kinetik
WELLBEING

**Blood Glucose Test Strips**
**Instructions for use**
Model: EGS-2003

***Important safety instructions***

- The meter and lancing device are for single patient use only. Do not share with anyone including other family members.
- All parts of the Kinetik AG-607 Blood Glucose Monitoring System are considered bio-hazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

Refer to the following links for more information:
"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)
*http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm*
"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)
*http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html*
Refer to the Cleaning and Disinfection section of the Owner's Manual for cleaning and disinfection procedures.

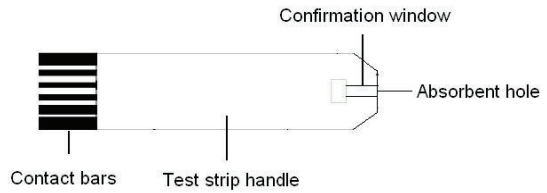
***Intended Use***

The EGS-2003 Blood Glucose Test Strips are for use with the Kinetik AG-607 Blood Glucose Monitoring System to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh. They are intended for single patient use only and should not be shared. They should only be used for monitoring and not be used for the diagnosis of or screening for diabetes, or for neonatal use.

***Test Principle***

The test is based on the measurement of an electrical current generated by the reaction of glucose with the reagent of the test strip. The meter measures the current and converts to the corresponding blood glucose level.

***Test Strip Parts***




**Absorbent hole** - Apply a drop of blood here. The blood will be drawn in automatically.
**Confirmation window** - If sufficient blood has been drawn into the absorbent hole of the test strip this window will be completely covered with blood.
**Test strip handle** - Hold this part to insert the test strip into the strip port.
**Contact bars** - Insert this end of the test strip into the meter. Push it in firmly until it will go no further.
**Attention:** Test results might be inaccurate if the contact bars is not **fully** inserted into the strip port.

***Warning and Precautions***

- For in vitro diagnostic use (external use only).
- Do not reuse.
- For self-testing.
- Please review this instruction sheet and the Kinetik AG-607 Blood Glucose Monitoring System owner's manual before you use EGS-2003 Blood Glucose Test Strips. For reliable results and to maintain the manufacturer's complete service, support, and warranty.
- As with all small parts, the test strips and lancets should be kept away from small children. If any parts are swallowed, promptly see a doctor for help.
- If you have questions or need assistance outside the Customer Service days and time, please contact your healthcare provider.
- Please wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- The meter and lancing device should be cleaned and disinfected. Please refer to the Cleaning and Disinfection section of the Owner's Manual for cleaning and disinfection procedures.
- Used lancet and test strips may be potentially hazardous. Please discard them carefully according to instructions found in the Kinetik AG-607 Blood Glucose Monitoring System Owner's Manual.
- Never make significant changes to your diabetes control program or ignore physical symptoms without consulting your healthcare professional.
- You should only adapt the treatment if you has received the appropriate training to do so.

***Test Procedure***

1. Wash hands or the puncture site using soap and warm water. Rinse and dry thoroughly.

***Note:*** *If you use an alcohol swab, ensure that the puncture site is completely dry prior to obtaining a sample.*

2. Remove a test strip from its vial and insert the test strip into the strip port of the meter. The contact bars must be all the way into the meter.
3. Puncture the test site using the lancing device and gently squeeze and/or massage the area until a round drop of blood of at least 0.7 microliter forms. Do not squeeze the puncture site excessively.
4. Apply your blood to the absorbent hole of the test strip until the confirmation window is fully filled with blood, please refer to the diagram below.

***Note:*** *Make sure the confirmation window of the test strip is completely filled with your blood sample.*

5. Get your blood glucose result.
6. Remove the test strip from the meter. Discard the used lancet directly into a container designed for sharp objects.

***Note:***

*1. A lancing device is intended only for a single user and should not be shared, otherwise it will bring the risk of blood-borne pathogen transmissions.*
*2. Lancets are for single use only.*
*3. A new, sterile lancet should be used each time a test is performed.*

Please consult the Kinetik AG-607 Blood Glucose Monitoring System Owner's Manual for detailed directions and illustrations.

***Questionable or Inconsistent Results***

If you are receiving test results that are unusual or inconsistent with how you are feeling:
>Make sure that the drop of blood completely covers the confirmation window of the test strip.
>Confirm that the test strips are not expired.
>Check the performance of the meter and test strips using the control solution.
Please keep in mind that high or low blood glucose levels can indicate a possibly serious medical condition. If you continue to get results that are unusually high or low, consult your healthcare professional.

