells

Squamous Epithelial Cells

Non-Squamous Epithelial Cells

Calcium Oxalate - Dihydrate

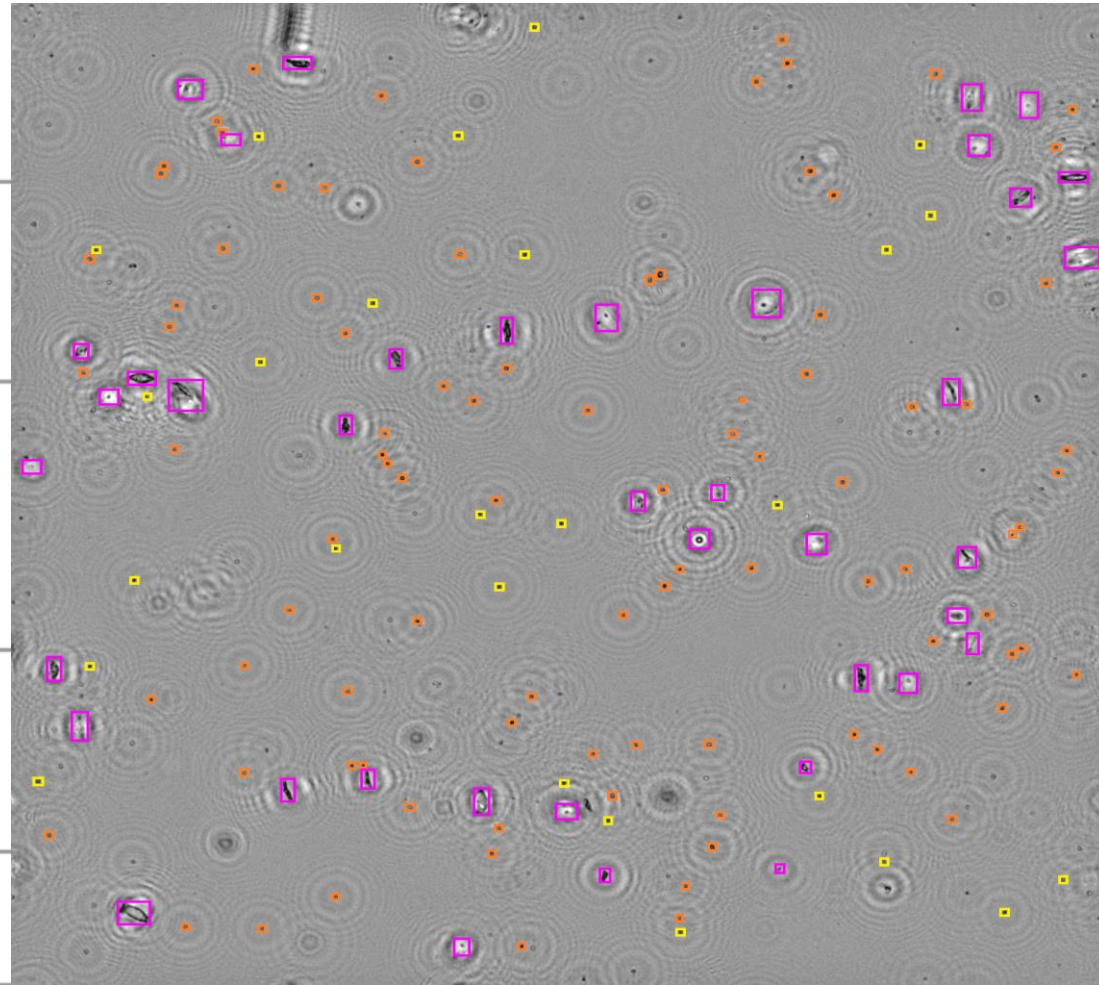
Triple Phosphate

Unclassified

Hyaline Casts

Non-Hyaline Casts

