anvajo

anvajo vet fluidlab 1

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1. Strategic intent and general conception

Introduction

Urinalysis is an important laboratory test that can be readily performed in veterinary practice and is considered as part of a minimum database. Microscopic examination of urine should be also a solid part of a routine urinalysis to get a comprehensive report on the urine status. But despite being an immensely useful tool, urine analysis is still perhaps the most underused test in veterinary practice.

One of the main reasons is the lack of suitable tools to analyse urine directly in the veterinarian's office. Manual microscopic examination is time-consuming, labour-intensive and requires well-trained personnel with minimum technical skills as well as appropriate equipment e.g. microscope, centrifuge, microscopy slides. The automated urine analysers (Idexx, Abaxis) are good solutions for high-throughput analysis at veterinary clinics or laboratories, on the other hand, due to the high cost and the need for frequent intensive maintenance they are not affordable for individuals.

Therefore, the fluidlab 1 brings an elegant solution for convenient urine analysis available to individual veterinarians as well as to laboratories with a smaller number of samples. Intuitive user interface, minimal maintenance and simplicity of the measurement allows its use even without laboratory training. In addition, the small size and portability of the device allows remote testing to address immediate healthcare concerns or monitor patients directly on the field.

2. Product details

Overview

The fluidlab 1 is a **compact and portable semi-automated urine microscope** that allows quick, cost-effective, and accurate analysis of clinically significant parameters anywhere - at laboratory, veterinary office or directly on the field.

Analysis is easy and does not require any special equipment or sample processing since the device was designed for **direct measurement of uncentrifuged native urine samples** from cystocentesis, catheterisation and spontaneous urine.

Method

The fluidlab 1 uses the principle of **Digital Holographic Microscopy** (DHM). Contrary to brightfield microscopy, DHM does not use optical lenses but generates so called holograms containing optical signals from the objects presented in the sample. The hologram then needs to undergo a digital reconstruction on the bases of which is obtained a three-dimensional view of the observed objects and output as the test result. Thus, DHM is a two-step process in when first a hologram is recorded and then reconstructed.

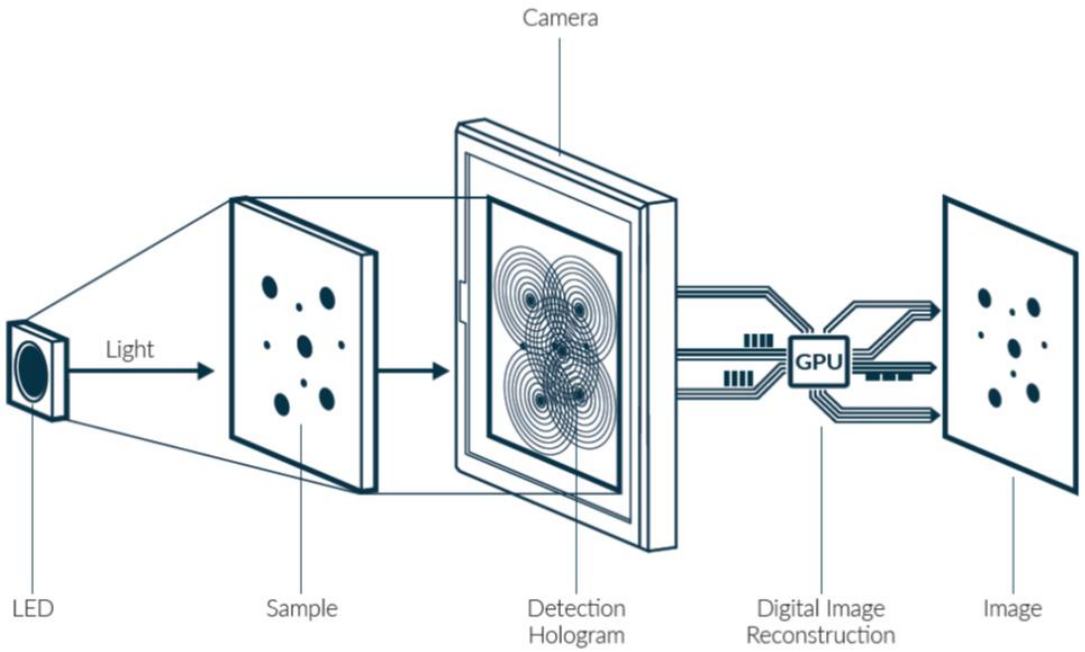


Fig.2: In DHM, the sample is illuminated with light. As light passes through the sample, some of it gets diffracted according to its refractive index while some travels through without 'seeing' the sample. Behind the sample, the diffracted light interacts with the non-diffracted light, thus creating a hologram as it hits the camera. The hologram is then reconstructed digitally to retrieve an image, which contains valuable information about the different elements like blood cells, crystals or casts distributed within the sample.

