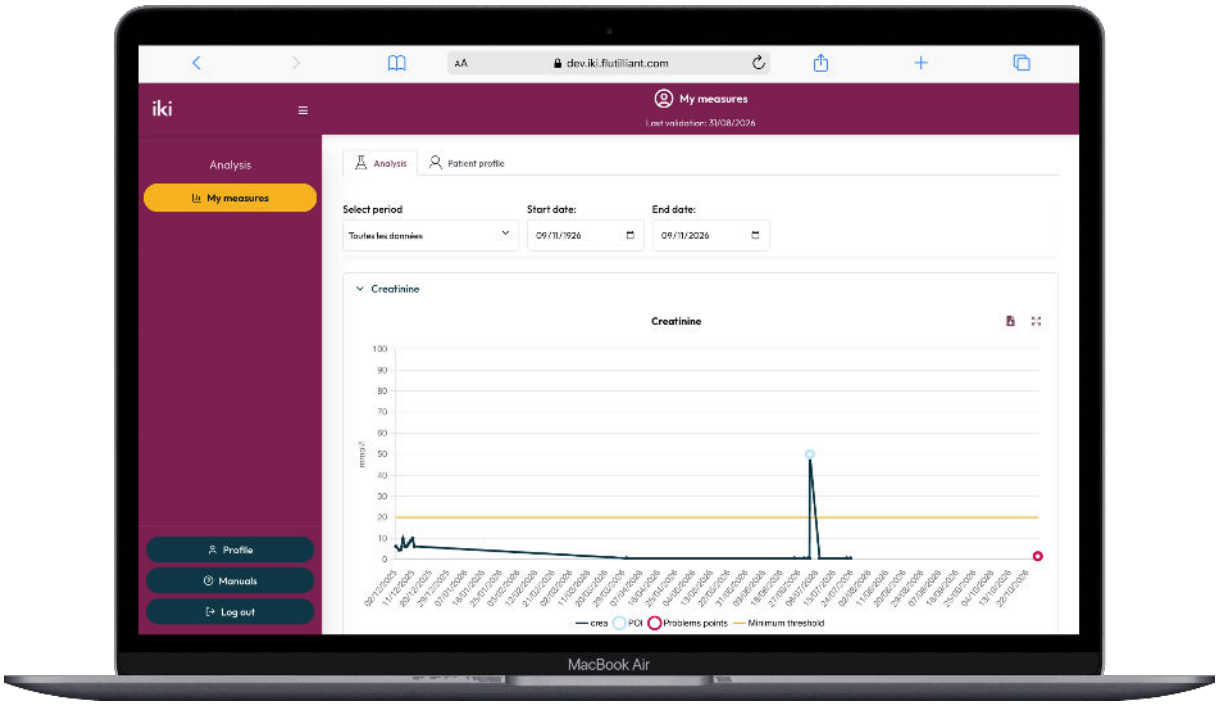
INSTRUCTIONS FOR USE

Uriki® Board web application



IKI – 1 place Pierre Potier 31100 Toulouse, France – contact@iki-diag.com

Contents

1. INTRODUCTION 3

2. SYMBOLS USED 3

3. PRECAUTIONS FOR USE 4

4. THE URIKI® SYSTEM 5

5. HOW TO USE THE URIKI® BOARD PLATFORM 7

5.1. GETTING STARTED 7

5.1.1. Setting up your account 7

5.1.2. Logging in 7

5.1.3. Navigation menu 8

5.1.4. Resetting your password 8

5.2. FEATURES 9

5.2.1. Viewing an overview of your results 9

5.2.2. Accessing your patient profile 10

5.2.3. Accessing your profile 11

5.2.4. Accessing the instructions for use for Uriki® products 12

6. SECURITY 12

7. WHAT SHOULD YOU DO IF A PROBLEM OCCURS? 12

8. EXPECTED CLINICAL BENEFIT 13

8.1. SCIENTIFIC VALIDITY 13

8.2. LITERATURE REVIEW 17

9. ANALYTICAL PERFORMANCE OF URIKI TEST K CARTRIDGES 22

These instructions for use apply to version 1.4.0 and later of the Uriki Board platform. Once you have logged in to the web platform, you can find the version number in the bottom left-hand corner of your computer screen.

1. Introduction

Uriki® Board is connected software intended for healthcare professionals and patients to consult the results of urine tests performed using the Uriki® connected reader and Uriki® Test cartridges outside a laboratory setting. For patients, the Uriki® Board platform, like the My Uriki® smartphone app, allows them to view their data and read feedback from their healthcare team.

2. Symbols used

Documentation symbol	Meaning
CE	Complies with the requirements of European Directive 98/79/EC
	Manufacturer
IVD	In vitro diagnostic medical device
	Warning

Application symbol	Meaning
	Edit information
	Display information
	Return to the previous page

IKI – 1 place Pierre Potier 31100 Toulouse, France – contact@iki-diag.com

3. Precautions for use



Read these instructions for use carefully before using the device. The performance of the device may be impaired if it is used in a manner not specified by the manufacturer.

- The number of tests to be performed and the frequency at which results must be submitted are specific to each patient. You must agree on an appropriate number and frequency of tests with your healthcare professional.
- Your measurement results will only be visible to you in the My Uriki® smartphone app or the Uriki® Board web application once a healthcare professional responsible for your care has validated the measurements.
- The web application does not replace regular medical appointments with a healthcare professional.
- Before linking the Uriki® connected reader to another user, you must upload your most recent measurements to ensure they are not lost.
- For disposal of the Uriki® Test urine cartridges and the Uriki® reader, refer to their instructions for use (to access these instructions, see section 5.2.4).

URIKI BOARD is compatible with the following browsers: Edge, Mozilla, Firefox, Chrome and Brave. A stable internet connection is required to use URIKI BOARD. Make sure that you use the latest version of your web browser and regularly update your operating system.
URIKI BOARD was not developed for use on mobile devices (i.e. smartphones).
To protect the personal and health data processed through URIKI BOARD against unauthorised access, URIKI BOARD users are advised to:

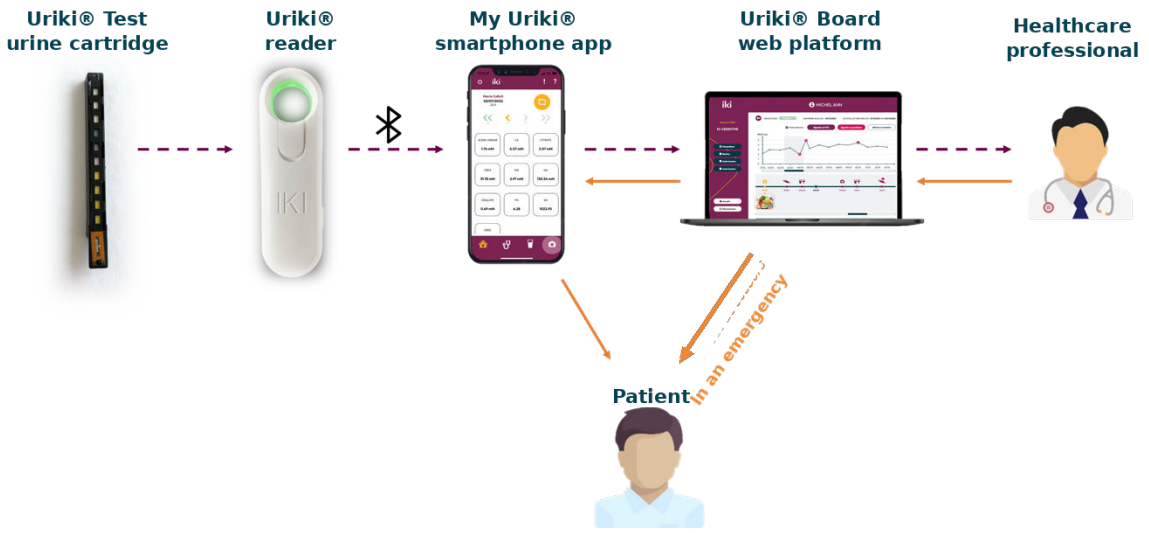
- Use a password-protected computer and keep its operating system, browser and applications up to date.
- Use a trusted internet connection (avoid unsecured public Wi-Fi networks when accessing URIKI BOARD).
- Do not share login credentials or leave a session open on a computer accessible to other people.
- Enter only the data necessary for the intended use of URIKI BOARD, and do not export or share data outside authorised uses.
- Notify IKI immediately if you suspect loss of equipment, unauthorised access or a possible breach of data associated with URIKI BOARD.

