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Diagnostic accuracy of urine protein–creatinine ratio dipstick test in the diagnosis of preeclampsia

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Abstract:

INTRODUCTION: Hypertension disorders in pregnancy cause significant number of maternal morbidity and mortality. In local statistics for the years 2019–2022, hypertension causes 13.8% of the maternal mortality. Thus, accurate diagnosis of Preeclampsia is crucial to prevent disease progression and to provide timely intervention for improved maternal outcomes. It is widely accepted that 24-h urine protein is the gold standard for detecting proteinuria in patients with preeclampsia, but since the process of collection is too long and complicated, recent studies focus on other less complex yet reliable methods of determining proteinuria for the diagnosis of preeclampsia, including the protein–creatinine ratio (PrCr) dipstick tests.

GENERAL OBJECTIVE: This study aims to determine the diagnostic accuracy of urine protein detection in patients with preeclampsia, using a urine PrCr dipstick test.

MATERIALS AND METHODS: A prospective, cross-sectional study using purposive sampling was used in this study. A total of 153 admitted pregnant patients with gestational hypertension and preeclampsia, without other comorbidities or significant past medical history, were tested for proteinuria using the 24-h urine protein test and urine PrCr dipstick test. Statistical analysis to assess diagnostic accuracy used was the sensitivity, specificity, positive predictive value, and negative predictive value.

CONCLUSIONS: The urine PrCr dipstick test has comparable diagnostic accuracy with 24-h urine protein test in detecting proteinuria, with a sensitivity of 88%, a specificity of 64%, and a high positive predictive value of 94%. It is a simpler, faster, yet useful alternative to a more tedious, time and resource consuming process of urine collection in the 24-h urine protein in identifying patients with proteinuria, and therefore, preeclampsia.

Keywords:

Preeclampsia, proteinuria, twenty four hour urine protein, urine protein–creatinine ratio dipstick test

Introduction

Hypertension disorders in pregnancy cause significant number of maternal morbidity and mortality. In the United States, data from the Centers for Disease Control and Prevention shows that these disorders have increased over the past 2 decades.[1] In local statistics for the years 2019–2022, hypertension, which is consistently been included in the top five causes of maternal death, causes 13.8% of the maternal mortality.[2] In the DOH Philippines health statistics for 2019, eclampsia, which is a disease progression of preeclampsia, is specifically mentioned as one of the top 3 causes of maternal mortality.[3] With these data, accurate diagnosis of preeclampsia is crucial to prevent disease progression and to provide timely intervention for improved maternal outcomes.

Preeclampsia, one of the four types of hypertension in pregnancy, refers to the

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hypertension of new-onset and proteinuria, or the new onset of hypertension and significant end-organ dysfunction, with or without proteinuria, typically developing after 20 weeks of gestation in a previously normotensive woman.[4] Diagnosis of preeclampsia thru the detection of proteinuria remains an important diagnostic criterion that reflects the system-wide endothelial leak that characterizes the preeclampsia syndrome.[5]

As published from the latest Practice Guidelines from ACOG, proteinuria during pregnancy is defined as 300 mg/dL of protein or more in a 24-h urine collection or a protein/creatinine ratio (PrCr) of 0.3 mg/dL, or the presence of protein in urine protein dipstick reading.[6] It is widely accepted that 24-h urine protein is the gold standard for detecting proteinuria in patients with preeclampsia, but since the process of collection is too long and complicated, recent studies focus on other less complex yet reliable methods of determining proteinuria for the diagnosis of preeclampsia, including the PrCr dipstick tests.

Some of the urine PrCr dipstick tests that were used in studies were PRO, LAD Pr/Cr, Siemens Multistix, and urine protein–creatinine ratio dipstick test (Test-it PrCr).[7-9] In the study of Wang *et al*., they evaluated the application of a dipstick which detects urine protein and creatinine.[10] The study concluded that in comparison with the conventional dipsticks, the urine PrCr dipsticks can provide higher sensitivity and specificity of the protein test.

Objectives

This study aims to determine the diagnostic accuracy of urine protein detection in patients with preeclampsia, using Test-it PrCr.

The specific objectives are as follows:

1. To correlate urine protein detected in Test-It PrCr and 24-h Urine Protein using quantitative values
2. To calculate the sensitivity and specificity of Test-it PrCr using 24-h Urine Protein as the gold standard in the diagnosis of preeclampsia
3. To calculate the positive and negative predictive values of Test-it PrCr using 24-h Urine Protein as the gold standard in the diagnosis of preeclampsia.

