

# Urinary Dipstick Proteinuria Testing: Does Automated Strip Analysis Offer an Advantage Over Visual Testing?

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## Abstract

**Objective:** To compare the diagnostic test properties of automated and visually read urine dipstick screening for detection of a random protein:creatinine ratio (PrCr)  $\geq$  30mg/mmol.

**Methods:** Urine samples were collected prospectively from 160 women attending high-risk maternity clinics at a tertiary care facility. Samples were divided into two aliquots; one aliquot was tested using two different urine test strips, one read visually and one by an automated reader. A second aliquot of the same urine was analyzed for urinary protein and creatinine. Performance of visual and automated dipstick results (proteinuria  $\geq$  1+) were compared for detection of PrCr  $\geq$  30 mg/mmol using non-dilute urine samples (urinary creatinine  $\geq$  3 mmol/L).

**Results:** Both urine test strips showed low sensitivity (visual 56.0% and automated 53.8%). Positive likelihood ratios were 15.0 for visual dipstick testing (95% CI 5.9 to 37.9) and 24.6 for automated (95% CI 7.6 to 79.6). Negative likelihood ratios were 0.46 for visual dipstick testing (95% CI 0.29 to 0.71) and 0.47 for automated (95% CI 0.31 to 0.72).

**Conclusion:** Automated dipstick testing was not superior to visual testing for detection of proteinuria in pregnant women in a primarily outpatient setting. Sensitivity may depend on the test strips and/or analyzer used.

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## Résumé

**Objectif :** Comparer les propriétés diagnostiques du dépistage automatisé par bandelette réactive urinaire et du dépistage visuel par bandelette réactive urinaire pour ce qui est de la détection d'un rapport protéines/créatinine (PrCr) aléatoire  $\geq$  30 mg/mmol.

**Méthodes :** Des échantillons d'urine ont été prélevés de façon prospective chez 160 femmes fréquentant des cliniques de consultations obstétricales pour patientes exposées à des risques élevés au sein d'un établissement de soins tertiaires. Les prélèvements ont été répartis en deux aliquots : un aliquot a été testé au moyen de deux bandelettes réactives urinaires différentes (une faisant l'objet d'une lecture visuelle et l'autre faisant l'objet d'une lecture automatisée). Un deuxième aliquot utilisant la même urine a été analysé pour ce qui est des taux urinaires de protéines et de créatinine. Le rendement des résultats de la lecture visuelle et de la lecture automatisée (protéinurie  $\geq$  1+) a été comparé pour ce qui est de la détection d'un PrCr  $\geq$  30 mg/mmol au moyen de prélèvements d'urine non diluée (taux urinaire de créatinine  $\geq$  3 mmol/l).

**Résultats :** Les deux bandelettes réactives urinaires ont présenté une faible sensibilité (lecture visuelle : 56,0 % et lecture automatisée : 53,8 %). Les rapports de vraisemblance positifs ont été de 15,0 pour le dépistage visuel par bandelette réactive urinaire (IC à 95 %, 5,9 - 37,9) et de 24,6 pour le dépistage automatisé par bandelette réactive urinaire (IC à 95 %, 7,6 - 79,6). Les rapports de vraisemblance négatifs ont été de 0,46 pour le dépistage visuel par bandelette réactive urinaire (IC à 95 %, 0,29 - 0,71) et de 0,47 pour le dépistage automatisé par bandelette réactive urinaire (IC à 95 %, 0,31 - 0,72).

**Conclusion :** Le dépistage automatisé par bandelette réactive urinaire ne s'est pas révélé supérieur au dépistage visuel pour ce qui est de la détection de la protéinurie chez des femmes enceintes dans un contexte de services principalement externes. La sensibilité pourrait dépendre des bandelettes réactives et/ou de l'analyseur utilisés.