Users are informed that following these rules forms part of the measures required to comply with Regulation (EU) 2016/679 on data protection (GDPR) and with the rules applicable to health data.

4. The Uriki® system

Uriki® is a connected urine testing system. Patients use Uriki® Test cartridges and the Uriki® connected reader, then synchronise their measurement data with the My Uriki® smartphone app via Bluetooth® so that the data can be sent to their healthcare team.

When patients log in to the Uriki® Board web application, they can view their test results once these have been validated by a healthcare professional.



⚠ You cannot view your results in the mobile app until a healthcare professional has validated them in the Uriki® Board application.

5. How to use the Uriki® Board platform

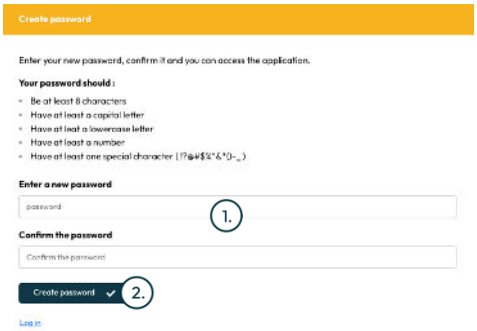
Additional equipment required:

- Uriki® connected reader,
- Uriki® Test cartridges,
- My Uriki® smartphone app.

5.1. Getting started

5.1.1. Setting up your account

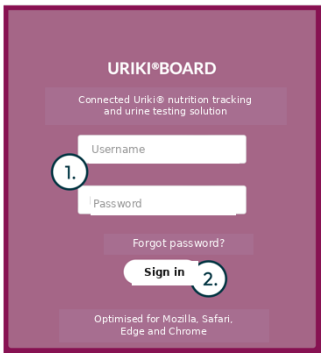
To use Uriki® Board, an account must first have been created for you by your solution provider or your group's Uriki® Board administrator. Once your account has been created, you will receive an email containing your username and a link to set up your password.



Note: This email may be in your spam or junk mail folder.

Click the setup link and choose a password that meets the stated requirements (1.). Click the confirmation button (2.) to set up your password. You will then receive a confirmation email containing your username and a link to the Uriki® Board web platform.

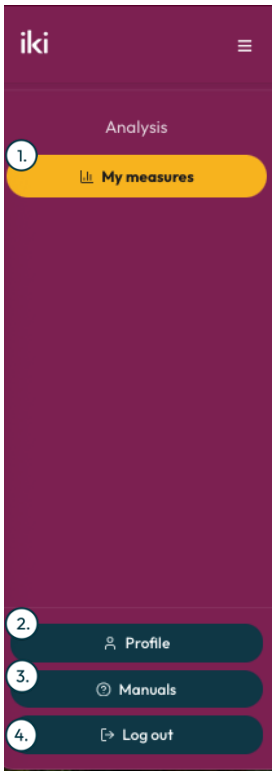
5.1.2. Logging in



To log in to Uriki® Board, click the link in the email confirming that your password has been created.

Enter your username and password (1.) in the form, then click the Sign in button (2.).

5.1.3. Navigation menu



Once you have logged in, a navigation menu appears on the left-hand side of the screen.

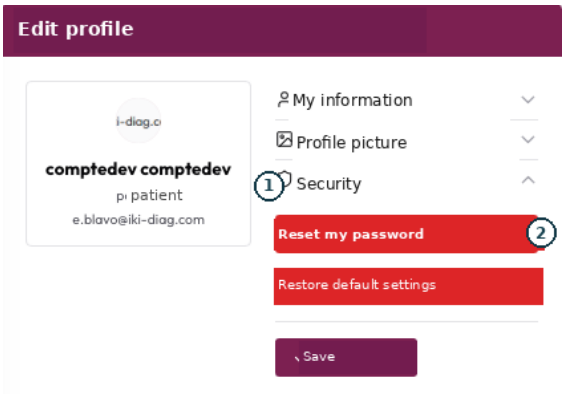
The main navigation menu gives access to the following pages:

- "My measurements": view your biomarkers and test results (①).
- "Profile": view and edit your profile information (②).
- "Instructions for use": access instructions for use for the various products in the Uriki® system (③).
- "Log out": sign out of your user account (④).

5.1.4. Resetting your password

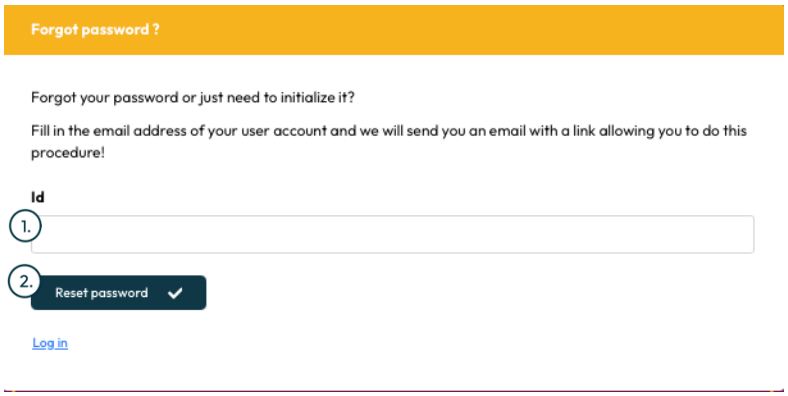
You can reset your password in two ways:

- On your profile page (see section 5.2.3), click "Security" (①) and request a password reset (②). You will receive an email containing a reset link. Click it and follow the instructions. Once the password has been reset, a second email will confirm the change.



IKI – 1 place Pierre Potier 31100 Toulouse, France – contact@iki-diag.com

- On the platform login page, click “Forgot password?”, enter your username (1.) and submit the reset request (2.). You will receive an email with a reset link. Follow the instructions. After resetting your password, you will receive a second confirmation email.



Note: You can also enter your email address instead of your username, provided it is associated with only one account.

