Urine albumin test

Country of origin | Sweden

Health problem addressed
Chronic kidney disease (CKD) is common and harmful yet can be easily treated if detected early through a simple urine test and the measurement of low levels of albumin in the urine. If not detected, it may escalate to end stage renal disease (ESRD) which requires expensive treatment and risk of poverty due to inability to work.

Product description
This device uses a quantitative rapid turbidimetric immunoassay of albumin in human urine using a specially-designed analyzer.

Product functionality
The system can be used for the quantitative determination of low levels of albumin in human urine for the purpose of screening, diagnosing, monitoring and to supplement the clinical evidence in the treatment of microalbuminuria.

Developer’s claims of product benefits
Current devices are semiquantitative dipsticks, some with visual reading only. In comparison, this new system provides lab equivalent results in 90 seconds, and is easy to use by anyone. It requires minimal maintenance since it is factory calibrated, does not require any further recalibration, and results can be compared between sites. The system makes it possible to perform large screening programs in rural settings as long as power supply is available.

Operating steps
The microcuvette serves as pipette, mixing and reaction chamber and the correct specimen volume is obtained by capillary action. First, the cuvette is filled, then it is placed in the analyzer. The result can then be read.

Development stage
The system has not been part of any clinical studies, but has been evaluated. The system has been used during a World Kidney Day screening event in Kenya, in hospitals in Kenya, in a large screening program in Morocco and Mexico, in the Nordic Countries, in the US, and in Europe.

Future work and challenges
The scope of the problem and the need is huge, but the awareness of it and the priority on health care are limited. The subjects who are not detected early may face a devastating future as the treatment in the later stages, such as dialysis and transplantation, is not available or very expensive. However, through early detection and cost-effective treatment, a near normal life can be lived.

User and environment
User: Physician, technician, nurse, midwife, anyone also without laboratory education
Training: Easy to follow documentation is provided with the analyzer. Distributors can support training.
Maintenance: Minimal maintenance - cleaning.

Environment of use
Settings: Rural, urban, ambulatory, primary (health post, health center), secondary (general hospital)
Requirements: Continuous power supply

Product specifications
- Dimensions (mm): 170 x 115 x 66
- Weight (kg): 0.350
- Consumables: Urine Albumin Microcuvettes
- Life time: >7 years
- Shelf life: >7 years
- Retail Price (USD): N/A
- List price (USD): 600 (device) 2.99-3.99 (consumables)
- Other features: portable, single-use
- Year of commercialization: 2006
- Currently sold in: US, Europe, Mexico, Kenya, South Africa, Russia

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