

PreventID® Gluten Detect Urinski test

Navodila za uporabo

PreventID® **Gluten Detect** hitri test za zaznavanje glutena v urinu

Predvidena uporaba

PreventID® Gluten Detect test je hiter imunokromatografski test za zaznavanje imunogenih peptidov glutena (IPG; produkti presnovne razgradnje glutena v telesu) v vzorcih urina. Bolniki lahko uporabljajo test za spremljanje diete brez glutena.

Uvod

Ljudje, ki po zaužitju obroka, ki vsebuje gluten, občutijo fizično nelagodje, trpijo za preobčutljivostjo na gluten/pšenico, alergijo na pšenico ali imajo celiakijo, avtoimunsko bolezen, ki se kaže kot vnetna črevesna bolezen. Simptome povzročajo različne skladiščne beljakovine v zrnatih semenih, ki so povzete z izrazom "gluten". Simptomi segajo od kronične utrujenosti, izgube teže, bolečine v sklepih, odrevenelosti v nogah do mišičnih krčev in driske. Trenutno je edino učinkovito zdravljenje teh boleznih sledenje strogi vseživljenjski dieti brez glutena. Glutenu se je v vsakdanjem življenju težko popolnoma izogniti, saj ga kot sestavino ali aditiv vsebujejo različni izdelki ali pa je celo nenamerno vnesen s proizvodnim procesom.

Tako lahko pride do nenamernega vnosa glutena kljub vsem previdnostnim ukrepom. **PreventID® Gluten Detect** lahko uporabite za hitro in neposredno ugotavljanje, če je vzrok za vaše težave vnos glutena, saj lahko presnovne produkte (IPG) zaznamo v urinu. To vam omogoča hiter odziv in prilagoditev vaše prehrane.

Merljiva količina IPG v vzorcu blata ali urina kaže na to, da je prišlo do zaužitja glutena in zato test predstavlja točno in zelo koristno orodje za spremljanje kratkoročne in dolgoročne diete brez glutena.

Princip delovanja

PreventID® Gluten Detect test je imunokromatografski test, ki v urinu omogoča detekcijo peptidov, ki so nastali po gastrointestinalni razgradnji zaužitega glutena. Za izvedbo testa je potrebno vzorec urina preprosto zmešati s pripravljeno raztopino. Ta ga pripravi na detekcijski korak, ki temelji na reakciji glutenskih peptidov v vzorcu z obarvanim konjugatom, ki je predhodno nanešen na kromatografski trak. V prisotnosti glutenskih peptidov, peptidokonjugatni kompleksi sledijo kapilarnemu toku in se nakopičijo v testnem območju, kar se pokaže kot vidna RDEČA testna črta (T). Odsotnost RDEČE črte pomeni negativen rezultat. Če je gluten prisoten ali ne, bo drugi obarvani konjugat prav tako sledil kapilarnemu toku in se nakopičil v kontrolnem območju; prikaže se ZELENA črta (kontrolna črta), ki potrjuje, da je test pravilno potekal. V primeru, da se ZELENA črta ne pojavi, je rezultat testa neveljaven.

Priloženi materiali

- 1 testna naprava s sušilnim sredstvom (ni potrebno za test) [GlutenDetect Sticks REF: RS-6403]
- 1 steklenička s pripravljeno raztopino [Conditioning solution, REF: RS-6401]
- 1 sterilna brizga [Nipro 2 part syringe, REF: SY2B-2SC-W-ETR]
- Navodila za uporabo

Dodatno potrebno: skodelica za zbiranje urina, štoparica

Skladiščenje in obstojnost

PreventID® Gluten Detect shranjujte pri 4–30 °C. Ne zamrzujte ga. Testna naprava je občutljiva na vlago in visoke temperature, zato je potrebno test zaščititi pred ekstremnimi temperaturami in ga uporabiti takoj po odprtju vrečke. Testa se ne sme izvajati po preteku roka uporabe. Vse komponente paketa po uporabi lahko odvržete v navadne smeti ali ustrezen smetnjak za recikliranje.