Materials and Methods

Study design and participants

We conducted a prospective, cross-sectional study using purposive sampling. The study population included all pregnant patients with gestational hypertension and preeclampsia (blood pressure [BP] >140/90 mmHg on 2 occasions, 4 h apart, or >160/110 mmHg), ≥20 weeks age of gestation, with no other comorbidities, admitted at our institution. The study was reviewed and approved by the Research Ethics Committee of Tondo Medical Center. Patient confidentiality was maintained as stated in the obtained patient informed consent.

Sample size

At a confidence level of 95% and a margin of error of 5%, the sample size for the study was calculated using the formula designed by Krejcie and Morgan (1970):

$$s = \chi^2 NP\,(1–P) + d^2\,(N – 1)\,\chi^2\,P\,(1 – P)$$

Where:

s = sample size

χ^2 = Tabular value of Chi-square at 1° of freedom at a confidence interval set at 95%

n = population size

P = population proportion set at 0.50 to provide maximum sample size

d = margin of error at 5%

Last 2019 and 2020, there were 122 and 202 admitted patients, respectively, diagnosed with gestational hypertension (2019 = 55 and 2020 = 58) and preeclampsia (2019 = 67 and 2020 = 114). From this annual data, a population size of 200 was estimated for the year 2021, with monthly average admission of 17. The study was conducted for 9 months, with a calculated population of 153, and from this population, a sample size of 110 was derived from the formula designed by Krejcie and Morgan.

Inclusion criteria

All pregnant patients diagnosed with gestational hypertension and preeclampsia who were:

- Seen at the outpatient department that warrants admission
- Seen at the emergency room that warrants admission
- Already admitted.

Exclusion criteria

- Presence of other comorbidities other than hypertension (e.g., gestational diabetes mellitus, systemic lupus erythematosus, seizure disorder, cardiac pathology, and thyroid pathology)
- Chronic hypertension
- Eclampsia

- Previous cesarean section secondary to hypertensive disorder of pregnancy
- Renal pathology (Ex. urinary tract infection, glomerulonephritis, acute and chronic kidney disease).

Withdrawal criteria

Patients who did not complete the 24-h urine protein collection were withdrawn from the study.

Study procedure

The study was conducted in the obstetrics (OB) Ward of our institution. The 24-h urine protein is a routine diagnostic test for our hypertensive OB patients to detect proteinuria. The medical staff of the OB ward are knowledgeable on the proper collection of specimens for the 24-h urine protein test. The following study procedure was implemented.

Upon eligibility of the patients, informed consents for the research study were obtained by the OB-resident on duty.

All eligible patients were inserted with French 16 Foley catheter.

A urine sample prior to 24-h urine protein collection was collected in a urine specimen bottle.

The Test-It PrCr was carried out using Test-it PrCr test strips [Figure 1] that were donated by a private company [Appendix A].

The Test-it PrCr Kit was stored between +8°C and +28°C, which was good for 3 months of use once opened.

A test strip was briefly dipped, for 1 s, into the urine specimen so that both reagents were wet [Figure 2].

The test strip was removed and blotted on an absorbent paper to remove excess urine [Figure 3].

After exactly 60 s, the color on the test strip was compared with the color scale on the container of the Test-it PrCr Kit [Figure 4].

To narrow down possible bias, three, blinded individuals (either an OB Nurse, an OB Resident, or an OB Ward staff) were asked to compare the test strip with the color scale on the container. The majority of the result was accepted as the final result, and recorded.

The result was recorded as the presence or absence of proteinuria by plotting in the table where the protein and creatinine results meet [Figure 5].

