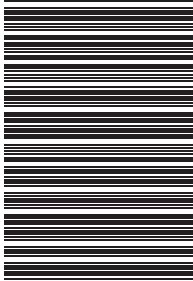


# ONETOUCH<sup>®</sup> Verio<sup>®</sup> Test Strips

Tiras reactivas

AW 06703910A



*In vitro* diagnostic. For self-testing.

**IMPORTANT:** Please read this insert and your User Guide or Owner's Booklet before using. The User Guide or Owner's Booklet has full instructions for blood glucose and control solution testing. **Do Not** use new test strips if the vial is open or damaged in any way. This could lead to error messages or inaccurate blood glucose results. Contact Customer Service right away if you have questions about your test strips, test results or these instructions. As your partner in diabetes care, we welcome you to contact us (7 days a week, 8:00 AM - 8:00 PM Eastern Time) at 1 888 567-3003 (English), 1 888 567-3010 (Español), or www.OneTouch.com.

Refer to your User Guide or Owner's Booklet for important information about cleaning and disinfecting your meter, lancing device, and caps.

The meter and lancing device are for single patient use. **Do Not** share them with anyone including other family members! **Do Not** use on multiple patients! All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

**⚠WARNING: Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV) or other bloodborne pathogens.**

## Intended Use

The OneTouch Verio<sup>®</sup> Test Strips are used with the OneTouch Verio<sup>®</sup> Family of Blood Glucose Monitoring Systems (OneTouch Verio<sup>®</sup>, OneTouch Verio IQ<sup>®</sup>, OneTouch VerioSync<sup>®</sup>, OneTouch Verio Flex<sup>®</sup>, OneTouch Verio Reflect<sup>™</sup>) for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The OneTouch Verio<sup>®</sup> Family of Blood Glucose Monitoring Systems is intended to be used by a single person and should not be shared.

The OneTouch Verio<sup>®</sup> Family of Blood Glucose Monitoring Systems is not to be used for the diagnosis of or screening of diabetes or for neonatal use.

Refer to the User Guide or Owner's Booklet that came with your meter for the full system intended use.

## Storage and Handling

- The expiration date is printed on the vial.
- The discard date is 6 months after you first open a test strip vial. When you open a new vial, write the discard date on the label.
- Do Not** use after the expiration or discard date, whichever comes first.
- Store the test strip vial in a cool dry place between 41°F and 86°F and below 90% relative humidity. Keep away from direct sunlight and heat. **Do Not store the test strip vial in rooms where the air is humid such as the kitchen, laundry room or bathroom.** Exposure to temperatures outside the storage limits, as well as moisture and humidity, may cause inaccurate readings.
- Store your test strips in the **vial only**. To avoid damage or contamination, **Do Not** put test strips in any other container.
- Open the vial **only** when taking out a test strip for use.
- Close the vial lid tightly right away after removing a test strip. Use each test strip **as soon as you take it out** of the vial.
- Do Not** use test strips from a vial that is damaged or left open to air.
- Do Not** get dirt, food or liquids on the test strip. You may touch the test strip anywhere on its surface with clean, dry hands.
- Do Not** bend, cut or alter test strips in any way.
- Test strips are for single use only.
- Never reuse a test strip that already has blood or control solution on it.**
- Make sure your meter and test strips are about the same temperature before you test.
- Apply only OneTouch Verio<sup>®</sup> Control Solution or a blood sample to the test strip.
- Do Not** put the used test strip back in the vial after taking a test.
- Used test strips may be considered biohazardous waste in your area. Be sure to follow your healthcare professional's advice or local laws when throwing them away.

**⚠WARNING: Keep the test strip vial away from children. Test strips are a choking hazard. Do Not swallow test strips. The test strip vial may contain drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation. Do Not ingest or swallow any items.**

## Testing your blood glucose

Read your system User Guide or Owner's Booklet for instructions on running a blood test and getting a blood sample.

## Test Results

The OneTouch Verio<sup>®</sup> Family of Meters shows results between 20 and 600 mg/dL.

