Instruction For Use (Not Package Insert)

For in-vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Kit for human Chorionic Gonadotropin
Auxiliary reagent for diagnosis of pregnancy

HCG Quick CHECKER Dip

[General caution]

1) This product is for in-vitro diagnostic use only. Do not use for other purpose.
2) Diagnosis should be made properly in conjunction with the assessment of clinical symptom and other test results.
3) The procedures that are not described in instruction for use are not guaranteed.

[Kit composition]

Test strip - 10 tests
- Mouse monoclonal antibody to hCG
- Mouse monoclonal antibody to hCG conjugated with colloidal gold

[Intended Use]

Detection of human Chorionic Gonadotropin (hCG) in urine

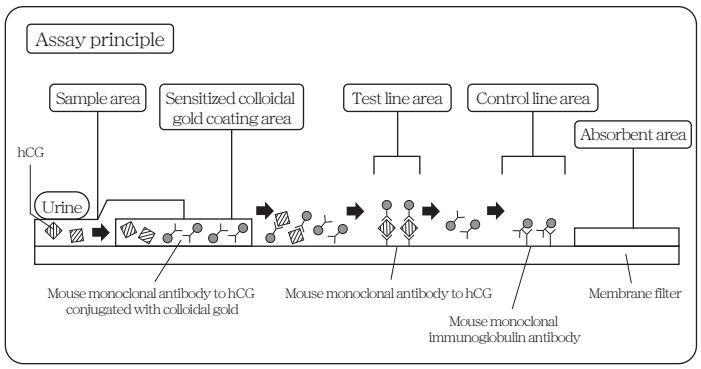
[Principle of the test]

HCG QuickChekcer Dip is in-vitro reagent for detection of hCG in urine based on immunochromatographic assay.

Mouse monoclonal antibody to hCG conjugated with colloidal gold are coated in sensitized colloidal gold coating area in membrane filter in test strip. And mouse monoclonal antibody to hCG are immobilized in test line area and anti-mouse immunoglobulin antibody are immobilized in control line area in membrane filter in test strip.

In case that hCG exists in urine, hCG in urine migrates from sample area and binds with mouse monoclonal antibody to hCG conjugated with colloidal gold to form complex in sensitized colloidal gold coating area. This complex which migrates by immunochromatographic principle is caught by immobilized mouse monoclonal antibody to hCG and form sandwich complex in test line area. As a result, purple-red line appears by colloidal gold.

Purple-red line is also visible for cathching mouse monoclonal to hCG conjugated with colloidal gold by immobilized anti-mouse immunoglobulin in control line area, regardless of presence of hCG.



[Procedural notes]

1) Characteristics of measurement sample・Collecting method
- Perform test immediately after collecting urine in clean cup.
- Serum or other body of fluids cannot be used as sample besides urine.
- Refrigerated specimen must be brought to 15 ～ 35℃ before testing.
- If the specific gravity of sample is too high or sample is too viscous, there is a possibility of poor absorption which may interfere with results.
- Do not use highly hemolytic sample.

2) Interferring substances and medications

Following substances did not interfere the performance of this product at the concentrations listed below.

Names of substances	Concentrations
Ascorbic acid	2 g/L
Ascorbate	4 g/L
Acetaminophen	2 g/L
Albumin (Human)	6 g/L
Caffeine	4 g/L
Glucose	100 g/L
Salicylic acid	1.75 g/L
Uric acid	240 mg/L
Urea	50 g/L
Bilirubin	300 mg/L
Hemoglobin	5 g/L

3) Cross reactivity

Cross reactivity were not observed until LH 1000mIU/mL, FSH 1000mIU/mL and TSH 1 mIU/mL.

