iVYCHECK GIP Urine

For *research* use only

KT-6412R: Rapid test for the detection of Gluten immunogenic peptides (GIP) in urine samples, 10 Tests.
KT-6411R: Rapid test for the detection of Gluten immunogenic peptides (GIP) in urine samples, 25 Tests.

LIST OF PRODUCT VARIANTS

Product	Contents	REF
iVYCHECK GIP Urine, 10T	10 test	KT-6412R
iVYCHECK GIP Urine, 25T	25 test	KT-6411R

INTRODUCTION

Celiac disease is a chronic disorder of autoimmune origin that is characterised by a permanent intolerance to the proteins of gluten.

It appears in genetically predisposed people, both adults and children. It has an average prevalence in the population of above 1:100, being most frequent in children. The disease affects the small intestine and provokes the atrophy of the intestinal villi and thereby interferes with the absorption of nutrients such as proteins, fats, carbohydrates, salts and vitamins. It doesn't only affect the intestine but is in fact a systemic disease which can cause lesions in the skin, joints and other organs.

The strict adherence to the Gluten Free Diet (DFG) is essential for reducing those symptoms of the disease, avoiding nutritional deficiencies and improve the quality of life of the patient. However, based on multiple different studies, dietary transgressions, whether voluntary or involuntary, are frequent (32.6-55.4%) in celiac patients, especially in adults.

At present, they is no direct method for the monitoring the adherence to the DFG. The gluten immunogenic peptides (GIP) are fragments of gluten proteins which are resistant to gastrointestinal digestion and trigger immune responses in celiac patients. The recuperation of measurable quantities of GIP in urine indicates that a patient has consumed gluten. The present of GIP in the urine constitutes a precise, direct marker for the control of the GFD in the long and short term.

INTENDED USE AND CHARACTERISTICS

Indication	Healthcare product
Function	Detection of the presence of GIP in urine samples
Target	Monitoring of the GFD (celiac disease)
Method Type	Manual
Analysis Type	Qualitative
Sample Type	Urine
Testing population	Celiac patients, patients with non-celiac wheat sensitivity, gluten-allergy or other disorders related to gluten.
Intended Use	iVYCHECK GIP Urine is intended for professional use for the qualitative monitoring of the gluten-free diet via the detection of GIP in urine samples from celiac patients or patients with other gluten-related disorders.
Intended User	For research use only
Assay Type	Rapid immunochromatographic test

TECHNICAL SPECIFICATIONS

Sample quantity	1 mL
Diagnostic sensitivity *	90,18%, (IC95: 84,22- 96,14%)
Diagnostic specificity *	98,28% (IC95: 95,48- 100%)
Positive predictive value *	98,06% (IC95: 94,91- 100%)
Negative predictive value *	91,20% (IC95: 85,83-96,57%)
Reproducibility	97% (IC95: 95%-98%)
Repeatability	98% (IC95: 94-100%)
Lower detection limit **	2,5 ng GIP***/mL of urine

Upper detection limit	1 µg GIP***/mL of urine

** Associated with people without restrictions on gluten consumption in the diet. Intake not controlled.*
*** It is defined as the value where 95% of the samples at that concentration have a positive result.*
**** Based on the 33-mer peptide of α-gliadin.*

INTERFERENCES

No interference detected to date.

KIT CONTENTS

References	Description	KT-6412R	KT-6411R
RS-6429R	Conditioning Solution	1 uds	1 uds
RS-6514R	iVYCHECK Stick (with plastic pipette)	10 uds	25 uds

Non-provided, required materials:
Sample collection pot, 100ul-1ml pipette and disposable tips, plastic vials, powder-free nitrile gloves, laboratory coat, (96-100%) ethanol.

SECURITY INFORMATION

Component	Dangerous Reagent	Risk Symbol	Hazard Warnings	Precautions
RS-6429	EDTA (Ethylenediaminetetraacatic acid) (5-10) %		319	264, 280, 305+351+338, 337+313

Safety Indications:

H319 Causes serious eye irritation

Precaution:

P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection
P337+P313 IF eye irritation persists: Get medical advice/attention
P305 + P351 P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

RECOMMENDATIONS, PRECAUTIONS AND LIMITATIONS

Any serious incident which occurs related to the use of the kit should be communicated to the manufacturer and the relevant authority.