Figure 1: Test-it protein-creatinine ratio dipstick test Strips

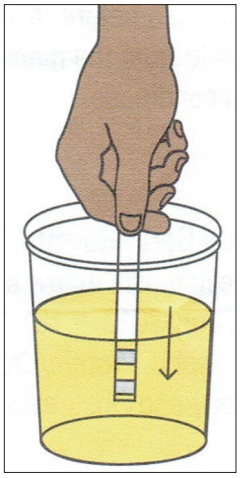

Figure 2: Dip the test strip into the urine specimen

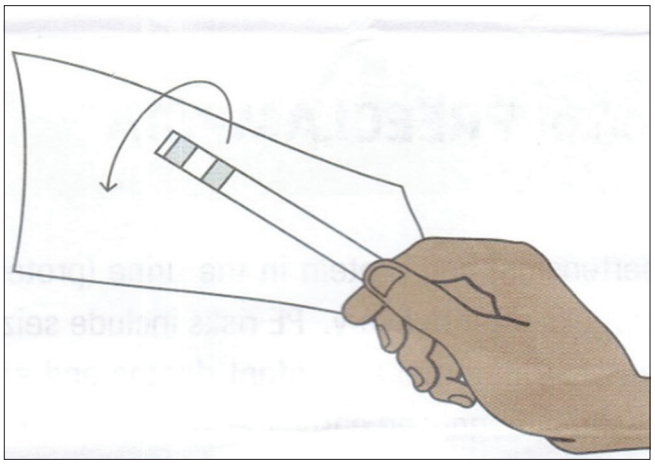

Figure 3: Remove excess urine using an absorbent paper

The materials used (dipstick strip, urine specimen) were disposed of properly.

The 24-h urine was collected by draining the urinary bag every 4 h or as needed if the urine bag

was almost full, and stored in a plastic container [Figure 6].

The plastic container was placed in an insulated cooler with ice for proper preservation of the specimen for 24 h until the end of collection [Figure 6].

After the collection, the 24-h urine was submitted to the laboratory for the 24-h urine protein test, and the materials used (insulated cooler, plastic container) were cleaned and stored properly.

This ended the participation of the patient in the study.

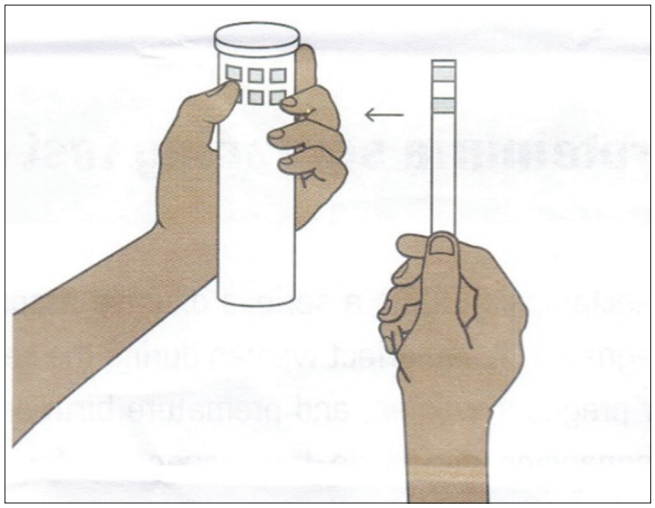

Figure 4: Compare the color with the color scale on the container

The laboratory staff sent the 24-h urine collected to Hi-Precision laboratory for detection of the protein content.

Result of the 24-h urine protein was recorded.

Proteinuria detection with the Test-It PrCr Kit was compared with the 24-h urine protein test.

Results were recorded and analyzed using the 2 × 2 table for sensitivity, specificity, and positive and negative predictive values.

Data collection

Data were recorded in a hardbound notebook and encoded in a Data Collection Form excel file [Appendix B]. Data of the patient included the hospital number, age, BP on admission, admitting diagnosis, and final diagnosis. The 24-h urine protein result and the proteinuria using the Test-it PrCr dipstick test were recorded. Patients' demographics were tabulated [Table 1].

Data analysis

Statistical analysis used was the sensitivity, specificity, positive predictive value and negative predictive value, which were the standard tests to be used for diagnostic accuracy of a test. They were computed using the 2 × 2 table with the urine protein–creatinine dipstick test as the test under investigation and the 24-h urine protein as the gold standard test [Figure 7].