4) Influence by pH

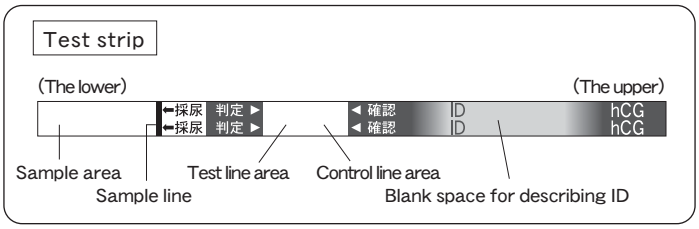
Test results were not influenced by urine which are ranged between 4.0 and 10.0

[Assay procedure]

1) Preparation method of reagent

No prior preparation required

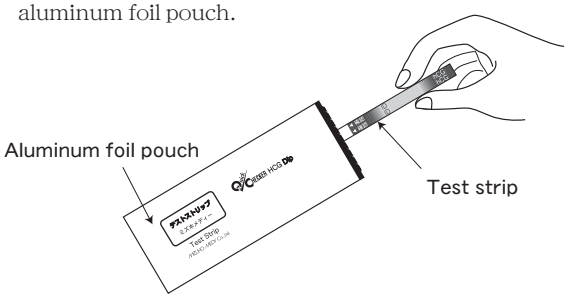
2) Details of test strip



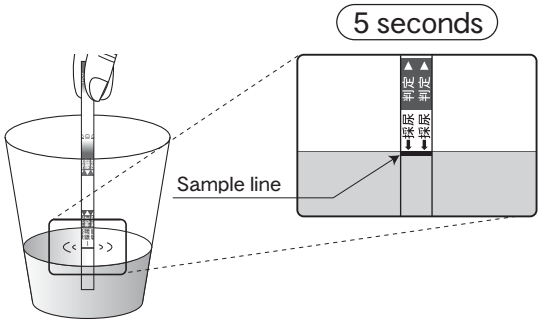
3) Test procedure

Bring test strip to 15 ～ 35℃ before test is performed.

① Take out test strip from aluminum foil pouch.

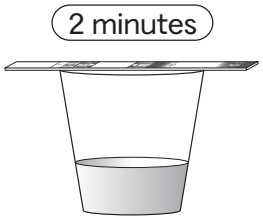


② Immerse sample area of test strip in urine sample, collected in paper cup etc. up to sample line and leave it for full 5 seconds.



Be careful not to wet test line area and control line area.
In case of immersing sample area of test strip in urine beyond the sample line, test line and control line could not appear.

③ Remove test strip from urine sample and place it on surface of paper cup etc. horizontally, facing test results area up.
(Do not put test strip on paper etc. which have water absorbability or do not wipe the sample area off.)



④ Interpret test results at 2 minutes after immersing in urine sample. Streak line might appear temporarily before 2 minutes due to migration of colloidal gold. Do not interpret the temporal streak line as appearance of test line.

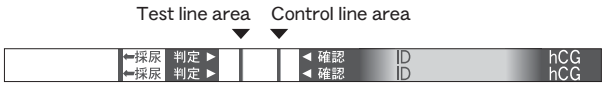
[Interpretation of test results]

1) Interpretation method

Interpret test results by red-purple lines which appear in test line area and control line area of test strip.

《Positive》

If lines appear in both test line area and control line area, interpret the test result as positive.



《Negative》

If a line appears in control line area only, interpret the test result as negative.

《Retest》

If both test line and control line do not appear or only test line appear with no control line, recheck the test procedure and retest with new test strip.

2) Note for interpretation

① Interpret the test results at the time of 2 minutes after immersing in urine. Please note that there is a possibility that exact test results may not be read in case of interpretation after a long time pass.

② The following cases may cause positive result besides normal pregnancy.

- Menopause
- If you are administered gonadotrophic hormone including hCG as ovulation inducer
- hCG producing tumor (Chorioepithelioma etc.)
- After delivery, miscarriage, or artificial abortion

③ The following cases may cause negative result even though you are pregnant.

