For professional use

Humasis hCG Combo

One Step Pregnancy Test

Please read the instructions carefully before use!

[INTENDED USE]

Humasis hCG Combo is a one step in vitro diagnostic test based on immunochromatographic assay. It is designed for qualitative determination of human chorionic gonadotropin(hCG) in specimen(urine and serum) as an aid in the early determination of pregnancy.

[SUMMARY AND EXPLANATION]

hCG is a glycoprotein hormone secreted by the placenta shortly after implantation. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after fertilization. The appearance of hCG in both specimen and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

[PRINCIPLE OF THE TEST]

Humasis hCG Combo uses monoclonal antibodies specific to intact whole hCG for accurate determination of pregnancy. Specimen is added to sample well on the test device. If hCG is present in the specimen at levels of 25mIU/mL or greater, a colored line is appeared in the test line region. If hCG is present at a lower levels, or not present in the specimen, the test line region will remain colorless. The sample continues to move to the control line region and forms a colored line, indicating the test is working and its result is valid.

[CONTENTS]

Test devices
Disposable pipettes
Instruction manual

[COMPONENTS]

Mouse anti-hcg monoclonal antibody 1	0.045±0.01㎍
Mouse anti-hcg monoclonal antibody 2	0.32±0.06㎍
Anti-mouse immunoglobulin G	0.8±0.16㎍
Gold conjugate pad	4±1 X 7±4mm
Sample pad	4±1 X 20±4mm
Absorbance pad	4±1 X 20±4mm
Nitrocellulose membrane	4±1 X 25±4mm

[PRECAUTIONS]

1. For in vitro diagnostic use only.
2. Do not use the test device after expiry date.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious reagent. The test cassette should be discarded in a proper biohazard container after testing.
4. Do not open the test foil pouch until ready to perform the test.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

[TEST PROCEDURE]

1. Bring all materials and specimen to room temperature.
2. Open the foil pouch and place the test device on a clean, dry and level surface.
   NOTE 1 : Once the foil pouch is opened, the device should be used as soon as possible.
3. Use the disposable pipette to deliver 3 drops (about 100㎕) of specimen into the sample well, and then start the timer. The test device should not be handled or moved until the test is completed and ready for reading.
4. Wait for the red line(s) to appear. Interpret test results at 5 minutes.
   NOTE 2 : A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 5 minutes.

[STORAGE AND SHELF-LIFE]

1. Store the test device packaged in a sealed foil pouch at 1~30℃(34~86℉). Do not freeze.
2. Shelf-life : 24 months from manufacturing date

[SPECIMEN COLLECTION AND PREPARATION]

[Urine assay]

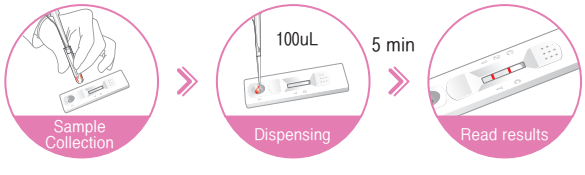
1. Urine specimen may be collected in any clean, dry plastic or glass container.
2. Using a fresh urine specimen is recommended and the test should run as soon as possible after collection. Do not leave or store for prolonged period.
3. Specimen centrifugation or filtration is not required. However, Urine samples exhibiting visible precipitates should be centrifuged, filtered to obtain a clear sample for testing.

[serum assay]

1. Blood should be collected aseptically into a clean tube without anticoagulants.
2. Separate the serum from blood as soon as possible to avoid hemolysis.
3. Use clear non-hemolyzed specimens when possible.
4. Heat inactivation of specimens, which may cause protein denaturation, should be avoided.

[Specimen Storage]

1. Urine or serum specimen may be stored at 2-8℃ for up to 48 hours prior to testing. For prolonged storage, samples may be frozen and stored below -20℃.
2. Frozen samples should be thawed and mixed before testing.



[INTERPRETATION OF RESULTS]

1. Negative

If the test line region(T) has no color line and the control line region(C) displays a colored line, this result indicates that you are not pregnant.

2. Positive

If the test line region(T) has a colored line and the control line region(C) displays a colored line, this result indicates that you are pregnant. The test result can be read as soon as a distinct colored line appears in test line region.

3. Invalid

If there is no color line in the control line region(C) , the result is invalid. This is due to deterioration of the test device or improper test procedure. Repeat the test with a new test device.

[QUALITY CONTROL]

The appearance of the control line indicates that sufficient sample fluid was added for capillary flow to occur and all of the reagents in the test device are working properly. The absence of the control line may indicate that insufficient sample added or the test device is inactivated.