***Reference Values***

| Time of day | People without diabetes |
|---|---|
| Fasting and before meals | <100mg/dL |
| 2 hours after meals | <140mg/dL |

Source: American Diabetes Association: Classification and Diagnosis of Diabetes (Position Statement). Diabetes Care 39 (Supp. 1) S15, 2016.
Please consult your healthcare provider to determine a target range that is best for you.

***Warning: Alternative Site Testing (AST)***
**Important: There are limitations for doing AST. Please read the** Kinetik AG-607 **Blood Glucose Monitoring System Owner's Manual and consult your healthcare professional before you do AST.**

- Alternative site testing (AST) should not be used to calibrate continuous glucose monitoring systems (CGMs).
- Results from alternative site testing should not be used in insulin dose calculations.

***Control Solution Testing for Performance Checking***

The control solution(Level II)contains a known amount of glucose concentrate that reacts with test strips. By comparing your control solution test results with the expected range printed on the test strip vial label, you can check that the meter and the test strips are working together as a system and that you are performing the test correctly.
It is very important that you do this simple check routinely to make sure you get accurate results. Read the Kinetik AG-607 Blood Glucose Monitoring System Owner's Manual for complete testing details.
**Control solution test should be performed:**
>When your test strips are exposed to extreme environmental conditions (See Warning and Precautions section of this document).
>When your blood glucose test results are not consistent with how you feel, or when you think your results are inaccurate.
>Whenever you suspect the meter or test strips are not working properly.
>At least once a week.
>When you want to practice testing with the meter.
>When you drop or damage the meter.
> Each time a new vial of test strips is opened.
**Caution:** The control range can change with each new vial of test strips. Always use the control range on the label of your current vial of test strips.
If the control solution test result falls outside the specified range printed on the test strip vial:
(1) Repeat the Quality Control Test.
(2) Review the Quality Control Section of the Owner's Manual to confirm your procedure and techniques.
(3) Check the expiration date of your test strips and control solution.
(4) Check your meter for damage (dropping the meter, immersing in liquid).

***Test Results***

Your blood glucose test results are displayed in mg/dL or mmol/L.
If your result is below 20mg/dL, repeat your test with a new test strip to confirm this reading. This indicates very low blood glucose levels or severe hypoglycemia. You should immediately treat hypoglycemia by following the recommendations of your healthcare professional.
If your result is above 600mg/dL, repeat your test with a new test strip to confirm this reading. This indicates very high blood glucose levels, or severe hyperglycemia. You should seek immediate medical attention.

***Storage and Handling***

In order to ensure that your test strips are effective, please use them according to the following recommendations.
**IMPORTANT:** Do not use the test strips if expired or results will be inaccurate.

To keep your test strips in the best possible condition, read the following recommendations thoroughly:

1. Test strips expire 5 months after opening. Write the expiry date on the test strip vial when first opening.
   *Store the test strip vial between 39°F ~ 86°F(4° C to 30° C) and 10% ~ 85% relative humidity.*
2. Do not refrigerate or freeze.
3. Keep the test strips away from direct sunlight. Do not store the test strips in areas of high humidity.
4. Test strips must be stored in their original vial only. Do not transfer them to a new vial or other container.
5. Do not touch the test strips when your hands are wet.
6. Use each strip promptly after removing it from the vial. Close the vial lid quickly after removing a new test strip.
7. Keep the vial lid closed at all times.
8. Do not bend, cut or alter the test strip. Doing so will lead to inaccurate results.
9. Do not use if vial is damaged.

***Chemical Components in Each Test Strip***

1. FAD-GDH >0.04mg
2. Other ingredients
   (Electron shuttle, enzyme protector, non-reactive ingredients etc.) >0.05mg

***Limitations***

>Hematocrit: The glucose result is not affected when hematocrit is between 20% and 60%. Please consult your healthcare professional if you do not know your hematocrit level.
> Neonatal Use: The EGS-2003 Blood Glucose Test Strips are not intended for neonatal testing.
> Metabolites: Uric acid，bilirubin and hemoglobin at normal blood concentration does not significantly affect glucose readings. High concentrations of acetaminophen and ascorbic acid may cause inaccurate test results. Blood glucose readings should be interpreted with caution.
>Lipemic Effects: Elevated blood triglycerides up to 2000 mg/dL do not significantly affect the results.
>The below table of substances shows the highest concentration without significant interference (± 10% error).

| Compounds | Limitation |
|---|---|
| Ascorbic acid | ＞4mg/dL |
| Uric acid | ＞10mg/dL |
| Acetaminophen | ＞5mg/dL |
| Bilirubin | ＞40mg/dL |
| Triglycerides | ＞2000mg/dL |
| Hemoglobin | ＞450mg/dL |

> Do not use during or soon after xylose absorption testing.
> If you are a patient on peritoneal dialysis, check with your doctor before testing your blood glucose. The dialysis solution may lead to incorrect results.
> Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
> Not for use on critically ill patients.
> Not to be used for patients who are dehydrated, hypertensive, hypotensive or in shock.
>Altitude Effects: Test strips may be used at altitudes up to 10,744 feet（3,275 meters） without an effect on test results.

