

Mission/Vita-Chem urinalysis strips evaluated in a large clinical practice

In a busy GP surgery and clinic in Buckinghamshire, Brynmor Neal, Jackie Collins and Nicola Husbands compare urinalysis test strips from two manufacturers.

Using modern urinalysis technology, up to 11 different tests can be carried out on one sample of urine in one rapid and simple procedure. The robust and reliable nature of this technology permits qualitative and semiquantitative examination of urine in clinics or GP surgeries as well as other point-of-care centres. For several decades, strip urinalysis has played a vital role in diagnostics, as the screening and monitoring of various conditions can provide early indication of renal, hepatic and metabolic disorders. Importantly, results can provide valuable information in two minutes or less.

Automation has revolutionised many aspects of diagnostics testing by eliminating errors inherent in manual methods, and many companies now supply strip readers. However, for this product evaluation, manual/visual readings were deemed to be sufficient. In this study, the Acon Mission/Vita-Chem 10-parameter urinalysis strip was compared to a leading product for semiquantitative analysis. The choice of the market-leading urinalysis strip for this comparison was made on the basis that it is the gold-standard benchmark for testing

and the product of choice for the US Food and Drug Administration (FDA) for such comparative studies.

Evaluation objectives

The objective of this evaluation was to compare Acon Mission/Vita-Chem urinalysis test strips with a leading brand to assess their ease of use

in a busy general practice, the aim being to assess in excess of 50 urine samples from patients and controls with the test strips used by at least three different operators.

Semiquantitative analysis was performed by visual comparison to the manufacturers' colour charts supplied. Qualitative analysis of assessment included:

- ease of storage
- ease of opening and closing the container
- quality of desiccator pack within the container
- ease of accessing the strips
- ease of handling the strips
- rigidity of strips
- ease of reading against the colour chart

Table 1. Results for the various analytes tested.

	Test strip	Number tested	Negative	Positive
Glucose	Acon	50	50	0
	Competitor	50	49	1
Bilirubin	Acon	50	50	0
	Competitor	50	50	0
Ketone	Acon	50	50	0
	Competitor	50	49	1
Specific gravity	Acon	50	50	0
	Competitor	50	50	0
Blood	Acon	50	50	0
	Competitor	50	50	0
pH	Acon	50	50	0
	Competitor	50	50	0
Protein	Acon	50	47	3
	Competitor	50	49	1
Urobilinogen	Acon	50	50	0
	Competitor	50	50	0
Nitrite	Acon	50	48	2
	Competitor	50	49	1
Leucocytes	Acon	50	48	2
	Competitor	50	49	1

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STRIP COMPARISON AND ASSESSMENT

Table 2. Summary of the qualitative assessments made by clinic staff.

		Acon Mission Vita-Chem	Competitor urinalysis strip
Containers	Ease of storage	3	3
	Ease of opening and closing	1	1
	Quality of desiccator pack	1	1
	Ease of accessing the strips	3	3
Strips	Ease of handling	3	3
	Rigidity of Strips	3	3
	Ease of reading	5	0
Charts	Quality of colour chart	5	5
	Ease of reading	5	0
	Ease of interpretation	5	0
Insert literature	Ease of interpretation	3	3
Scores	0 = Poor; 1 = Fair; 3 = Good; 5 = Excellent		

- quality of colour chart provided
- ease of interpretation of results
- degree of information supplied with the insert sheet
- ease of interpretation of insert sheet
- overall ease of use and user confidence in results.

Colour comparisons

Materials included 10-parameter urine test strips from two manufacturers: Acon Mission/Vita-Chem from Chiltern MediCare UK, and strips from a leading competitor. All strips were provided with a colour comparison chart and package insert.

The method employed included the following steps:

- evaluation performed on 50 patient urine samples during routine GP clinics
- patient samples obtained as midstream urine samples during routine clinic visits
- all materials stored at room temperature or 4°C according to manufacturers' instructions
- only those strips required for use were removed from the container at any one time
- urine was allowed to reach room temperature and mixed well prior to testing

- reagent strips were fully immersed in the urine, ensuring all pads were covered
- surplus sample was removed by gently wiping the strip against the sample container rim and then by touching the horizontal edge against an absorbent paper towel
- strips were laid on a strip of paper towel, pad side up, and allowed to stand for the required time
- pad colour was assessed against the chart provided and recorded on the results sheet provided
- all samples were tested by staff in the clinic, with results read by visual interpretation.

The evaluation protocol was developed by Chiltern MediCare UK in cooperation with clinic staff.

Results of assessment

Semiquantitative results were recorded on all 10 parameters on both strips with 50 different patient samples. In all except two cases the difference in results fell within one colour pad of reactivity. Only one result (for nitrite) differed by two pads (Acon positive, competitor negative) and one result (for leucocytes) differed by two

pads (Acon ++, competitor ±). Qualitative assessment was made by the clinic staff and the results are presented in Tables 1 and 2). Similar results were achieved for 992 out of 1000 parameters tested (99.2%) in this comparative study, with only eight parameters showing any degree of disparity. In all except two of these cases, the difference fell within one colour pad of reactivity. Using standard FDA protocols for carrying out trials and comparative studies on such products, this would register as full compliance.

Quality and quantity

In the case of glucose and ketone, the results differed by one pad (Acon negative, competitor ±); for protein, two results differed by one pad (Acon ±, competitor negative); for nitrite, one result differed by two pads (Acon positive, competitor negative); and for leucocytes, one result differed by two pads (Acon ++, competitor ±). A comparison of the sensitivity and detection range values published in the package insert by the two manufacturers may go some way to answer the differences observed (Table 3). In a research trial, laboratory analysis would follow to determine the exact concentration of any positive parameter and therefore confirm or refute the accuracy of the initial visual assessment; however, this was beyond the scope of this evaluation.

Vita-Chem Urinalysis product



Strip urinalysis plays a vital role in diagnostics, as screening and monitoring can provide early indication of renal, hepatic and metabolic disorders

Table 3. A comparison of the sensitivity and detection range values published in the package inserts by the two manufacturers.

	Acon	Competitor	
Leucocytes	10–25	5–15	(WBCs)
Nitrite	0.05–0.1	0.06–0.1	(mg/dL)
Urobilinogen	0.20–1.0	0.2–1.0	(mg/dL)
Protein	7.5–20	15–30	(mg/dL)
pH	5–9	5–9	
Blood	0.015–0.062	0.015–0.062	(mg/dL)
Specific gravity	1.00–1.03	1.00–1.03	
Ketones	2.5–5.0	5.0–10.0	(mg/dL)
Bilirubin	0.4–0.8	0.40–0.8	(mg/dL)
Glucose	50–100	75–125	(mg/dL)

In qualitative user assessment, the Acon strip scored higher for ease of use and ease of interpretation with the clinic staff

In qualitative user assessment, the Acon strip scored higher in ease of use and ease of interpretation with the clinic staff. The Acon strip can be read vertically against the colour chart on the container, while the competitor strip had to be read horizontally and around the circumference of the container, which can lead to difficulty in alignment and the possibility of misinterpretation. In a full research trial, to increase the objectivity of qualitative assessment, input and feedback from several users would be taken and compared; however, this was beyond the scope of the present evaluation.

Final interpretation

In conclusion, the Acon Mission/Vita-Chem urinalysis strip compared well with a UK leading brand of urinalysis strip in terms of tests results. However, based on the experience



Jackie Collins in the Rectory Meadow Medical Centre clinic.

of its use in a busy GP practice, the Acon Mission/Vita-Chem product produced results that were easier to read and interpret.

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