A number of patients who tested positive and negative for proteinuria using the 24-h urine protein and urine

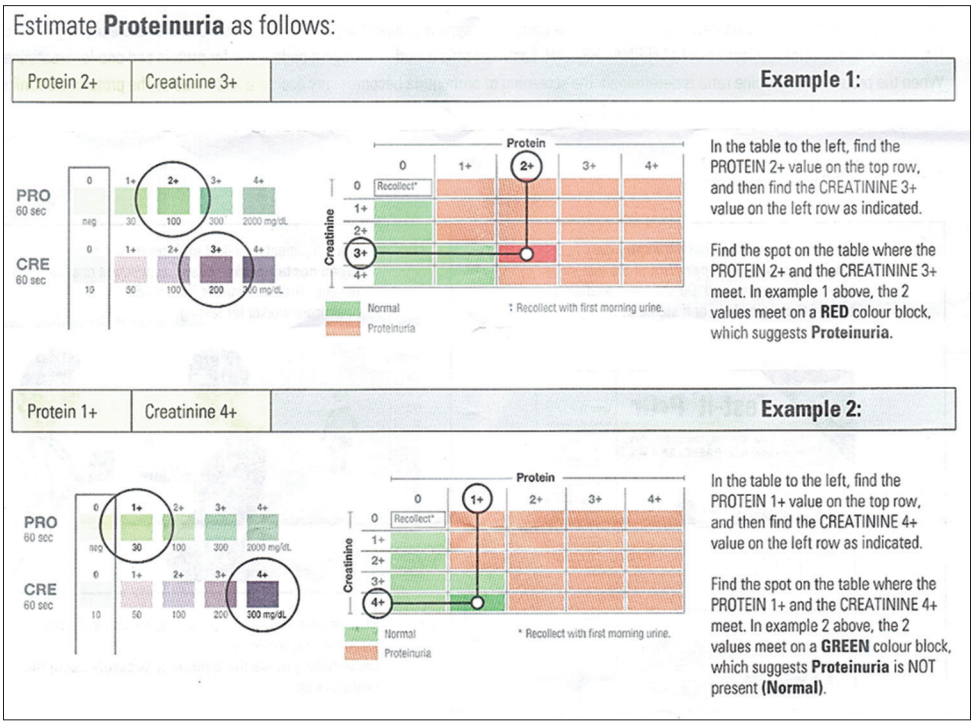

Figure 5: Interpretation of color change in the test strip

PrCr dipstick test were calculated [Table 2]. The presence of proteinuria based on the urine protein–creatinine dipstick Test and 24-h urine protein was also compared [Table 3]. Statistical analysis results are summarized in Table 4.

Results

In 9 months, the desired sample size of 110 pregnant women was enrolled and included in the study [Table 1].

Table 1: Demographics of patients

Variable	*n*=110, *n* (%)
Age (years)	
<20	8 (7.3)
20–30	57 (51.8)
31–35	19 (17.3)
>35	26 (23.6)
Gravidity	
Primigravid	39 (35.5)
Multigravid	71 (64.5)
Age of gestation (weeks)	
20–36 6/7	21 (19.1)
37–41 6/7	89 (80.9)
>42	0
BP upon admission (mmHg)	
<160/110	43 (39.1)
>160/110	67 (60.9)

BP: Blood pressure

Table 2: Number of patients who tested positive and negative for proteinuria using the 24-h urine protein and urine protein-creatinine ratio dipstick test (test-it protein-creatinine ratio)

24-h urine protein (mg/dL)	Number of patients
Positive proteinuria	96
Negative proteinuria	14
Total	110
Urine PrCr dipstick test (test-it PrCr)	**Number of patients**
Positive proteinuria	90
Negative proteinuria	20
Total	110

PrCr: Protein/creatinine ratio

Figure 6: Insulated cooler with plastic containers

No dropouts were recorded. The study population was composed of 8 patients aged <20 years old (7.3%), 57 aged 20–30 years old (51.8%), 19 aged 31–35 years old (17.3%), and 26 aged >35 years old (23.6%). The majority were multigravid (64.5%), at term age of gestation (80.9%), and with BP >160/110 mmHg (60.9%).

Table 2 shows the number of patients who tested positive and negative for proteinuria with the Test-It PrCr and the 24-h urine protein. The Test-It PrCr showed no proteinuria in nine patients who are truly negative by the gold standard and showed proteinuria in five patients who are truly negative by the gold standard, gaining a specificity of 64%. Among the 96 patients who are truly positive for proteinuria by the gold standard, Test-It PrCr showed no proteinuria in 11 patients, and showed proteinuria in 85 patients who are truly positive by the gold standard, gaining a sensitivity of 88%.

Table 3 summarizes the diagnostic accuracy of Test-It PrCr. With a sensitivity of 88% and a specificity of 64%, it also has a positive predictive value of 94% and a negative predictive value of 45%.