Pomembne informacije

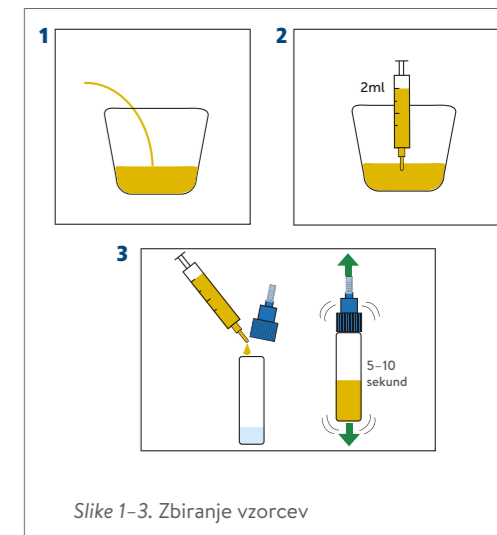
1. Samo za analizo vzorcev urina. Ne zaužijte nobenih komponent testa.
2. Med rokanjem z vzorcem ne jejte ali kadite. Če so na voljo, uporabljajte zaščitne rokavice, po opravljenem testu pa si temeljito umijte roke.
3. Izogibajte se škropljenju ali nastajanju aerosola.
4. Skrbno očistite vse kontaminirane površine. Vse sestavne dele testa in vzorce odvrzite v običajne odpadke.
5. Testa ne uporabljajte v primeru, da je aluminijasta vrečka raztrgana ali če je membrana na testni napravi poškodovana.
6. Če pridejo koža ali oči v stik s pufrom, takoj sperite z obilo vode.
7. Shranjujte izven dosega otrok.
8. V primeru vprašanj prosimo, da nas kontaktirate na spodnjem naslovu.

Odvzem vzorca

1. Za zbiranje urina uporabite čist standardni lonček za zbiranje urina (ni vključen), (5 mL urina bo dovolj za en test) (Slika 1).
2. Z novo plastično brizgo odmerite in prenesite 2 mL urinskega vzorca v epruveto s pripravljeno raztopino (Slika 2).
3. Tesno zaprite s pokrovčkom in nežno stresajte epruveto 5–10 sekund, da se vzorec urina premeša s

pripravljeno raztopino (Slika 3).

4. Test mora biti izveden takoj po odvzemu vzorca, pri sobni temperaturi.

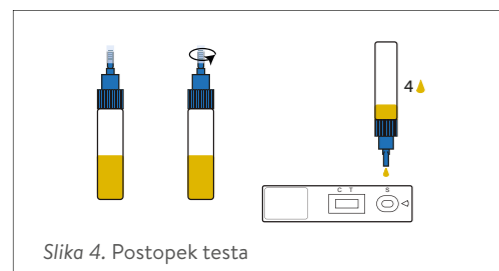


Slika 1–3. Zbiranje vzorcev

Postopek testa

Po odvzemu vzorca, prenesite vse sestavne dele testa na sobno temperaturo.

1. Neposredno pred izvedbo testa odprite vrečko z zaščitno folijo in vzemite ven testno napravo. Napravo položite vodoravno, na čisto površino (Slika 4). Testno napravo uporabite neposredno po odprtju embalaže.



Slika 4. Postopek testa

2. Odvijte prozorni zamašek na epruveti z modrim zamaškom in previdno dodajte 4 kapljice na cono S na testni napravi. Počakajte 15 minut.
3. Zelena kontrolna črta (C) označuje pravilno izvedbo testa.
4. Za končni rezultat počakajte 15 minut. Če je v vzorcu urina visoka koncentracija glutena, se rezultat lahko prikaže v manj kot 1–2 minutah.

Opomba: rezultati po 15 minutah niso zanesljivi. Priporočamo, da rezultate preberete v 15. minuti.

Razlaga rezultatov testa (Slika 5)

Zelena kontrolna črta (C), označuje, da je test potekal pravilno. Odvisno od koncentracije IPG v vzorcu se dodatno pojavi rdeča testna črta (T).

Negativno:

Na osrednjem delu traku (kontrolno območje), se pojavi samo zelena črta (kontrolna črta).

