



WOMEN'S HEALTH

Pregnancy

MRK220004

Human Chorionic Gonadotropin (hCG)

The Pregnancy One Step Rapid Test is an *in vitro* diagnostic qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine and/or serum specimen to aid in the detection of pregnancy. The test utilizes highly sensitive colloidal gold nanoparticles to provide a distinct, visually-read result.

Human chorionic gonadotropin (hCG) is a hormone, produced by the developing placenta shortly after conception and secreted into the urine.

FEATURES

- Read in 5 minutes
- Urine and/or serum specimen
- Available in Strip, Cassette, Midstream formats
- 99% Accuracy rate
- 24-month shelf life from date of manufacture
- OEM & private label available

BENEFITS

- Easy-to-read results
- FDA-Cleared and CLIA-Waived (See ordering details)
- OTC (Over-the-Counter) available



TEST MENU

Item Code	Cut-off (mIU/mL)	Format	Specimen	UOM (Tests/Kit)
Analog Pregnancy Tests				
GAHCG-102a (CE, FDA 510k)	25	Cassette	Urine	25
GAHCG-102b (CE)	10	Cassette	Urine	25
GAHCG-103a (CE, FDA 510k)	25	Midstream	Urine	1/2/20
GAHCG-103b (CE)	10	Midstream	Urine	1/2/20
GAHCG-202a (CE)	25	Cassette	Urine/Serum	25
GAHCG-202b	10	Cassette	Urine/Serum	25
Digital Pregnancy Tests				
GAHCG-D103a (CE)	25	Midstream	Urine	1





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Ovulation

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Luteinizing Hormone (LH) Rapid Test

The LH Ovulation test is a lateral flow immunoassay for qualitative detection of luteinizing hormone (LH) in female urine. The test is intended to aid in the tracking of the ovulation cycle in women.

The test provides a systematic approach to predicting the time of ovulation and peak fertility by detecting an LH surge in urine. LH surges indicate that ovulation is likely to occur within the next 24 - 36 hours.

FEATURES

- Qualitative, visually read result
- Detection of luteinizing hormone (LH) in urine
- Ambient Temperature Storage
- 510(K) Exempt

BENEFITS

- Assists in identifying ovulation cycle
- Time to Results: 10 minutes
- Storage: 2 - 30°C / 35.6 - 86°F
- Shelf Life: 24 months from date of manufacture



TEST MENU

Item Code	Cut-off (mIU/mL)	Format	Specimen	UOM (Tests/Kit)
GALH-101a (CE)	25	Strip	Urine	100
GALH-101b (CE)	40	Strip	Urine	100
GALH-102a (CE)	25	Cassette	Urine	25
GALH-102b (CE)	40	Cassette	Urine	25
GALH-103a (CE)	25	Midstream	Urine	1/5/20
GALH-1103b (CE)	40	Midstream	Urine	1/5/20