## INTRODUCTION

Testing for urinary protein excretion has become central to the care of all pregnant women, but particularly those who are at increased risk of developing preeclampsia.<sup>1</sup>

There are many options for assessing proteinuria. Random (spot) urine samples may be assessed by dipstick test strips, protein:creatinine ratio (PrCr), or albumin:creatinine ratio; dipstick testing is employed for screening at routine antenatal visits, whereas random urinary PrCr testing is currently reserved for use as confirmatory testing when urinary dipstick proteinuria is detected or when there is another reason to suspect preeclampsia. Although the 24-hour urine collection has been considered to be the gold standard for confirmation of proteinuria in pregnancy, the recognition that it is cumbersome and frequently inaccurate has promoted enthusiasm for PrCr.<sup>2-4</sup>

Screening for proteinuria by visual analysis of urinary test strips is accepted practice, given its convenience and low cost, even though it has been recognized to lack sensitivity. In a review of six studies involving 1738 women and using a cut-off of  $\geq 1+$  for detection of significant proteinuria, measured by either 24-hour urine collection or random PrCr, sensitivity was 55%, with specificity of 84%.<sup>5</sup>

Diagnostic test performance of visually read dipstick proteinuria measurement may be improved with use of an automated test strip reader. In theory, automation may also reduce subjectivity; nevertheless, published sensitivities (41%,<sup>6</sup> 82%,<sup>7</sup> 90%,<sup>8</sup> and 100%<sup>9</sup>) and corresponding specificities (100%, 81%, 86%, and 37%) for automated reading have varied widely, even when the prevalence of proteinuria in the study populations was similar (i.e., 45%<sup>7</sup> and 48%<sup>6</sup>).

The most up-to-date (2010) National Institute of Health and Clinical Excellence (NICE) pregnancy hypertension guidelines recommend use of automated urinary test strip screening as an alternative to visual proteinuria screening, with confirmation by random PrCr of  $\geq 1+$ .<sup>10</sup>

Two studies have compared the diagnostic test properties of automated screening with visually read urinary test strips for proteinuria.<sup>7,8</sup> Although one study compared test strip screening with 24-hour urinary protein excretion (g/d)<sup>7</sup> and the other used 24-hour urinary protein concentration (g/L) as the comparator,<sup>8</sup> both studies demonstrated superior diagnostic test properties of automated testing compared with visual.

Given the cost of purchasing automated urine test strip readers, we sought to further test the hypothesis that

automated testing has diagnostic test properties that are superior to visually read urine test strips for detecting a random urinary PrCr of  $\geq 30$  mg/mmol.

## METHODS

This prospective cohort study took place at British Columbia Women's Hospital and Health Centre in Vancouver, BC, from January 27 to March 31, 2011. Consecutive high-risk pregnant women were evaluated. Inpatients were recruited from the assessment room or delivery suite where they were seen for evaluation of hypertension. Outpatients were recruited from our (primarily morning) ambulatory medicine or high-risk obstetric clinics. Women were excluded if they had ruptured membranes or were in labour. Random midstream urine samples obtained as part of normal clinical care were divided into two aliquots to avoid leaching of test strip reagent into the sample, which could interfere with subsequent laboratory assays. The first aliquot underwent point-of-care testing for proteinuria by regular obstetric clinic and hospital staff (nurses and registered nursing assistants) who were familiar with the visual reading method; outpatient staff were specifically trained to use the automated strip reader Urisys 1100 using Chemstrip 10A strips (both Roche Diagnostics, Laval, QC). For visual dipstick proteinuria testing, the Multistix 10SG test strips (Siemens Healthcare Diagnostics, Inc., Tarrytown, NY) were used. These strips categorize proteinuria as negative, trace, 0.3 g/L, 1.0g/L, or 3.0 g/L, corresponding to negative, trace, 1+, 2+, and 3+, respectively; a positive test was considered to be  $\geq 0.3$  g/L ( $\geq 1+$ ). The Chemstrip 10A strips categorize proteinuria as negative, 0.25 g/L, 0.75 g/L, and 1.5 g/L, corresponding to negative/trace, 1+, 2+, and 3+, respectively; a positive test was considered to be  $\geq 0.25$  g/L ( $\geq 1+$ ). Clinicians were unaware of the automated urine test strip results.

The second aliquot of urine was sent to the hospital laboratory, where it was centrifuged at a speed of 1500 rpm for five minutes and then tested in batches. If testing did not occur right away, samples were refrigerated at 4°C, and tested within the time frame of stability for the assay (i.e., 3 days for protein and 5 days for creatinine). Automated analysis of urinary protein and creatinine (both on Vitros 5,1 FS or Vitros 5600, Ortho-Clinical Diagnostics, Rochester NY) was followed by calculation of the random PrCr.

