plusmed
health management

EN

fasTTest DailyCheck
Control Solution Instruction Manual

Cautions:

- Read the Owner's Manual of the Plusmed Blood Glucose Monitoring System before using the product
- The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
- The patient should only adapt the treatment if he has received the appropriate training to do so.

【Product Name】

Generic Name: Control Solution

【Model】

fasTTest DailyCheck

【Accessories】

- Blood Glucose Meter
- Blood Glucose Test Strips
- Control Solution
- Lancing Device
- Lancet

【Product Description】

fasTTest DailyCheck Control Solution is a (2ml per vial) red and transparent solution, which has three glucose concentration levels to monitor the performance of the Blood Glucose Monitoring System.

【Intended Use】

The Plusmed fasTTest DailyCheck Control Solution is used with the Plusmed Blood Glucose Monitoring System to check that the meter and test strips are working together as a system and that you are performing the test correctly. It is very important that you do control solution tests routinely to make sure you are getting accurate results.

The product is intended for in vitro diagnostic use (For self testing) only (outside the body).

【Test Principle】

The Plusmed fasTTest DailyCheck Control Solution contains a known amount of glucose that reacts with fasTTest DailyCheck Blood Glucose Test Strips (hereafter referred to as the "test strips"). A test with control solution is similar to a blood test except that you use the Plusmed fasTTest DailyCheck Control Solution instead of a drop of blood. The test result using control solution should fall within the range of results that you will find printed on the vial of the test strips that you are using.

Cautions:

- The control solution range printed on the test strip vial is for control solution only. It is used to test meter and test strip performance.
- It is not a recommended range for your blood glucose level.

【Main Composition】

The Plusmed fasTTest DailyCheck Control Solution is a stable, red buffer which contains preservatives and glucose. The control solution does not contain any the body's or biological raw materials.

【Storage and Handling】

- Store and use control solution at normal room temperature between 1℃～30℃ (33.8℉～86℉). Do not refrigerate or freeze it.
- Control solution are valid before either 24 months after produced or 90 days after opening vials.
- Opened date write the first opened date on the package. Do not use expired control solution. Write the first date of opened vial on its label to make sure you can use the product effectively.

【Impotent Safety Information】

- The control solution range printed on the test strip vial is for control solution only.
- The control solution is intended for use outside the body (in vitro diagnostic use). Do not ingest or inject;
- Use the control solution at normal room temperature between 20℃～30℃ (68℉～86℉). If the control solution temperature is too low that you will use, you can continue to use after its temperature restores up to room temperature;
- Shake the control solution before each using;
- Do not touch the lip of the vial when using to avoid contamination and decrease of the lifetime;
- Immediately recap the vial after using.
- Be careful your clothes and trousers when using, which may be stained by the product that is a red glucose solution.
- Please make sure that the fasTTest DailyCheck Control Solution is only for the use of the Plusmed Blood Glucose Monitoring System before using.

Warnings:

- Do not swallow. Not for human consumption.
- Do not apply control solution to the skin or eyes as it may cause irritation.

- To practice the test process, instead of using blood.
- First time use the blood glucose meter.
- Whenever you open a new vial of test strips.

- Whenever you suspect the system are not working properly.
- At least once a week.
- When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate if you drop or damage the meter.

A control solution test that is within the expected range printed on the test strip vial will tell you the meter and test strips are working together and you are doing the test properly.

【Usage Methods】

1. Testing Procedures

- Insert the test strip;
- Shake the vial before each using; squeeze out the first drop of the control solution and discard;
- Squeeze out the second drop of the control solution; apply it to the top edge of the test strip and then wipe redundant dropping liquid and recap the vial after using;
- Read out the result from the blood glucose meter and see if the result is within the CTRL range.

2. Expected Results

Use control solution at normal room temperature between 20℃～30℃ (68℉～86℉) to check the blood glucose monitoring system, and above 95% test results should be within the CTRL range that is printed on package/vial of test strips. If results are within the CTRL range, the blood glucose monitoring system works properly. If results are not within the CTRL range:

- Confirm whether to follow the procedures for testing the control solution;
- Check the valid time of the control solution and the test strip. Make sure the control solution and the test strip should be used up within 90 days after opening;
- Confirm that the caps of vials which contain test strips or the control solution are closed tightly;
- Confirm that the test is performed at normal room temperature between 20℃～30℃ (68℉～86℉);
- Confirm that what you used is the Plusmed fasTTest DailyCheck control solution;
- Confirm that the sample which is applied to the test strip is adequate and siphon speed of the test strip is proper;
- After confirming all the above items, use the new test strip to perform a test for the control solution again. If the test results are still beyond the concentration range showed on the vial of test strips, which show that your blood glucose meter cannot work properly. Please timely contact your manufacturer or dealers.

【Limitations】

The product is used for evaluating the overall performance of the blood glucose meter. It is not used as a calibration standard, and cannot replace other quality control process. Please refer to test strip packages of different batches to obtain a reportable range of the blood glucose meter.

【Traceability】

The traceability of the control solution is referenced to the EKF BIOSEN C line-Clinic glucose analyzer. The EKF is the reference method used to assess the accuracy with which glucose results are obtained using the system. The value of the calibrator for glucose is traceable to the National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 917c (D-Glucose).

Concentration: 12mmol/L±0.25mmol/L, diluted 51-fold, ready for use.

【Performance Characteristics】

- Precision:

Intermediate Precision	Control Solution$_{av}$ 2.5mmol/L CV=5.8% Control Solution$_{av}$ 7.4mmol/L CV=4.5% Control Solution$_{av}$ 20.7mmol/L CV=3.8%

- This study shows that at room temperature, the Plusmed fasTTest DailyCheck control solution test results can fall within the expected range printed on the test strip vial label about 95% of the time.

CTRL1(Low)= 2.5-5.5mmol/L	N	Test results (2.5-5.5mmol/L)	Test results (<2.5mmol/L)	Test results (>5.5mmol/L)
	100	99 (99%)	0 (0%)	1(1%)
CTRL2(Medium)= 7.0-13.0mmol/L	N	Test results (7.0-13.0mmol/L)	Test results (<7.0mmol/L)	Test results (>13.0mmol/L)
	100	100(100%)	0(0%)	0(0%)
CTRL3(High)= 16.0-24.0mmol/L	N	Test results (16.0-24.0mmol/L)	Test results (<16.0mmol/L)	Test results (>24.0mmol/L)
	100	98 (98%)	1(1%)	1 (1%)

【Symbol Index】

On the packaging, you may encounter the following symbols shown below. They have the following meanings:

	Consult instructions for use
	In vitro diagnostic medical device
	Caution
	Batch code
	Manufacturer

EC REP	Authorized representative in the European Community
	Temperature limitation
	Use by
CE 0197	The product conforms to the requirements of the EC Directive IVDD (98/79/EC) on in vitro diagnostic medical devices.

İthalatçı/Distributor: Trimpeks İth. İhr. Tur. ve Tic. A.Ş.
Sultan Selim Mah. Yunus Emre Cad. No:1/11 Kağıthane 34415,
İSTANBUL TÜRKİYE Tel +90 212 319 50 00 Fax +90 212 319 50 50

Made in China

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