BIOTEST

Your reliable home test kits series

Diabetes Test Kit

Product Code 9 555223 208050
For in vitro diagnostic and self-testing use
Store at (15-30ºC)

Test Principle

Diabetes is a common disease caused by a high sugar (glucose) level in the blood. This condition is called hyperglycaemia 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 the 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 Diabetes. 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 Diabetes. 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 a tool to screen for diabetes.

People 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 medical assistance could help to prevent the development of these symptoms.

In the diagnosis of diabetes, doctors always advise to check for ketone to further confirm the diabetic status. Ketones are a group of organic compounds that result from the metabolism of fatty acids. Normal people use glucose as an 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 is the case when the diabetes is more advanced) the more fatty acids are consumed and accordingly more ketones is produced. This condition is known as diabetic ketoacidosis. As the level of ketones increases in the blood, it will start to appear in urine.

The BIOTEST Diabetes Test Kit contains two dip-and-read test strips and its main use is to check for glucose and ketone levels in urine specimens as an aid in screening for diabetes. The test provides results by the visual comparison with the colour chart printed on the box. Each colour denotes a range of concentrations of glucose and ketone.

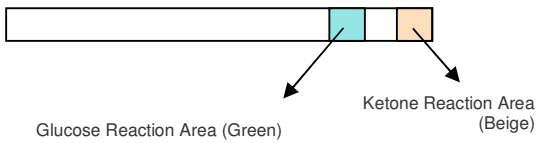
Precautions & Warnings

- Please read all the information in this leaflet before performing the test.
- Do not use the test after the expiration date.
- If the package is not completely sealed do not use the test.
- Do not open the test foil pouch until it has reached room temperature and you are ready to start the test.
- The test should be performed in a well-lit area.
- Use the test device immediately after opening it.
- Do not touch the test area. This could affect results and may also harmful.
- Use the provided collection cup and discard after performing the test.
- The pouch contains a silica gel pack to absorb humidity. Do not open the pack. Throw it away with the remainder of the test.
- Do not freeze.
- At the end of the test, wrap everything you have used in a plastic bag and throw in the bin. Do not forget to wash your hands properly.
- The remaining urine sample should be discarded and flushed in the toilet.
- Keep out of the reach of children.
- For in vitro diagnostic and self-testing use. Not to be taken internally.

How to Use

Use the provided collection cup to collect the urine. Test the urine as soon as possible after collection. This procedure MUST BE FOLLOWED EXACTLY to achieve reliable test results.

1. Prepare the urine specimen.
2. Remove the strip from the pouch. Familiarize yourself with the position of the reaction area of both ketone and glucose. The beige reaction area is for ketone and the green area is for glucose. Also, familiarize yourself with the colour chart on the box.



3. Dip the test strip in the urine until the reaction areas are completely immersed for no more than 1 second.
4. 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.
5. Leave the strip for 30 seconds for the reaction to take place.
6. Read the results by comparing the colours of the reaction on the strip to those on the box. While comparing, keep the strip in a horizontal position to avoid possible mixing of colours between the two reaction areas on the strip.
7. Identify the best colour match on the colour chart and the corresponding concentration range. A change in colour 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 the test strip with the colour blocks printed on the box. See the table below for test interpretation and recommendations.

Glucose Results	Ketone Results	Interpretation
Negative	Negative	Not a 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 a 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	You could be a diabetic. You may be developing a condition called diabetic ketoacidosis. Check with your doctor for proper and urgent medication.
++	Trace	
+++	Trace	
++++	Trace	
Negative	+	Not a diabetic. The presence of ketone may be associated with the presence of other conditions such as diarrhoea, vomiting or weight loss.
Trace	+	Repeat the test. If this result continues to appear, consult your physician. You may be developing diabetes.
+	+	You could be a diabetic. You may be developing a condition called diabetic ketoacidosis. Check with your doctor for proper and urgent medication.
++	+	
+++	+	
++++	+	

Negative	++	Not a diabetic. The presence of ketone may be associated with the presence of other conditions such as diarrhoea, vomiting or weight loss.
Trace	++	Repeat the test. If this result continues to appear, consult your physician. You may be developing diabetes.
+	++	You could be a diabetic. Most likely you are developing a condition called diabetic ketoacidosis. Check with your doctor for proper and urgent medication.
++	++	
+++	++	
++++	++	
Negative	+++	Not a diabetic. The presence of ketone may be associated with the presence of other conditions such as diarrhoea, vomiting or weight loss.
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 a low glucose level.
+	+++	You could be a diabetic. Most likely you are developing a condition called diabetic ketoacidosis. Check with your doctor for proper and urgent medication.
++	+++	
+++	+++	
++++	++++	
Negative	++++	Not a diabetic. The presence of ketone may be associated with the presence of other conditions such as diarrhoea, vomiting or weight loss.
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 a low glucose level.
+	++++	You could be a diabetic. Most likely you are developing a condition called diabetic ketoacidosis. Check with your doctor for proper and urgent medication.
++	++++	
+++	++++	
++++	++++	

Advice

The BIOTEST Diabetes Test Kit serves only as the first step in screening your glucose and ketone level. There are limitations to the test where certain substances may affect the result. Drugs known to affect the results of glucose include ascorbic acid, levodopa, methyldopa, methyldopate hydrochloride, phenazopyridine and salicylates. Drugs known to affect the results of ketone include ascorbic acid, levodopa, pyridium, phthalein compounds given for liver or kidney tests and valproic acid.

If you are positive, we advise that you immediately seek medical advice and perform a more clinical and comprehensive check again. If you are negative, you are advised to continue performing this test once every six months.

Please note that the BioTest range of health screening tests is intended for first step screening only and cannot be used as a confirmatory diagnostic tool. Discuss your test result with your doctor or pharmacist.

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Manufactured by Atlas Medical
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