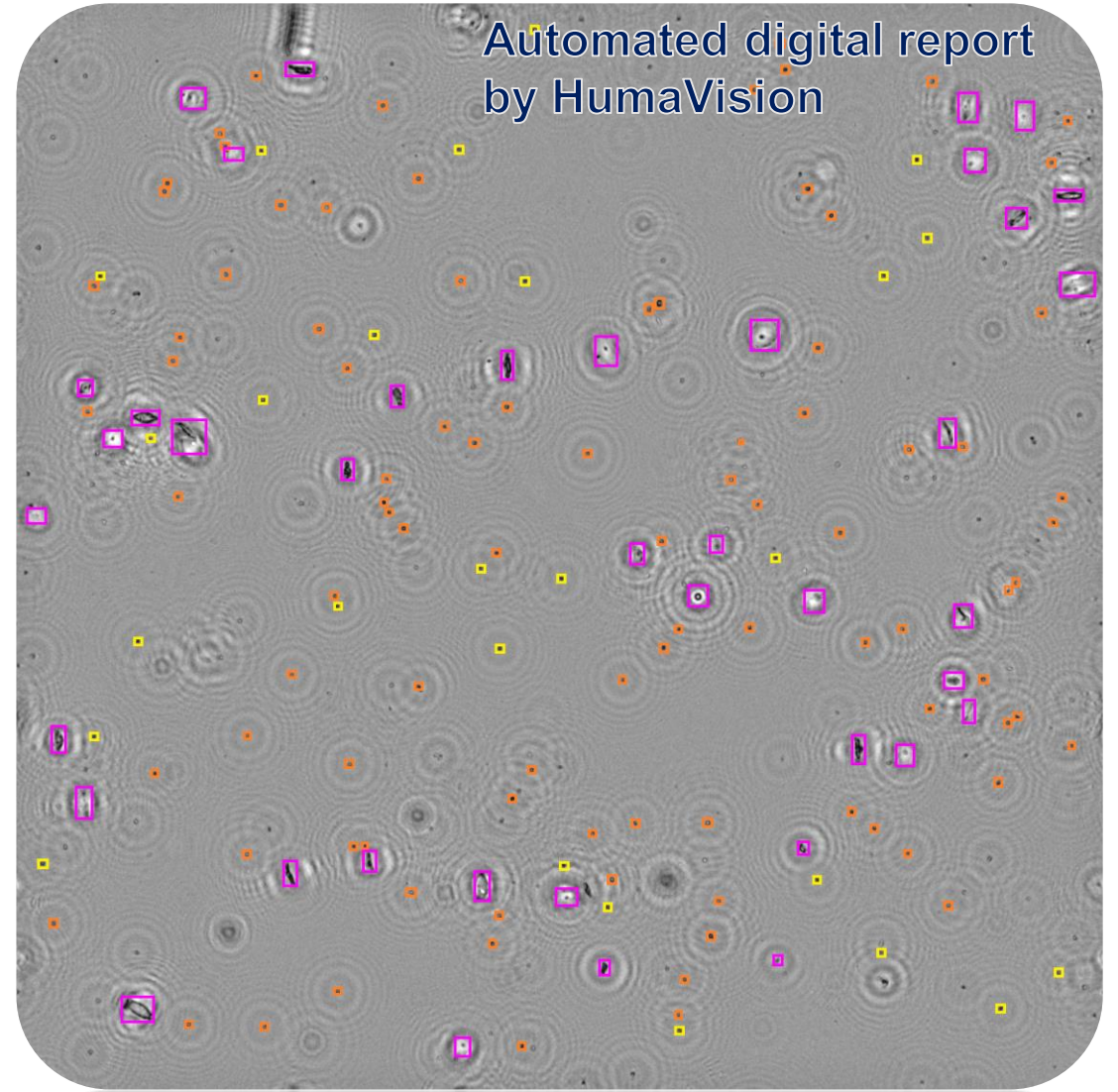
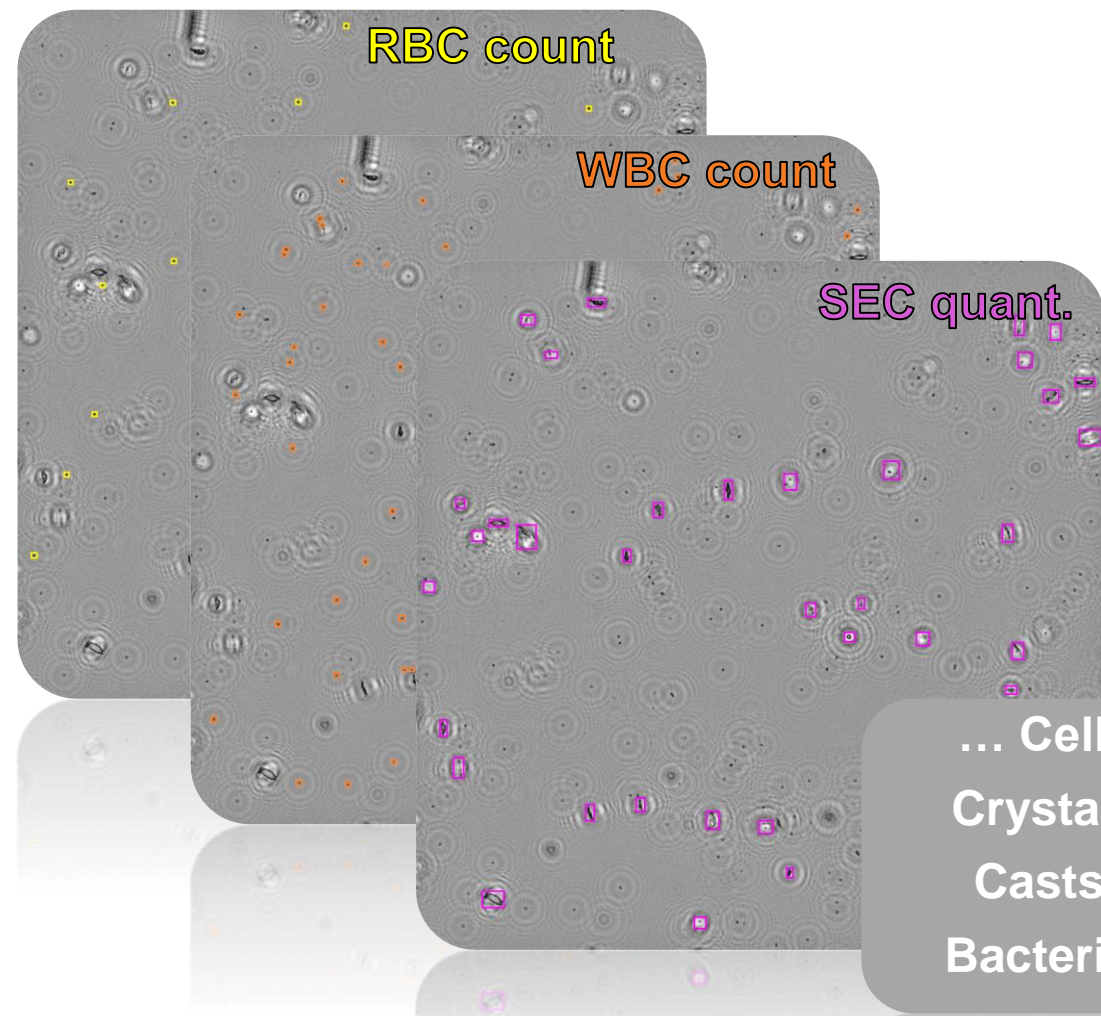
Bacteria





