

Peer Review File

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Reviewer A

1. First, the title needs to indicate the consistency for BLD, LEU, PRO, and GLU between UA-5600 and other standard tests. The title also needs indicate the focus of the development and validation of the diagnostic model based on machine learning.

We appreciate the reviewer's suggestions. We have therefore revised the title of the article and the new title is "UA-5600 has good agreement between the main test parameters and the corresponding gold standard test results and constructs a machine learning model for suggesting renal diseases through the test results of 11 test strips".

2. Second, the abstract needs some revisions. The background needs indicate the clinical needs for this diagnostic model and why there is a need to test the accuracy of UA-5600 for BLD, LEU, PRO, and GLU. In the methods, the authors need to describe how the kidney diseases were diagnosed and how the diagnostic model was developed and validated. In the results, please briefly describe the clinical sample used and the main clinical characteristics.

Thank you for your suggestion, we have made changes in the abstract section, the clinical needs for this diagnostic model added to the background section (Page 2, line 19~21). And added the reason why there is a need to test the accuracy of UA-5600 for BLD, LEU, PRO, and GLU (Page 2, line 21 and 23). Add to the methodology how to diagnose kidney disease (Page 3, line 4~5). Because of the code involved in the development of the model it is not reflected in the methodology, but the relevant elements of the validation model have been added. (Page 3, line 6~7). Added the clinical sample used and the main clinical characteristics in the results section (Page 3, line 10~14).

3. Third, in the introduction of the main text, the authors need to analyze the knowledge gap on the performance of UA-5600 and explain the clinical needs for testing its accuracy. The urine dry chemistry parameters are used for the diagnoses of kidney diseases, so the authors need to explain why there is a need to develop the diagnostic model based on these parameters.

As the reviewer's suggestion. We add the knowledge gap on the performance of UA-5600 and explain the clinical needs for testing its accuracy in the introduction,

see Page 4, line 16~21. And explain why there is a need to develop the diagnostic model based on these parameters (Page 4, line 30~Page 5, line 1~3).

4. Fourth, in the methodology of the main text, please describe the clinical research design and sample size estimation of this study. The authors need to analyze the accuracy of UA-5600 for testing BLD, LEU, PRO, and GLU in older patients separately. The authors need to describe the threshold AUC values for a good diagnostic test, including sensitivity and specificity.

Thank you for your suggestion, because this is a retrospective study it does not involve the clinical research design and sample size estimation. Because patients aged 70 years or older were already included in the sample analysed for accuracy, data for this group of older patients are not presented separately. Increase the threshold AUC values for a good diagnostic test (Page 13, line 30~ Page 14, line 1~4).

5. Finally, please consider to cite several related papers: 1. Bai L, Xu Q, Wu Z. Performance analysis of urine formed element analyzer EH-2090 was found to have good accuracy in detecting RBCs and WBCs when compared to manual microscopic. *Transl Androl Urol* 2024;13(2):218-229. doi: 10.21037/tau-23-626. 2. Xie R, Li X, Li G, Fu R. Diagnostic value of different urine tests for urinary tract infection: a systematic review and meta-analysis. *Transl Androl Urol* 2022;11(3):325-335. doi: 10.21037/tau-22-65.

Thank you for your suggestion, we choose the article “Performance analysis of urine formed element analyzer EH-2090 was found to have good accuracy in detecting RBCs and WBCs when compared to manual microscopic.” for citation, see Page 11, line 28~30.

Reviewer B

1. Please check the timeframe.

29 **Methods:** Urine samples from outpatients and inpatients at the First Affiliated Hospital of Sun
30 Yat-Sen University were collected from August to September 2022 to evaluate the performance
31 of the Mindray UA-5600 dry chemistry analyzer and test strips. The evaluation of the UA-5600
17 outpatient, inpatient, and physical examination patients from the First Affiliated Hospital of
18 Sun Yat-Sen University from August to September 2022 were randomly collected for
16 (Figure 1). Hospital data spanning the period from August 2022 to October 2022 were obtained.

