



Pregnancy Test

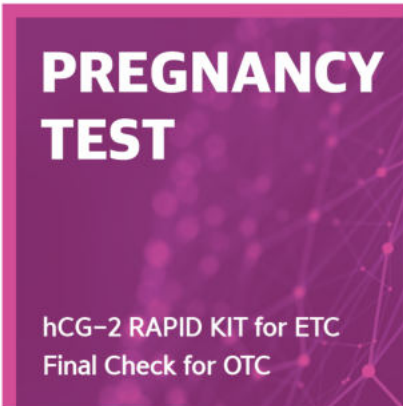
- hCG-2 RAPID KIT
- Final Check

ADTech Co., LTD

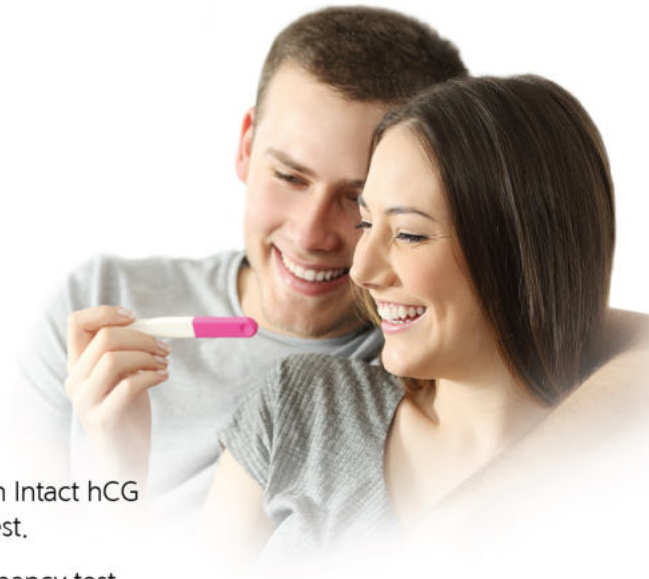
에이디텍 주식회사

TOTAL IVD SOLUTION PROVIDER

NOVEL IMMUNOASSAY



New Marker β core fragment hCG



- ✓ Inaccurate test only with Intact hCG in existing pregnancy test.

Feel free & safe in pregnancy test with β core fragment hCG

β core fragment hCG (βcf hCG)?

- βcf hCG is one of the hCG hormones released during pregnancy and only present in urine as New pregnancy diagnostic marker.
- Because βcf hCG can be detected accurately even at high concentration of hCG, βcf hCG as new marker can prevent False Negative errors caused by Hook-effect.
- ※ β-hCG is a blood marker to diagnose pregnancy and Intact hCG is the standard urine marker to diagnose pregnancy.
- ※ βcf hCG is a metabolite of Intact hCG and is not same with β-hCG.

Product information

hCG-2 RAPID KIT

- For Hospital and clinics(ETC)
- Ref. : C 0402
- Result check in 3 min
- Package: 20 Tests@kit
- Storage : room temperature storage (4°C~30°C/ 39.2°F~86°F)
- Expiry date: 2 years from manufactured



hCG-2 RAPID KIT

Cut-off Value
Intact hCG : 25 mIU/ml
β core fragment hCG : 1.0 pmol/ml

Final Check

- For individuals(OTC)
- Ref. : C 0404(1 Test) / C 0405 (2 Test)
- Result check in 3 min
- Package 1 Test @kit / 2 Tests @kit
- Storage : room temperature storage (4°C~30°C/ 39.2°F~86°F)
- Expiry date: 2 years from manufactured



Final Check

Cut-off Value
Intact hCG : 25 mIU/ml
β core fragment hCG : 0.1 pmol/ml



Patent application

Korea 10-2019-0080618
PCT PCT/KR2019/009573
USA 16/572,364
Japan 2019-563176

* Certification : KFDA(Korea) #JEIN 19-4344 / #JEIN-19-4960

ADTech Final Check, Why so accurate?

01



Problem

Existing pregnancy test kit can detect only Intact hCG.

“ Possible occurrence of False Negative (Hook effect) ”

02



Solution

By adding β core fragment hCG as new marker, Intact hCG and β core fragment hCG can be detected separately at a time.

“ Using new pregnancy marker ”

03

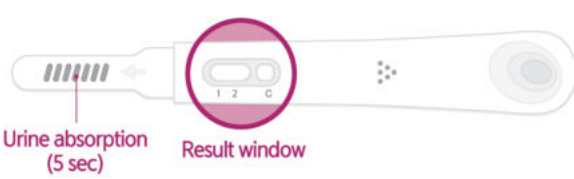



Result


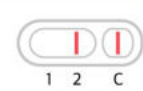






More precise analysis to prevent False Negative errors in Pregnancy test.

“ 3-line Pregnancy test, Final Check ”

Final Check vs existing test



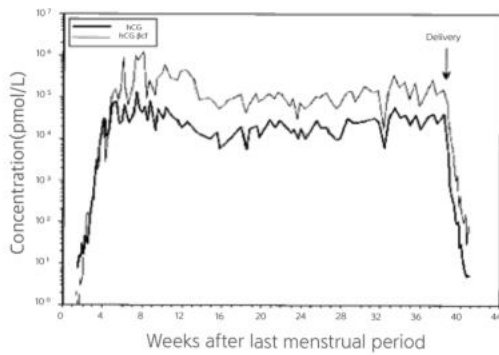


Comparison with conventional pregnancy test				
Result	Negative	Positive		
Status	Not Pregnant	Early	Pregnant	Hook effect (High concentration of hCG)
Final Check				
	Negative	Positive		
Existing Test				
	Negative	Positive	False Negative	

* In case C(control line) does not show up, re-test is required.



Change in secretion of hormones during pregnancy



Weeks since LMP	mIU/mL
3	5-50
4	5-426
5	18-7,340
6	1,080-56,500
7-8	7,650-229,000
9-12	25,700-288,000
13-16	13,300-254,000
17-24	4,060-165,400
25-40	3,640-117,000

Intact hCG

Clinical study for "effect of β cf hCG in pregnancy test"

Clinical Chemistry 55:7
1389-1394 (2009) Endocrinology and Metabolism

False-Negative Results in Point-of-Care Qualitative Human Chorionic Gonadotropin (hCG) Devices Due to Excess hCG β Core Fragment

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Nominated as neo technology candidate by HIRA (Health Insurance Review and Assessment Service)



ADTech's Final Check

can prevent the False Negative errors by using novel marker, and diagnose more precisely.
 NOW, finally check the pregnancy test with 3-line Final Check.

hCG-2 RAPID KIT(ETC)



hCG-2 RAPID KIT(ETC) 20 Tests @ kit

Final Check (OTC)



Final Check 1 Test/ 2 Tests



Q&A for Final Check

Q False Negative?

A The test result that is originally positive appears to be negative as a test error.

Q Why is the new marker, β cf hCG so important?

A To diagnose hCG(Intact hCG) alone has the potential error of False- Negative, so to diagnose hCG and β cf hCG simultaneously improves the accuracy of pregnancy test. Final Check can detect pregnancy more precisely with β cf hCG, even if hCG is not detected due to hook effect.

Q Hook effect?

A When hCG is highly concentrated in urine, hCG line may not be detected or appear very dimly and this is one of the main causes of False Negative errors in Pregnancy test.

Q What is Test lines ?

A The test line C(control line) is a control line that must appear in the diagnostic test. If the control line does not appear, you must retest. Test line T1 detects β cf hCG and T2 detects Intact hCG.



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인류의 행복과 무병 장수의
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