# AI-based Differentiation and Counting

Quantitative urine partical results



Automated digital report  
by HumaVision

# Value Propositions – Starting with a Need/Problem

Problem	Feature	Value
Interobserver variability	<ul style="list-style-type: none"> <li>Technology</li> <li>automated results</li> </ul>	<ul style="list-style-type: none"> <li><b>Standardization of results</b>, flexibility any lab-technician can do it.</li> </ul>
Lack of <b>qualified personal</b>	<ul style="list-style-type: none"> <li>AI-based-system</li> </ul>	<ul style="list-style-type: none"> <li>Available <b>at any time</b></li> <li>(no closing time, illness, vacation, strike)</li> </ul>
Lack of laboratory <b>staff</b>	<ul style="list-style-type: none"> <li>Automated system, batch mode analysis</li> </ul>	<ul style="list-style-type: none"> <li>Qualified results</li> <li><b>Freeing-up staff</b> for more important tasks</li> </ul>
Loss on RBC, WBC and epithelia <b>cells</b>	<ul style="list-style-type: none"> <li>Use of uncentrifuged native urine</li> </ul>	<ul style="list-style-type: none"> <li>Better <b>patient care</b> by improved diagnostic</li> </ul>
Urine transport time from health post to central lab	<ul style="list-style-type: none"> <li>Collect sample at health post by batch-mode and analyze during traveling</li> </ul>	<ul style="list-style-type: none"> <li><b>Correct results</b>, correct no. of crystals, no loss of particles, better patient care</li> </ul>
<b>Immediate results needed</b> (dialysis center, hospital ward, doctor´s office, elderly home), no time to sent it in	<ul style="list-style-type: none"> <li>Automated system, easy to use</li> <li>Digital reporting</li> </ul>	<ul style="list-style-type: none"> <li><b>Diagnostic-based-therapy</b>, confident physician, happy patient (treatment at first visit)</li> </ul>
Second look by <b>another nephrologist</b> (training). Dried-out slide, decayed urine	<ul style="list-style-type: none"> <li>Digital image</li> <li>Transfer via WIFI, LIS</li> </ul>	<ul style="list-style-type: none"> <li>Easy availability and <b>exchange of reports</b> on HMS, mobile phone..</li> </ul>
<b>Loss of results</b> (no documentation), redo of urine sampling / lab work	<ul style="list-style-type: none"> <li>Digital reporting</li> <li>Easy transfer to mobile phone, laptop...</li> </ul>	<ul style="list-style-type: none"> <li><b>Improved efficiency</b></li> </ul>
Limited financial resources – <b>investment</b> of automated system and <b>lab space</b>	<ul style="list-style-type: none"> <li>Hand-held system, complete solution together with HumaCombilyzer</li> </ul>	<ul style="list-style-type: none"> <li>Made in Germany, <b>smallest urine-particle-analyser</b> on the market</li> </ul>
Difficulties during <b>accreditation</b> to standardize process (not quantitative, no count. chamber)	<ul style="list-style-type: none"> <li>Automated system, standardized reporting of absolute numbers/intervals</li> </ul>	<ul style="list-style-type: none"> <li><b>Better reputation</b> by accreditation</li> </ul>

# Market and Positioning



Urinalysis market and HumaVision



Positioning HumaVision



Competitive instrument comparison



# Market Urinalysis

Report: Marketresearch365



## Clinical importance (Urine contributes to ~ 30 % of the laboratory market volume)

- Urinalysis plays a pivotal role in preventative healthcare, disease management, and substance screening.
- Urinalysis serves as a diagnostic tool for conditions like urinary tract infections (UTIs), kidney disorders, diabetes, liver irregularities, and more.

**Global Urinalysis market = 3.6 Billion USD in 2022, with a growing CAGR of ~4.1%**  
(Clin.Chem. ~13 Billion USD in 2022)

**Fastest growing market: Asian Pacific**

## Challenges (not enough trained lab-technicians, too high costs for automated systems)

Nevertheless, the urinalysis market confronts several challenges. A notable obstacle revolves around the scarcity of **proficient professionals capable of conducting urinalysis tests and accurately interpreting the results.** Furthermore, the **exorbitant costs associated with technologically advanced urinalysis instruments and consumables** may hinder affordability for certain healthcare facilities and patients.

# Feedback New Product Ideas at our Regional Meetings

In Palm Urine-Diagnostic (POCT), unique German product!

Urine-microscopy, quantitative semi-automated solution for red/white blood cells, epithelial cells, crystals, casts, bacteria

High market potential, IVDR OEM made in German, in a market segment relevant for our customers



Region	Market Potential / %		Sales Share of Urinalysis - Distributors
	Yes	No	In %
Latin America	92	0	9,14
Middle East	63	38	7,27
Southeast Asia	87	9	21,28
Central Asia	89	0	12,78
<b>Summary</b>	<b>83</b>	<b>12</b>	<b>12,62</b>

❖ **Urinalysis is of high importance for your business**

# Need of on-the-spot Results

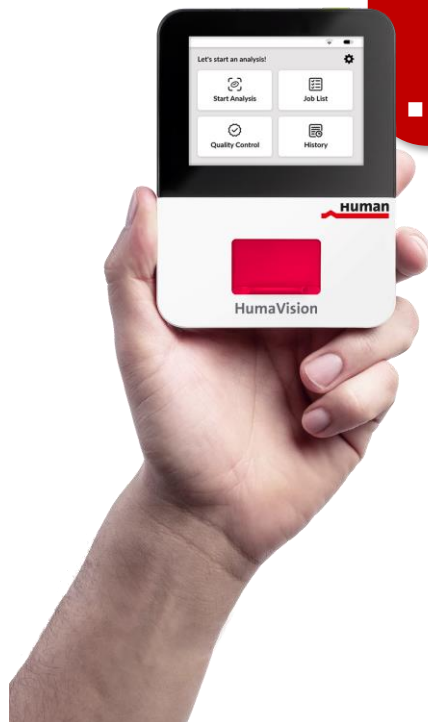
Brings medical diagnosis to the patient - not sample to the central lab