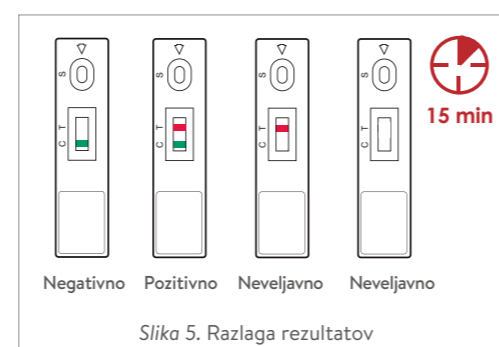
Pozitivno:

V kontrolnem območju se poleg zelene kontrolne črte pojavi tudi rdeča (testna črta).

Opomba: intenzivnost rdeče črte v kontrolni coni je odvisna od koncentracije IPG v vzorcu. Prisotnost kakršnega koli odtenka rdeče črte v kontrolnem območju (T) pomeni pozitiven rezultat, neglede na to, kako svetla je.

Neveljavno:

V primeru, da se zelena kontrolna črta ne prikaže, se rezultat testa šteje za neveljavnega, tudi če se na kontrolnem območju pojavi rdeča črta. Najpogostejša vzroka za neveljaven rezultat sta nepravilen postopek izvedbe testa ali pokvarjeni reagenti v kompletu. V primeru neveljavnega rezultata je potrebno preizkus ponoviti z novim testom v skladu s pravilnim postopkom. Če težava ostane, prenehajte z uporabo testa in kontaktirajte spodnji naslov.



Slika 5. Razlaga rezultatov

Karakteristike testa

Analitična občutljivost

Meja zaznave **PreventID® Gluten Detect** je 2.2 ng IPG/mL vzorca urina.

Analitična specifičnost

Test je sposoben zaznati prisotnost razgradnih produktov glutena, zlasti IPG iz prolaminov v pšenici (gliadin), rži (sekalin), ječmenu (hordein) in, kadar je prisoten v velikih količinah, v ovsu (avenini). Ni opažene navzkrižne reaktivnosti z naravnimi brezglutenskimi živili, ki so smatrana kot varna za bolnike s celiakijo, kot so riž, koruza, ajda, soja, proso, kvinoja in amarant.

Omejitev testa

Kljub temu, da je **PreventID® Gluten Detect** test zelo natančen pri odkrivanju IPG, se lahko z nizko incidenco pojavijo napačni rezultati. V primeru vprašljivih rezultatov so potrebni drugi klinično dostopni testi. Rezultati testa so zanesljivi samo, če natančno sledite navodilom za uporabo.


Testno napravo uporabite le enkrat.

Literatura

- Shan L et al.; „Structural basis for gluten intolerance in celiac sprue“; Science; 2002; 297: 2275-9.
- Silvester JA et al.; „Long-term follow-up of individuals with celiac disease: an evaluation of current practice guidelines“; Canadian Journal of Gastroenterology; 2007; 21:557-564.
- Walker MM et al.; „An update in the diagnosis of coeliac disease“; Histopathology; 2011; 59:166-179.
- Comino I et al.; „Monitoring of gluten-free diet compliance in celiac patients by assessment of gliadin 33-mer equivalent epitopes in feces“; The American journal of clinical nutrition; 2012; 95: 670-677.
- Comino I et al.; „Diversity in oat potential immunogenicity: basis for the selection of oat varieties with no toxicity“; Gut; 2011; 60: 915-922.
- Comino I et al.; „Fecal Gluten Peptides Reveal Limitations of Serological Tests and Food Questionnaires for Monitoring Gluten-Free Diet in Celiac Disease Patients“; The American Journal of Gastroenterology; 2016; 111:1456-1465 (doi:10.1038/ajg.2016.439).

Status: 2018-01-09

 Temperaturna omejitev	 Proizvajalec
 Hranite na suhem	 Serijska številka
 Kataloška številka	 Datum izteka roka uporabnosti
 Zaščitite pred sončnimi žarki	 Za enkratno uporabo
 Preberite navodila za uporabo	 zadostuje za <n> testov

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PreventID® Gluten Detect Urine test

Test instructions

PreventID® **Gluten Detect** rapid test for the detection of gluten in urine

Intended use

PreventID® Gluten Detect test is a rapid immunochromatographic test for the detection of gluten immunogenic peptides (GIP, metabolic degradation products of gluten in the body) in urine samples. Patients can use the test for monitoring of gluten free diet.