Read these cautions when your test results are higher or lower than what you expect.

### ⚠CAUTION:

#### Low glucose results

If your blood glucose result is below 70 mg/dL or a low glucose warning is displayed, (meaning the result is less than 20 mg/dL), it may mean hypoglycemia (low blood glucose). You may need to treat low glucose right away. Follow your healthcare professional's advice. The result could be due to a test error, but it is safer to treat first, then test again.

#### High glucose results

If your test result is above 180 mg/dL, it may mean high blood glucose (hyperglycemia). You should think about re-testing. Talk to your healthcare professional if you are concerned about high blood glucose.

A high glucose warning is shown when your blood glucose level is over 600 mg/dL. You may have very high blood glucose (severe hyperglycemia). Re-test your blood glucose. If the result is a high glucose warning again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional right away.

#### Repeated unexpected glucose results

If you get repeated unexpected results:

- Run a control solution test to check your system.
- Make sure you follow all instructions in your User Guide or Owner's Booklet.
- If your symptoms don't match your blood glucose results, call your healthcare professional.

Never ignore symptoms or make significant changes to your diabetes management program without speaking to your healthcare professional.

## Range of Expected Values

Blood glucose management requires the help of a healthcare professional. Talk to your healthcare professional about:

- The target blood glucose range that is right for you.
- When to test.
- What your blood glucose results mean.

Expected blood glucose levels for non-pregnant people without diabetes<sup>1</sup>:

| Time                | Range, mg/dL  |
|---------------------|---------------|
| Fasting             | Less than 100 |
| 2 hours after meals | Less than 140 |

<sup>1</sup>American Diabetes Association, Standards of Medical Care in Diabetes, Diabetes Care Vol. 41, Supplement 1, S1-S2, January 2018.

## Checking the System

Use only OneTouch Verio<sup>®</sup> Control Solution

A control solution test is used to check that:

- The meter and test strips are working together properly.
- You are doing the test correctly.

#### Do a control solution test

- When you open a new vial of test strips.
- If you think the meter or test strips are not working properly.
- If you get repeated unexpected blood glucose results.
- If you drop or damage the meter.

Read your system User Guide or Owner's Booklet for instructions on how to run a control solution test.

## Limitations of Procedure

OneTouch Verio<sup>®</sup> Test Strips give accurate results under the following conditions:

- Use only fresh capillary whole blood.
- A hematocrit (percentage of your blood that is red blood cells) that is either very high (above 60%) or very low (below 20%) can cause false results.
- OneTouch Verio<sup>®</sup> Test Strips may be used at altitudes up to 10,000 feet with no effect on test results.
- Test results may be falsely low if the patient is severely dehydrated, in shock or in a hyperosmolar state (with or without ketosis).
- Critically ill patients should not be tested with the OneTouch Verio<sup>®</sup> Family of Meters.
- Uric Acid at concentrations greater than 8 mg/dL may cause falsely low results when using the OneTouch Verio<sup>®</sup> Family of Meters with the exception of OneTouch Verio Reflect<sup>™</sup>.

### ⚠CAUTION:

- The OneTouch Verio<sup>®</sup> Family of Blood Glucose Monitoring Systems should not be used within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high glucose results with your meter.
- Do Not** use the OneTouch Verio<sup>®</sup> Family of Blood Glucose Monitoring Systems if you are being treated for organophosphate poisoning with PAM (Pralidoxime) as it may cause inaccurate glucose results with your meter.
- Dehydration and low glucose results**  
You may get false low glucose results if you are severely dehydrated. If you think this is the case, contact your healthcare professional right away.

## Alternate Site Limitations

**Do Not** use the OneTouch Verio<sup>®</sup> Family of Meters for alternate site testing (AST).

Refer to the User Guide or Owner's Booklet that came with your meter for the full system intended use.