5.2. Features

5.2.1. Viewing an overview of your results

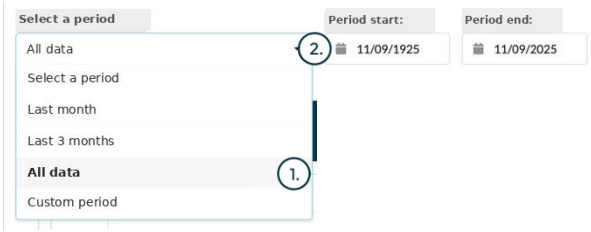
Your results are displayed in an overview. To access it, click “My measurements” (see section 1.1.3); you will automatically be taken to the Analyses tab.

The page is divided into several sections:

- The first section lets you configure how results are displayed.
- The second section contains the patient’s test results.

Part one: Display settings

Here you can select the period for which you want to view your data. Choose a predefined period from the drop-down list (1.) or specify the start and end dates using the calendars (2.).

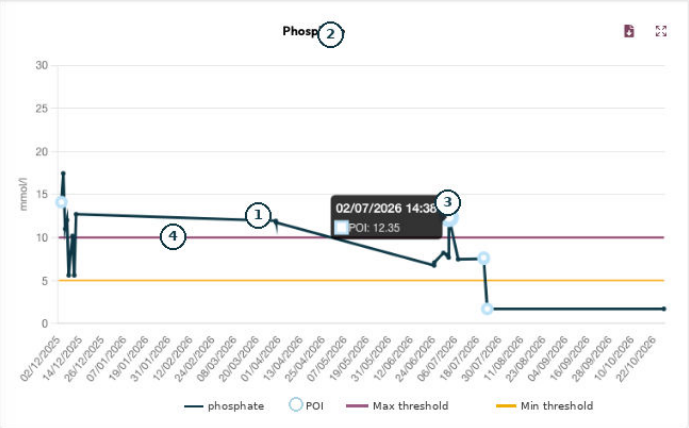


IKI – 1 place Pierre Potier 31100 Toulouse, France – contact@iki-diag.com

Part two: Data

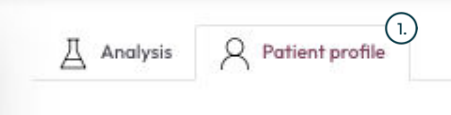
Here you can view how the test results change over time (1.) for each biomarker (2.).

Each point on the graph represents the biomarker value on a particular date. You can display it by hovering over the point (3.). If the healthcare team has set a threshold, it appears as a solid line (purple for a maximum threshold and yellow for a minimum threshold) on the graph (4.).



5.2.2. Accessing your patient profile

To access your patient profile, click the Patient profile tab (1.).



Your profile displays:

Alert threshold settings

1.

Biomarker name	Threshold value	CREA ratio	Threshold type
pH	5.5	No	max

History 2

Date	Author	Comment	Report	Attachment
13/10/26	comptedev rsi	test validation new	↓	Nutrition plan.pdf
30/09/26	comptedev rsi	test mesures 2	↓	No file

- The list of alert thresholds assigned to you (1.),
- The history of comments sent to the patient by the healthcare team (2.), including the date, author, comment, generated analysis report and any file attached to the feedback, such as a nutrition plan.

On the same page, you will also find a radar chart summarising the answers to the goal questions (2.), as well as a summary of the initial setup questions (3.).



3.

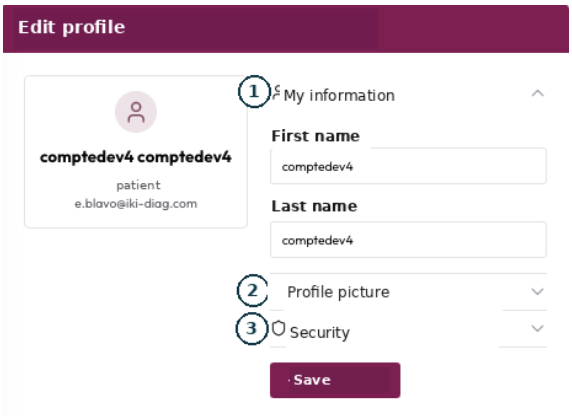
Initial questions Completed answers: 10

Question	Patient answer
Manage your fatigue?	Yes
Manage your stress?	Yes
When you do not eat ready-made meals, do you prepare the meals yourself?	Sometimes
Do you mainly eat ready-made meals (manufactured or from a caterer)?	Yes
Can you give the first name of the person who prepares your meals when you do not cook?	ifi
Are you able to talk about your illness with people close to you?	Yes

5.2.3. Accessing your profile

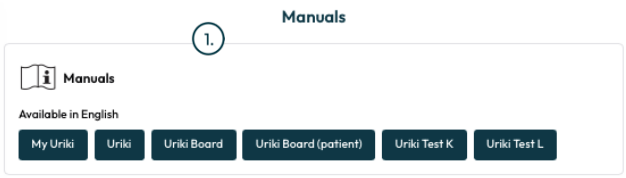
You can view and edit your profile by clicking “Profile” in the navigation menu. On this page, you can:

- Change your first and last names by clicking “My information” (1.), entering the new details and clicking Save.
- Change your profile picture by clicking “Profile picture” (2.), selecting a new image and clicking Save.
- Request a password reset by clicking “Security” (3.) and then the reset button (see section 5.1.4 for more information).



5.2.4. Accessing the instructions for use for Uriki® products

To consult the instructions for use for each Uriki® product, open the “Instructions for use” page in the navigation menu. Click the product you are interested in (1.); the download starts automatically.



6. Security

The application gives access to personal health data. These data are secured by a user account protected with a strong password.

Data stored by the Uriki® connected reader are automatically deleted once synchronisation with the My Uriki® smartphone app has been completed successfully.

7. What should you do if a problem occurs?

- If you cannot log in to your account, reset your password.
- If you experience a display issue, check that you are using a compatible web browser and refresh the page.
- If any data have been entered incorrectly, contact the person responsible for the web application at your healthcare facility.
- If you do not receive your measurement results despite their validation by a healthcare professional, contact the person responsible for the web application at your healthcare facility.

If a problem is not resolved by these instructions, report it to the person responsible for the web platform at your healthcare facility. That person must contact the manufacturer.

IKI – 1 place Pierre Potier 31100 Toulouse, France – contact@iki-diag.com

Note: If there is a problem with the My Uriki® smartphone app, the patient can also access their measurement results (graphs and profile only) in the Uriki® Board web application. To do so, the patient must contact the account administrator at their healthcare facility, who will provide the link to the Uriki® Board web application. The login credentials are the same as those used for the My Uriki® smartphone app.

The Bluetooth® word mark and logo are registered trademarks owned by Bluetooth SIG, Inc. Any use of these marks by IKI is under licence. Other trademarks and trade names are the property of their respective owners.

In the event of a serious or even fatal incident, please contact the competent authority in your country and IKI at the following address: 1 place Pierre Potier, 31100 Toulouse, France, contact@iki-diag.com.

8. Expected Clinical Benefit

8.1. Scientific Validity

The scientific validity of the device is based on:

1. A review of published, peer-reviewed scientific literature demonstrating the medical relevance of the markers and the reliability of the colorimetric reactions used.

