Uriki® Test K

Reagent cartridges for urinalysis in nutritional monitoring

IVD CE

INTENDED PURPOSE

Uriki® Test K cartridges contain reagent test strips intended for in vitro quantitative measurement of pH, specific gravity and the concentrations of sodium, calcium, magnesium, urea, uric acid, phosphate, creatinine and citrate in urine. Uriki® Test K cartridges are intended for use by patients outside a laboratory setting to help a healthcare professional diagnose their nutritional status.

Uriki® Test K cartridges are used with the Uriki® connected reader, the My Uriki® smartphone app and the Uriki® Board web app.

CONTENTS

Check that the outer cardboard packaging is intact and that all items are included. If in doubt, do not use the kit and contact your distributor or the manufacturer.

5 or 10 sleeves, depending on the product reference

5 or 10 absorbent sticks, depending on the product reference

1 copy of the instructions for use

PRECAUTIONS AND WARNINGS

• Read these instructions carefully before using the device.

• Keep these instructions in a safe place, for example in the carrying case for the Uriki® connected reader.

• Follow medical advice on when and how often to perform the test.

• Do not change your diet without consulting the healthcare professional who prescribed this device.

• Uriki® Test cartridges are for single use. Use a new cartridge for each test.

• Do not reinsert a cartridge that has already been inserted into the URIKI reader. It can no longer be used.

• Dispose of the used cartridge with household waste.

• Do not insert the absorbent stick into the reader without the sleeve.

• Make sure to reseal the pouch containing the absorbent sticks.

• Keep the devices and their accessories out of the reach of children.

• This test does not replace a medical consultation or the results of tests performed by a clinical laboratory.

• Uriki® Test K results are not as precise as results from a clinical laboratory.

• Do not touch the reagent strip inside the sleeve.

• Incorrect results may occur in the following situations.

- The test is not performed as directed in these instructions.
- The pouch containing the sleeve is damaged, or the sleeve is not used immediately after the pouch is opened.
- The specified storage conditions are not followed.
- The urine-soaked absorbent stick is exposed to air for too long before it is inserted into the sleeve and then into the reader.

• Results will not be displayed if the test is performed after the expiry date shown on the box and on the sleeve packaging. In this case, dispose of the cartridge with household waste.

• Do not use expired absorbent sticks. Check the expiry date on the pouch label. Dispose of expired sticks with household waste.

• Perform the test at room temperature (15–25 °C) in a dry environment.

MATERIALS



UT-K sleeve

UT-K absorbent stick

Materials required but not supplied are the Uriki® reader, the My Uriki® smartphone app and the Uriki® Board web platform.

SAMPLE COLLECTION AND PREPARATION

Collect the urine sample by urinating directly onto the absorbent stick.
If direct collection is not possible, collect urine in a clean container with no detergent residue. The container must allow you to fully immerse the absorbent (white) part of the stick.

No more than 5 minutes may elapse between urine collection and insertion into the reader.

Insert the cartridge into the reader immediately after inserting the absorbent stick into the sleeve.

TEST PROCEDURE

1. When ready to perform a measurement, take one absorbent stick and reseal the pouch.
2. Urinate onto the absorbent stick. The entire absorbent paper must come into contact with urine.
3. Tear open the pouch at the notch and remove the sleeve.
4. Insert the absorbent stick into the sleeve with the urine-soaked absorbent part facing the inside of the sleeve.
5. Use the Uriki® reader as described in its instructions for use.
6. After use, dispose of the cartridge with household waste.

TEST PRINCIPLES

Uric acid. Uric acid reduces cupric ions in an alkaline medium. In the presence of bicinchoninic acid, the reduced ions form a purple complex.

Calcium. Calcium ions (Ca2+) react with murexide to form an orange complex.

Citrate. Citrate competes with copper ions for complexation with murexide. In the absence of citrate, the murexide complex is yellow. When citrate is added, murexide is converted to mure and the colour turns violet.

Creatinine. Creatinine reacts with 3,5-dinitrobenzoic acid in an alkaline medium to form a violet complex, according to the principle of the Benedict–Behre reaction.