Be aware the fluidlab 1 images are not intended to be used for visual classification by the user. The classification of individual elements by fluidlab 1 is based on their specific refractive indexes and/or their tiny differencies, which is difficult to distinguish by the naked human eye. This is the major difference compared to the visual bright-field microscopy where the classification of the given elements is based solely on their morphological appearence or differences.

Field of view

Field of view (FOV) usualy defined as an open observable area visible either though operator's eyes or via an optical device. In case of fluidlab 1, the FOV is defined by the size of the camera and corresponds to 1 µL of observed sample volume.

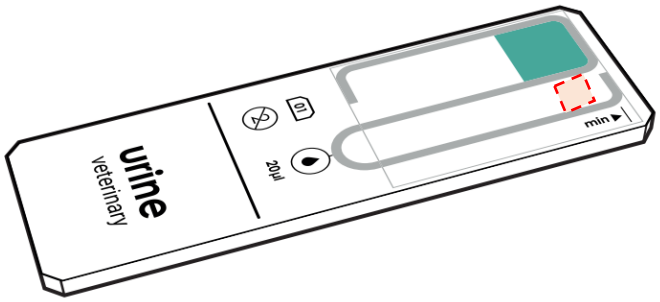


Fig.4: Optical area of the sample carrier (orange)

Result reporting and customization

Laboratory test results reported as numbers are not meaningful by themselves. Their meaning comes from comparison to reference values. These values are often determined by consensus of medical experts based on the results of clinical outcome studies and refers to values that are expected for healthy individuals, therefore, they are often called “normal” or “negative” values.

Why Labs Are Using Different Reference Ranges?

Because there is no universal reference range for most laboratory tests, ranges will vary from laboratory to laboratory. This means that it is possible to get a negative/normal result from one laboratory and an abnormal result for the same test from another laboratory, and vice versa.

Reference ranges should be established for each marker by every lab by carrying out their own reference interval studies. Recruiting a healthy reference group and getting their informed consent is expensive and time-consuming, so most laboratories opt to instead use the reference ranges provided by the test manufacturers. But such reference ranges can differ based on the source the manufactures used to define them – it can be either values found in literature, recommendation of local clinical society or results of their own clinical studies.

Decision Limits

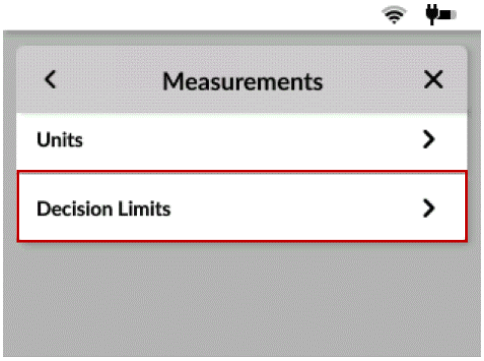
Another way how to report the test results is using Decision Limits that is better than reference ranges in making diagnoses and treatment decisions. A decision limit is a cutoff point where values above or below are linked to a certain risk of developing specific diseases or their stages. Their purpose is to indicate when intervention is necessary to prevent or treat the disease as

well as to monitor the disease progression or effect of treatment. Decision limits may also be based on doctors' clinical experience.

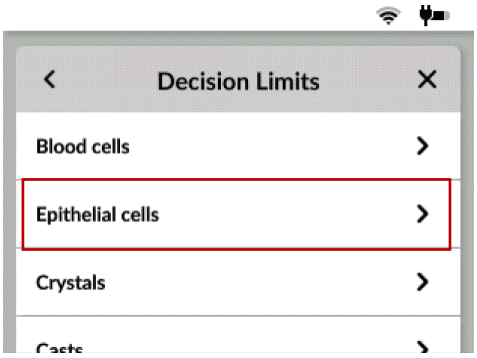
fluidlab 1 combines both systems and allows to set the reference ranges (category "Negative") and decision limits for each parameter individually. Thus, it gives the users higher flexibility to adjust the results reporting according to their individual needs and streamline the process of making immediate clinical decision.