- Easy to use, portable
- Automated, quantitative, digital resulting
- Battery driven

Present solution,  
by manual microscopy



- Need for a laboratory specialist (not available).
- Time and labor intensive- centrifugation, multiple pipetting.
- Non-quantitative (no counting chamber used).
- Poor documentation of result.



# Causes of Diagnostic Errors



- Potential loss of erythrocytes, leukocytes and epithelia cells



2 glass slides as urine sample carrier

- No defined volumes, so no quantitative result



Manual microscopy by experienced lab technician

- Typing errors 1-5 % wrong results



Type in of results

## Interobserver variability<sup>(1)</sup>

- Good agreement on broad and fatty casts (79%)
- Poorest on dysmorphic RBC & WBC (31%)
- Kappa = 0.54 on squamous epithelia cells
- Kappa = 0.52 on hyaline casts
- Kappa = 0.14 transitional epithelia cells
- Kappa = 0.06 on fatty casts

## Conclusions:

Nephrologists achieved slight to moderate agreement in the identification of structures that are commonly observed in the urine sediment.

**Poor Standardisation, so a kidney disease or infection could be missed!**

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



# Need of on-the-spot Results

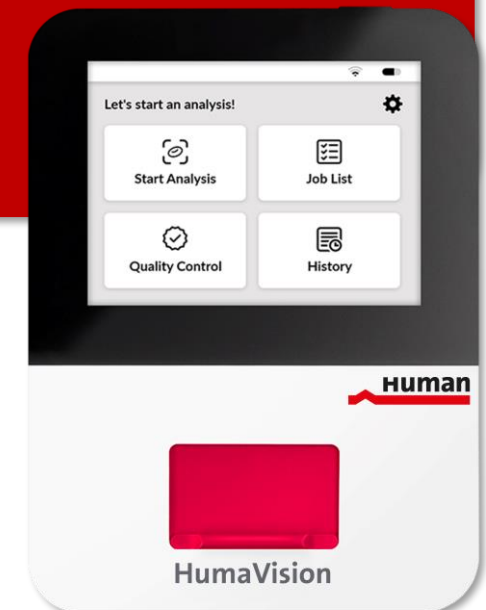
Brings medical diagnosis to the patient - not sample to the central lab

Present solutions,  
by fully automated  
systems,



- Very high investment costs.
- High lab space requirement and good energy supply is needed.
- Need for well-trained laboratory personnel.
- Need for reagents and calibrators.

- **Small, easy to use**
- **Low investment costs**
- **Low maintenance**
- **No extra tubes**
- **No reagents**
- **Powerful by AI**



# 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



# Positioning Urine-Sed.-Analysers

Investment costs/€

80.000  
20.000  
6.000  
2000  
1000  
400

Manual microscopy



Quantitative with counting chamber

Qualitative with slide

>8 steps

3 steps

2 steps

1 steps

Grade of automation

Fully automated systems from Siemens, Dirui, Beckam, Roche, Sysmex...



US-500 (semi-automated)



UriSed Mini (semi-automated)