Specific gravity. A polyelectrolyte polymer changes the pH of the medium according to the specific gravity of the urine. The pH change is measured with bromothymol blue, a colour indicator for pH.

Magnesium. Magnesium ions (Mg2+) react with xylidyl blue in an alkaline medium to form a violet complex.

pH. Urine pH is measured with bromothymol blue and methyl red, both of which are colour indicators for pH.

Phosphate. Phosphate forms a phosphomolybdate complex with ammonium molybdate in an acidic medium. Malachite green forms a second coloured complex with the phosphomolybdate.

Sodium. Sodium ions (Na+) are measured using a sodium-selective ionophore. A purple complex forms on contact with sodium.

Urea. The enzyme urease catalyses the conversion of urea to ammonia. Ammonia changes the pH of the medium. This change is measured with phenol red, a colour indicator for pH.

STORAGE

Store at 15–25 °C and at a humidity below 19.94%. Protect from light.

Check the expiry date on the box lot label or on the sleeve packaging. The maximum storage period is 49 days.

REFERENCE INTERVALS

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
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

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ANALYTICAL PERFORMANCE

Interference

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 (8mmol/l) • Sodium chloride (400mmol/l)
Citrate	• Magnesium (10mmol/l) • Uric acid (3.5mmol/l) • Indoxyl sulfate (0.3g/l)
Creatinine	-
Specific gravity	-
Magnesium	• Acidic pH (pH = 5) • Phosphate (30mmol/l) • Bilirubin (58mg/l) • Calcium (15 mmol/l)
pH	• Haemoglobin (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 (10g/l) • Nitrites (0.9 mg/l)

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
Creatinine	1.8 mmol/l
Specific gravity	1004.2
Magnesium	1.2 mmol/l
pH	NA
Phosphate	5.6 mmol/l
Sodium	33.2 mmol/l
Urea	4.7 mmol/l

Measurement precision

Repeatability

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

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	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 lots, 5 different days
N1 = low concentration level for calcium, creatinine, specific gravity, magnesium, phosphate, sodium and urea, and high level for pH and uric acid.
N2 = high concentration level for calcium, creatinine, specific gravity, magnesium, phosphate, sodium and urea, and low 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=0.9297X +0.0338	-0.12 mmol/l	Uricase/PAP method
Calcium	0.83	Y=0.8786X +0.5158	0.034 mmol/l	Atomic absorption
Citrate	0.68	Y=0.8288X +0.2487	0.002 mmol/l	High-performance ion chromatography
Creatinine	0.78	Y=0.9904X +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 method
Sodium	0.65	Y=1.0983X +0.326	-0.33 mmol/l	Direct potentiometry (Horiba)
Urea	0.86	Y=1.0399X-3.1005	-0.11 mmol/l	Urease/GLDH method

For information: comparison of test strips with a refractometer and a pH meter

Biomarker	R^2		Bias	Method
Specific gravity Multistix 8SG test strips + Clinitek reader	0.53	Y=0.7775X -229.3	-0.047	Refractometer
pH Multistix 8SG test strips + Clinitek reader	0.85	Y=0.7693X +1.7751	0.19	pH meter

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(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
(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

DISPOSAL

Dispose of used cartridges with household waste.

TROUBLESHOOTING

If the absorbent stick is only partly soaked with urine, repeat the test.

If the absorbent stick was inserted into the reader without the sleeve, stop using the reader and contact the manufacturer.

If any component is deformed or has come apart, do not use it and contact the manufacturer.

If the sleeve is damaged when you open the pouch, do not use it and contact the manufacturer.

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.

Symbol	Meaning
CE	Complies with Directive 98/79/EC on in vitro diagnostic medical devices
IVD	In vitro diagnostic medical device
	Manufacturer
	Date of manufacture
REF	Catalogue number
	Consult the instructions for use at https://iki-diag.com/notices/
	Protect from light
	Do not reuse
LOT	Batch code
Σ	Number of cartridges per kit
	Storage temperature limits

Expected Clinical Benefit

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]

[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

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- 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]
- 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).

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[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

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

[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

enables the large-scale consolidation of clinical and biological 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.

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 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.

[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
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.

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