Introduction

People who feel physical discomfort after a gluten-containing meal suffer, for example, from a gluten/wheat sensitivity, wheat allergy or celiac disease, an autoimmune disease, which can manifest itself as an inflammatory intestinal disease. The symptoms are caused by the various storage proteins in grain seeds, which are summarised under the term "gluten". The symptoms range from chronic fatigue, weight loss, joint pain, numbness in the legs to muscle cramps and diarrhea.

Currently, the only effective treatment of these ailments is following a strict, life-long gluten-free diet (GFD). However, a complete avoidance of gluten in everyday life can be very difficult because gluten is contained in a variety of products as an ingredient or additive or even unintentionally by the manufacturing process. Therefore, despite all precautions, this can accidentally lead to a gluten intake. You can use the **PreventID®**

Gluten Detect to check quickly and directly whether the cause of your complaints is a gluten intake because the degradation products, the immunogenic gluten peptides ("GIP"), are detectable in urine. This allows you to react very fast and adapt your diet. A recovery of measurable amounts of GIP from stool or urine samples indicates that there has been gluten consumption and therefore constitutes an accurate and very helpful monitoring tool for a short-term and long-term GFD.

Test principle

PreventID® Gluten Detect test is an immunochromatographic test that allows detection in urine of peptides resulting from gastrointestinal degradation of ingested gluten. To perform the test, a urine sample is simply mixed with a conditioning solution that prepares it for the detection step, which is based on the reaction of the gluten peptides in the sample with a colored conjugate, previously loaded in a chromatography strip. In the presence of gluten peptides, the peptideconjugate complexes follow the capillary flow in the strip and accumulate in the test zone, resulting in a visible RED test line (T). The absence of the RED line therefore indicates a negative result. Whether or not gluten is present, a second colored conjugate will also follow the capillary flow in the strip and accumulate in the control zone, resulting in a visible GREEN line (control line) confirming that the test has func-

tioned properly. If the GREEN line does not appear, the result of the test is considered invalid.

Materials provided

- 1 test device with drying agent (not required for the test) [GlutenDetect Sticks REF: RS-6403]
- 1 bottle with conditioning solution [Conditioning solution, REF: RS-6401]
- 1 sterile syringe [Nipro 2 part syringe, REF: SY2B-2SC-W-ETR]
- test instructions

Additionally required: Urine collection cup, timer or stop watch

Storage and Stability

The test **PreventID® Gluten Detect** should be stored at 4–30 °C. Do not freeze. The rapid test device is susceptible to humidity and high temperatures. Therefore, this test should be protected from extreme temperature and should be run immediately after opening of the pouch. This test should not be run after the expiration date.

All components of the kit are fully disposable in ordinary trash or in appropriate recycling bin.

Important information

1. For the analysis of urine samples only. Do not ingest any test component.
2. Do not eat or smoke while handling specimen. Wear protective gloves if available and wash hands thoroughly after performing the test.
3. Avoid splashing or aerosol formation.
4. Clean all contaminated surfaces carefully. Dispose all test components and samples in conventional garbage.
5. Do not use test if the aluminum pouch is torn or if the membrane of the rapid test device is visibly damaged.
6. If your skin or eyes had contact with the buffer immediately wash with plenty of water.
7. Keep away from children.
8. If you have questions please contact Preventis GmbH.

Specimen collection

1. Use a standard, clean urine collection cup (not included) to collect the urine sample (5 mL of urine will be enough for one test) (Fig. 1).
2. Use a fresh plastic syringe to measure and transfer 2 mL of urine sample to the conditioning solution tube (Fig. 2).
3. Close the cap tightly and shake the tube gently for 5–10 seconds to allow mixing of the urine with the conditioning solution (Fig. 3).

4. The test should run immediately after collecting the samples at room temperature.

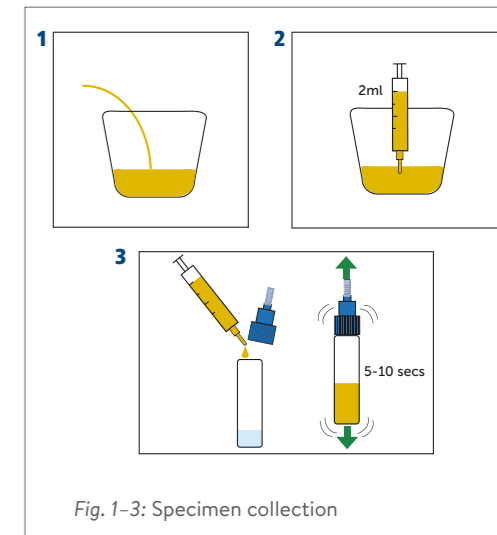


Fig. 1–3: Specimen collection

Test procedure

After specimen collection bring all test components to room temperature.