A rigorous review of peer-reviewed scientific literature was conducted to establish the medical relevance of the selected biomarkers and the reliability of the colorimetric reactions used in the Uriki Test K device. Three key articles were selected for each biomarker, highlighting the effects of diet on its urinary concentration:

- Urinary citrate and pH are primarily influenced by the intake of plant foods (fruit and vegetables).
- Urinary urea, uric acid, phosphate and creatinine are strongly associated with the consumption of animal products, particularly proteins and purines.
- Urine specific gravity primarily reflects hydration status.
- Urinary calcium and sodium correlate with dietary calcium and sodium intake.

These findings, supported by their bibliographic sources, are presented in detail in Section “1.3.2 Literature Review”.

2. The adoption of recognized analytical principles that have been used in clinical laboratories for several decades. The absence of radically new analytical principles further strengthens their intrinsic validity.

The Uriki Test K device relies exclusively on robust, recognized and validated analytical principles that have been widely used in clinical laboratories worldwide for several decades. These established methods provide a high degree of intrinsic reliability while avoiding the introduction of new techniques that could compromise measurement robustness and reproducibility.

The analytical principles applied to each biomarker are summarized below:

- Phosphate: A method based on the formation of a phosphomolybdate complex with ammonium molybdate in an acidic medium, followed by formation of a colored malachite green complex, according to Feng et al. (2011).[1]
- Citrate: A measurement based on Tavallali et al. (2019), using competition between citrate and murexide for binding copper ions (Cu^{2+}), resulting in the formation of a violet complex.[2]
- Calcium: Based on the principles described by Carubelli et al. (1959) and Scarpa et al. (1972), in which calcium (Ca^{2+}) forms an orange-colored complex with murexide.[3][4]
- Sodium: A method using a sodium-selective chromoionophore that forms a purple-colored complex in the presence of Na^{+}, according to Wang et al. (2015).[5][6][7][8]
- Magnesium: A measurement based on the reaction of magnesium (Mg^{2+}) with xylidyl blue in an alkaline medium, forming a violet complex, according to Ratge et al. (1986).[9]
- Uric acid: Uric acid reduces cupric ions in an alkaline medium, forming a purple complex with bicinchoninic acid, according to the method published by Blichar et al.[10]
- Urea: The urease enzyme catalyzes the conversion of urea into ammonia, which changes the pH of the medium. This change is detected using phenol red, a colored pH indicator, based on Soni et al. (2018).[11]

---

[1] Feng et al., Analytical Biochemistry Volume 409, Issue 1, 1 February 2011, Pages 144-149

[2] Hossein Tavallali, Mohammad Ali Karimi & Omid Espergham (2019) Efficient ensemble and IDA system based on the
metal binding motif for highly sensitive and selective detection and determination of carbonate and citrate ions, International Journal of Environmental Analytical Chemistry,
99:8, 776-795, DOI: 10.1080/03067319.2019.1610172

[3] Carubelli et al., Clinical Chemistry, Volume 5, Issue 1, 1 February 1959, Pages 45–49,
https://doi.org/10.1093/clinchem/5.1.45

[4] Antonio Scarpa, Methods in Enzymology, Volume 24, 1972, Pages 343-351, https://doi.org/10.1016/0076-
6879(72)24082-4

[5] Seller et al., Article in Clinical Chemistry · September 1991, DOI: 10.1093/clinchem/37.8.1350 ·

[6] Chan et al., Microchemical Journal, Volume 72, Issue 2, July 2002, Pages 201-207 https://doi.org/10.1016/S0026-
265X(02)00034-6

[7] Wang et al., Angew Chem Int Ed Engl. 2017 September 18; 56(39): 11826–11830. doi:10.1002/anie.201706147.

[8] Shibata et al., December 2017The Analyst 143(3), DOI : https://doi.org/10.1039/C7AN01952A

[9] Ratge et al., Clinica Chimica Acta, Volume 159, Issue 2, 15 September 1986, Pages 197-203

[10] Ratge et al., Clinica Chimica Acta, Volume 159, Issue 2, 15 September 1986, Pages 197-203

[11] Soni et al., Sensors and Actuators B: Chemical, Volume 269, 15 September 2018, Pages 346-353

- pH: A conventional measurement using the color indicators methyl red and bromothymol blue, which are standard in urine test strips (e.g. Siemens Multistix).
- Urine specific gravity: A measurement based on a polyelectrolyte polymer that changes the pH according to urine specific gravity. The change is detected using bromothymol blue, a colored pH indicator, in line with common practice (e.g. Bayer Multistix).
- Creatinine: Creatinine reacts with 3,5-dinitrobenzoic acid in an alkaline medium through the Benedict–Behre reaction to form a violet complex.

Each method is based on robust chemical reactions validated by the scientific community, thereby supporting the accuracy and reliability of the results obtained with the device.

3. The clinical relevance of the markers, as confirmed by clinical guidelines.

The clinical relevance of the biomarkers has been confirmed by the latest clinical guidelines, including the 2024 KDIGO CKD Guidelines. These guidelines address biomarkers associated with various conditions, such as chronic kidney disease and urinary stone disease:

- Urinary urea is a reliable marker for estimating protein intake.
- Uric acid, citrate, calcium and magnesium play key roles in the formation of urinary or kidney stones. Calcium and uric acid are considered risk factors, whereas magnesium and citrate have protective effects.
- The guidelines also recommend limiting sodium and protein intake in patients with chronic kidney disease.
- Urine specific gravity is used to assess hydration status.
- Creatinine allows nutritional intakes observed through other biomarkers to be standardized.

4. Demonstrated reproducibility of these reactions in a test-strip format suitable for use outside the laboratory

The reproducibility of the colorimetric reactions used has been demonstrated in a test-strip format designed for use outside the laboratory. This format supports reliable measurements under practical conditions. For further details, refer to the measurement precision report (Measurement Precision Report).

5. Integration into a digital system that improves traceability, reading and interpretive accuracy.

The scientific validity of the Uriki Test K device is strengthened by its integration into an advanced digital system, which improves data traceability, reading accuracy and the quality of result interpretation. This approach is consistent with international best practices supported by recent studies and examples of real-world implementation.

- Diagnostic Connectivity and Increased Traceability

A study conducted in Uganda (Mujuni et al., 2024) demonstrated the effectiveness of a digital solution that automatically integrates data from different diagnostic devices (e.g. GeneXpert

and X-ray equipment) into an interactive dashboard with automated reports. This digital integration improves test traceability, provides clear visualization of results and facilitates interpretation through integrated analytical tools—key elements in ensuring reliable and robust clinical follow-up.[12]

- Mobile Platforms and Remote Reading

The World Health Organization (WHO) emphasizes the importance of mobile technologies, such as smartphones and optical readers, for optimizing the reading of rapid tests and the real-time transmission of results to a central database. This method improves reading accuracy, automates traceability and accelerates clinical decision-making (Peeling, 2015).[13]

- Artificial Intelligence for Test Interpretation

A recent innovation involves integrating artificial intelligence into a mobile application that captures the test reading area, automatically determines the result (positive, negative or invalid) and provides an associated confidence level. This solution makes tests easier for everyone to use, including people with visual impairments, and significantly increases the accuracy and reliability of interpretation (Dastagir et al., 2024).[14]

- Integrated Diagnostics for Better Clinical Interpretation

In advanced diagnostic systems, the computerized integration of data from clinical tests, laboratories and medical imaging improves the speed and accuracy of diagnosis. This concept of "integrated diagnostics" is widely recognized as the future of laboratory medicine (Lippi & Plebani, 2020).[15]