- This kit has been designed for professional use.
- Use the appropriate PPE (disposable protective gloves, laboratory coat) when working with kit reagents and samples.
- The kit should be used at standard room temperature conditions.
- Close the bottle and vial that contain the components of the kit immediately after use and do not interchange lids.
- Do no combine no exchange reagents between kits.
- Once the lateral flow device has been removed from the sealed metallic pouch, it must be used as soon as possible in strict clean conditions.
- Dispose of the unused reagents and waste material in accordance with the relevant regulation.
- It is important to use the indicate amount of sample. The usage of more or less than recommended could result in erroneous results.
- Homogenise the sample well. An insufficient homogenisation could cause variability in the replicates of a sample.
- Pay attention to the mixing process. A weak or shortened mixing process could lead to false negatives.
- The usage of this kit should comply with the safety documentation provided.

- The avoidance between clinical samples can be avoided solely by the application of good laboratory practise and the careful compliance with the protocol provided in the instructions for use. All reagents should be monitored for impurities and contaminations. Any reagent with suspected issues should be disposed of.
- Control should be taken during the management of clinical material. Incorrect manipulation of samples could result in a contamination and/or deterioration of components of the kit. BIOMEDAL S.L. will not be responsible for the incorrect usage of the kit.
- Alcohol based disinfectants can damage the labels on the bottles and vials.
- Poor vision, colour-blindness or poor illumination can affect the capacity to correctly interpret the kit.

Procedural Limitations

- Read all of the instructions thoroughly before employing the kit.
- Adequate systems for collection, transportation, storage and processing of samples are required for the optimal usage of the product.
- Do not use the kit after the expiry date.

Clinical Limitations

- This kit is not valid for the analysis of neonatal samples.

COLLECTION AND STORAGE OF SAMPLES

Sample collection recommendations:

• It is recommended to collect the first urine in the morning or the last urine at night.
• It is recommended to reduce fluid intake in the hours prior to performing the test (between 2 and 4 hours) as it could affect sensitivity (Do not exceed two litres prior to performing the test).
• If gluten ingestion is suspected, please consider the following information:

Maximum detection time from ingestion	3-15 hours
Optimal detection time from ingestion*	6-9 hours
Minimum amount of detectable gluten	50mg

**To maximize the probability of detection of the kit, sampling is recommended 6-9 hours after gluten intake.*

At least 1 mL of urine should be collected. These samples must be collected in a clean, dry container without any added chemical additives or preservatives.

For a follow-up of the gluten-free diet, it is recommended to collect three urines samples a week (for example: Monday, Wednesday and Friday or home, work and restaurant).

Storage of urine samples:

Storage at room temperature	Maximum time 48 hours
Storage at 4°C	Maximum time 72 hours
Storage at -20°C	Maximum time 12 months
Freeze/Thaw Cycles	Maximum five cycles