Discussion

The diagnostic accuracy of a test is determined using the following statistical tests: Sensitivity, specificity, positive predictive value, and negative predictive value. One test is not superior to the other but the correlation between these statistical tests of a certain diagnostic method is significant to determine its accuracy.

A test with high sensitivity will not miss a number of patients who have the disease, while a test with high specificity will infrequently identify patients as having a disease when they do not. In this study, the urine PrCr dipstick test demonstrated 88% sensitivity for the detection of significant proteinuria, as defined by a 24-h urine protein test. The sensitivity was high enough to determine proteinuria in patients who really had proteinuria and were diagnosed with preeclampsia. However, the observed specificity of 64% indicates a significant rate of false positive classifications.

There were 11 out of 20 patients (55%) who were falsely negative for proteinuria while 9 patients (45%) tested as

Urine Protein-Creatinine Ratio Dipstick Test (Test-it PrCr)	Protenuria using 24-hour urine protein (gold standard)	
	Positive	Negative
Positive	a	b
Negative	c	d

$$\text{Sensitivity} = \frac{a}{a+c} \times 100 \qquad \text{Positive Predictive Value} = \frac{a}{a+b} \times 100$$

$$\text{Specificity} = \frac{d}{b+d} \times 100 \qquad \text{Negative Predictive Value} = \frac{d}{c+d} \times 100$$

Figure 7: Formula for sensitivity, specificity, positive and negative predictive values

Table 3: Proteinuria

Urine PrCr dipstick test (test-it PrCr)	24-h urine protein (mg/dL)	
	≥300	<300
Positive proteinuria	85 (true positive)	5 (false positive)
Negative proteinuria	11 (false negative)	9 (true negative)
Total	96	14

True positive, true negative, false positive, and false negative. PrCr: Protein/creatinine ratio

Table 4: Diagnostic accuracy of urine protein-creatinine ratio dipstick test (test-it protein-creatinine ratio) in comparison with the 24-h urine protein

	Urine PrCr dipstick (test-it PrCr)
Sensitivity	88%
Specificity	64%
Positive predictive value	94%
Negative predictive value	45%

PrCr: Protein/creatinine ratio

true negative. This statistically determined the negative predictive value of the urine PrCr dipstick test. The result can be interpreted that the urine PrCr dipstick test had 45% of detecting the absence of proteinuria in patients without proteinuria, and therefore not diagnosed with preeclampsia but only gestational hypertension. In a total of 90 patients who had positive proteinuria in urine PrCr dipstick test, 85 of them, or 94%, were true positives, and only 5 of them, or 6%, were false positives. Therefore, the urine PrCr dipstick test has a positive predictive value of 94%, which determined proteinuria in hypertensive pregnant patients who really had proteinuria and therefore were diagnosed to have preeclampsia. One possible reason for false-positive or false-negative results is due to maternal hydration status, which may influence the presence of proteinuria in urine dipstick test. Dehydration may lead to a trace of protein being reported as significant, whereas overhydration can result in missed detection of proteinuria.[8] The alkalinity of urine and the presence of infections may also alter the urine dipstick test result for proteinuria.[8]

The occurrence of false positive results may lead to the administration of unnecessary interventions, with risks of medical side effects and financial implications. While in cases of false negative results, the clinical suspicion of preeclampsia may necessitate further evaluation with a 24-h urine protein assessment, thereby imposing additional burden and expense on the patient. However, the determination of the urine PrCr in a spot urine sample offers a viable alternative to the traditional 24-h urine protein measurement for the assessment of significant proteinuria, as demonstrated by the statistical analysis results of this study. This approach offers a more convenient and efficient approach, and advantages in terms of patient convenience and expedited clinical decision-making.

Conclusions

The urine PrCr dipstick test is sensitive to patients with proteinuria but not specific to those patients. However, the urine PrCr test exhibits a high positive predictive value of 94% for the detection of significant proteinuria, thereby increases its likelihood of determining proteinuria in patients to be diagnosed with preeclampsia. Conversely, the low negative predictive value of 45% underscores the limitation of using a negative test result as the sole criterion for excluding preeclampsia. Although it may still not be as accurate as the 24-h urine protein collection in determining proteinuria, the results were comparable. The urine PrCr dipstick test is a good alternative in determining proteinuria, especially in institutions and patients that are not suitable to undergo the tedious and time-consuming collection of 24-h urine. In this study, the urine PrCr dipstick test was concluded to be a fast, easy, accurate and reliable test in determining proteinuria in hypertensive pregnant patients to be diagnosed to have preeclampsia.