17 Ethical approval for this study was obtained from the Medical Ethics Committee of the First

Confirmation has been made that data collected in August to September 2022 was for the dry chemical performance validation portion of the data, while August to October 2022 was for ML model construction.

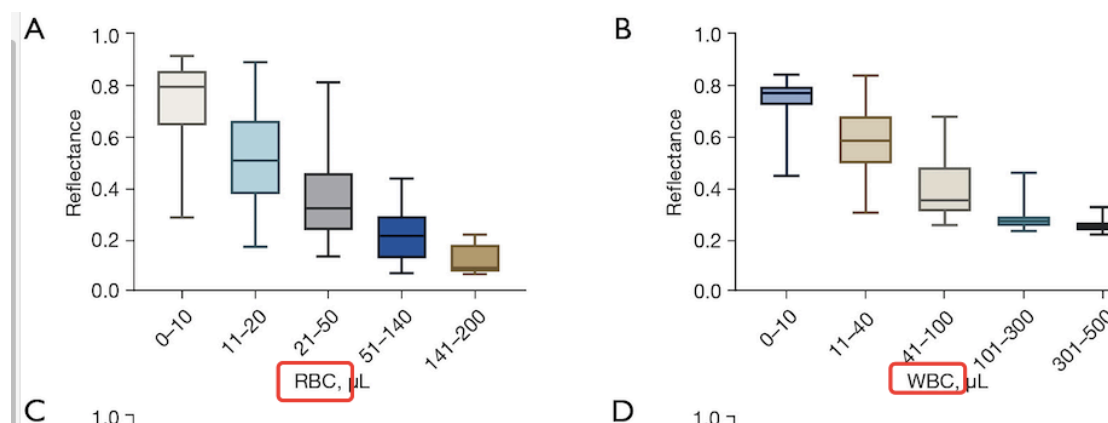
2. Figure 2

a. A summarized legend for a figure with different parts should be provided, followed by legends for each part.

Relevant content has been added.

b. Please check whether the figure legends (A, B) match the figures A, B. Please also check the main text.

- 2 **Figure 2** UA-5600 performance evaluation (A) box-plot results for the BLD parameters. (B)
- 3 Box-plot results for the LEU parameters. (C) Box-plot results for the PRO parameters. (D) Box-

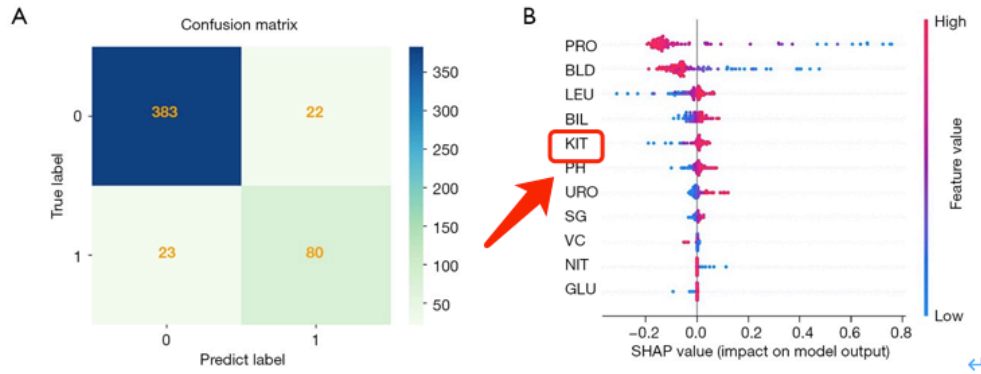


- 1 The box-plot results are shown in **Figure 2**. The semi-quantitative test results for BLD and LEU
- 2 obtained using the UA-5600 and the quantitative test results for urine sediment obtained using
- 3 the EH-2090 were well correlated (**Figure 2A,2B**). As the RBC and WBC content increased,

The box plot in Figure 2 reflects the relationship between the BLD parameters and the gold standard (RBC), so the horizontal coordinate in the plot is the concentration of RBC, and the same principle is true for LEU.

3. Figure 4 and Table 4

Please check if “KIT” should be “KET”.