We calculated sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood

**Table 1. Baseline characteristics of the 109 women providing a non-dilute sample and 51 women providing a dilute sample in the study cohort**

	Women who gave a non-dilute urine sample(s) n = 109	Women who gave a dilute urine sample(s) n = 51	P
<b>Maternal characteristics</b>			
Median maternal age, years (interquartile range)	34 (31 to 36)	35 (31 to 37)	0.261
Primiparous, n (%)	50 (45.9)	25 (49.0)	0.71
Multiple pregnancy, n (%)	3 (2.8)	2 (3.9)	0.654
<b>Pregnancy characteristics at the time of urine sampling</b>			
Outpatient, n (%)	88 (80.7)	43 (84.3)	0.584
Median gestational age when last urine sample taken, weeks (interquartile range)	27 (22 to 34)	23 (22 to 29.5)	0.041
On antihypertensive therapy, n (%)	23 (21.1)	9 (17.6)	0.611
Hypertensive disorder at sampling, n (%)	41 (37.6)	20 (39.2)	0.781
Pre-existing hypertension only, n (%)	17 (15.6)	8 (15.7)	—
Pre-existing hypertension with baseline proteinuria, n (%)	3 (2.8)	0	—
Gestational hypertension without dipstick proteinuria, n (%)	12 (11.0)	7 (13.7)	—
Preeclampsia (including HELLP syndrome), n (%)	9 (8.3)	5 (9.8)	—
Other medical comorbidities (one/more), n (%)	49 (45.0)	11 (21.6)	0.004
Two or more medical comorbidities, n (%)	18 (16.5)	3 (5.9)	0.079
Diabetes (pre-gestational or gestational), n (%)	14 (12.8)	2 (3.9)	0.095
Pre-existing renal disease, n (%)	8 (7.3)	0	0.056
Other,* n (%)	38 (34.9)	9 (17.6)	0.026
<b>Pregnancy outcome after urine sampling</b>			
Delivery at BCWH or postpartum follow-up, n (%)	82 (75.2)	30 (58.8)	0.035
Not known or lost to follow-up, n (%)	27 (24.8)	21 (41.2)	0.035
Miscarriage or elective termination, n (%)	4 (4.9)	0	0.307
Stillbirth, n (%)	1 (1.2)	0	0.999
Placental abruption or other APH, n (%)	2 (2.4)	1 (2.0)	0.999
Preterm pre-labour rupture of membranes, n (%)	3 (3.7)	1 (2.0)	0.999
Chorioamnionitis, n (%)	1 (1.2)	0	0.999
Median gestational age at delivery, weeks (interquartile range)	38 (37 to 39)	38 (37 to 39)	0.688
Delivery at < 37 weeks, n (%)	14 (17.1)	3 (5.9)	0.272
Small for gestational age infants, n (%)	14 (17.1)	5 (9.8)	0.58
Neonatal intensive care unit admission, n (%)	9 (11.0)	3 (5.9)	0.753

APH: antepartum hemorrhage; BCWH: British Columbia Women's Hospital and Health Centre; HELLP: hemolysis, elevated liver enzyme, low platelet syndrome

\*Other medical comorbidities included the following:

thyroid disorders (12)	multiple sclerosis (1)	polycythemia vera (1)	hepatitis B (1)
systemic lupus erythematosus (6)	immune thrombocytopenia (2)	polymyositis (1)	hyperaldosteronism (1)
another connective tissue disorder (3)	Raynaud's (1)	scleroderma (1)	asymptomatic bacteriuria (1)
depression (3)	diabetes insipidus (1)	Addison's disease (1)	and/or solitary kidney (1)
anemia (4)	hypercholesterolemia (1)	Crohn's disease (1)	
antiphospholipid antibody syndrome (3)	biliary colic (1)	celiac disease (1)	
polycystic ovarian syndrome (1)	deep vein thrombosis (1)	histiocytosis (1)	

ratios (LR+ and LR–, respectively), with 95% confidence intervals, for visual and automated test strip proteinuria testing to detect a random PrCr  $\geq 30$  mg/mmol, as well as for the lowest (17mg/mmol) and highest (57 mg/mmol) reported cut-offs for random urine PrCr that correspond to a 24-hour urinary protein of 0.3 g/d.<sup>3</sup> All of these measures are independent of disease prevalence. LR+ and LR– results were interpreted as excellent ( $> 10$  or  $< 0.10$ , respectively), good (5.1 to 10 or 0.1 to 0.19, respectively), or fair-poor (2.1 to 5.0 or 0.2 to 0.5, respectively) according to accepted standards.<sup>11</sup> The proportion of false negatives and false positives for each of the visual and automated reading methods was compared using the non-parametric McNemar's test, with a  $P$  value  $< 0.05$  considered to be statistically significant. The Pearson chi-squared test, Fisher exact test, and Mann-Whitney  $U$  test were used to calculate  $P$  values where appropriate. The sample size was chosen by convenience, and the study included all consecutive women seen in the clinic ( $N = 160$ ). The final study sample ( $N = 109$ ) had greater than 80% power to detect a 20% difference in sensitivity between visual and automated strip testing, a difference compatible with the published literature (two-sided alpha, error 0.05; sensitivity of visual method assumed to be 55%).<sup>5,7</sup>