How to customize the result reporting?

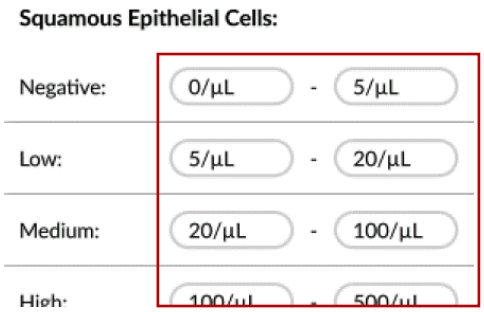
1. Open the settings menu of the fluidlab 1 by tapping the Settings gear (≡) once.
2. Tap on the menu item "Measurement".
3. Tap on the "Decision Limits"



4. Tap on the selected parameter.



5. Tap on the lower/upper value of the given range.



6. Enter appropriate value and confirm by pressing the confirmation button ( ).

Note: Units in results history and decision limits are always displayed according to current unit setup.

Default settings of Decision Limits

	Decision Limits				
	Negative	Low	Medium	High	Very High
RBC	0 – 5/HPF	5 – 25/HPF	25 – 100/HPF	>100/HPF	
WBC	0 – 3/HPF	3 – 6/HPF	6 – 20 /HPF	20 – 50/HPF	>50/HPF
EC	0 – 1/HPF	1 – 5/HPF	5 – 10/HPF	10 – 20/HPF	>20/HPF
CRY	0 – 1/HPF	1 – 6/HPF	6 – 21/HPF	21 – 50/HPF	>50/HPF
	Negative		Present		
CAS	0/LPF		>1/LPF		

(1) Labordiagnostik in der Kleintierpraxis, Michael D. Willard, Harold Tvedten, Urban & Fischer Verlag 2004

(2) „Components of urine sediment “, Ernst und Judith Leidinger, Invitro Diagnostic Lab, Vienna,

Specification overview		
Device	Method	Digital Holographic Microscopy (DHM)
	Sample Volume	20 µL of uncentrifuged urine
	Parameters	Red Blood Cells, White Blood Cells Epithelial Cells (Squamous, Non-Squamous) Crystals (Calcium Oxalate dihydrate, Struvites, Unclassified) Casts (Hyaline, Non-Hyaline) Bacteria (flagging of suspected presence)
	Microscope Resolution	3 µm – 100 µm

	Sample Carrier	Urine Sediment (chamber hight 100 µm)
	Sample identification	Sample ID via manual entry or predefined worklist (scil VIP)
	Memory	Internal Flash Memory
	Interface	Capacitive colour touch screen (3.5”)
	Connectivity	Wireless
General	Dimensions	128 x 94 x 33 mm
	Weight	240 g
Working conditions	Temperature	10 °C to 40 °C
	Humidity	< 80 %, without condensation at 31°C

Consumables and accessories

Standard package of anvajo vet fluidlab 1 contains:

- anvajo vet fluidlab 1 (device)
- USB battery charger
- USB-C connection cable
- Standard pipette
- Cleaning swab
- Adapter
- Adapter key
- User manual
- Quick Start Guide
- Dilution Guide

Language support

Currently, the anvajo vet fluidlab 1 GUI is available in following languages:

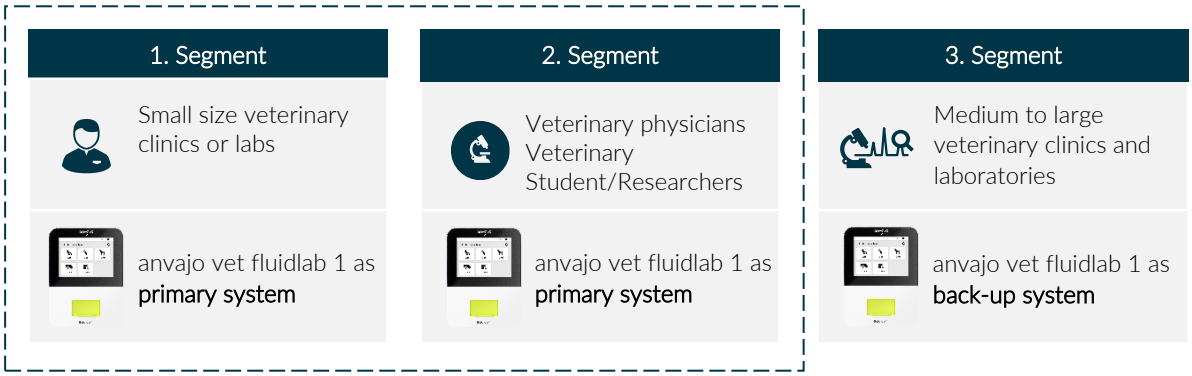
- English (default setting on delivery)
- German
- French
- Italian
- Spanish
- Russian
- Chinese

If additional language version is required please contact the respective Business Development Manager.