- Smart Hospitals and Medical Device Interoperability

Hospital projects, including one in Germany, have demonstrated the feasibility and value of interconnecting several hundred medical devices through international standards (HL7, FHIR, DICOM). This interoperability enables the large-scale consolidation of clinical and biological

---

[12] Mujuni, D., Tumwine, J., Musisi, K., Otim, E., Farhat, M. R., Nabulobi, D., Abdunoor, N., Tumuhairwe, A. K., Mugisa, M. D., Oola, D., Semitala, F., Byaruhanga, R., Turyahabwe, S., & Joloba, M. (2024). Beyond diagnostic connectivity: Leveraging digital health technology for the real-time collection and provision of high-quality actionable data on infectious diseases in Uganda. *PLOS digital health, 3*(8), e0000566. https://doi.org/10.1371/journal.pdig.0000566

[13] Peeling R. W. (2015). Diagnostics in a digital age: an opportunity to strengthen health systems and improve health outcomes. *International health, 7*(6), 384–389. https://doi.org/10.1093/inthealth/ihv062

[14] Dastagir et al., 2024 – *AI-Driven Smartphone Solution for Digitizing Rapid Diagnostic Test Kits* : IA pour interprétation précise avec niveau de confiance.

https://doi.org/10.48550/arXiv.2411.18007

[15] Lippi, G., & Plebani, M. (2020). **Integrated diagnostics: the future of laboratory medicine?**. *Biochemia medica*, *30*(1), 010501. https://doi.org/10.11613/BM.2020.010501

data, enhancing traceability and consistency of the information used for diagnosis (Martens et al., 2024).[16]

Drawing on these advances and scientific references, the Uriki Test K device therefore offers strong scientific validity based not only on established analytical principles but also on effective digital data management, ensuring accuracy, traceability and reliable result interpretation.

These elements are documented and referenced in accordance with the requirements of Regulation (EU) 2017/746, and contribute to confirming that the device can reliably assess relevant medical parameters, thereby supporting its scientific validity.

8.2. Literature Review

Objective

The objective of this targeted review was to identify and select recent scientific studies examining correlations between diet and the urinary excretion of metabolic biomarkers, as part of the assessment of the Uriki device's analytical performance.

The biomarkers of interest were sodium, calcium, citrate, magnesium, phosphate, urea, uric acid, urinary pH, urine specific gravity and creatinine.

Results

Thirty studies were selected, corresponding to three scientific references for each target urinary biomarker. All included studies were published from 2015 onward, conducted in humans and focused exclusively on urinary excretion. The results are organized by biomarker and describe the observed effects of diet on urinary concentrations.

Biomarker	Findings
Phosphate	Diets high in phosphorus, particularly from animal products or food additives (soft drinks, processed meats), result in a marked increase in urinary phosphate excretion. Differences between low- and high-phosphorus diets can reach up to +200 mg/day of excretion.
Citrate	Alkalinizing diets (rich in fruit and vegetables) promote a significant increase in urinary citrate excretion. Conversely, acid-forming diets or diets high in animal protein reduce

[16] Martens, E., Haase, H. U., Mastella, G., Henkel, A., Spinner, C., Hahn, F., Zou, C., Fava Sanches, A., Allescher, J., Heid, D., Strauss, E., Maier, M. M., Lachmann, M., Schmidt, G., Westphal, D., Haufe, T., Federle, D., Rueckert, D., Boeker, M., Becker, M., … Müller, A. (2024). Smart hospital: achieving interoperability and raw data collection from medical devices in clinical routine. *Frontiers in digital health*, *6*, 1341475. https://doi.org/10.3389/fdgth.2024.1341475

Biomarker	Findings
	citrate excretion. This effect is associated with urinary pH and the prevention of urinary stones.
Calcium	Urinary calcium excretion increases in response to high dietary calcium or sodium intake. A dose-response relationship has been demonstrated, particularly in older adults and women. High-sodium diets lead to increased urinary calcium excretion, suggesting an indirect interaction.
Sodium	The selected studies show a strong, statistically significant correlation between dietary sodium intake and urinary sodium excretion. Whether measured in 24-hour urine collections or spot samples, urinary sodium excretion closely reflects dietary salt intake. Differences of several hundred mg/day are observed between diets.
Magnesium	A positive correlation has been observed between dietary magnesium intake and urinary magnesium excretion. Studies show that magnesium-rich foods (nuts and seeds, vegetables and whole grains) affect urinary magnesium excretion, although homeostatic mechanisms partly limit the urinary response.
Uric Acid	Purine-rich diets (meat, organ meats and fish) increase urinary uric acid excretion. Conversely, plant-based or alkalinizing diets improve urinary uric acid clearance by raising urinary pH.
Urea	Protein intake strongly affects urinary urea excretion. Changes in urinary nitrogen excretion are consistently observed with vegetarian, omnivorous and animal-protein-enriched diets. Urinary urea is recognized as a reliable biomarker of protein intake.
pH	Urinary pH is directly affected by the dietary acid load. Diets rich in fruit and vegetables (alkali-forming foods) raise pH, while high-protein or processed-food diets lower it. Changes of ±0.5 pH units have been observed over four weeks.
Specific Gravity	Urine specific gravity is sensitive to hydration and the osmolarity of food. High-salt diets or low fluid intake increase urine specific gravity, whereas water-rich foods and fluid consumption significantly reduce it.
Creatinine	Urinary creatinine excretion is affected by protein intake and muscle mass. High-protein diets, particularly those based on animal products, are associated with increased urinary creatinine excretion. However, it remains an indirect marker of lean body mass.

Table of Scientific References by Biomarker	
Biomarker	Reference
Phosphate	Pendón-Ruiz de Mier MV, Vergara N, Rodelo-Haad C, López-Zamorano MD, Membrives-González C, López-Baltanás R, Muñoz-Castañeda JR, Caravaca F, Martín-Malo A, Felsenfeld AJ, De la Torre EJ, Soriano S, Santamaría R, Rodríguez M. Assessment of Inorganic Phosphate Intake by the Measurement of