- Abnormal pregnancy (ectopic pregnancy etc.)
- Insufficient hCG in urine due to early stage of pregnancy
- The concentration of hCG in urine go beyond the measurement range (In case of hydatidiform mole or there are rare cases where the concentration of hCG in urine go beyond the measurement range around third months of pregnancy or later. In that case, retest the urine after diluting it tenfold with purified water or saline)

④ If test results are unclear, retest after several days.

⑤ This product is the reagent which is used as aid in the diagnosis of pregnancy. It is recommended that the confirmation of pregnancy be made in conjunction with other clinical findings etc. comprehensively.

[Performance]

1) Sensitivity

When in-house hCG positive controls (12.5 mIU/mL) are tested, positive results are obtained.

2) Accuracy

- When in-house hCG positive controls (12.5mIU/mL) are tested, positive results are obtained.
- When in-house hCG negative controls are tested, negative results are obtained.

3) Reproducibility

- When in-house hCG positive controls (12.5mIU/mL) are tested three times simultaneously, positive results are obtained in all cases.
- When in-house hCG negative controls are tested three times simultaneously, negative results are obtained in all cases.

In-house hCG negative control:
Urine sample, not including hCG

In-house hCG positive control:
Buffer sample, including hCG (WHO International Standard for Human Chorionic Gonadotrophin)

4) Detection limit

12.5 mIU/mL

However, negative result could be caused by prozone effect in concentrations of 2×10^6 mIU/mL or more.

5) Correlation

HCG QuickChecker Dip showed good correlations in comparison with approved existing products (Immunochromatographic assay) as follows:

HCG QuickChecker Dip

Other product 1

	Positive	Negative	Total
Positive	63	0	63
Negative	0	66	66
Total	63	66	129

Positive agreement rate : 100%
Negative agreement rate : 100%
Total agreement rate : 100%

HCG QuickChecker Dip

Other product 2

	Positive	Negative	Total
Positive	63	0	63
Negative	0	66	66
Total	63	66	129

Positive agreement rate : 100%
Negative agreement rate : 100%
Total agreement rate : 100%

[Precaution for use and handling]

1) Precaution for handling (Prevention of danger)

①Be careful of handling specimen as potentially viral or bacterial infectious material.Wear disposable gloves for avoiding potential infection at the time of testing.

②Be careful not to touch specimen or extraction reagent solution directly to skin or eyes.

③This product includes sodium azide. Do not touch the side surface (sensitized colloidal gold coating area) of "採尿、判定"directly.

④Raw material of membrane used for test strip is nitrocellulose. Do not perform test near fire because nitrocellulose is extremely flammable material.

⑤Wipe scattered specimen off by alcohol for disinfection.

2) Precaution for use

①This product is reagent for detecting hCG in urine qualitatively. Do not use this product for the purpose of detecting quantitatively.

②Do not use beyond expiration date.

③Do not touch Specimen area, Test line area and Control line area by hands directly.

④If test strips are stored at temperatures below 15 ℃, test strips must be brought to 15～35℃ before opening aluminum foil pouch.

⑤Immediately use test strip after opening of aluminum foil pouch. If it is left in air for long time after opening, it could be non-reactive due to getting moistened.

⑥Be careful not to immerse sample area of test strip in urine beyond the sample line because it could avoid appearances of test line and control line.

⑦Do not wipe off sample area with tissue etc. It could interfere with the reaction due to insufficient volume of sample.

⑧Use sample for testing as soon as possible after taking sample. If sample have to be stored necessarily, store it with frozen temperature.

⑨If test line area and control line area of test strip are contacted by urine etc. directly, it could cause wrong test results. In that case, stop using the test strip and retest with new test strip.

3) Precaution for waste disposal

Dispose of products or container etc. contacted by sample as infective wastes in accordance with your local rule/ internal rule.

[Storage・Expiry]

・Storage : 1～30℃

・Expiry : 18 months

Technical information
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