

**Atlas Home Diabetes Test**  
**For In-Vitro Diagnostic and self testing Use**  
**Store At room temperature (15-30°C)**  
**Detects Glucose and Ketones in urine**



**INTRODUCTION:**

Diabetes is a common disease caused by high sugar (glucose) level in blood. This condition is called Hyperglycemia, and is caused by reduced insulin secretion or action. Insulin is a hormone that is secreted from the pancreas. The major role of this hormone is to regulate sugar level in blood. There are two types of diabetes: I and II. Type I is characterized by absolute deficiency of insulin production so it is called Insulin-Dependent type. Type II is characterized by relative deficiency of insulin, which means that insulin is produced in lower amounts or it does not act properly. This type is called Non-Insulin-Dependent. As the level of glucose increases in the blood above the kidney capacity it starts to appear in the urine. So, measuring the presence of glucose in urine can be used as tool to check for diabetes.

Persons with diabetes are more susceptible to develop specific complications such as retinopathy (A pathological disorder of the retina) with blindness, kidney failure, nerve damage and circulatory problems, which may lead to heart disease and stroke. Therefore detection of glucose and seeking early medical assistance as applicable could help preventing the development of these symptoms.

In diagnosis of diabetes, doctors always advise to check for Ketones to further confirm the diabetic status. Ketones are group of organic compounds that result from the metabolism of fatty acids. Normal people use glucose as energy source. In diabetic people, glucose is not passed to the cells, so cells will use fatty acids as the energy source instead. The less glucose absorbed by cells (as in case when the diabetes is more advanced) the more fatty acids are consumed and accordingly more ketone is produced. This condition is known as diabetic ketoacidosis. As the level of ketone increase in the blood, it will start to appear in urine.

**INTENDED USE:**

Atlas Diabetic Check kit contains a dip-and-read test strips and intended for use to check for glucose and Ketones level in urine specimens as an aid in diagnosing diabetes. The test provides results by the visual comparison with color chart printed on the pouch. Each color denotes a range of concentrations of glucose and Ketones.

**KIT COMPONENTS:**

1. Test strips individually pouched.
2. Package Insert.

**STORAGE:**

Store at room temperature between 15°-30°(59°F-86°F). Do not store the strips in the refrigerator or freezer.

Since the test strips are sensitive to specific environmental factors, such as moisture, heat and light, do not expose strips to these factors. Use the strip immediately after removing it from the pouch.

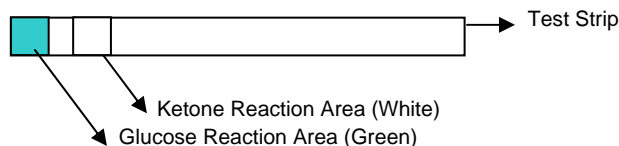
**SPECIMEN COLLECTION AND PREPARATION:**

- Collect fresh urine sample in a clean and dry disposable container. The container has to be devoid of any detergent traces. Test the urine as soon as possible after collection.

**PROCEDURE:**

This procedure **MUST BE FOLLOWED EXACTLY** to achieve reliable test results.

1. Check that the product is within the expiration date shown on he kit pack.
2. Prepare the urine specimen.
3. Remove the strip from the pouch. Familiarize yourself with the position of the reaction area of both ketone and glucose. White reaction area is for Ketones and green area is for glucose. Also, familiarize yourself with the color chart on the pouch.



4. Dip the test strip in the urine until the reaction areas are completely immersed for no more than 1 second.
5. Remove the dipstick from the urine and tap the strip on the rim of the cup to remove excess urine and place it horizontally with the reaction areas facing up.
6. Leave the strip for 30-60 seconds for the reaction to take place.
7. Read the results by comparing the colors of the reaction on the strip to those of the chart. While comparing, keep the strip in a horizontal position to avoid possible mix of colors between the two reaction areas on the strip.
8. Identify the best match color on the color chart and the correspondent concentration range. A change in color that appears only along the edges of the reaction areas indicates that the reaction did not take place properly so we recommend redoing the test with another strip. Results read after 60 seconds are not valid.

**RESULTS:**

The results are obtained by direct comparison of test strip with the color blocks printed on the pouch. See the table below for test interpretation and recommendations.

**LIMITATIONS OF THE TEST:**

Substances that cause abnormal urine color, such as some drugs may affect the color development on the strip. The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that could be interpreted visually as a false positive. It is therefore recommended that in case of doubt, the test should be repeated after stopping the medication.