1. Directly before performing the test, open the protective foil pouch and take out the test device. Place the device horizontally, on a clean surface (Fig. 4). Use the test device directly after opening the packaging.

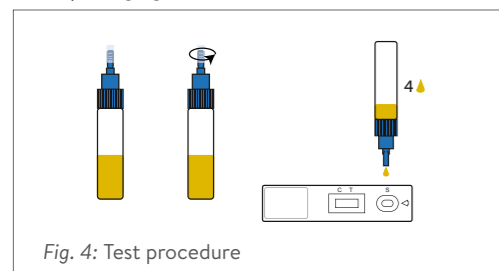


Fig. 4: Test procedure

2. Unscrew the transparent cap on the blue cap tube and carefully add 4 drops to the S zone on the test device. Set timer to 15 minutes.
3. A green control line (C) indicates a correct test run.
4. Wait 15 minutes to read the final result. If there is a high concentration of gluten in the urine sample, the result may appear in less than 1–2 minutes.

Note: After 15 minutes, the results are not reliable. We recommend to read the results at 15 minutes.

Test interpretation (Fig. 5)

The green control line at (C) indicates that the test has run correctly. Depending on the concentration of gluten immunogenic peptides (GIP) in the sample additionally a red test line (T) appears.

Negative:

A single green line (control line) appears in the central part of the strip (control zone).

Positive:

In addition to the control green line, a red line (test line) appears in the test zone.

Note: The intensity of the red line in the test zone will vary depending on the GIP concentration present in the sample. The presence of any faint line in the test zone (T) will indicate positive results no matter how light it is.

Invalid:

If the green control line does not appear, the result of the test is considered invalid, even if the red line appears in the test zone. The most common causes of an invalid result are an incorrect procedure or deterioration of the kit reagents. In case of invalid results, it is necessary to repeat the experiment with a new test always following the correct procedure. If the problem persists, please stop using the test and contact Preventis GmbH.

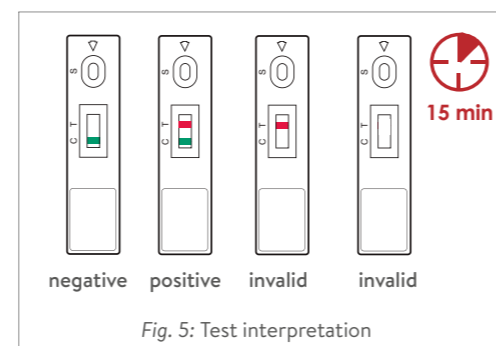


Fig. 5: Test interpretation

Test characteristics

Analytical sensitivity

The limit of detection of **PreventID® Gluten Detect** is 2.2 ng GIP/mL of urine sample.

Analytical specificity

The test is capable of detecting the presence of gluten degradation products, especially of GIP from prolamins in wheat (gliadin), rye (secalin), barley (hordein) and, when present in high amounts, oat (avenins). No cross-reactivity is detected with naturally gluten-free foods that are considered safe for celiacs, such as rice, corn, buckwheat, soybean, millet, quinoa and amaranth.

Limitations of the test











Although the **PreventID® Gluten Detect** is very accurate in detecting GIP, a low incidence of false results may occur. Other clinically available tests are required if questionable results are obtained. Test results are only reliable if you follow the instructions for use carefully.

Use the test device only once.

Literature

- Shan L et al.; „Structural basis for gluten intolerance in celiac sprue“; Science; 2002; 297: 2275-9.
- Silvester JA et al.; „Long-term follow-up of individuals with celiac disease: an evaluation of current practice guidelines“; Canadian Journal of Gastroenterology; 2007; 21:557-564.
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Status: 2018-01-09

 Temperature limitation	 Manufacturer
 Keep dry	 Lot number
 Catalogue number	 Expiry date
 Keep away from sunlight	 Do not reuse
 Read user instructions	 Contains sufficient for <n> tests

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