STUDY
OVERVIEW

anvajo

Clinical evaluation of the anvajo fluidlab 2 -

A novel DHM based urine particle analyzer

One page summary; for original paper please see https://doi.org/10.1515/cclm-2025-1202

In this study, fluidlab 2 provided accurate and clinically desirable quantitative counts of urine particles. This makes the device particularly attractive for satellite laboratories or facilities in rural or low-density regions, where long sample transport times can compromise the pre-analytical phase. Its compact footprint and rapid analysis make it an ideal intermediary between full-scale core laboratories and near-patient testing, offering a practical solution in settings where delays in central lab processing may degrade sample integrity.

Urinalysis plays a crucial role in the diagnosis and management of kidney and urinary tract diseases. Anvajo has developed the fluidlab 2 particle analyzer – a device that uses digital holographic microscopy (DHM) in combination with neuronal network object detection to classify particles. Unlike traditional imaging techniques, DHM enables label-free, high-contrast, three-dimensional visualization of transparent microscopic structures. This allows for precise analysis of cells and particles in fluids without the need for staining or contrast agents.

The study investigated the performance of the fluidlab 2 particle analyzer in the detection and classification of urinary particles compared with reference visual microscopy using phase-contrast optics, as suggested in the recently published EFLM European Urinalysis Guideline. 450 mid-stream urine specimens were selected from the specimens sent to the Clinical Laboratory of the Ghent University Hospital between February and October 2024. Urine particle results obtained by the Anvajo fluidlab 2 were compared with the counts obtained by visual phase-contrast microscopy, performed blindly by one of the two experienced technicians in the laboratory participating in this study.

The precision of fluidlab 2 is comparable to that of automated particle analyzers applying fluorescence flow cytometry or digital flow cell morphology. The linearity of RBC and WBC counts extended to concentrations relevant for health assessment. The LoQ also met clinically significant concentrations in the selected specimens. Fluidlab 2 demonstrated RBC, WBC, and SEC counts that correlated with visual microscopy within the desirable limits outlined in the 2023 EFLM European Urinalysis Guidelines, similar to the results reported for the UF-5000, UriSed 3 PRO, and AI-4510 analyzer [see figure next page].

Particle	Limit of positivity	Number of positive cases	Sensitivity	Specificity	Agreement of classification[a]
RBC	5	360	90.3 % (95 % CI: 86.4–93.1 %)	55.6 % (95 % CI: 44.7–66.0 %)	0.92
	19	203	84.2 % (95 % CI: 78.5–89.0 %)	91.9 % (95 % CI: 87.8–95.0 %)	
WBC	5	313	93.3 % (95 % CI: 89.9–95.8 %)	72.4 % (95 % CI: 64.0–79.8 %)	0.93
	19	206	88.4 % (95 % CI: 83.2–92.4 %)	90.9 % (95 % CI: 86.5–94.2 %)	
SEC	5	179	94.6 % (95 % CI: 86.6–95.2 %)	92.7 % (95 % CI: 85.6–97.0 %)	0.96
	19	96	93.7 % (95 % CI: 90.1–96.3 %)	99.7 % (95 % CI: 98.4–100 %)	
NSEC	5	117	79.5 % (95 % CI: 71.0–86.4 %)	85.0 % (95 % CI: 80.7–88.7 %)	0.82
	19	36	86.1 % (95 % CI: 70.5–95.3 %)	98.8 % (95 % CI: 97.2–99.6 %)	
CASTS[b]	3	64	71.9 % (95 % CI: 59.2–82.4 %)	98.2 % (95 % CI: 96.3–99.3 %)	0.86
	10	15	93.3 % (95 % CI: 68.1–99.8 %)	99.5 % (95 % CI: 98.4–99.9 %)	
Crystals	5	29	86.2 % (95 % CI: 68.3–96.1 %)	80.7 % (95 % CI: 73.3–84.7 %)	0.33
	19	23	70.8 % (95 % CI: 48.9–87.4 %)	91.3 % (95 % CI: 88.0–94.0 %)	
Bacteria[c]	±	163	57.7 % (95 % CI: 49.7–65.4 %)	63.5 % (95 % CI: 54.5–71.9 %)	0.51
	+	126	89.9 % (95 % CI: 85.8–93.1 %)	86.7 % (95 % CI: 82.5–90.2 %)	

RBC, red blood cells; WBC, white blood cells; SEC, squamous epithelial cells; NSEC, non-squamous epithelial cells; CI, confidence interval. [a]Weighted Cohen's kappa coefficient from the ordinal scale cross-tables. [b]Including hyaline and non-hyaline casts. [c]Visual microscopy of bacteria counts was reported in ordinal scale.