IKI – 1 place Pierre Potier 31100 Toulouse, France – contact@iki-diag.com

Table of Scientific References by Biomarker	
Biomarker	Reference
	the Phosphate/Urea Nitrogen Ratio in Urine. Nutrients. 2021 Jan 20;13(2):292. doi: 10.3390/nu13020292. PMID: 33498560; PMCID: PMC7909516.
Phosphate	Li X, Zhang W, Huang T, Chen Y, Li J, Ding F, Wang W. The Effect of Dietary Phosphate Load on Urinary Supersaturation and Phosphate Metabolism in Non-Stone-Forming Asian Individuals. Ann Nutr Metab. 2025;81(2):97-104. doi: 10.1159/000543068. Epub 2024 Dec 11. PMID: 39662081..
Phosphate	Penczynski KJ, Remer T, Menzel J, Abraham K, Weikert C. Urinary Potential Renal Acid Load (uPRAL) among Vegans Versus Omnivores and Its Association with Bone Health in the Cross-Sectional Risks and Benefits of a Vegan Diet Study. Nutrients. 2022 Oct 24;14(21):4468. doi: 10.3390/nu14214468. PMID: 36364731; PMCID: PMC9656555.
Citrate	Perinpam M, Ware EB, Smith JA, Turner ST, Kardia SLR, Lieske JC. Association of urinary citrate excretion, pH, and net gastrointestinal alkali absorption with diet, diuretic use, and blood glucose concentration. Physiol Rep. 2017 Oct;5(19):e13411. doi: 10.14814/phy2.13411. Epub 2017 Oct 16. PMID: 29038354; PMCID: PMC5641929.
Citrate	Fakier S, Rodgers A. Exploring the Potential Relationship Between Phytate Ingestion, Urinary Phytate Excretion, and Renal Stone Risk in a Unique Human Model: No Hard Evidence in Support of Phytate as a Stone Inhibitor. J Ren Nutr. 2020 Sep;30(5):396-403. doi: 10.1053/j.jrn.2019.10.006. Epub 2020 Jan 9. PMID: 31928801.
Citrate	Zhu W, Liu Y, Lan Y, Li X, Luo L, Duan X, Lei M, Liu G, Yang Z, Mai X, Sun Y, Wang L, Lu S, Ou L, Wu W, Mai Z, Zhong D, Cai C, Zhao Z, Zhong W, Liu Y, Sun Y, Zeng G. Dietary vinegar prevents kidney stone recurrence via epigenetic regulations. EBioMedicine. 2019 Jul;45:231-250. doi: 10.1016/j.ebiom.2019.06.004. Epub 2019 Jun 13. PMID: 31202812; PMCID: PMC6642359.
Calcium	Prezioso D, Strazzullo P, Lotti T, Bianchi G, Borghi L, Caione P, Carini M, Caudarella R, Ferraro M, Gambaro G, Gelosa M, Guttilla A, Illiano E, Martino M, Meschi T, Messa P, Miano R, Napodano G, Nouvenne A, Rendina D, Rocco F, Rosa M, Sanseverino R, Salerno A, Spatafora S, Tasca A, Ticinesi A, Travaglini F, Trinchieri A, Vespasiani G, Zattoni F; CLU Working Group. Dietary treatment of urinary risk factors for renal stone formation. A review of CLU Working Group. Arch Ital Urol Androl. 2015 Jul 7;87(2):105-20. doi: 10.4081/aiua.2015.2.105. Erratum in: Arch Ital Urol Androl. 2016 Mar 31;88(1):76. doi: 10.4081/aiua.2016.1.76.. Ferraro, Manuel [added]. PMID: 26150027.
Calcium	Mansouri K, Greupner T, Hahn A. Blood Pressure Stability and Plasma Aldosterone Reduction: The Effects of a Sodium and Bicarbonate-Rich Water - A Randomized Controlled Intervention Study. Blood Press. 2024 Dec;33(1):2291411. doi: 10.1080/08037051.2023.2291411. Epub 2023 Dec 21. PMID: 38124675.
Calcium	Greupner T, Schneider I, Hahn A. Calcium Bioavailability from Mineral Waters with Different Mineralization in Comparison to Milk and a Supplement. J Am Coll Nutr. 2017 Jul;36(5):386-390. doi: 10.1080/07315724.2017.1299651. Epub 2017 Jun 19. PMID: 28628402.
Sodium	Ma Y, He FJ, Sun Q, Yuan C, Kieneker LM, Curhan GC, MacGregor GA, Bakker SJL, Campbell NRC, Wang M, Rimm EB, Manson JE, Willett WC, Hofman A, Gansevoort RT, Cook NR, Hu FB. 24-Hour Urinary Sodium and Potassium Excretion and Cardiovascular Risk. N Engl J Med. 2022 Jan 20;386(3):252-263. doi: 10.1056/NEJMoa2109794. Epub 2021 Nov 13. PMID: 34767706; PMCID: PMC9153854.
Sodium	Chiang BM, Ye M, Chattopadhyay A, Halezeroglu Y, Van Blarigan EL, Abuabara K. Sodium Intake and Atopic Dermatitis. JAMA Dermatol. 2024 Jul 1;160(7):725-731. doi: 10.1001/jamadermatol.2024.1544. PMID: 38837130; PMCID: PMC11154362.

Table of Scientific References by Biomarker	
Biomarker	Reference
Sodium	Moreira S, Moreira P, Sousa AS, Guerra RS, Afonso C, Santos A, Borges N, Amaral TF, Padrão P. Urinary Sodium Excretion and Adherence to the Mediterranean Diet in Older Adults. Nutrients. 2021 Dec 24;14(1):61. doi: 10.3390/nu14010061. PMID: 35010935; PMCID: PMC8747036.Biochem. 2022;99:110637.
Magnesium	Schutten JC, Joris PJ, Groendijk I, Eelderink C, Groothof D, van der Veen Y, Westerhuis R, Goorman F, Danel RM, de Borst MH, Bakker SJL. Effects of Magnesium Citrate, Magnesium Oxide, and Magnesium Sulfate Supplementation on Arterial Stiffness: A Randomized, Double-Blind, Placebo-Controlled Intervention Trial. J Am Heart Assoc. 2022 Mar 15;11(6):e021783. doi: 10.1161/JAHA.121.021783. Epub 2022 Mar 5. PMID: 35253448; PMCID: PMC9075273.
Magnesium	Okamoto H, Kawakami Y, Kaneko M, Ishida E, Sato M, Matsukawa H, Hosaka T, Arai H. The Urinary Excretion of Magnesium as an Effective Magnesium Deficiency State Indicator: A Controlled Intervention Trial. J Nutr Sci Vitaminol (Tokyo). 2023;69(1):21-27. doi: 10.3177/jnsv.69.21. PMID: 36858537.
Magnesium	Nielsen FH. Guidance for the determination of status indicators and dietary requirements for magnesium. Magnes Res. 2016 Apr 1;29(4):154-160. doi: 10.1684/mrh.2016.0416. PMID: 28132953.
Uric Acid	Wang W, Zhou X, Liu Y, Sang M, Sun Z, Qiu S. Association between Regular Exercise and Urinary Uric Acid Excretion in Chinese Adults: A Cross-sectional Study. J Physiol Investig. 2024 Mar 1;67(2):64-68. doi: 10.4103/ejpi.EJPI-D-24-00001. Epub 2024 Apr 30. PMID: 39468016.
Uric Acid	Trinchieri A, Montanari E. Biochemical and dietary factors of uric acid stone formation. Urolithiasis. 2018 Apr;46(2):167-172. doi: 10.1007/s00240-017-0965-2. Epub 2017 Feb 28. PMID: 28246885.
Uric Acid	Takayanagi F, Uchino T, Motoki N, Uchida K, Asakura H, Uno-Eder K, Nomura T, Tsukamoto K, Fukuuchi T, Yamaoka N, Kaneko K. Purine content of hospital meals and its effect on serum uric acid, urine pH, and urinary uric acid excretion. Nucleosides Nucleotides Nucleic Acids. 2022;41(12):1296-1304. doi: 10.1080/15257770.2022.2106492. Epub 2022 Aug 3. PMID: 35921584.
Urea	Okuda M, Asakura K, Sasaki S. Protein Intake Estimated from Brief-Type Self-Administered Diet History Questionnaire and Urinary Urea Nitrogen Level in Adolescents. Nutrients. 2019 Feb 1;11(2):319. doi: 10.3390/nu11020319. PMID: 30717308; PMCID: PMC6412261.
Urea	Sohouli MH, Mirmiran P, Seraj SS, Kutbi E, Alkahmous HAM, Almuqayyid F, Arafah OA, Barakeh ARR, Abu-Zaid A. Impact of low-protein diet on cardiovascular risk factors and kidney function in diabetic nephropathy: A systematic review and meta-analysis of randomized-controlled trials. Diabetes Res Clin Pract. 2022 Sep;191:110068. doi: 10.1016/j.diabres.2022.110068. Epub 2022 Sep 6. PMID: 36084854.
Urea	Streng KW, Hillege HL, Ter Maaten JM, van Veldhuisen DJ, Dickstein K, Ng LL, Samani NJ, Metra M, Ponikowski P, Cleland JG, Anker SD, Romaine SPR, Damman K, van der Meer P, Lang CC, Voors AA. Clinical implications of low estimated protein intake in patients with heart failure. J Cachexia Sarcopenia Muscle. 2022 Jun;13(3):1762-1770. doi: 10.1002/jcsm.12973. Epub 2022 Apr 14. PMID: 35426256; PMCID: PMC9178387.
pH	Perinpam M, Ware EB, Smith JA, Turner ST, Kardia SLR, Lieske JC. Association of urinary citrate excretion, pH, and net gastrointestinal alkali absorption with diet, diuretic use, and blood glucose concentration. Physiol Rep. 2017 Oct;5(19):e13411. doi: 10.14814/phy2.13411. Epub 2017 Oct 16. PMID: 29038354; PMCID: PMC5641929.
pH	Siener R, Bitterlich N, Birwé H, Hesse A. The Impact of Diet on Urinary Risk Factors for Cystine Stone Formation. Nutrients. 2021 Feb 6;13(2):528. doi: 10.3390/nu13020528. PMID: 33561968; PMCID: PMC7915598.