4
 5 **Figure 4** NB model confusion matrix and SHAP model. LEU, leukocyte; URO, urobilinogen;
 6 PRO, protein; BIL, bilirubin; GLU, glucose; VC, Vitamin C; SG, Specific Gravity; **KET**, ketone

Changes have been made to the image.

Table S4 Carry-over contamination rate

	BLD		LEU		GLU		PRO		URO		BIL		KIT		VC	
	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
le1	3+	-	3+	-	4+	-	3+	-	3+	-	3+	-	/	/	3+	-
le2	3+	-	3+	-	/	/	3+	-	3+	-	/	/	/	/	3+	-
le3	3+	-	3+	-	/	/	3+	-	3+	-	/	/	/	/	3+	-

LEU, leukocyte; URO, urobilinogen; PRO, protein; BIL, bilirubin; GLU, glucose; VC, Vitamin

C; SG, Specific Gravity; **KET**, ketone bodies; NIT, nitrite; PH, pH; BLD, blood.

Changes have been made to the table.

4. **Table 1, Table 2 and Table S4**

Please add a table header.

1 **Table 1 Distribu**

+	
↔	P
UA-5600 BLD↔↔	↔
Positive↔	1:
Negative↔	2:
Total↔	2:
UA-5600 LEU↔↔	↔
Positive↔	2:
Negative↔	2:
Total↔	2:

Table 2 Diagnosti

+	
↔	BI
Positive consistency rate↔	89.
Negative consistency rate↔	73.

Additional information: BI

↔	
	BI
	Hi
Sample1↔	3+
Sample2↔	3+
Sample3↔	3+

Table header has been added.

5. *No “SG, PH” in table S4, but they were explained in the table footnote. Please revise.*

Table S4 Carry-over contamination rate

	BLD		LEU		GLU		PRO		URO		BIL		KIT		VC		NIT	
	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
Sample1	3+	-	3+	-	4+	-	3+	-	3+	-	3+	-	/	/	3+	-	/	/
Sample2	3+	-	3+	-	/	/	3+	-	3+	-	/	/	/	/	3+	-	/	/
Sample3	3+	-	3+	-	/	/	3+	-	3+	-	/	/	/	/	3+	-	/	/

U, leukocyte; URO, urobilinogen; PRO, protein; BIL, bilirubin; GLU, glucose; VC, Vitamin C; SG, Specific Gravity; KET, ketone bodies; NIT, nitrite; PH, pH; BLD, blood.

Changes have been made to the table footnote.

6. When using **abbreviations** in table/figure or table/figure description, please mention the entire expression in a footnote below the corresponding table/figure.

Please check and revise. Such as:

Figure 2: RBC, WBC, PRO, GLU, PB

Figure 3: AUC.

Figure 4: SHAP

Relevant content has been added.

7. Please spell out abbreviations **at their first use both in the abstract:**

21 better assist clinicians in identifying potential problems. **BLD, LEU, PRO and GLU** are the four
 22 most important parameters in urine testing, and the accuracy of their results is a key concern

32 and its test strips focused on the agreement of the urine blood (BLD) and leukocyte esterase

1 (LEU) readings with the red blood cell (RBC) and white blood cell (WBC) counts obtained by
 2 the Mindray EH-2090 urine formed element analyzer. We also compared the protein (PRO) and
 3 glucose (GLU) readings with the results of the Mindray BS-2800M biochemistry analyzer.

Relevant content has been added.

8. References

References 18 and 19 are the same. Please delete one of them and update the citations in the paper. Please note that references should be cited consecutively and consistently according to the order in which they first appear in the text.

18. Szmulik M, Trzeźniewska-Ofiara Z, Mendrycka M, et al. A novel approach to screening and managing the urinary tract infections suspected sample in the general human population. *Front Cell Infect Microbiol* 2022;12:915288.

19. Szmulik M, Trzeźniewska-Ofiara Z, Mendrycka M, et al. A novel approach to

screening and managing the urinary tract infections suspected sample in the general human population. Front Cell Infect Microbiol 2022;12:915288.

Modifications have been made.