This study was part of a large quality improvement project of proteinuria assessment in our tertiary maternity hospital.<sup>12,13</sup> We included only women who provided non-dilute urine samples with urinary creatinine concentration  $\geq 3$  mmol/L in our primary analysis. We did this because we observed falsely elevated urinary PrCr results on dilute urine samples related to our laboratory's proteinuria method, an issue covered in a separate publication.<sup>13</sup> We chose urinary creatinine concentration as the method to identify dilute urine because the urine test strip specific gravity is a less reliable measure of urinary dilution.<sup>14</sup> In addition, we performed a sensitivity analysis using only the last sample for each woman.

This study was approved by the University of British Columbia Clinical Research Ethics Board.

## RESULTS

Of the 160 women who provided 233 samples at our hospital over the study period, we included 109 women who provided 163 non-dilute samples at one or more antenatal visits. Seventy-three women (67.0%) provided only one sample.

The baseline characteristics of this study cohort of the 109 women who provided a non-dilute random sample when attending the clinic and the 51 women whose

samples were excluded because they were dilute are shown in Table 1. Among those who provided a non-dilute sample, most had singleton pregnancies, were evaluated as outpatients in the second trimester, and were not on antihypertensive therapy at the time of urine sampling. Almost all of the outpatient clinics were run in the morning. One third had a hypertensive disorder of pregnancy, most commonly pre-existing hypertension. Compared with those who provided dilute samples, women who provided non-dilute samples were at higher risk, in that they had more medical comorbidities (other than a hypertensive disorder of pregnancy,  $P = 0.004$ ), and delivered at our tertiary perinatal unit ( $P = 0.035$ ). Although the results did not reach statistical significance, women who provided non-dilute samples may also have delivered earlier (and preterm) and had small for gestational age babies.