Table of Scientific References by Biomarker	
Biomarker	Reference
pH	Trinchieri A, Montanari E. Biochemical and dietary factors of uric acid stone formation. Urolithiasis. 2018 Apr;46(2):167-172. doi: 10.1007/s00240-017-0965-2. Epub 2017 Feb 28. PMID: 28246885.
Urine Specific Gravity	Reale R, Slater G, Cox GR, Dunican IC, Burke LM. The Effect of Water Loading on Acute Weight Loss Following Fluid Restriction in Combat Sports Athletes. Int J Sport Nutr Exerc Metab. 2018 Nov 1;28(6):565-573. doi: 10.1123/ijsnem.2017-0183. Epub 2018 May 3. PMID: 29182412.
Urine Specific Gravity	Travers S, Prot-Bertoye C, Daudon M, Courbebaisse M, Baron S. How to Monitor Hydration Status and Urine Dilution in Patients with Nephrolithiasis. Nutrients. 2023 Mar 28;15(7):1642. doi: 10.3390/nu15071642. PMID: 37049482; PMCID: PMC10097240.
Urine Specific Gravity	Wilson PB. Associations of Urine Specific Gravity With Body Mass Index and Lean Body Mass at the Population Level: Implications for Hydration Monitoring. Int J Sport Nutr Exerc Metab. 2021 Nov 1;31(6):475-481. doi: 10.1123/ijsnem.2021-0140. Epub 2021 Sep 1. PMID: 34470907.
Creatinine	Hiller L, Foulis P, Goldsmith S, Epps J, Wright L. Estimation of 24-hour urinary creatinine excretion from patient variables: A novel approach to identify patients with low muscle mass and malnutrition and relationship to outcomes. Nutr Clin Pract. 2023 Oct;38(5):1082-1092. doi: 10.1002/ncp.11009. Epub 2023 Jun 5. PMID: 37277930.
Creatinine	Salamah S, Post A, Alkaff FF, van Vliet IMY, Ipema KJR, van der Veen Y, Doorenbos CSE, Corpeleijn E, Navis G, Franssen CFM, Bakker SJL. Association between objectively measured protein intake and muscle status, health-related quality of life, and mortality in hemodialysis patients. Clin Nutr ESPEN. 2024 Oct;63:787-795. doi: 10.1016/j.clnesp.2024.08.011. Epub 2024 Aug 17. PMID: 39154804.

9. Analytical Performance of URIKI TEST K Cartridges

REFERENCE INTERVALS

Calcium[b]	Male	[0.225-9.47] mmol/L
	Female	[0.125-8.92] mmol/L
Citrate[c]	< 40 years, Male	[0.049-4.54] mmol/L
	>= 40 years, Male	[0.037-5.94] mmol/L
	< 40 years, Female	[0.021-10.2] mmol/L
	>= 40 years, Female	[0.053-8.2] mmol/L
Creatinine(d)	< 40 years, Male	[2.12-3.46] mmol/L
	>= 40 years, Male	[1.94-2.9] mmol/L
	< 40 years, Female	[1.41-2.89] mmol/L
	>= 40 years, Female	[1.32-2.46] mmol/L
Specific Gravity(e)	NA	[1002-1030]
Magnesium(f)	< 40 years	[0.86-9.54] mmol/L
	>= 40 years	[0.25-5.63] mmol/L
pH[g]	NA	[4.5-8]
Phosphate[h]	Male	[1.6-61] mmol/L
	Female	[2.3-48] mmol/L
Sodium[i]	< 40 years, Male	[25-301] mmol/L
	>= 40 years, Male	[18-214] mmol/L
	< 40 years, Female	[15-267] mmol/L
	>= 40 years, Female	[15-237] mmol/L
Urea(j)	Male	[51.8-550] mmol/L
	Female	[47.1-581] mmol/L
Uric Acid(a)	< 40 years, Male	[0.53-3.7] mmol/L
	>= 40 years, Male	[0.35-6.7] mmol/L
	< 40 years, Female	[0.35-4.2] mmol/L
	>= 40 years, Female	[0.24-5.5] mmol/L

ANALYTICAL PERFORMANCE

Linearity

Biomarker	R^2	Min	Max
Uric Acid	0.95	0.25 mmol/l	3 mmol/l
Calcium	0.97	0.25 mmol/l	20 mmol/l
Citrate	0.98	0.2 mmol/l	10 mmol/l
Creatinine	0.87	2 mmol/l	50 mmol/l
Specific Gravity	0.97	1000	1030
Magnesium	0.96	0.25 mmol/l	8 mmol/l
pH	0.95	5	7.9
Phosphate	0.99	1 mmol/l	25 mmol/l
Sodium	0.98	5 mmol/l	250 mmol/l
Urea	0.99	5 mmol/l	400 mmol/l

Limit of Quantification

Biomarker	Limit
Uric Acid	0.5 mmol/l
Calcium	2.8 mmol/l
Citrate	0.6 mmol/l
Citrate	1.8 mmol/l
Creatinine	1004.2
Specific Gravity	1.2 mmol/l
Magnesium	NA
Phosphate	5.6 mmol/l
Sodium	33.2 mmol/l
Urea	4.7 mmol/l