[LIMITATIONS OF THE TEST]

1. Humasis hCG Combo is for the qualitative detection of hCG in urine and serum.
2. A number of medical conditions other than normal pregnancy, including ectopic pregnancy, trophoblastic disease and certain non-trophoblastic neoplasm such as testicular tumors, prostate cancer, breast cancer and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in the specimen should not be used to diagnose pregnancy unless these conditions are ruled out.
3. hCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion, therapeutic abortion or hCG injection.
4. Positive results from early pregnancy may later prove negative due to natural termination of the pregnancy. This is estimated to occur in 22% of clinically unrecognized pregnancies and 31% of pregnancies overall. It is therefore recommended when using a sensitive hCG assay such the Humasis hCG Combo that weak positive results be retested 48~72 hours later.
5. Test results must always be evaluated with other data available to the physician.
6. Humasis hCG Combo cannot discriminate abnormal pregnancyn like ectopic pregnancy or abortion from normal pregnancy. Therefore these conditions should be ruled out when diagnosing pregnancy.
7. Early pregnancy associated with a low level of hCG may show color development after 5 minute procedure time. If a negative result is obtained but pregnancy is suspected, hCG levels may be too low diluted for detection.
8. False positive results may appear in sensitive immunoassays due to the presences of heterophilic antibodies like human anti-mouse antibodies or nonspecific protein binding.

[EXPECTED VALUES]

Healthy man and non-pregnant women do not have hCG levels detectable by the Humasis hCG Combo plus. In normal pregnancy levels of 20mIU/ml hCG can be reached 2-3 days before the first missed menstrual period. HCG levels peak 8-10 weeks after the LMP and decrease to lower values during the remained period of the pregnancy. Following delivery, hCG levels rapidly decrease and returns to normal within days after parturition. Humasis hCG Combo is not showing prozone phenomenon with 500.000 mIU/ml high level of hCG samples in human urine or serum specimens.

[PERFORMANCE CHARACTERISTICS]

1. Analytical sensitivity and precision

The detection limit was evaluated in conjunction with the precision / reproducibility data. The results showed positive more than 25mIU/mL hCG and confirmed reproducibility of each Lot and each sample type (urine and serum).

2. Cross-reactivity

Below potential cross-reactive substances did not affect performance of the Humasis hCG Combo.

Homologous hormones	Source	Code No.	Concentration tested
LH	NIBSC	2nd IS (80/552)	500mIU/mL
FSH	NIBSC	1st IS (92/512)	1000mIU/mL
TSH	NIBSC	1st IS (03/192)	1000mIU/mL

3. Interference

Below potential interfering substances did not affect performance of the Humasis hCG Combo.

Analytes	Concentration tested	Analytes	Concentration tested
Amoxicillin	20 mg/dL	Glucose	2000 mg/dL
Ampicillin	20 mg/dL	Hemoglobin	10 mg/dL
Ascorbic acid	20 mg/dL	Human Albumin	20 mg/dL
Bilirubin	20 mg/dL	Human IgG	10 mg/dL
Caffeine	20 mg/dL	Oxalic acid	10 mg/dL
Cyanocobalamine	1 mg/dL	Sodium Chloride	10 mg/dL
Ethanol	10 mg/dL	-	-

4. Clinical evaluation

A comparison study was performed to determine the accuracy of the Humasis hCG Combo using various positive and negative urine samples. Each specimen was tested simultaneously with both the Humasis hCG Combo and the comparative device.

A 203 positive and 258 negative urine sample was confirmed through Medical History and ultrasound diagnosis method. The following results were obtained.

Humasis hCG Combo	Comparative device		Total
	Positive	Negative	
Positive	203	0	203
Negative	0	258	258
Total	203	258	461

Relative sensitivity: >99% (203/203) (95% CI: 98.1% - 100%)
Relative specificity: >99% (258/258) (95% CI: 98.5% - 100%)
Accuracy: >99% (461/461)

A comparison study was performed to determine the accuracy of the Humasis hCG Combo using a total of 70 serum samples consisted of 20 positive samples and 50 negative samples. Each specimen was tested simultaneously with both the Humasis hCG Combo and the comparative device.

A positive and negative serum sample was confirmed through Medical History and ultrasound diagnosis method. The following results were obtained.

Humasis hCG Combo	Comparative device		Total
	Positive	Negative	
Positive	20	0	20
Negative	0	50	50
Total	20	50	70

Relative sensitivity: >99% (20/20) (95% CI: 83.9% - 100%)
Relative specificity: >99% (50/50) (95% CI: 92.9% - 100%)
Accuracy: >99% (70/70)

[REFERENCES]

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IVD : For *in vitro* diagnostic use
LOT : Lot number
REF : Catalogue number
: Consult instructions for use
: Store at 1~30℃
: Do not reuse
EC REP : Authorized Representative
: Manufactured by
EXP : Use by / Expiry date
CE : This product fulfills the requirements for Directive 98/79/EC on *in vitro* diagnostic medical devices

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