Alere™

hCG Easy (25 mIU/mL)

IVD

Intended Use

Alere™ hCG Easy (25 mIU/mL) is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine as an aid in the diagnosis of pregnancy. For professional *in vitro* diagnostic use only.

Introduction

hCG is a glycoprotein hormone produced by the blastocyst.[1,2] hCG normally begins to be detected in the urine from 7 days after conception. The sudden rapid rise in concentration of hCG in urine following conception makes it an excellent marker for pregnancy.[3,4]

Test Principle

Urine is added to the absorbent sampler, which contains blue beads attached to anti-hCG monoclonal antibodies. Urine mobilises the labelled antibodies and moves up the test strip, which contains regions of immobilised antibody. If hCG is present at ≥25 mIU/mL, a blue Result Line (R) should become visible in the Result Window (see Figure 1). No Result Line (R) indicates the test is negative. To serve as a procedural control, a blue line will always appear in the control line region. If the control line does not appear, the test result is not valid.

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Kit Contents and Storage

Materials Provided

20 individually foil wrapped devices. 1 package insert. Store at 2-30 °C. Do not use after the expiry date.

Materials Required But Not Provided

- Specimen collection container
- Timer
- Pipette

Precautions

1. Do not open the foil pouch until ready to test.
2. Do not use devices that have become wet, or if the foil pouch has been damaged.
3. Do not use kit beyond expiration date printed on the outside of the kit carton.
4. Do not reuse device.
5. Do not eat, drink or smoke in the area where the specimens or kits are handled.
6. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing.
7. It is recommended that disposable gloves should be

worn while handling specimens.

8. All specimens and specimen contaminated materials should be disposed of in accordance with local biohazard waste disposal protocol.
9. To obtain accurate results, the package insert instructions must be followed.

Sample Collection and Storage

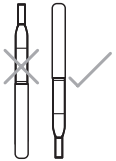
A urine sample collected any time of day is suitable but a first morning urine sample is recommended.[5] Urine samples must be collected in **clean**, dry plastic or glass containers. Samples may be stored in the refrigerator (2-8 ºC) for up to 72 hours, or frozen once at -20 ºC for up to 3 months. Samples **must** be allowed to reach room temperature (18-30 ºC) prior to testing. No sample preparation is required, although particulate matter should be allowed to settle before testing. **Alere™ hCG Easy (25 mIU/mL)** is not validated for use with samples containing preservatives.

Assay Procedure

Ensure all **Alere™ hCG Easy (25 mIU/mL)** devices and samples are at 18-30 ºC. When ready to test, tear open the foil wrapper and remove the device.

After use of device in test, place cap over absorbent sampler.

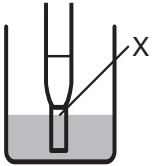
Do not invert the device during testing



Follow **one** of the following procedures:

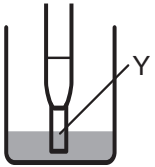
Method A – Dip

- Dip the absorbent sampler into the sample to point X, as shown in the diagram.
- **DO NOT** immerse any plastic parts in urine.
- Hold in place for 15 seconds.
- Remove the device from the sample.
- Place the cap over the absorbent sampler. **DO NOT** invert the device.
- Read result at 3-10 minutes after applying sample. It is important that the background is clear before the result is read.



Method B – Dip And Leave

- Dip **half** of the absorbent sampler into the sample to point Y, as shown in the diagram.
- Leave in place for 3 to 10 minutes.
- Remove the device from the sample.
- Place the cap over the absorbent sampler. **DO NOT** invert the device.
- Read result straight away. It is important that the background is clear before the result is read.



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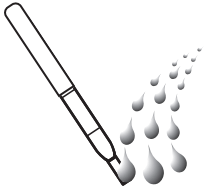
Method C – Pipette

- Place the device on a clean, dry, flat surface with the absorbent side of the sampler facing upwards.
- Pipette 100µL of the urine sample onto the absorbent sampler.
- Place the cap over the absorbent sampler. **DO NOT** invert the device.
- Read result at 3-10 minutes after applying sample. It is important that the background is clear before the result is read.

