



# Early Detection Pregnancy Test Package Insert

REF	L031-20198-101	English
REF	L031-20198-102	
REF	L031-20198-103	

### For Self-Testing

#### INTENDED USE

The *HealthyMe*® Early Detection Pregnancy Test is an aid for the early detection of pregnancy intended for home use. The test performs qualitative detection of human chorionic gonadotropin (hCG) in urine. This test can help determine pregnancy as early as 6 days before the day of the missed period (5 days before the day of the expected period).

For questions about your results or how to use the *HealthyMe*® Early Detection Pregnancy Test, please call us toll-free at 1-800-838-9502.

#### PRECAUTIONS

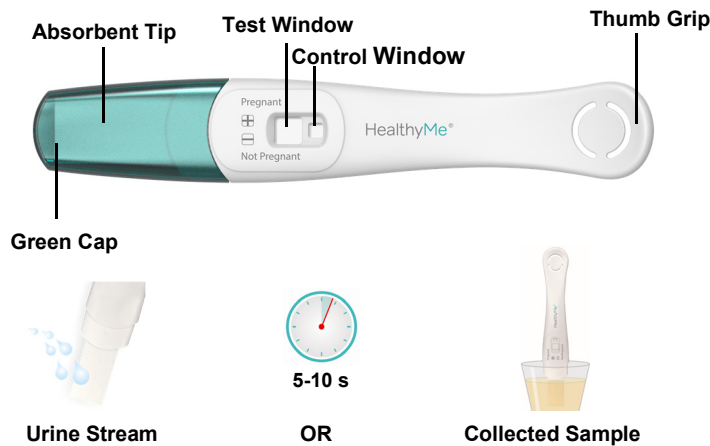
Please read all information in the package insert before using the test.

- Do not use after the expiration date printed on the foil pouch.
- Store in a dry place at 36-86°F (2-30°C). Do not freeze.
- Perform the test at room temperature (59-86°F or 15-30°C).
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For in vitro diagnostic use. Not to be taken internally.
- Do not open the test foil pouch until you are ready to start the test.
- Do not touch the plastic film in the test window.
- Single-use device. Do not reuse.

#### KIT CONTENTS

- Pregnancy Test(s)
- Package insert

#### DIRECTIONS FOR USE



If you are testing before your expected period, use your first-morning urine, as it contains the most pregnancy hormone. If testing on the day of or any day after your expected period, you can test any time of the day.

1. Remove the test from the pouch and remove the green cap. You can perform the test by either of two methods:

- a. **Midstream method:** Hold the device by the Thumb Grip with the absorbent tip pointed downwards directly in the urine stream and the Result Window facing away from your body. Keep the test in the stream for 5 -10 seconds.
  - b. **Collected sample method:** Collect a sample of your urine in a clean, dry container. Hold the device by the Thumb Grip with the absorbent tip pointed downwards into the collected urine sample. Keep the tip submerged for 5-10 seconds.
2. Next, remove the test from your urine and immediately replace the green cap over the absorbent tip. Lay the test on a flat surface while results develop.
  3. Results will develop over the course of 3 minutes. Do not interpret the results after 10 minutes.

#### READING THE RESULTS

As the test begins to work, you may notice a light blue color flowing across the Test and Control windows. This is part of the test process.

A 'Pregnant' result may be observed as early as 1 minute after testing. However, you must wait 3 full minutes to confirm a 'Not Pregnant' result.

A vertical line must be present in the Control Window when you read your result. This line shows that the test has worked. If no vertical line appears in the Control Window within 3 minutes, the test is invalid (See Question 5).



#### Images A-C

These results indicate 'Pregnant'. A blue vertical line must be present in the Control Window. A blue vertical and a blue horizontal line must be present in the Test Window. The darkness of the lines does not affect the result – as long as all lines are present, this result indicates 'Pregnant'.

#### Image D

This result indicates 'Not Pregnant'. To confirm a negative result, there must be a vertical line in the control window and a blue horizontal line in the Test Window by the end of the 3 minutes. If you receive a 'Not Pregnant' result, but suspect you are pregnant, please seek further instructions (See Question 7).

#### Images E/F

This result likely indicates there was an error in the test procedure. Any valid result needs to include a vertical line in the Control Window. See Question 5 for more information.

#### LIMITATIONS

This test provides a presumptive diagnosis for pregnancy. A number of conditions other than pregnancy can cause elevated levels of hCG and could cause false results. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated. Medications containing human chorionic gonadotropin (hCG) can affect the test results.

#### QUESTIONS AND ANSWERS

##### 1. Q: How does the test work?

**A:** The *HealthyMe*® Early Detection Pregnancy Test detects a hormone in your urine that your body produces during pregnancy (hCG - human Chorionic Gonadotropin). The amount of pregnancy hormone in your body increases as pregnancy progresses.

##### 2. Q: How soon after I suspect that I am pregnant can I take the test?

**A:** You can use Early Detection Pregnancy Test up to 6 days before your missed period (5 days before the day of your expected period). If you test before your expected period and get a "Not Pregnant" result, there is still a chance that you may

be pregnant. See the chart below for results from clinical testing of *HealthyMe*® Early Detection Pregnancy Test with early pregnancy samples.

Testing Early					
Number of days before the expected period	-1	-2	-3	-4	-5
% of samples from pregnant women giving a 'pregnant' result	>99%	>99%	97%	94%	75%

##### 3. Q: Do I have to test with my first morning urine?

**A:** If you are testing before your expected period, we recommend that you test with your first morning urine as it is usually the most concentrated of the day and would have the most pregnancy hormone (hCG) in it. If you're testing on the day of or after your missed period, you can test at any time of the day. Please avoid excessive fluid intake before testing.

##### 4. Q: How accurate is the test?

**A:** A clinical evaluation was conducted comparing the *HealthyMe*® Early Detection Pregnancy Test to the predicate device. The results demonstrated >99% overall accuracy when testing from the day of the expected period.

##### 5. Q: How do I know that the test was run properly?

**A:** The appearance of a blue vertical line in the Control Window indicates that the correct amount of urine was applied to the absorbent tip and the test was performed properly. If there is no blue vertical line in the control window and/or no blue '-' (minus) symbol in the Test Window the test was not performed properly and the result is invalid. Please repeat the test with a new test. Make sure to apply urine to the absorbent tip for at least 5 seconds, but no more than 10 seconds.

##### 6. Q: What should I do if the result shows that I am pregnant?

**A:** If you received a 'Pregnant' result but believe that you are not pregnant, schedule an appointment with your doctor. You may have a health condition, not pregnancy, that is raising your hCG level.

##### 7. Q: What should I do if the result shows that I am not pregnant?

- A:** The test may indicate 'Not Pregnant' for a few different reasons.
- Your hCG levels may not be developed enough to be detected yet. If you tested early, you should test again in 3 days with another *HealthyMe*® Early Detection Pregnancy Test.
  - If you do not get your period within 7 days, you should retest with another *HealthyMe*® Early Detection Pregnancy Test. If this second test also indicates 'Not Pregnant' and you still have not had your period, see your doctor.

**You are encouraged to take the following steps to increase your chances for a healthy pregnancy and a healthy baby.**

1. If you get a positive result, schedule a visit with your doctor to confirm results and begin prenatal care.
2. Maintain a well-balanced diet, stop smoking, and avoid alcohol consumption.

**ACON**®  
ACON Laboratories, Inc.  
San Diego, CA 92121, USA  
Customer Support 1-800-838-9502

Number: 1151623001  
Effective day: 2024-11-06