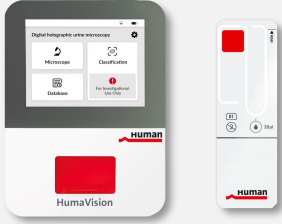





HumaVision - portable



# Competitors

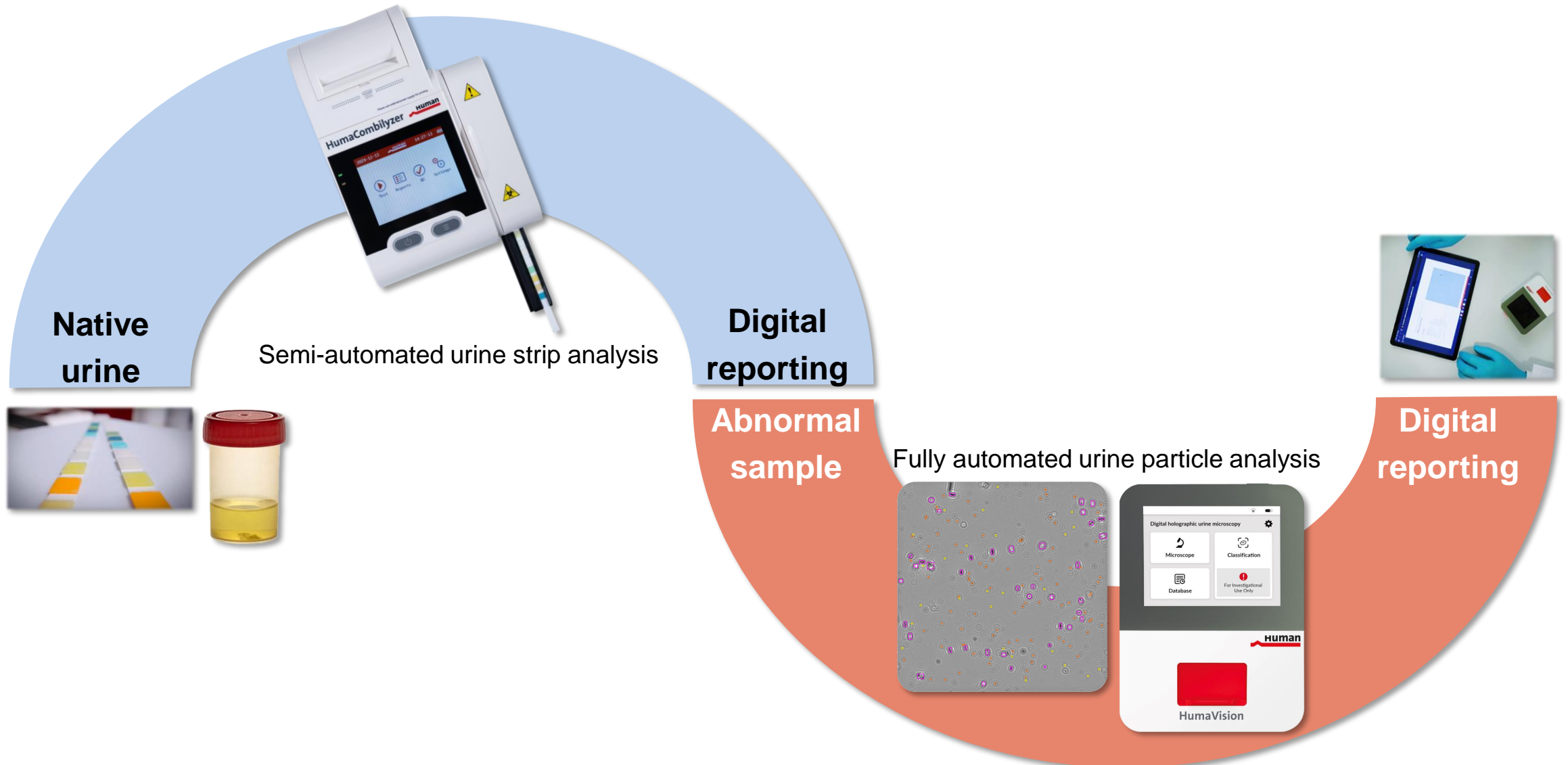
## Portable semi-automated urine sedimentation analysis

Instrument	HumaVision	Manual Microscopy	Semi-automated e.g. UriSed Mini	Semi-automated e.g. US-500
Feature				
Native Urine	Yes, only 20µl	No, sediment	No, <b>internal centrifuge</b>	No, <b>sediment</b>
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-system, digital	<b>No, no reporting, no second look</b>	Yes, but focal plane adjustment	Yes
Operator skills	Low	<b>Very high</b>	Moderate	Moderate
Investment costs	Low	Low	<b>High</b>	<b>High</b>
Time to result	3-7 min.	<b>~ 25 min.</b>	2 min.	2 min.

➤ **Economical**

# Human Portable Urine Analysis Solution

Typical workflow (starting always with native urine)



# Urinalysis – Solutions by HUMAN

How to develop the urinalysis market?