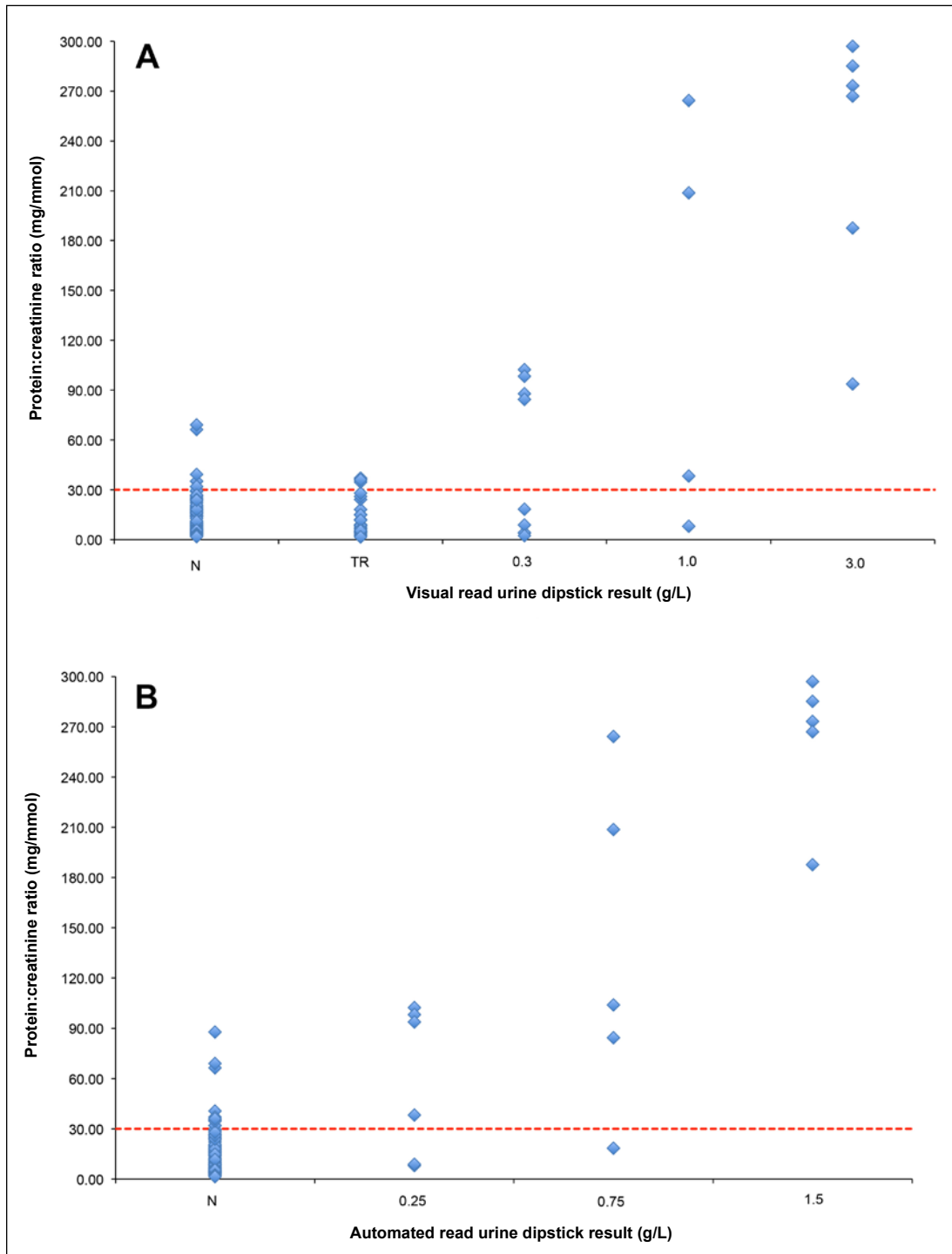
Of the 163 non-dilute samples from 109 women, 159 (97.5%) were evaluated for dipstick proteinuria by visual reading, and all were evaluated for proteinuria by automated reading.

The individual readings for visual and automated urine test strip methods according to the random urine PrCr result from the same (split) urine sample are shown in the Figure (A and B, respectively). Urine test strip proteinuria of  $\geq 1+$  was seen in 20 visually read samples (12.7%) and 17 samples by automated reading (10.4%).

The diagnostic test properties of each urine test strip assessment method are shown in Table 2. The false-positive and false-negative rates for automated test strip methods (2.2% and 43.8%, respectively) and visually read test strip methods (4.4% and 40.0%, respectively) were not significantly different ( $P = 0.999$  for sensitivity and  $P = 0.248$  for specificity). Using a random PrCr cut-off of 30 mg/mmol, the LR– point estimates for each of the visual and automated dipstick methods were “fair-poor” (i.e., 0.2 to 0.5). The LR+ point estimates for visual and automated testing were “excellent,” but the 95% confidence intervals overlapped almost entirely. The LR+ was still “excellent” for both visual and automated testing when a random PrCr cut-off of 57 mg/mmol was used, but the 95% confidence intervals again overlapped substantially.

The diagnostic test properties of visual and automated dipstick testing were similar when only the last sample for each woman was used in the analysis (Table 3). The LR– point estimates were “fair to good” and the LR+ “excellent” for both visual and automated testing, particularly for detection of a random PrCr of  $\geq 57$  mg/mmol.

Results of dipstick testing according to random urinary protein to creatinine ratios (PrCr, mg/mmol). A. Visually read urinary dipstick testing according to random urine PrCr result. B. Automated urinary dipstick testing (g/L) according to random urine PrCr result. The horizontal dotted line represents a PrCr of 30 mg/mmol, the current cut-off for detection of 0.3 g/d proteinuria.



N: negative; TR: trace

**Table 2. Diagnostic test properties of the visual and automated read urinary dipstick testing methods for detection of a random urinary PrCr of 30 mg/mmol (range 17 mg/mmol to 57 mg/mmol) using all non-dilute urine samples**