Method D – Urine Stream

- Ask the patient to hold the absorbent sampler pointing downwards in their urine stream for 3 to 7 seconds **only**.
- Place the cap over the absorbent sampler. **DO NOT** invert the device.
- Place the device on a flat surface.
- Read result at 3-10 minutes after applying sample. It is important that the background is clear before the result is read.



Interpretation of Results

The test can be read 3-10 minutes after applying the sample, regardless of which test procedure is used. See Figure 1.

- **POSITIVE: Two blue lines appear.** One line should be in the Control Line region (C) and another line should be in the Result Line region (R) of the Result Window. The color intensities of lines may vary. Therefore, any shade of color in the Result Line region (R) should be considered positive.
- **NEGATIVE: One blue line appears in the Control Line region (C).** No apparent blue line appears in the Result Line region (R) of the Result Window.
- **INVALID: Control Line (C) fails to appear.** Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new device. If the problem persists, discontinue using the kit immediately and contact your local distributor.
- Any result that appears after 10 minutes must be ignored.

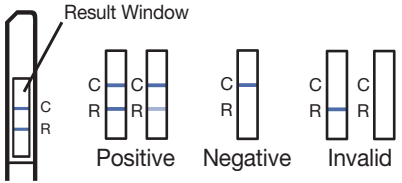


Figure 1

Quality Control

A procedural control is included in the test. A colored line appearing in the control region(C) is the internal procedural control. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the result may be invalid.

It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing “0” mIU/mL hCG) be evaluated to verify proper test performance when a new shipment of tests are received.

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Limitations of the Test

1. Positive results from very early pregnancy may later prove negative as natural termination is estimated to occur in 31% of all conceptions.[6] It is therefore recommended that weak positive results are re-tested 48-72 hours later with a first morning urine sample.
2. A negative result may be obtained if a urine sample is too dilute. If pregnancy is still suspected, it is recommended the patient should be retested 48-72 hours later with a first morning urine sample.
3. Concentrations of hCG are generally lower in ectopic pregnancy than expected normal values for a given gestational age. Abnormal pregnancy cannot be distinguished from normal pregnancy by hCG levels alone.[2,7]
4. hCG remains elevated for a time after pregnancy.[8] Pregnancy tests carried out less than 3 weeks after giving birth or 9 weeks after natural loss or termination may need further evaluation.
5. A number of conditions other than pregnancy can cause elevated levels of urinary hCG e.g. menopause, trophoblastic disease, and certain non-trophoblastic neoplasms.[9]
6. Samples containing <25 mIU/mL hCG may test positive but samples containing <5 mIU/mL should be negative.
7. Drugs containing hCG may interfere with **Alere™ hCG Easy (25 mIU/mL)**, and produce misleading results.
8. False positive and false negative pregnancy tests may be observed in patients with abnormal bladder or kidney function e.g. enterocystoplasties[10] and renal failure.
9. If the test result with **Alere™ hCG Easy (25 mIU/mL)** is not consistent with clinical evidence, further evaluation may be required.
10. Inconsistent results may be obtained if the urine sample contains excessive amounts of bacteria.
11. **Alere™ hCG Easy (25 mIU/mL)** has not been validated for use with samples containing preservatives.

12. Concentrations of hCG greater than 250,000 mIU/mL may elicit a prozone effect.
13. If the test result is inconsistent with, or unsupported by, clinical evidence, results should also be confirmed by an alternative hCG method. **Unexpected test results should be confirmed using a quantitative hCG assay prior to the performance of any critical medical procedure.**

Expected Values

Urine samples from healthy males and post-menopausal females generally contain <10 mIU/mL hCG.[11] On the first day of the first missed period, the levels of maternal urinary hCG are normally 50-250 mIU/mL. During the first trimester hCG levels peak at up to 200,000 mIU/mL in a typical pregnancy.[3,12]

Alere™ hCG Easy(25 mIU/mL) can detect hCG in urine at concentrations of ≥ 25 mIU/mL. Samples containing < 5mIU/mL hCG should be negative.