## Test for professional use

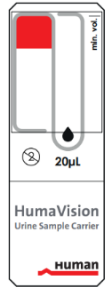
- High throughput (fast mode: 120 test/h)
- Screening - cost efficient

### HumaCombilyzer



**HumaCombina 10/13**

for more detailed examinations



### HumaVision

## Entry to on-the-spot results

- Easy to use
- Automated, quantitative digital resulting
- Mobily solution - battery driven

# Urinalysis – Solutions by HUMAN

How to develop the urinalysis market?

## Replacing Both

- Urine strip analysis and
- Urine microscopy

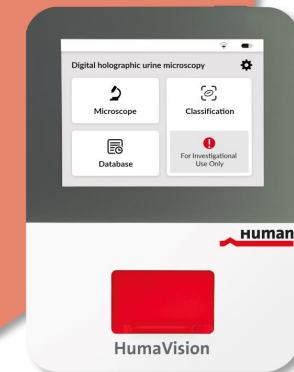


## Entry-level solutions

- Automated urine strip analyzer
- Automated urine microscopy

## At low investment costs

- No need for a fully automated strip reader
- No need for a fully automated sediment analyzer



# Objection Handling and Keyselling Arguments



SWOT analysis and objection handling



HumaVision key selling points







# Testimonial – Evaluation Report

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



# Testimonial – Evaluation Report

## Clinical Result Details (Customer North Mazedonia)



Epithelial cells and Casts are reported summative in our labs. Only 1 Crystal, so not statistics on it.

	Threshold [LPF]	No. of samples	Sensitivity	Specificity
RBC	16	194	1	0,33
WBC	16	194	0,99	0,2
EC	1	194	0,91	0,47
Casts	1	194	1	1
Bact.	1	194	0,91	0,38



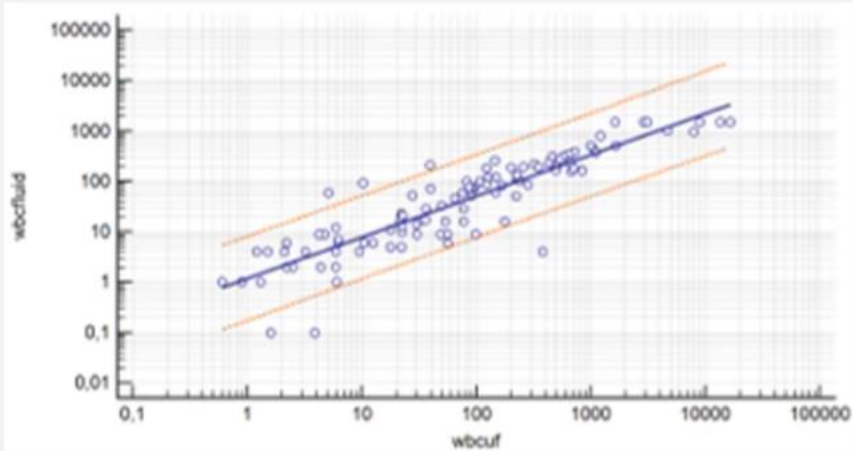
Excellent **sensitivity** for all parameters, when comparing manual microscopy to automated HumaVision

Study design problem: Comparing to LPF is difficult, since reported ranges in LPF are too wide and cut-offs are within reported ranges. Sensitivity could not be defined, needs to be compared to a HPF setting.

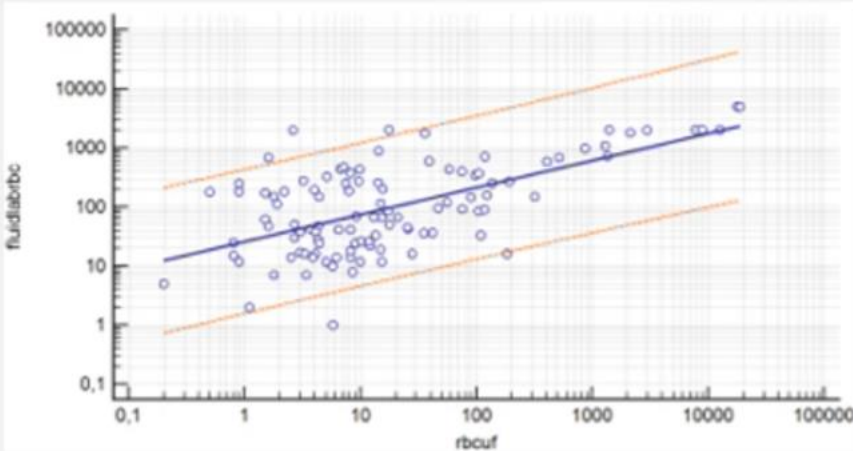
# HumaVision – Digital Urine Microscopy, eval. Data