***Performance Characteristics***

System Measurement Range: 20 to 600mg/dL (1.1 ~ 33.3 mmol/L)
Hematocrit Range: 20% ~ 60%
Sample: Whole blood, capillary
Not less than Blood Sample Size: 0.7 μ L
Test Time: 5 seconds
Calibration: plasma equivalents

**Precision**

These studies were performed in the laboratory with whole blood. The blood glucose level was adjusted to five ranges.

| Glucose concentration (mg/dL) | 30-50 | 51-110 | 111-150 | 151-250 | 251-400 |
|---|---|---|---|---|---|
| Number | 100 | 100 | 100 | 100 | 100 |
| Average | 41.5 | 88.7 | 118.9 | 200.0 | 311.5 |
| SD (mg/dL) | 2.1 | 2.3 | 2.5 | 3.1 | 4.4 |
| CV (%) | 5.0 | 2.6 | 2.1 | 1.5 | 1.4 |

**System Accuracy**

The System was tested on 100 capillary blood samples. The system accuracy was compared to the laboratory method（The laboratory method traceability and validation of calibration are traceable to NIST standard reference material (SRM) 917c）. The tables below show how well the two methods compared.

Table 1 represents samples for glucose results < 100mg/dL.

| Difference range in values between blood glucose monitoring system's value and the laboratory value | Within 5mg/dL | Within 10mg/dL | Within 15mg/dL* |
|---|---|---|---|
| blood glucose monitoring system | 39/56（70%） | 54/56（96%） | 56/56（100%） |

Table 2 represents samples for glucose results ≥100mg/dL.

| Difference range in values between blood glucose monitoring system's value and the laboratory value | Within 5% | Within 10% | Within 15%* |
|---|---|---|---|
| blood glucose monitoring system | 79/144（55%） | 113/144（78%） | 139/144（97%） |

*Acceptance criteria in ISO 15197 are that 95% of all differences in glucose values should be within 15mg/dL for glucose values less than 100mg/dL or within 15% for glucose values greater than 100mg/dL.

**Testing Accuracy of the Alternative Sites**

100 subjects were tested on the alternative sites: the palm, the forearm, the upper arm, the calf and the thigh. The tables show differences in glucose values between alternative sites and laboratory values (finger stick sample).

Table 3 represents samples for glucose results < 100mg/dL.

| Difference range in values between the alternative sites' value and the laboratory value | Within 5mg/dL | Within 10mg/dL | Within 15mg/dL* |
|---|---|---|---|
| Palm | 8/12(67%) | 9/12(75%) | 12/12(100%) |
| Forearm | 7/12(58%) | 11/12(92%) | 12/12(100%) |
| Upper arm | 8/12(67%) | 10/12(83%) | 12/12(100%) |
| Calf | 9/12(75%) | 11/12(92%) | 12/12(100%) |
| Thigh | 7/12(58%) | 10/12(83%) | 12/12(100%) |

Table 4 represents samples for glucose results ≥ 100mg/dL

| Difference range in values between the alternative sites' value and the laboratory value | Within 5% | Within 10% | Within 15%* |
|---|---|---|---|
| Palm | 38/88(43%) | 67/88(76%) | 86/88(98%) |
| Forearm | 39/88(44%) | 71/88(81%) | 86/88(98%) |
| Upper arm | 37/88(42%) | 73/88(83%) | 85/88(97%) |
| Calf | 37/88(42%) | 71/88(81%) | 85/88(97%) |
| Thigh | 38/88(43%) | 72/88(82%) | 85/88(97%) |

Lay user performance:
A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:
100% within ±15mg/dL(±0.83mmol/L) of the medical laboratory values at glucose concentrations below 100mg/dL (5.55mmol/L), and 100% within ±15% of the medical laboratory values at glucose concentrations at or above 100mg/dL (5.55mmol/L).

**Return Policy**

Product may be returned if faulty, please contact the Retailer or Kinetik directly if you're experiencing issues with your product. This does not affect your statutory rights. Please note the retailer's own return policy may still be valid, contact the retailer for more information.

If you have questions or need assistance outside the operational days and times, please contact your health care provider.

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***Symbols in use***


Do not Reuse


Consult Instructions for Use


In Vitro Diagnostic Medical Device


Storage Temperature Limitation


Symbol for "Manufacture Date"


Use by


Manufacturer


Authorised Representative in the European Community

CE 0197 Complies with IVD98/79/EC Requirements