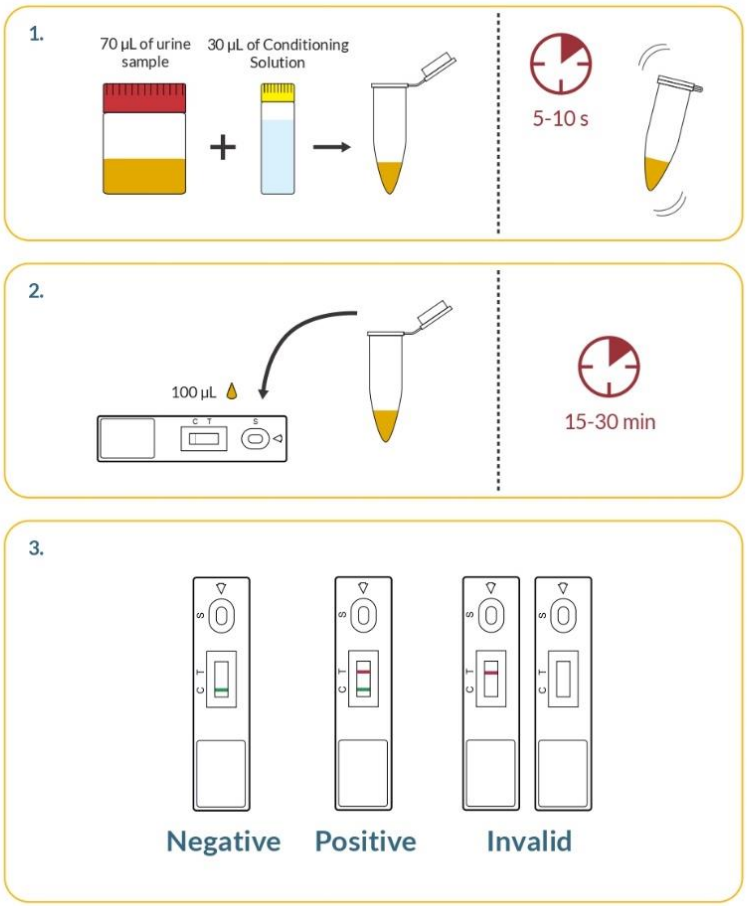
PROTOCOL

1. Defrost any frozen simples. Samples should be collected following the indicated methodology. The sample must be completely defrosted before its analysis.
2. In the case of freshly collected samples, use a standard urine collection flask (not included) to collect a fresh urine sample.
3. Homogenize the urine sample before starting the assay
4. Mix 70µl of urine with 30µl of the conditioning solution in a vial using a manual pipette. The mix volume (100 microlitres) will be sufficient for the test (to analyse each sample multiple times, prepare a larger volume of mix, however, always maintaining a 70:30 ratio). Homogenise the mix pipetting up and down, or via soft shaking of the tube for 5 to 10 seconds.

5. Open the metallic pouch and remove the IVYCHECK Stick. Discard the included pipette, which will not be necessary. Place the lateral flow device in horizontal on a flat surface and add 100µl of the prepared mix to the hole marked (S).
6. Make a visual assessment of the result from the lateral flow device after 15 minutes (a positive result will be observed for samples containing GIP peptide above the limit of detection). In the case of now observing a RED line after 15 minutes, wait until 30 minutes as, in some cases, low levels of GIP require a longer time to result in a positive result

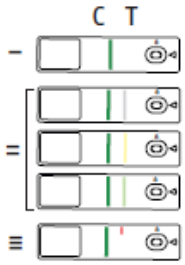
   Do not read the result after more than 30 minutes

DIAGRAMATIC PROTOCOL



RESULT INTERPRETATION

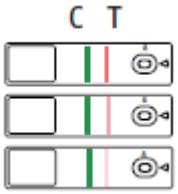
- **NEGATIVE**



I. A single green line appears in the Control Zone (C). The intensity of the line Control (C) is not relevant.
II. If a line appears in the Test Zone (T) of a color other than red (eg grey, yellow, green) and a green line appears in the Control Zone (C).
III. If the red line is not complete (eg red dots appear in the T zone) and a green line appears in the Control Zone (C).

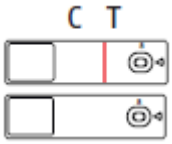
No gluten has been detected in the urine sample.

- **POSITIVE**



If a GREEN line in the Control Zone (C) is visible next to a red line in the Test Zone (T), independently of
the intensity obtained; the test result is positive.
If you have obtained a positive result, there is a high probability that there has been a gluten ingestion 3-15 hours before performing the test. Check the food eaten to identify the origin of the gluten.

- **INVALID**



If the GREEN line does not appear, the test has not worked correctly and the results are invalid. Review the instructions and perform the test again following the instructions.

INTERNAL QUALITY CONTROL

Each batch is subject to an internal quality control before its release for sale. The quality control is performed using real positive and negative samples as well as urine samples spiked with GIP.

The following acceptance criteria are applied:

- ✓ The tested samples should give the anticipated result
- ✓ The samples spiked to the Limit of Detection should give a positive result.

SYMBOLS

Research Use Only


Manufacturer

Catalogue number

Batch code


Use by (expiration date)


Contains sufficient for <n> tests


Consult instructions for use


Keep dry


Caution


Temperature limitation

REFERENCES

- Coto L., et al.: “Dynamics and Considerations in the Determination of the Excretion of Gluten Immunogenic Peptides in Urine: Individual Variability at Low Gluten Intake”;. Nutrients 2021;13(8):2624.
- Ruiz-Carnicer A., et al.: “Negative predictive value of the repeated absence of gluten immunogenic peptides in the urine of treated celiac patients in predicting mucosal healing: new proposals for follow-up in celiac disease”,: The American Journal of Clinical Nutrition 2020; 112(5): 1240–1251.
- Silvester J., et al.: “Celiac Disease Patients Should No Longer Be Consuming Measurable Amounts of Gluten”; Gastroenterology; 2020; 158: 1497-1499.

MODIFICATIONS IN THE LATEST VERSION

M-168R

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For more information, please visit our website or contract us: info@biomedal.com