Excellent correlation to fully automated systems

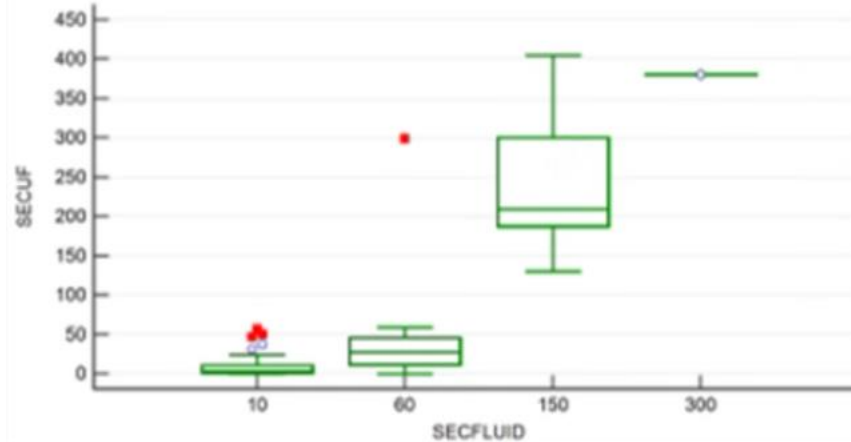
White Blood Cell Count,  $R^2 = 0,8$



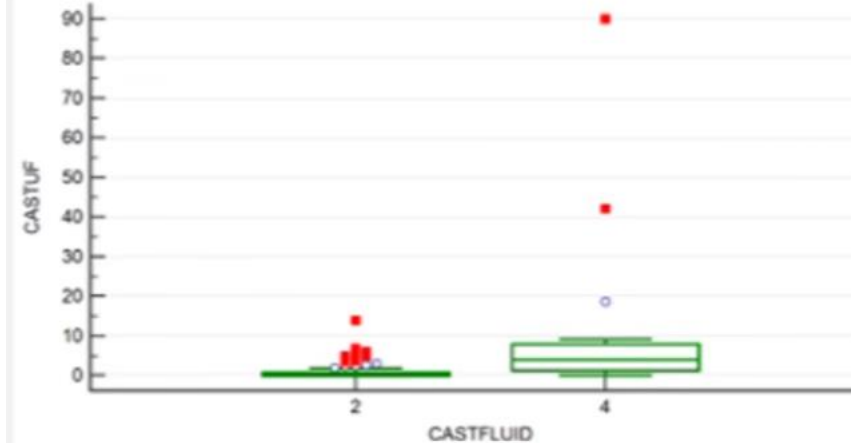
Red Blood Cell Count,  $R^2 = 0,9$



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**



# Marketing Support



Can be found in the HUMAN [login area](#)

## General

Urinalysis Flyer

[English version](#) | [Spanish version](#) | [French version](#)

Specification Sheet HumaVision

[English version](#)

Frequently Asked Questions (FAQ)

[English version](#)

Sales Cheat Sheet

[English version](#) | [Spanish version](#) | [French version](#)

HumaVision Sales Presentation

[English version](#)





# Marketing Support



Can be found in the HUMAN [login area](#)

User Manual on HumaVision  
[English version](#)

Quick Guide Application  
[English version](#)

Quick Guide Dilution  
[English version](#)

HumaVision Calculation Tool  
[English version](#)

Will be sent to you by customer service on request  
[support@human.de](mailto:support@human.de)



For more informations write an email @:  
[HumaVision@human.de](mailto:HumaVision@human.de)



# Marketing Support



## Videos

Engage and educate your audience with our selection of informative videos:

Urinalysis Video (EN)

[English version](#) | [Spanish version](#) | [French version](#)

HumaVision Teaser Video (EN)

[English version](#)

Urinalysis Exhibition Totem Video (ideal for mobile phones, status advertisement)

[English version](#)

HumaVision Application Video

(A step-by-step guide on how to use HumaVision)

[English version](#)