Interferences

Biomarker	Interfering Substances
Uric Acid	• Extreme pH (pH = 5 and pH = 8) • Urea (1 mol/L)
Calcium	• Bilirubin (58 mg/L) • Sulfate (30 mmol/L) • Citrate (8 mmol/L) • Sodium Chloride (400 mmol/L)
Citrate	• Magnesium (10 mmol/L) • Uric Acid (3.5 mmol/L) • Indoxyl Sulfate (0.3 g/L)
Creatinine	-
Specific Gravity	-
Magnesium	• Acidic pH (pH = 5) • Phosphate (30 mmol/L) • Bilirubin (58 mg/L) • Calcium (15 mmol/L)
pH	• Hemoglobin (3 mg/L)
Phosphate	• Urea (1 mol/L) • Extreme pH (pH = 5 and pH = 8) • Bilirubin (58 mg/L)
Sodium	• Creatinine (50 mmol/L)
Urea	• Glucose (10 g/L) • Nitrites (0.9 mg/L)

Iki
1 place Pierre Potier
31100 Toulouse, France
www.iki-diag.com
Tel: 05 82 95 92 79

CE IVD

Measurement Precision

Repeatability

N = 80 per concentration level, 1 URIKI reader, 1 cartridge batch, 20 different days
N1 = low concentration level for calcium, creatinine, specific gravity, magnesium, phosphate, sodium and urea; high concentration level for pH and uric acid.
N2 = high concentration level for calcium, creatinine, specific gravity, magnesium, phosphate, sodium and urea; low concentration level for pH and uric acid.

Biomarker	Standard Deviation	CV (%)	Concentration Level
Uric Acid	0,28	15,60%	N1
	0,26	17,31%	N2
Calcium	0,71	10,38%	N1
	0,63	6,74%	N2
Citrate	0,42	12,16%	N1
	0,83	10,72%	N2
Creatinine	0,79	12,49%	N1
	3,46	17,55%	N2
Specific Gravity	1,88	0,19%	N1
	1,99	0,19%	N2
Magnesium	0,75	16,92%	N1
	0,58	12,39%	N2
pH	0,13	1,68%	N1
	0,12	2,08%	N2
Phosphate	2,36	13,35%	N1
	2,86	14,09%	N2
Sodium	20,49	22,64%	N1
	21,06	20,27%	N2
Urea	12,75	17,67%	N1
	28,78	17,53%	N2

Intermediate Precision

N = 80 per concentration level, 1 URIKI reader, 1 cartridge batch, 20 different days
N1 = low concentration level for calcium, creatinine, specific gravity, magnesium, phosphate, sodium and urea; high concentration level for pH and uric acid.
N2 = high concentration level for calcium, creatinine, specific gravity, magnesium, phosphate, sodium and urea; low concentration level for pH and uric acid.

Biomarker	Standard Deviation	CV (%)	Concentration Level
Uric Acid	0,28	16,00%	N1
	0,27	18,32%	N2
Calcium	1,38	20,13%	N1
	1,07	11,46%	N2
Citrate	0,58	16,97%	N1
	1,57	20,30%	N2
Creatinine	0,97	15,28%	N1
	4,11	20,86%	N2
Specific Gravity	1,93	0,19%	N1
	1,80	0,18%	N2
Magnesium	0,80	18,02%	N1
	0,64	13,70%	N2
pH	0,19	2,41%	N1
	0,16	2,77%	N2
Phosphate	3,60	20,37%	N1
	3,08	15,20%	N2
Sodium	24,24	26,79%	N1
	22,76	21,91%	N2
Urea	13,43	18,62%	N1
	33,80	20,58%	N2

Reproducibility

N = 225 per concentration level, 3 URIKI readers, 3 cartridge batches, 5 different days
N1 = low concentration level for calcium, creatinine, specific gravity, magnesium, phosphate, sodium and urea; high concentration level for pH and uric acid.
N2 = high concentration level for calcium, creatinine, specific gravity, magnesium, phosphate, sodium and urea; low concentration level for pH and uric acid.

Biomarker	Standard Deviation	CV (%)	Concentration Level
Uric Acid	0,42	18,29%	N1
	0,35	15,67%	N2
Calcium	1,37	25,23%	N1
	2,03	27,85%	N2
Citrate	1,26	34,92%	N1
	1,42	24,66%	N2
Creatinine	2,87	33,05%	N1
	4,50	25,65%	N2
Specific Gravity	3,49	0,35%	N1
	6,06	0,59%	N2
Magnesium	0,57	15,41%	N1
	0,57	14,05%	N2
pH	0,20	2,62%	N1
	0,32	5,38%	N2
Phosphate	4,12	19,45%	N1
	3,51	14,11%	N2
Sodium	18,80	13,84%	N1
	22,03	15,66%	N2
Urea	31,96	29,02%	N1
	45,80	23,73%	N2

Comparability and Trueness

Using 100 samples

Biomarker	R^2		Bias	Method
Uric Acid	0.68	Y=0.9297 X+0.0338	-0.12 mmol/l	Uricase/PAP Technique
Calcium	0.83	Y=0.8786 X+0.5158	0.034 mmol/l	Atomic Absorption
Citrate	0.68	Y=0.8288 X+0.2487	0.002 mmol/l	CIHP
Creatinine	0.78	Y=0.9904 X+0.3181	-0.1 mmol/l	Jaffé Method
Specific Gravity	0.62	Y=0.9371X +663.625	-0.188	Refractometer
Magnesium	0.64	Y=0.894X +0.3681	-0.08 mmol/l	Atomic Absorption
pH	0.95	Y=1.0528X +0.326	-0.076	pH Meter
Phosphate	0.69	Y=0.8219X +2.7784	0.017 mmol/l	Ammonium Molybdate Technique
Sodium	0.65	Y=1.0983X +0.326	-0.33 mmol/l	Direct Potentiometry (Horiba)
Urea	Urea	Y=1.0399X -3.1005	-0.11 mmol/l	Urease/GLDH Technique

For Information: Comparison of Test Strips with a Refractometer and pH Meter

Biomarker	R^2		Bias	Method
Specific Gravity Multistix 8SG Test Strips + Clinitek Reader	0.53	Y=0.7775 X-229.3	-0.047	Refractometer
pH Multistix 8SG Test Strips + Clinitek Reader	0.85	Y=0.7693 X+1.7751	0.19	pH Meter

REFERENCES

(a) Clinical guide to laboratory Test, 4th ed., N.W. TIETZ (2006), p.1100
(b) Clinical guide to laboratory Test, 4th ed., N.W. TIETZ (2006), p.204
(c) Clinical guide to laboratory Test, 4th ed., N.W. TIETZ (2006), p.266
(d) Clinical guide to laboratory Test, 4th ed., N.W. TIETZ (2006), p.318
(e) Clinical guide to laboratory Test, 4th ed., N.W. TIETZ (2006), p.1000
(f) Clinical guide to laboratory Test, 4th ed., N.W. TIETZ (2006), p.706

Iki
1 place Pierre Potier
31100 Toulouse, France
www.iki-diag.com
Tel: 05 82 95 92 79

CE IVD

(g) Clinical guide to laboratory Test, 4th ed., N.W. TIETZ (2006), p.836
(h) Clinical guide to laboratory Test, 4th ed., N.W. TIETZ (2006), p.854
(i) Clinical guide to laboratory Test, 4th ed., N.W. TIETZ (2006), p. 994
(j) Clinical guide to laboratory Test, 4th ed., N.W. TIETZ (2006), p.1096

Iki
1 place Pierre Potier
31100 Toulouse, France
www.iki-diag.com
Tel: 05 82 95 92 79

IVD