3. Sales and USPs

Market segmentation and key targets

Basically, the veterinary laboratory medicine market can be divided into three segments:



The most of our target customers are individual veterinary physicians or small veterinary practices with low sample workload. Therefore, the emphasis is not on the device throughput, but on the:

- simplicity of measurement
- ease of the device operation
- no maintenance
- comprehensibility of results

fluidlab 1 can also be a great tool for education of veterinary students at high schools or universities. Moreover, the low sample volume allows the examination of small laboratory animals. Therefore, the device fits perfectly into research centres and laboratories as well.

However, fluidlab 1 might be also a good solution for larger laboratories requiring effective back-up for their fully automated platform or as a main system at their emergency rooms or night shift laboratories.

USPs

USPs are deduced from key features of the device and describe how it is going to solve the customers' main challenges.

Affordable solution for individuals

When it comes to urinalysis, there are currently only two options available for the individual veterinarians or smaller clinics/labs - manual microscopy or sending the sample to a clinical laboratory.

The manual microscopy requires space for the equipment (microscope, centrifuge, slides, staining reagents), time for sample centrifugation, slide preparation, reading and evaluation and skilled operators to perform the analysis always with the same accuracy and precision. Therefore, it does not really fit into the busy everyday routine of an ordinary veterinarian who has to perform several clinical and laboratory examinations in order to immediately address the healthcare concerns of the given patient.

On the other hand, sending the urine samples to the larger clinical laboratories does not meet one of the most critical preanalytical requirements - short time between sample collection and its actual analysis. Moreover, such a service goes hand in hand with higher cost per test.

Even though urine is considered as a valuable source of information about the health status of the patient, the labour-intensive, time-consuming, unstandardized and/or expensive procedure is one of the main reasons why the analysis of the urine is still one of the most unused clinical examination in veterinary primary care. The fluidlab 1 directly addresses this gap and offers not only automated and standardized urinalysis for the veterinary primary care but also reduces the overall expenses for patient examination due to its simple, maintenance-free and financially inexpensive operation.

fluidlab 1 reduces the turnaround time (TAT)

In clinical practice, the TAT is the time interval from the time of submission of a process – sample collection, to the time of the completion of the process – result reporting.

As already mentioned, time is the most critical preanalytical requirement. According to the European Urinalysis Guidelines (2007), the sample must be processed within 30 minutes after its collection. However, most often the reality does not meet this requirement at all.

Why is it so important to keep a short time interval between sample collection and its analysis? Due to the different pH values and ionic strength urine is not a physiological environment for cellular particles especially RBCs or WBCs. Therefore, longer storage of the sample can cause some morphological changes or can lead to their complete lysis. In addition, prolonged time before analysis can initiate formation of crystals or growth of bacteria in the sample. Ultimately, improper preanalytical treatment of the sample can lead in a worst case to an incorrect clinical decision.

The fluidlab 1 directly tackles the most painful and critical point of the whole measurement procedure by enabling the immediate analysis of native uncentrifuged urine sample after its collection and thus eliminates the need for transport or any preanalytical sample processing (see Fig. 1).