## Test Principle

The OneTouch Verio<sup>®</sup> Family of Meters is plasma-calibrated for easy comparison of results with lab methods. Glucose in the blood sample mixes with special chemicals on the test strip to produce an electrical current. The strength of the current changes with the amount of glucose in the blood sample. The OneTouch Verio<sup>®</sup> Family of Meters measures the current, calculates your blood glucose level and shows your result.

## Reagent Composition

Each test strip contains: flavin adenine dinucleotide dependent glucose dehydrogenase or FAD-GDH (from Aspergillus sp.) - 2 U; potassium ferricyanide 41 µg; and other ingredients (buffer, etc.). The vial contains a drying agent.

## Performance Characteristics

The performance of the OneTouch Verio<sup>®</sup> Test Strip has been evaluated both in laboratory and in clinical tests.

Measurement Range: The measurement range of the OneTouch Verio<sup>®</sup> Family of Meters is 20 to 600 mg/dL.

**The following data is representative of the OneTouch Verio<sup>®</sup> Family of Meters except the OneTouch Verio Reflect<sup>™</sup> Meter. Refer to your system Owner's Booklet for performance data specific to your system.**

### System Accuracy

Samples from 100 patients were tested using both the OneTouch Verio<sup>®</sup> System and the YSI 2300 Glucose Analyzer laboratory instrument.

#### System Accuracy Results for Glucose Concentrations <75 mg/dL

Percent (and number) of meter results that match the laboratory test

| Within ±5 mg/dL | Within ±10 mg/dL | Within ±15 mg/dL |
|-----------------|------------------|------------------|
| 50.7% (35/69)   | 89.9% (62/69)    | 100.0% (69/69)   |

#### System Accuracy Results for Glucose Concentrations ≥75 mg/dL

Percent (and number) of meter results that match the laboratory test

| Within ±5%      | Within ±10%     | Within ±15%     | Within ±20%    |
|-----------------|-----------------|-----------------|----------------|
| 62.3% (144/231) | 89.2% (206/231) | 97.8% (226/231) | 100% (231/231) |

### System Accuracy Results across the entire Glucose Range

Percent (and number) of meter results that match the laboratory test

| Within ±15 mg/dL or ±20% |
|--------------------------|
| 100% (300/300)           |

### Regression Statistics

Samples were tested on each of three test strip lots. Results indicate that the OneTouch Verio<sup>®</sup> System compares well with a laboratory method.

| # of Subjects | # of Tests | Slope | Intercept (mg/dL) |
|---------------|------------|-------|-------------------|
| 100           | 300        | 0.99  | 5.14              |

| 95% CI Slope | 95% CI Intercept (mg/dL) | Std. Error (S <sub>y,x</sub> ) (mg/dL) | R <sup>2</sup> |
|--------------|--------------------------|--|----------------|
| 0.98 to 1.00 | 3.06 to 7.23             | 9.72                                   | 0.99           |

### Precision

Within Run Precision (300 Venous Blood Tests per glucose level)

Data generated using the OmniPod<sup>®</sup> Insulin Management System.

| Target Glucose (mg/dL) | Mean Glucose (mg/dL) | Standard Deviation (mg/dL) | Coefficient of Variation (%) |
|------------------------|----------------------|----------------------------|------------------------------|
| 40                     | 47.0                 | 1.37                       | 2.92                         |
| 100                    | 105.8                | 2.62                       | 2.47                         |
| 130                    | 136.4                | 3.62                       | 2.65                         |
| 200                    | 212.6                | 5.21                       | 2.45                         |
| 350                    | 366.8                | 9.16                       | 2.50                         |

Results show that the greatest variability observed between test strips when tested with blood is 2.65% or less.