Performance Characteristics

Sensitivity

Alere™hCG Easy (25mIU/mL) can detect hCG in urine at concentrations of ≥25 mIU/mL. The test has been standardized to the W.H.O 4th International hCG Standard. Samples containing <5 mIU/mL hCG should be negative.

Prozone Effect

Alere™ hCG Easy (25 mIU/mL) has been shown to produce positive results with samples containing up to and including 250,000 mIU/mL hCG, which is higher than the maximum level expected during a typical pregnancy.

Specificity

Cross-reactivity

The addition of LH (500 mIU/mL), FSH (200 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) samples showed no cross-reactivity.

Interference

No interference was detected when the following substances were added to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG):

- Acetylsalicylic acid (0.2 mg/mL)
- Albumin (12 mg/mL)
- Ascorbic acid (2 mg/mL)
- Bilirubin (10 µg/mL)
- Caffeine (0.2 mg/mL)
- Glucose (10 mg/mL)
- Haemoglobin (3.6 mg/mL)
- Oestrone-3-glucoronide (1 µg/mL)
- Pregnanediol-3-glucuronide (1 µg/mL)

Summary tables Alere™ hCG Easy (25 mIU/mL)

Shown below are the results of Alere™ hCG Easy (25 mIU/mL) compared directly with a quantitative method for hCG analysis. These results, excluding samples in the equivocal range 5-25 mIU / mL, demonstrate an accuracy of ≥ 99.5% for all sampling methods, at 3 minutes and at 10 minutes read-time.

Agreement between Alere™ hCG Easy (25 mIU/mL) at 3 mins and quantitative method for hCG analysis

		Quantitative hCG reference method		
hCG Sampling Method	**Alere™ hCG Easy (25 mIU/mL) read at 3 mins**	**Positive**	**Negative**	**Total**
Dip	**Positive**	94	0	94
	Negative	0	96	96
	Total	94	96	190
	Sensitivity 100.0% (96.9%-100%)			
	Specificity 100.0% (96.9%-100%)			
	Accuracy 100.0% (98.4%-100%)			

		Quantitative hCG reference method		
hCG Sampling Method	Alere™ hCG Easy (25 mIU/mL) read at 3 mins	Positive	Negative	Total
Dip and Leave	Positive	96	0	96
	Negative	0	95	95
	Total	96	95	191
	Sensitivity 100.0% (96.9%-100%)			
	Specificity 100.0% (96.9%-100%)			
	Accuracy 100.0% (98.4%-100%)			

		Quantitative hCG reference method		
hCG Sampling Method	Alere™ hCG Easy (25 mIU/mL) read at 3 mins	Positive	Negative	Total
Pipette	Positive	94	0	94
	Negative	1	95	96
	Total	95	95	190
	Sensitivity 98.9% (94.3%-100%)			
	Specificity 100.0% (96.9%-100%)			
	Accuracy 99.5% (97.1%-100%)			

		Quantitative hCG reference method		
hCG Sampling Method	Alere™ hCG Easy (25 mIU/mL) read at 3 mins	Positive	Negative	Total
Urine Stream	Positive	86	0	86
	Negative	0	90	90
	Total	86	90	176
	Sensitivity 100.0% (96.6%-100%)			
	Specificity 100.0% (96.7%-100%)			
	Accuracy 100.0% (98.3%-100%)			

All samples (n=15) in the equivocal range 5-25 mIU/mL were excluded. 7 samples in the range 5-25 mIU/mL were positive by **Alere™ hCG Easy (25 mIU/mL)** with each sampling method.

Alere™ Product Support

Contact one of the following Alere™ Product Support Care Centers or your local distributor if you have any questions regarding the use of your Alere™ product. You may also contact us at www.alere.com.

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Index of Symbols

	Consult instructions for use		Use-by Date
IVD	*in vitro* diagnostic medical device	LOT	Batch code
2°C 30°C	Store between 2-30°C	EC REP	Authorized representative in the European Community
	Manufacturer		Do not reuse
Σ	Contains sufficient for <*n*> tests	REF	Catalogue Number