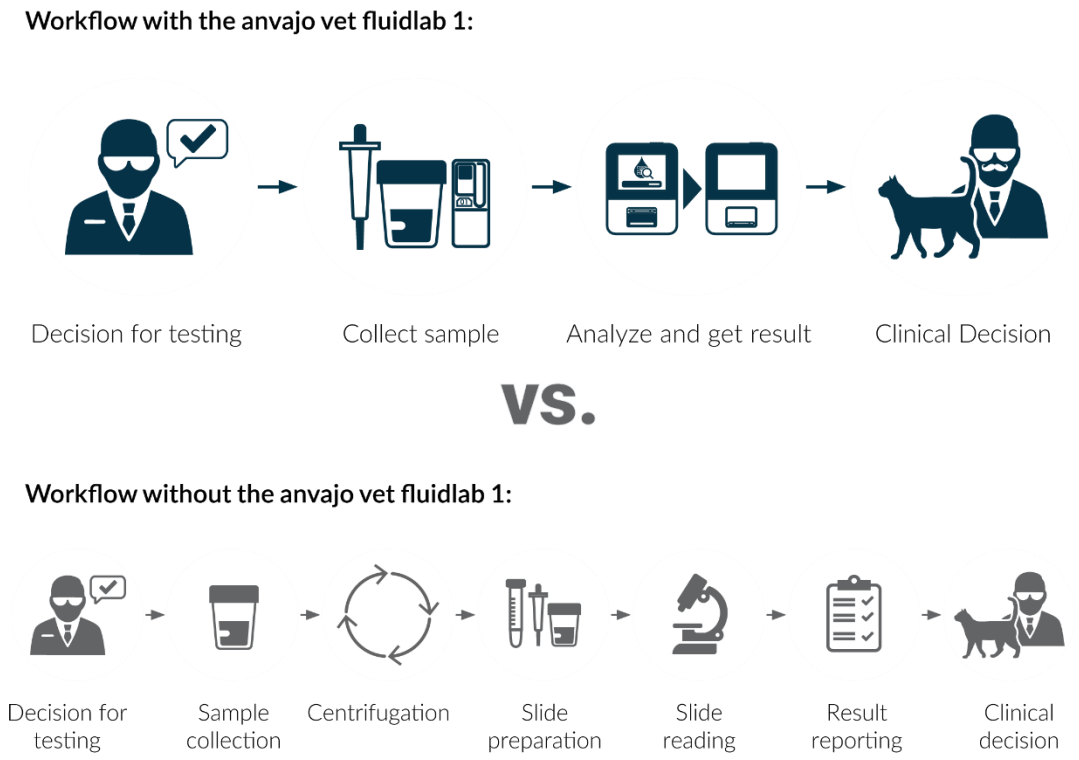


Fig. 1: Comparison of traditional urine analysis vs. analysis with fluidlab 1

Size and portability

Because the size matters! The fluidlab 1 with its pocket size fits perfectly into smaller laboratories struggling with the space as well as into crowded veterinary offices full of many other analytical devices, examination tools, medical supplies, and medicine.

In addition, the combination of small size and portability gives veterinarians the opportunity to increase the level of home/field care services and thus reduce the stress of their patients by examining them in their home environment.

Minimalistic design

The fluidlab 1 emphasizes the simplicity and comprehensibility of its use and the whole measurement procedure so that the device can be operated by anyone even without previous laboratory or technical training or reading the user manual.

Sustainable sample carriers

The acella Sample Carriers are made of glass and are therefore more sustainable than using disposable plastic slides.

The sample carriers can be placed directly under the microscope after starting the measurement. This simplifies the observation of the sample for bacteria if the suspected presence is indicated on the instrument.

Also, the cell components can be quantified again for comparison purposes. However, care must be taken not to leave the sample carrier in the vertical position in the instrument for too long, otherwise the concentration in the field of view will increase.

Competition overview

Competitor overview contains comparison with 2 main competitors presented on the market – SediVue from Idexx and Vetscan SA from Abaxis – see Appendix

However, the main direct competitor is still manual microscopy since this is the only affordable solution for the lower or middle market segment. Compared to fluidlab 1, manual microscopy clearly shows several disadvantages:

- Centrifugation
  - often causes a loss of part of the cellular elements, especially in the samples with low SG or high pH
  - often damages or even completely destroys fragile elements like hyaline casts
- Labour-intensity
- Time-consuming
- Wide interobserver variability
  - highly dependent on operator's experience and the interpretation
- Slide preparation necessary

