Part no.	313-0000000-187
Product name	酮體/測試液說明書/NO LOGO/0000(共用)/英文/.標準品/
Spec	L210*W97mm/雙面/模造紙/長邊對2折(完成尺寸L52.5*W97mm)/70P/雙黑
Designer	Emily
Color	■ K100 ■ K20

β-KETONE CONTROL SOLUTION

Intended Use

β-Ketone Control Solution is intended for use with **β-Ketone Test Strip** made by **TaiDoc**. It is used to check that the meter and test strips are working together properly. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use by people with diabetes at home and by health care professionals in clinical settings as an aid to monitoring the effectiveness of diabetes control. It is important to do control solution tests routinely to ensure getting accurate results.

About Control Solution

β-Ketone Control Solution contains a known amount of β-ketone that reacts with test strips made by **TaiDoc**.

Operation of the control solution test is similar to **β-Ketone** test except that you use β-Ketone Control Solution instead of a drop of blood. The control solutions should provide results within an expected range printed on the test strip vial label.

IMPORTANT

The control solution range printed on the test strip vial may differ. Make sure to use the range printed on the current test strip vial label.

Quality Control Testing

When should the control solution test be performed?

- ► If it is mandatory following the local regulations in your country,
- ► If you suspect the meter or test strips are not working properly,
- ► If your **β-Ketone** test results are not consistent with how you feel, or if you think the results are not accurate,
- ► to practice the testing process, or
- ► If you have dropped or think you may have damaged the meter.

CAUTION

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 β-Ketone levels**.

Chemistry

β-Ketone Control Solution is a red solution that contains less than 0.08% β-Hydroxybutyrate.

The solution does not contain any human-derived or biological materials.

Ingredient	Percent
β-Hydroxybutyrate	0.012 - 0.08%
Inert ingredients	> 99.92%

Storage and Handling

- ► For *in vitro* diagnostic use only.
- ► Use only β-Ketone Control Solution with **β-Ketone Test Strip** made by **TaiDoc**.
- ► Check the expiration date on the vial. Do not use if expired.
- ► Tightly close the control solution and store at room temperature between 2°C and 30°C (35.6°F and 86°F). Do not freeze.
- ► Use only for 90 days after first opening. Record the date first opened on the control solution vial. Discard after 90 days.

Test Procedure

To do a test with β-Ketone Control Solution, follow the instructions printed in the Owner's Manual that came with the system.

CAUTION

Each test has respective control solutions. Always make sure you have the correct control solution corresponding to your test strip.

Accurate results depend upon following instructions carefully. Follow below technical pointers whenever you test with β-Ketone Control Solution:

1. It is recommended that the meter, control solution, and test strips come to room temperature (20°C-25°C / 68°F-77°F) before testing.
2. Shake the control solution well before using.
3. Discard the first drop of control solution you squeeze out.
4. Squeeze out another drop and touch with the absorbent hole of a test strip.
5. Wipe off the dispenser tip to keep it clean.

Expected Results

At room temperature, β-Ketone Control Solution test results should fall within the expected range printed on the test strip vial label.

If test results fall outside the expected range printed on the test strip vial, please check the troubleshooting guide in Owner's Manual and repeat the test. Results that fall outside the expected range may indicate:

► An error in the way you are doing the test.
► Expired test strips and control solutions.
► A problem with the meter.
► Control solution that is too warm or too cool.
► The meter code does not match the code printed on the test strip vial.
► Use of control solution with unmatched test strips.
► Failure to shake the control solution vial vigorously.

If the repeat result is still outside the range, the system may not be working properly. Do not use the system to test your blood. Please contact the dealer for service.

Availability

This control solution is available from retail pharmacies.

OUR COMMITMENT TO YOU

Our goal is to provide you with quality healthcare products and dedicated customer service. If you are not fully satisfied with this product, or if you have questions about the use of any **TaiDoc** product, please contact the dealer for service.

Symbol Information

Symbol	Referent	Symbol	Referent
IVD	*In vitro* diagnostic medical device	LOT	Batch code
	Consult instructions for use		Manufacturer
	Temperature limit	EC REP	Authorized representative in the European Community
	Use-by date	CE 0123	CE mark
	Caution	RoHS	RoHS Compliance
REF	Catalogue number		

EC REP **MedNet EC-REP GmbH**
Borkstraβe 10, 48163 Münster, Germany

TaiDoc Technology Corporation
B1-7F, No. 127, Wugong 2nd Rd., Wugu Dist.,
24888 New Taipei City, Taiwan
www.taidoc.com

For self-testing.

REF TD-4914 / TD-4915 / TD-4916 2°C 30°C IVD CE 0123