**Ketones:** False positive results may occur with highly colored urine specimens or those containing large amounts of certain drugs byproducts.

**Glucose:** The reaction decreases when there are a lot of salts in urine specimen or the urine is highly alkaline. Ascorbic acid (more than 50mg/dl) and Ketones bodies (more than 40mg/dl) may cause a false negative for a specimen containing a small amount of glucose (100mg/dl), however, the combinations of such Ketones levels and low glucose levels are unlikely to occur.

Glucose	Ketones	Result
Negative	Negative	Not Diabetic
Trace	Negative	Repeat the test. If this result continues to appear, consult your physician. You may be developing Diabetes.
+	Negative	You could be diabetic. Check with your doctor for proper medication.
++	Negative	

+++	Negative	
++++	Negative	
Negative	Trace	Not Diabetic. The presence of ketone is not of any importance.
Trace	Trace	Repeat the test. If this result continues to appear, consult your physician. You may be developing Diabetes.
+	Trace	
++	Trace	You could be diabetic. You may be developing a condition called diabetic ketoacidosis. Check with your doctor for proper and urgent medication.
+++	Trace	
++++	Trace	
Negative	+	
Trace	+	Repeat the test. If this result continues to appear, consult your physician. You may be developing Diabetes.
+	+	
++	+	You could be diabetic. You may be developing a condition called diabetic ketoacidosis. Check with your doctor for proper and urgent medication.
+++	+	
++++	+	
Negative	++	
Trace	++	Repeat the test. If this result continues to appear, consult your physician. You may be developing Diabetes.
+	++	
++	++	You could be diabetic. Most probably you are developing a condition called diabetic ketoacidosis. Check with your doctor for proper and urgent medication.
+++	++	
++++	++	
Negative	+++	
Trace	+++	Repeat the test. If this result continues to appear, consult your physician. You may be developing Diabetes. Although the presence of high Ketone is not likely with low glucose level.
+	+++	
++	+++	You could be diabetic. Most probably you are developing a condition called diabetic ketoacidosis. Check with your doctor for proper and urgent medication.
+++	+++	
++++	+++	
Negative	++++	
Trace	++++	Repeat the test. If this result continues to appear, consult your physician. You may be developing Diabetes. Although the presence of high Ketone is not likely with low glucose level.
+	++++	
++	++++	You could be diabetic. Most probably you are developing a condition called diabetic ketoacidosis. Check with your doctor for proper and urgent medication.
+++	++++	
++++	++++	
++++	++++	

#### PRECAUTIONS & WARNINGS

1. Please read all the information in this leaflet before performing the test.
2. Do not use the test after the expiration date.
3. If the package is not completely sealed do not use the test.
4. Do not open the test foil pouch until it has reached room temperature and you are ready to start the test.
5. The test should be performed in a well-lit area.
6. Use the test device immediately after opening it.
7. Do not touch the test area. This could affect results and may also impose personal hazards.
8. Use a disposable sample container to be discarded after performing the test.
9. The pouch contains a Silica Gel pack to absorb humidity. Do not open the pack. Throw it away with the remaining of the test.
10. Do not freeze.
11. At the end of the test, wrap every thing you have used in a plastic bag and throw away in the bin. Do not forget to wash your hands properly.
12. The remaining sample should be discarded and flushed in the toilet.
13. Keep out of the reach of children.
14. For *in vitro* diagnostic and self-testing use. Not to be taken internally.

#### QUESTIONS AND ANSWERS:

##### Q: When is the best time to do the test?

A: This test can be done anytime during the day. It is good to do the test once before eating and once after 2 hours of a mixed meal.

##### Q: If I dipped the strip for more than 1 second, is the result affected?

A: This reaction takes place immediately after dipping the strip. Leaving the strip for 2-3 seconds will not affect the result, but if kept for more than 5 seconds, results cannot be considered accurate and so you need to repeat the test.

##### Q: I left the strip for 10 minutes and then I read the results, shall I consider the results true?

A: Results read after more than 60 seconds (1 Minutes) must not be considered correct and so you need to repeat the test.

##### Q: What are the signs of Diabetes?

A: The most frequent signs of diabetes are: being very thirsty, urinating often, feeling very hungry or tired, losing weight, having sores that heal slowly, having dry itchy skin, having blurry eyes, losing the feeling in your feet or having tingling in your feet.

##### Q: What could I do to control glucose level?

A: Doing the following will certainly help controlling glucose level: follow a diet that is advised by your doctor or dietitian, be active and do some exercises for around 30 minutes each day and stop smoking.

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