eBuricacid Blood Uric Acid Test Strips

Please read this information before using eBuricacid Blood Uric Acid Test Strips.

Intended Use

The eBuricacid Blood Uric Acid Monitoring System is intended for the quantitative measurement of uric acid in fresh capillary whole blood. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (Over-the-counter [OTC]) by person with hyperuricemia, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of hyperuricemia. The test results are plasma equivalent. The measuring range of uric acid concentration in capillary whole blood is from 3 to 20 mg/dL (179-1190 μmol/L).

Storage

- 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 eBuricacid Blood Uric Acid 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 eBuricacid Blood Uric Acid Monitoring System is 3 to 20 mg/dL (179 to 1190 μmol/L).

Performing a Blood Uric Acid 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 eBuricacid blood Uric Acid Test Strip 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 uric acid testing.

2. Steps of Blood Uric Acid 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 15 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 15 to 1, your test result will appear 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.

Range of Expected Values

Blood uric acid monitoring requires the help of healthcare professionals in setting the expected range of your own blood uric acid values, arranging frequency of tests and discussing the meaning of your results. The normal value of blood uric acid concentration should be based on the definition of physiology and chemistry. That is, the fasting blood uric acid value of adults >7.0 mg/dL is hyperuricemia. In this case, please pay close attention to gout and other related complications.

Remember to repeat the test if the test result falls outside the expected range.

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

Quality Control Testing (Optional)

eB-series uric acid 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 uric acid 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 turn 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 uric acid control solution. The storing period of control solution is only for 3 months after the first opening or up to the expiry date, whichever comes first. **(Note: 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. **(Note: 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 begin to count down from 15 seconds.
Step 5. After counting down from 15 to 1, the control test result will appear 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

eBuricacid Blood Uric Acid Test Strips give accurate results when the following limitations are served :

- 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 systems.
- **DO NOT** remove the test strip while the measurement is proccessing.
- **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 the table below for the certain concentrations which can affect the function of the meter.

Substance	No Interference
Acetaminophen	<1.5 mg/dL
Ascorbic acid	<1.5 mg/dL
Bilirubin	<20 mg/dL
Cholesterol	<500 mg/dL
Dopamine	<0.09 mg/dL
L-Dopa	<1.3 mg/dL
Tolazamide	<1 mg/dL
Triglyceride	<1000 mg/dL

Test Principle

The technology used for the eBuricacid Blood Uric Acid Monitoring System is based on the principle that small electrical currents are produced when blood uric acid reacts with the reagent immobilized on the reaction area of the eBuricacid test strip and the current change is proportional to the amount of uric acid in the blood.

Reagent Composition

Each eBuricacid Blood Uric Acid Test Strip contains:

- Uricase ≧ 0.01 mg
- Other ingredients ≧ 0.02 mg

Calibration Reference

The eBuricacid Blood Uric Acid Monitoring System is calibrated plasma equivalent results, which is traceable to a NIST standard SRM 913b. The plasma was used for calibration and using the LANNER Uric acid reagent kit by HITACHI 704 automatic analyzer.

Accuracy

The accuracy of eBuricacid was assessed by comparing the eBuricacid readings with the reference values using HITACHI 704 automatic analyzer the uric acid concentrations of capillary blood samples were measured using eBuricacid meter. The uric acid concentrations of the venous blood samples were analyzed using the HITACHI 704 automatic analyzer. The results shown below are from a total of 100 subjects and 3 lots of strips attending the outpatient clinic.

Number of Sample	Slope	Intercept	Correlation Coefficient
100	0.9766	0.4102 mg/dL	0.9906

Layuser (eBuricacid) fingerstick vs HITACHI 704 automatic analyzer

<5 mg/dL N= 22			
Within ±0.5 mg/dL	Within ±1.0 mg/dL	Within ±1.5 mg/dL	
17/22 (77.3 %)	21/22 (95.5 %)	22/22 (100 %)	
≧5 mg/dL N= 78			
Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
49/78 (62.8 %)	69/78 (88.5 %)	77/78 (98.7 %)	78/78 (100 %)

Precision

Precision was determined using coefficients of variation (CVs) calculated from 100 measurements in series. To produce the 4 different uric acid concentrations for the 3 lots of strips, venous whole blood samples from healthy volunteers were spiked using different concentrations of uric acid solutions.

Repeatability

Uric acid levels (mg/dL)	**3.8**	**7.2**	**10.9**	**14.4**
Average (mg/dL)	4.0	7.4	11.1	14.5
C.V. (%)	4.8	3.8	3.0	2.7

Intermediate

Uric acid levels (mg/dL)	**4.4**	**9.2**	**13.8**
Average (mg/dL)	4.3	9.3	14.1
C.V. (%)	5.5	3.2	2.7

Reference

1. Taiwan guideline for the management of gout and Hyperuricemia updated 2016.
2. 2016 updated EULAR evidence-based recommendations for the management of gout.

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	LOT	Batch number
EC REP	Authorized representative in the European Community/ European Union		Manufacturer
	Paper recycling	CE 0123	This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices.

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