



## eBketone Blood Ketone Test Strips



Please read this information before using eBketone blood ketone test strips

### Intended Use

The eBketone blood ketone monitoring system is indicated for home (lay user) or professional use in the management of patient who might concern about ketone levels. It is for self-testing or healthcare professional use outside the body. Whether would like to have a reference to assess the weight loss program or<sup>[1]</sup> monitor the ketone level to prevent DKA. It's designed to quantitatively measure blood  $\beta$ -Ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the fingertip. These test strips are for *in vitro* (use outside the body) diagnostic use only also for self testing use. The test results are plasma equivalent. The measuring range of blood  $\beta$ -ketone concentration in capillary whole blood is from 0.0 to 8.0 mmol/L.

### Storage the Test strips:

- \*Store the test strips at room temperature between 4- 30°C (39-86°F). Do not freeze.
- \*Use test strips at temperatures between 10°C(50°F) and 40°C(104°F), and less than 85% humidity.
- \*Store your test strips in their original vial only; do not transfer them into a new vial or another container.
- \*Always close the container with container cap immediately after use.
- \*Write the discard date on the vial label when you open it at the first time. Discard remaining eBketone blood ketone test strips after 3 months from the first opening of the vial.



Keep the test strip vial away from children; the cap is a choking hazard. Also the cap or vial may contain drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

### System measurement range:

- \*The measurement range of the eBketone blood ketone monitoring system is 0.0~8.0 mmol/L

### Performing a blood ketone test

For accurate results, your meter should be calibrated with the code card every time when you open a new vial of test strips. When the calibrated meter is set and match the code number on the strips, you may begin testing.

#### 1 Steps of coding the meter

- Step 1. Open a new box of eBketone blood ketone test strips and take out the code card.
- Step 2. Insert the code card into the test slot. A beep sounds and a code number appears on the screen.
- Step 3. The code number shown on the screen should match the code on the vial of test strips.
- Step 4. Remove the code card and you are ready for blood ketone testing.

#### 2 Steps of blood ketone testing

- Step 1. Remove the cap from the lancing device.
- Step 2. Insert a lancet into the lancet holder firmly. Twist and remove the protective cover from the lancet.
- Step 3. Put the cap back onto the lancing device.
- Step 4. Adjust the depth setting of lancing device. Choose a desired skin penetration depth by rotating the top portion of the adjustable tip until the setting number lines up to the arrow.
- Step 5. Slide the ejection/cocking control back until it clicks.
- Step 6. Wash your hands with warm, soapy water. Rinse and dry thoroughly.
- Step 7. Open a new vial of test strips. Take out a test strip from the vial and fasten the cap properly. Make sure the triangle sign is facing up and insert the electrical contact end of the test strip fully into the test slot. The meter will be turned on automatically and the code number will be shown on the screen. Make sure that this number matches the code number on the vial of test strips.
- Step 8. To obtain a drop of blood, press the tip of the lancing device against your fingertip and press the release button. Gently squeeze your finger to form a small drop of blood.

- Step 9. Touch the drop of blood to the semicircle-shaped cutout on the top of the narrow channel of the test strip. The blood will be drawn into the strip automatically. Hold your blood to the strip until after the meter beeps. The meter starts counting down from 10 seconds. If you have enough blood inside the reaction chamber of the strip, the indication slot located inside triangle sign turns red (filled with blood). If the indication slot does not completely turn red before the meter begins to count down, discard the strip and do not try to add more blood to the strip.
- Step 10. After counting down from 10 to 1, your test result appears on the screen and is stored automatically in the meter's memory.
- Step 11. The meter will be turned off by removing the test strip.
- Step 12. Dispose the used test strip into a sealed container.
- Step 13. Remove the cap from the lancet device. Put the protective cover back onto the lancet and push the lancet out.
- Step 14. Dispose the used lancet in a sealed container.

### A range of expected values

eBketone blood ketone monitoring system is detected the levels of blood  $\beta$ -ketone, it's around 78% of the three ketone bodies in the blood. Expected blood  $\beta$ -ketone level for healthy people would be less than 0.6 mmol/L.<sup>[2]</sup>  $\beta$ -ketone may raise if a person fasts, exercises vigorously or become ill for diabetes.<sup>[3]</sup>

- \* Please consult your nutritionist or dietician before you start using this product to be a reference of your weight loss program.
- \* For diabetes, please consult your healthcare professional before you start using this product.

### REMEMBER TO REPEAT THE TEST IF THE TEST RESULT FALLS OUTSIDE THE EXPECTED RANGE.



If you get unexpected results: High blood ketone readings can indicate a potentially serious medical condition. Please consult your healthcare professional and follow his or her treatment advice.

### Checking blood ketone monitoring system and test strips (Optional)

**eB-series** ketone control solution is used to check if the monitoring system (meter working together with test strips) is functioning properly.

#### When to do a control solution test:

1. When you open a new vial of test strips.
2. Whenever you suspect that the meter or test strips are not working properly.
3. After dropping the meter.
4. Whenever you question your blood ketone results.

#### Steps of performing a control solution test:

- Step 1. Remove a test strip from the vial and fasten the cap properly. Make sure the triangle sign is facing up and insert the electrical contact end of the test strip fully into the test slot. The meter will be turned on automatically and the code number will be shown on the screen. Make sure that this number matches the code number on the vial of test strips.
- Step 2. Open a bottle of **eB-series** ketone control solution. The storing period of **eB-series** ketone control solution is only for 3 months after the first opening or up to the expiry date, whichever comes first. Always write down the opening date on the bottle.
- Step 3. Hold the bottle and gently squeeze the bottle to form a small drop of control solution on the tip of the bottle. Always shake the bottle well, discard the first drop before applying the control solution.
- Step 4. Touch the drop of control solution to the semicircle-shaped cutout on the top of the narrow channel of the test strip. The control solution will be drawn into the strip automatically. The meter starts counting down from 10 seconds.
- Step 5. After counting down from 10 to 1, the control test result appears on the screen.
- Step 6. Compare the result with the range printed on the vial of the test strips. The result should be within the range.