	Random urinary PrCr ≥ 30 mg/mmol (95% CI)	Random urinary PrCr ≥ 17 mg/mmol (95% CI)	Random urinary PrCr ≥ 57 mg/mmol (95% CI)
Visual read urinary dipstick (n = 159 samples)			
Sensitivity, %	56.0 (37.1 to 73.3)	26.9 (16.8 to 40.3)	86.7 (62.1 to 96.3)
Specificity, %	96.3 (91.6 to 98.4)	95.3 (89.5 to 98.0)	95.8 (91.2 to 98.1)
PPV, %	73.7 (48.6 to 89.9)	73.7 (48.6 to 89.9)	68.4 (43.5 to 86.4)
NPV, %	92.1 (86.0 to 95.8)	72.9 (64.6 to 79.9)	98.6 (94.4 to 99.8)
LR+	15.0 (5.9 to 37.9)	5.8 (2.2 to 15.1)	20.8 (9.3 to 46.7)
LR-	0.46 (0.29 to 0.71)	0.77 (0.65 to 0.91)	0.14 (0.04 to 0.51)
Automated read urinary dipstick (n = 163 samples)			
Sensitivity, %	53.9 (35.3 to 71.2)	25.9 (16.1 to 38.9)	81.3 (57.0 to 93.4)
Specificity, %	97.8 (93.8 to 99.3)	97.3 (92.2 to 99.1)	98.0 (94.2 to 99.3)
PPV, %	82.4 (55.8 to 95.3)	82.4 (55.8 to 95.3)	81.3 (53.7 to 95.0)
NPV, %	91.8 (85.8 to 95.5)	72.6 (64.5 to 79.5)	98.0 (93.7 to 99.5)
LR+	24.6 (7.6 to 79.6)	9.4 (2.8 to 31.4)	39.8 (12.7 to 125.0)
LR-	0.47 (0.31 to 0.72)	0.76 (0.65 to 0.90)	0.19 (0.07 to 0.53)

PPV: positive predictive value; NPV: negative predictive value; LR-: negative likelihood ratio; LR+ : positive likelihood ratio.

**Table 3. Diagnostic test properties of the visual and automated read urinary dipstick testing methods for detection of a random urinary PrCr of 30 mg/mmol (range 17 mg/mmol to 57 mg/mmol)**

Last urine sample from each woman	Random urinary PrCr ≥ 30 mg/mmol (95% CI)	Random urinary PrCr ≥ 17 mg/mmol (95% CI)	Random urinary PrCr ≥ 57 mg/mmol (95% CI)
Visual reading of urinary dipstick (n = 105 samples)			
Sensitivity, %	60.0 (35.8 to 80.2)	28.1 (15.6 to 45.4)	90.0 (59.6 to 98.2)
Specificity, %	95.6 (89.1 to 98.3)	94.5 (86.7 to 97.9)	95.8 (89.7 to 98.4)
PPV, %	69.2 (38.9 to 89.6)	69.2 (38.9 to 89.6)	69.2 (38.9 to 89.6)
NPV, %	93.5 (85.8 to 97.3)	75.0 (64.7 to 83.2)	98.9 (93.2 to 99.9)
LR+	13.5 (4.8 to 38.3)	5.1 (1.7 to 15.5)	21.4 (8.0 to 57.0)
LR-	0.42 (0.23 to 0.78)	0.76 (0.61 to 0.95)	0.10 (0.02 to 0.67)
Automated reading of urinary dipstick (n = 109 samples)			
Sensitivity, %	56.3 (33.2 to 76.9)	26.5 (14.6 to 43.1)	81.8 (52.3 to 94.9)
Specificity, %	97.9 (92.5 to 99.4)	97.3 (90.8 to 99.3)	98.0 (92.9 to 99.4)
PPV, %	81.8 (47.8 to 96.8)	81.8 (47.8 to 96.8)	81.8 (47.8 to 96.8)
NPV, %	92.9 (85.3 to 96.8)	74.5 (64.5 to 82.5)	98.0 (92.1 to 99.6)
LR+	26.2 (6.2 to 110.1)	9.9 (2.3 to 43.5)	40.1 (9.9 to 162.5)
LR-	0.45 (0.26 to 0.78)	0.76 (0.62 to 0.93)	0.19 (0.05 to 0.65)

PPV: positive predictive value; NPV: negative predictive value; LR-: negative likelihood ratio; LR+: positive likelihood ratio

## DISCUSSION

Proteinuria assessment by urinary test strip is an important part of the standard antenatal care of women with low-risk and high-risk pregnancies. In a cohort of pregnant women assessed primarily in an outpatient setting, we found that both visual reading and automated reading of test strips for proteinuria assessment had poor sensitivity (56.0% and 53.9%, respectively) for the detection of significant proteinuria, indicated by a urinary PrCr of  $\geq 30$  mg/mmol. The LR+ was “excellent” but the LR– was only “fair to poor.”