Total Precision (600 Control Solution Tests per glucose level)

Data generated using the OneTouch Verio IQ<sup>®</sup> Meter.

| Glucose Level Ranges (mg/dL) | Mean Glucose (mg/dL) | Standard Deviation (mg/dL) | Coefficient of Variation (%) |
|------------------------------|----------------------|----------------------------|------------------------------|
| Level 2 (38-62)              | 50.31                | 1.77                       | 3.52                         |
| Level 3 (102-138)            | 117.14               | 2.70                       | 2.31                         |
| Level 4 (298-403)            | 342.34               | 8.68                       | 2.53                         |

### The following data is representative of the OneTouch Verio Reflect<sup>™</sup> Meter.

Your OneTouch Verio Reflect<sup>™</sup> Meter result may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and the natural variation in the test technology.

The chart below shows the results of a study where 354 typical users used the OneTouch Verio Reflect<sup>™</sup> Meter to test their blood glucose level. For example, in this study, the OneTouch Verio Reflect<sup>™</sup> Meter gave results within 15% of their true blood glucose level 351 out of 354 times.

| Difference range between the true blood glucose level and the OneTouch Verio Reflect <sup>™</sup> Meter result | Within 5%       | Within 10%      | Within 15%      | Within 20%     |
|--|-----------------|-----------------|-----------------|----------------|
| The percent (and number) of meter results that match true blood glucose level within X%                        | 62.7% (222/354) | 94.1% (333/354) | 99.2% (351/354) | 100% (354/354) |

### Regression Statistics

Samples were tested on one of three test strip lots. Results indicate that the OneTouch Verio Reflect<sup>™</sup> System compares well with a laboratory method.

| # of Subjects | # of Tests | Slope | Intercept (mg/dL) |
|---------------|------------|-------|-------------------|
| 354           | 354        | 1.02  | -2.66             |

| 95% CI Slope | 95% CI Intercept (mg/dL) | Std. Error (S <sub>y,x</sub> ) (mg/dL) | R <sup>2</sup> |
|--------------|--------------------------|--|----------------|
| 1.01 to 1.04 | -5.40 to 0.09            | 10.58                                  | 0.98           |

### Precision

Within Run Precision (300 Venous Blood Tests per glucose level)

| Target Glucose (mg/dL) | Mean Glucose (mg/dL) | Standard Deviation (mg/dL) | Coefficient of Variation (%) |
|------------------------|----------------------|----------------------------|------------------------------|
| 40                     | 36.8                 | 1.05                       | 2.84                         |
| 90                     | 89.7                 | 2.46                       | 2.74                         |
| 130                    | 132.8                | 4.07                       | 3.07                         |
| 200                    | 206.8                | 5.53                       | 2.68                         |
| 350                    | 368.7                | 10.84                      | 2.94                         |

Data generated using the OneTouch Verio Reflect<sup>™</sup> Meter show that the greatest variability observed between test strips from three strip lots when tested with blood is 1.05 mg/dL SD or less at glucose levels less than 75 mg/dL or 3.07% CV or less at glucose levels at 75 mg/dL or above.

Total Precision (600 Control Solution Tests per glucose level)

Data generated using the OneTouch Verio Reflect<sup>™</sup> Meter.

| Glucose Level Ranges (mg/dL) | Mean Glucose (mg/dL) | Standard Deviation (mg/dL) | Coefficient of Variation (%) |
|------------------------------|----------------------|----------------------------|------------------------------|
| 30-50                        | 37.74                | 0.93                       | 2.47                         |
| 51-110                       | 69.00                | 1.40                       | 2.02                         |
| 111-150                      | 118.65               | 2.24                       | 1.89                         |
| 151-250                      | 200.53               | 3.70                       | 1.84                         |
| 251-400                      | 346.74               | 7.66                       | 2.21                         |

**IMPORTANT:** For instructions, technical data and a list of symbols used, read your system User Guide or Owner's Booklet.

## 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 LifeScan product, contact Customer Service. As your partner in diabetes care, we welcome you to contact us (7 days a week, 8:00 AM - 8:00 PM Eastern Time) at 1 888 567-3003 (English), 1 888 567-3010 (Español), or www.OneTouch.com. If you cannot reach Customer Service, contact your healthcare professional for advice.

For a complete list of all symbols used, refer to the User Guide or Owner's Booklet that came with your system.