## LIMITATIONS

eBketone blood ketone test strips give accurate results when the following limitations are observed:

- ✧ The test strips should not be used for the testing of neonate.
- ✧ The test strips are for single use only. DO NOT reuse.
- ✧ Handle the meter with care. DO NOT drop the meter on purpose or apply a strong force to the meter.
- ✧ DO NOT use code card from others test system.
- ✧ DO NOT remove the test strip while the measurement is processing.
- ✧ DO NOT test with the following specimen:
  1. Hematocrit range out of 30 % to 60 %.
  2. Plasma, serum, venous whole blood specimen.
- ✧ DO NOT perform the test if test strip is expired.
- ✧ Follow the regulations in your area to dispose the used test strips and lancing materials.
- ✧ Using universal blood precautions. All patient samples and materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection.
- ✧ Meter device storage condition describe as following :
  1. Should be avoid sunlight.
  2. Temperature: 0 - 50 (°C).
  3. Relative humidity: < 95 %.
- ✧ Test strip storage condition describe as following :
  1. Should be avoid sunlight.
  2. Should avoid be taken from children.
  3. Temperature: 4 -30 (°C).
- ✧ Interference: Please see the table below for the certain concentrations which can affect the function of the meter.

Substance	No interference
Acetaminophen	<1.0 mg/dl
Ascorbic acid	<1.2 mg/dl
Bilirubin	<12.5 mg/dl
Cholesterol	<500 mg/dl
Dopamine	<0.09 mg/dl
L-Dopa	<1.0 mg/dl
Gentisic acid	<1.5 mg/dl
Methyldopa	<0.5 mg/dl
Tolazamide	<2.0 mg/dl
Triglyceride	<2000 mg/dl
Uric acid	<12.5 mg/dl

## Test Principle

The technology used for the eBketone blood ketone monitoring system is based on the principle that a small electrical current produced when blood ketone reacts with the reagent immobilized on the reaction area of the eBketone test strips and the current change is proportional to the amount of ketone in the blood.

## Reagent Composition :

Each eBketone blood ketone test strip contains:

- $\beta$ -Hydroxybutyrate dehydrogenase (HBDH) (*Pseudomonas sp.*) 0.5 IU
- Diaphorase (DAD) 0.5 IU
- Mediator 0.015 mg
- Other ingredients 0.02 mg

## Calibration reference

The eBketone blood ketone monitoring system is calibrated to reflect plasma  $\beta$ -hydroxybutyrate using the RANDOX assay kit (RB1007) by HITACHI 704 Automatic Analyzer.

## Accuracy

The accuracy of eBketone was assessed by comparing the eBketone readings with the reference values using HITACHI 704 Automatic Analyzer. The ketone concentrations of capillary blood samples were measured using eBketone meter. The ketone concentrations of the venous blood samples were analyzed using the HITACHI 704 Automatic Analyzer. The results shown below are from a total of 110 subjects and 3 lots of strips attending the outpatient clinic.

Number of sample	Slope	Intercept	Correlation Coefficient
110	0.9663	0.0726 mmol/L	0.99

Lay-user eBketone fingerstick vs HITACHI (ketone range:0-6.5 mmol/L)			
< 1.5 mmol/L N=100			
Within $\pm 0.1$ mmol/L	Within $\pm 0.2$ mmol/L	Within $\pm 0.3$ mmol/L	
83/100 (83%)	93/100 (93%)	100/100 (100%)	
$\geq 1.5$ mmol/L N=10			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
8/10 (80%)	9/10 (90%)	10/10 (100%)	10/10 (100%)

## Precision

Precision was determined using coefficients of variation (CVs) calculated from 50 measurements in series. To produce the 4 different ketone concentrations for the 3 lots of strips, venous whole blood samples from healthy volunteers were spiked using different concentrations of ketone solutions.

## Repeatability

Ketone levels (mmol/L)	0.6	1.28	2.68	5.6
Average (mmol/L)	0.7	1.4	2.6	5.6
SD (mmol/L)	0.08	0.09	0.10	0.21
C.V. (%)	--	--	4.0	3.6

## Intermediate

Ketone levels (mmol/L)	0.52	2.29
Average (mmol/L)	0.5	2.2
SD (mmol/L)	0.04	0.08
C.V. (%)	--	3.8

## Reference:

- [1] : J. M. Freeman, E. P. Vining, D. J. Pillas, P. L. Pyzik, J. C. Casey, L. M. Kelly (1998) The efficacy of the ketogenic diet-1998: A prospective evaluation of intervention in 150 children, *Pediatrics* 102, 1358-1363.
- [2] : Wiggam MI, O'Kane MJ, Harper R, Atkinson AB, Hadden DR, Trimble ER, et al. Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management. *Diabetes Care* 1997;20:1347-52.
- [3] : Schade, D.S., Eaton, R.P. Metabolic and clinical significance of ketosis. *Special Topics in Endocrinology and Metabolism*. 1982;4:1-27.

## Labeling and Information:



Do not re-use



Consult *instructions for use*



Keep dry



Caution, consult accompanying documents



In vitro diagnostic *medical device*



Operating temperature limitation



Store temperature limitation



Use by date



Keep away from sunlight



Batch number



Manufacturer



Authorized representative in the European Community/European Union



Paper Recycling



This product meets the requirements of Directive 98/79/EC *in vitro* diagnostic medical devices.



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