The sensitivity for detection of proteinuria on random urine samples using a visual reading method (56.0%) was consistent with published values for visual reading tests (55%),<sup>5</sup> but still at the low end of the reported range for automated testing (53.9% vs. 41% to 100%, respectively).<sup>6–9</sup> Our specificities were high for both visually read (95.3%) and automated dipstick (97.3%) testing compared with published values (84% for visual and 37% to 100% for automated testing).<sup>5–9</sup>

We are aware of two studies that directly compared the diagnostic test properties of visual dipstick testing with automated testing.<sup>7,8</sup> For the comparator with test strips, Waugh et al. used 24-hour urinary protein excretion (g/d),<sup>7</sup> but Saudan et al. used 24-hour urinary protein concentration (g/L),<sup>8</sup> which is not an accepted standard. Waugh et al. recruited only outpatients presenting with de novo hypertension, but we enrolled a more diverse group of high-risk inpatient and outpatient pregnant women, and examined the ability of urinary test strip methods to detect a urinary PrCr of  $\geq 30$  mg/mmol (as used by Phelan et al. for automated dipstick<sup>15</sup>), an approach that mirrors NICE guidelines when a urinary dipstick test of  $\geq 1+$  proteinuria is detected.<sup>10</sup>

A strength of our study is that we assessed a broad spectrum of high-risk patients with and without significant proteinuria (diagnosed by a random urinary PrCr of  $\geq 30$  mg/mmol), consistent with published recommendations.<sup>10</sup> A second strength is that urinary dipstick testing was performed by experienced observers who work full-time in a high volume maternity clinic; laboratory staff provided these individuals with specific training on the use and maintenance of the automated test strip reader, consistent with good practice for point of care testing. Third, we assessed the relationship between urinary test strip results of  $\geq 1+$  proteinuria and the limits of the reported range over which a random urinary PrCr has been associated with 0.3g/d of proteinuria by 24-hour urine collection (i.e., 17 to 57 mg/mmol). Finally, our sample size was able to rule out all but a small difference in diagnostic test properties for the visual and automated

dipstick testing methods specified; if the very small differences in LR+ were significant, a study population of 6000 women would be required to assess differences.

A limitation of our study is that we recruited women with a low prevalence of proteinuria (12.7% by visual and 10.4% by automated dipstick testing), so we cannot rule out the possibility that inter-observer reliability may be lower (making automated testing more advantageous) at higher urinary protein concentrations.<sup>16</sup> However, a low prevalence of proteinuria is the reality of outpatient obstetric care, even in a tertiary perinatal unit such as ours which serves a high-risk population. A second limitation is that we excluded 51 women who provided 70 dilute urine samples, so our analysis of visual and automated dipstick testing was performed on 68.1% of women who provided 70.0% of the urine samples. Although we cannot exclude the possibility that automated urinary dipstick testing may perform better on dilute urine samples, there is no reason to believe that this would be the case; our choice to restrict analysis to non-dilute samples was based purely on our knowledge that our laboratory urinary protein concentrations were falsely elevated for dilute samples.<sup>13</sup>

Our results apply only to the test strips and the analyzer used in our study. We used the Urisys 1100 analyzer because we were able to adjust (and maximize) sensitivity; as a result, we had to use the Chemstrip 10A strips and could not use the Multistix 10SG strips (the strips used for visual analysis in the clinic) because these must be analyzed using the Clinitek automated reader (Siemens Healthcare Diagnostics, Inc., Tarrytown, NY) which does not have adjustable parameters.<sup>7,8</sup> It is possible, therefore, that sensitivity with the automated urinary dipstick analysis could have been higher if we had used the Multistix 10SG strips; this was the case when use of Multistix 10SG strips was compared with Chemstrip 10A strips on older automated laboratory strip readers.<sup>17</sup>

## CONCLUSION

We found that the use of an automated urine dipstick reader (Chemstrip 10A on the Urisys 1100 analyzer) did not provide more reliable results than visually read urine dipsticks (Multistix 10SG) in screening for proteinuria in random, non-diluted urine samples from a population of largely outpatient pregnant women screened by clinic staff. These results do not justify the purchase of this automated analyzer, or the time required for maintenance and daily quality control. It is possible, however, that the performance of automated test strip analysis may vary according to the test strips and analyzer used.

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