Appendix - Strengths, Weaknesses, Opportunities, and Threats Analysis

Strengths	anvajo vet fluidlab 1	SediVue Idexx	VETSCAN SA Abaxis
What are your business advantages?	A young company able to promptly respond to market demands	A large international company well established on the field of veterinary research and medicine - 35 years of experience	Offering complex solution for veterinary labs - biochemistry, immunoassays, blood gases, hematology,coagulation, urinalysis
What are your core competencies?	• direct semi-automated analysis or urine sediment affordable for individuals • bringing the accuracy of laboratory diagnostics directly to veterinarians • downsizing an IVD process and making it affordable even to individuals to enable rapid and direct diagnosis of patients	• targeting the largest segment of veterinary IVD with the highest throughput • broad portfolio even for livestock testing • offering complex solution - devices, consumables, SWs, support and education	• broad portfolio of diagnostic products • complexe solution including middleware to possibly connect all Abaxis analyzers • application even for cell phones and tablets
What are you doing well?	Networking	Active research	
Weaknesses	**anvajo vet fluidlab 1**	**SediVue Idexx**	**VETSCAN SA Abaxis**
Where do you lack resources?	Network of KOL and researchers (building up)		In general very low awareness of the product
What are you doing poorly?	Marketing	Often rely on the exclusive position on the market	
Where are you losing money?	Low awareness of the product within the target segment, targeting incorrect personas (e.g. large veterinary clinics instead of practicing veterinarians)	• Targeting the smallest market segment • Extensive maintenance and overall high operational costs	
What needs improvement?	Expectation management: What can the customer expect from the device and where are the (natural) limitations	Frequent maintenance what increases operational cost	
Opportunities	**anvajo vet fluidlab 1**	**SediVue Idexx**	**VETSCAN SA Abaxis**
Any beneficial trends?	Targeting market segment with very low competition	Good solution for veterinary laboratories	Solution for veterinary laboratories
Niches that competitors are missing?	• Easy-to-use affordable urinalysis for every veterinarian or smaller laboratory • No fixed running costs (minimal throughtput and maintenance) the customers pays always the same price, no matter on how many measurements/day/week/month were performed	"Pay per test" strategy	
New technologies?	Digital holographic microscopy as a next-gen tool for IVD	No - using digital microscopy has been used in IVD for more than 20 years	No - using flow measurement has been used in IVD for more than 20 years
New needs of customers?	Direct semi-automated analysis or urine sediment affordable for individuals	Increasing number of analyzed parameters	
Threats	**anvajo vet fluidlab 1**	**SediVue Idexx**	**VETSCAN SA Abaxis**
Obstacles to overcome?	The initial distrust of the customer coming from using a new technology and unusual workflow		Rejection of highly concentrated sample due to possible damage of measuremt chamber
Aggressive competitors?	Main competitor in our target segment is still manual microscopy	Good reputation and exclusive position for many years	Idexx - well know
Successful competitors?	Manual microscopy (historically)	Abaxis - but still not as strong as Idexx	Idexx
Negative economic conditions?	Veterinary market isn't as stable as human clinical market (e.g., stagnation of sales during the restrictions associated with the Corona virus)	Requires higher workload otherwise the cost per test is incresing due to frequent maintenance	Expensive operation - many consumables, very frequent maintenace
Government regulation?	US and CA	Already present at regulated markets	

Appendix – Competitor Analysis - technical

	anvajo vet fluidlab 1 - anvajo	sediVue - Idexx	Vetscan SA - Abaxis
Method	digital holographic microscopy	digital microscopy	flow imaging
Sample centrifugation	no	yes	no
Sample pipetting	yes	yes	no
Sample volume required for analysis	20 µl	165 µl	650 µl
Analyzed parameters	RBC	RBC	RBC
	WBC	WBC	WBC
	Squamous EC	Squamous EC	Squamous EC
	Non-squamous EC	Non-squamous EC	Non-squamous EC
	Hyaline casts	Hyaline casts	Hyaline casts
	Non-hyaline casts	Non-hyaline casts	Non-hyaline casts
	CaOX	CaOX	CaOX
	Struvites	Struvites	Struvites
		Ammonium biurate	
		Bilirubin	
	Unclasified crystals	Unclasified crystals	Crystals - others
	Bacteria (suspected presence)	Bacteria Rods	Bacteria Rods
		Bacteria Cocci	Bacteria Cocci
Optical area	20x HPF	45x HPF	96 images (size?)
Possibility to connect with urine strip reader	no	no	yes
Consumables	sample carriers	disposable plastic cuvettes	cleaner
			rinse A
			rinse B
Portable	yes	no	no
SW update	wifi	USB	USB
Memory	> 1000 tests		500 tests
Dimensions	128 x 94 x 33 mm	320 x 320 x 336 mm	485 x 383 x 427 mm
Weight	0,24 kg	15 kg	30 kg