eBketoway Blood Ketone Test strips

Please read this information before using eBketoway blood ketone test strips.

Intended Use

The eBketoway blood ketone monitoring system is indicated for home (lay user) or professional use in the management of patient who might concern about ketone levels. Whether would like to have a reference to assess the weight loss program or monitor the ketone level to prevent DKA. It's designed to quantitatively measure blood β-Ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the fingertip.

Storage of 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 lid immediately after use.
* Write the discard date on the vial label when you open it at the first time. Discard remaining eBketoway blood ketone test strips after 3 months since 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 eBketoway 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 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 **eBketoway** blood ketone test strip and take out the code card.
Step 2. Insert the code card into the test slot, you will hear a beep sound and a code number will appear 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 lancing device.
Step 2. Insert a lancet into 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 turn on automatically and the code number will appear 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 you hear the beep sound. The meter will begin to count down from 10 seconds. If you have enough blood inside the reaction chamber of the strip, the indication slot located inside triangle sign will turn 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 will appear on the screen and become stored automatically in the meter's memory.
Step 11. Record the ketone value in your log book.
Step 12. The meter will turn off automatically when removing the test strip.
Step 13. Dispose the used test strip into a sealed container.
Step 14. Remove the cap from the lancet device. Put the protective cover back onto the lancet and push the lancet out.
Step 15. Dispose the used lancet in a sealed container.

A range of expected values

eBketoway blood ketone monitoring system detects the levels of blood β-ketone, it's around 78% of the three ketone bodies in the blood. Expected blood β-ketone level for healthy people would be less than 0.6 mmol/L[1]. β-ketone may raise if a person fasts, exercises vigorously or become ill for diabetes[2].

*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 strip (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 will count down from 10 seconds subsequently.
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

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 other test system.
- DO NOT remove the test strip while the measurement is in 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.
- Use 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 avoid sunlight
  2.Temperature: 0 ~ 50 (°C).
  3.Relative humidity: < 95 %.
- Test strip storage condition describe as following:
  1.Should avoid sunlight.
  2.Should avoid to be within children's reach.
  3.Temperature: 4 ~ 30 (°C).
- Interference: Please see table below for certain concentrations which can affect proper functioning 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 **eBketoway** 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 **eBketoway** test strip and current change is proportional to the amount of ketone in the blood.

Reagent Composition :

Each **eBketoway** blood ketone test strip contains:

•β-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 **eBketoway** blood ketone monitoring system is calibrated to reflect plasma β-hydroxybutyrate using the RANDOX assay kit (RB1007) by HITACHI 704 Automatic Analyzer.

Accuracy

The accuracy of **eBketoway** was assessed by comparing the **eBketoway** readings with the reference values using HITACHI 704 Automatic Analyzer. The ketone concentrations of capillary blood samples were measured using eBketoway 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	0.9652	0.0658 mmol/L	0.9922

Lay-user eBketoway fingerstick vs HITACHI

< 1.5 mmol/L N=100			
Within± 0.1 mmol/L	Within± 0.2 mmol/L	Within± 0.3 mmol/L	
84/100 (84%)	95/100 (95%)	100/100 (100%)	
≧1.5 mmol/L N=10			
Within± 5%	Within± 10%	Within± 15%	Within± 20%
8/10 (80%)	10/10 (100%)	10/10 (100%)	10/10 (100%)

Precision

Precision was determined using coefficients of variation (CVs) calculated from 100 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)	**0.52**	**1.19**	**2.55**	**6.13**
Average (mmol/L)	0.5	1.1	2.5	6.1
SD (mmol/L)	0.05	0.06	0.12	0.12
C.V. (%)	--	--	4.9	2.1

Intermediate

Ketone levels (mmol/L)	**0.52**	**2.29**
Average (mmol/L)	0.5	2.2
SD (mmol/L)	0.05	0.11
C.V. (%)	--	4.9

Reference:

[I] Wiggam MI, O'Kane MJ, Harper R, Atkinson AB, Hadden DR, Trimble ER, et a1. Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management. Diabetes Care 1997;20:1347-52.
[2] Schade, D.S., Eaton, R.P. Metabolic and clinical significance of ketosis. Special Topics in Endocrinology and Metabolism. 1982;4:l-27.

Labeling and Information:

- Do not re-use
- Consult operating instructions
- Keep dry
- Caution, consult accompanying documents
- IVD — In vitro diagnostic medical device
- Operating temperature limitation (+10°C ~ +40°C)
- Store temperature limitation (+4°C ~ +30°C)
- Use-by date
- Keep away from sunlight
- LOT — Batch number
- Manufacturer
- EC REP — Uthorized representative in the European Community/ European Union
- Paper recycling
- CE 0123 — This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices.

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