Authorship contributions

Katrina T. Alimot, MD - Involved in the conceptualization, methodology, formal analysis, resources, data curation, writing of the original draft, review and editing, and visualization.

Michelle D. Garcia, MD - Involved in the formal analysis, data curation, writing of the original draft, review and editing, and visualization.

Catherine Joie Carelle R. Ong, MD - Involved in conceptualization, methodology, review and editing of the draft, visualization, supervision, and funding acquisition.

Financial support and sponsorship

The materials used for 24-h urine protein collection (insulated cooler, plastic bottles) were provided by the primary investigator to the eligible patients. The hospital administration paid for the 24-h urine protein of patients who did not meet the requirements for the No-Balance-Billing of the PhilHeath. The Test-it PrCr dipstick strips were provided for free.

Conflicts of interest

There are no conflicts of interest.

Data availability statement

The data that support the findings of this study are available on request from the corresponding author, KA.

References

1. Centers for Disease Control and Prevention. Data on Selected Pregnancy Complications in the United States; 2018. Available from: https://www.cdc.gov/reproductivehealth/

maternalinfanthealth/pregnancy-complications-data.htm. [Last accessed on 2021 Nov 02].
2. Eclarin PP, Irabon IS, Habana MA, Añonuevo AU, Capitulo RB, del Prado JC, *et al*. Maternal and perinatal health indicators from 2019 to 2022: Data from the POGS Nationwide Statistics System. Philipp J Obstet Gynecol 2024;48:1-9.
3. DOH Epidemiology Bureau. The 2019 Philippine Health Statistics. Available from: https://doh.gov.ph/sites/default/files/publications/2019PHS_Final_092121.pdf. [Last accessed on 2021 Nov 02].
4. August P, Baha S. Hypertensive Disorders in Pregnancy: Approach to Differential Diagnosis. Available from: https://www.uptodate.com/contents/hypertensive-disorders-in-pregnancy-approach-to-differential-diagnosis. [Last accessed on 2021 May 01].
5. Cunningham F, Leveno KJ, Bloom SL, Dashe JS, Hoffman BL, Casey BM, *et al*. Williams Obstetrics and Gynecology. 25th ed. USA: McGraw Hill Companies; 2018.
6. Gestational hypertension and preeclampsia. ACOG Practice Bulletin No. 222. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;135:e237–60.
7. Morris RK, Riley RD, Doug M, Deeks JJ, Kilby MD. Diagnostic accuracy of spot urinary protein and albumin to creatinine ratios for detection of significant proteinuria or adverse pregnancy outcome in patients with suspected pre-eclampsia: Systematic review and meta-analysis. BMJ 2012;345:e4342.
8. Stefańska K, Zieliński M, Zamkowska D, Adamski P, Jassem-Bobowicz J, Piekarska K, *et al.* Comparisons of dipstick test, urine protein-to-creatine ratio, and total protein measurement for the diagnosis of preeclampsia. Int J Environ Res Public Health 2020;17:4195.
9. Baba Y, Yamada T, Obata-Yasuoka M, Yasuda S, Ohno Y, Kawabata K, *et al.* Urinary protein-to-creatinine ratio in pregnant women after dipstick testing: Prospective observational study. BMC Pregnancy Childbirth 2015;15:331.
10. Wang JM, Lin CY, Tsai FA, Chen JY, Koa YC. Test dipstick for determination of urinary protein, creatinine and protein/creatinine ratio. J Biomed Lab Sci 2009;21. Available from: https://www.labmed.org.tw/upfiles/issues/200982017204. pdf. [Last accessed on 2025 Apr 03].

Appendixes

Appendix A: Test-it PrCr Kit

Manufactured for LIFESADX (PTY) LTB by Lifeassay Diagnostics (Pty) Ltd, Cape Town, RSA. Expiration date: 09/2021. LOT. PRCR05.

Appendix B: Data collection form

Patient						Test-it PrCr strip result (PrCr)					24-h urine protein result (mg/24 h)
Number	Hospital number	Age	Admitting diagnosis	Final diagnosis	BP upon admission	Observer 1	Observer 2	Observer 3	Final result (PrCr) (w/or w/o proteinuria)	Quantitave result (Pr)	

PrCr: Protein/creatinine ratio