Manufacturer
GENERAL LIFE BIOTECHNOLOGY CO., LTD.
5F., No.240, Shinshu Rd., Shin Juang Dist.,
New Taipei City 242, Taiwan

Tel : +886-2-22053698
Fax : +886-2-22080779
E-mail : service@glbiotech.com.tw
Website : www.BeneCheck.com.tw
www.glbiotech.com.tw

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

CE 0197

REF PP-E074

Doc No : 10-RN01-UM-02A Aug. 2012

BeneCheck™

Dual Monitoring System

Total Cholesterol
Blood Glucose

User's Manual

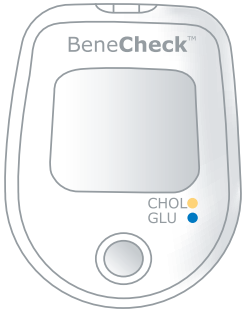


TABLE OF CONTENTS

Chapter 1 BeneCheck CHOL.GLU Dual Monitoring System
1.1 Introduction....1-2
1.2 Contents of the Kit....3
1.3 Labelling and Informations....4
1.4 System Components
Meter....5-6
Test Strips....7-8
Code Strip....9

Chapter 2 Setting-up the Meter
2.1 Installing/Replacing the Batteries....10-11
2.2 Set the Year....11
Set the Month/Day/Hour/Minute....12
Set the Measurement Unit/Patient Condition Index....13
2.3 Coding the Meter....14-16
2.4 Control Test....16-19

Chapter 3 How to Perform a Test
3.1 Before Testing....20-22
3.2 Testing procedures for Blood Total Cholesterol....23
3.3 Testing procedures for Blood Glucose....24
3.4 Care after the Test....24-25

Chapter 4 Meter Memory Function....26-27

Chapter 5 Storage and Handling of Meter and Strips....28

Chapter 6 Icon and Alert Tones....29

Chapter 7 Error Message and Trouble Shooting....30-32

Chapter 8 Specifications....33

Chapter 9 Limitations....34-38

Chapter 1 BeneCheck CHOL.GLU Dual Monitoring System

1.1 Introduction

Thank you for choosing BeneCheck CHOL.GLU Dual Monitoring System. The BeneCheck CHOL.GLU Dual Monitoring System is designed by General Life Biotechnology Co., Ltd and marketed all over the world.

The BeneCheck CHOL.GLU Dual Monitoring System provides you with accurate, plasma-calibrated results based on electrochemical sensor technology. The blood total cholesterol or blood glucose level is precisely calculated and displayed in a short time.

Intended Use :

The BeneCheck CHOL.GLU Dual Monitoring System is designed to measure blood total cholesterol or blood glucose level in whole blood. The test strips are for self-testing outside the body (in vitro diagnostic use). It should be used only for testing total cholesterol or blood glucose with fresh capillary finger blood samples. The system is suitable for users to monitoring their total cholesterol or blood glucose at home by themselves and also can be used at clinical sites by healthcare professionals.

The BeneCheck CHOL.GLU Dual Monitoring System is calibrated using venous plasma with calibrators which were referenced to the following standards and method.

Test	Standard	Method
Total Cholesterol	NIST SRM911b	Abell/kendall
Glucose	NIST SRM965	ID/MS

Please read the entire USER'S MANUAL carefully before using the BeneCheck CHOL.GLU Dual Monitoring System to test total cholesterol and blood glucose levels. This USER'S MANUAL guides you through the operation procedures with illustrated directions and help you find the required informations.

WARNING :
Please carefully read the instructions in this USER'S MANUAL and become familiar with the test procedures before using the system to test total cholesterol and blood glucose levels. User should consult with a healthcare professional before going ahead important medical decision.

1.2 Contents of the Kit

Please check the whole package for the BeneCheck CHOL.GLU Dual Monitoring System. The system includes the following items :

BeneCheck CHOL.GLU Meter

BeneCheck CHOL.GLU User's Manual

Kit Carrying Bag

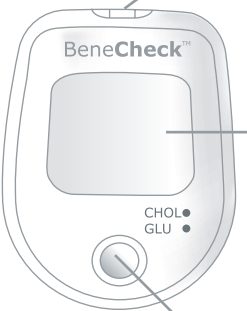
Optional :

BeneCheck Total Cholesterol Test Strip (vial)
BeneCheck Glucose Test Strip (vial)
BeneCheck Total Cholesterol Test Strip Instruction
BeneCheck Glucose Test Strip Instruction
BeneCheck Glucose Control Solution
Lancing Device
Lancets (Manufacturer : refer to the label on the package)

1.3 Labelling and Informations

	Do not re-use		Use by
	Keep dry		Read instructions
	Keep away from sunlight		Caution, consult accompanying documents
	Operation temperature limitation	EC REP	EU Representative
	Storage temperature limitation	REF	Catalogue number (Product number)
CE 0197	CE certification	IVD	In-vitro diagnostic
	Manufacturer	LOT	Lot number

1.4 System Components
Meter (Front Side)



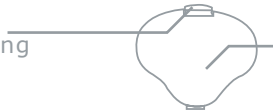
Test Port :
Where you insert the test strip for test.

LCD Screen :
for display of operating information and test results.

Front Button :
for on and memory mode operation.

Meter (Back Side)

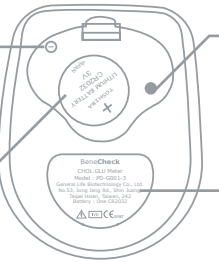
Battery Cover Lid :
Lift upward while replacing the battery.



Battery Cover :
For covering the battery.

Screw :
For holding the meter together, do not open or disassemble the BeneCheck CHOL.GLU Meter.

Battery :
3V lithium battery(CR2032)



Setting Button :
For setup and reset of the meter.

Tag :
Display information about the meter.

Test Strip
Total Cholesterol Strip

Electronic Contact Bar :
Insert Electronic Contact Bar of the test strip into the Test Port of the meter to activate it.

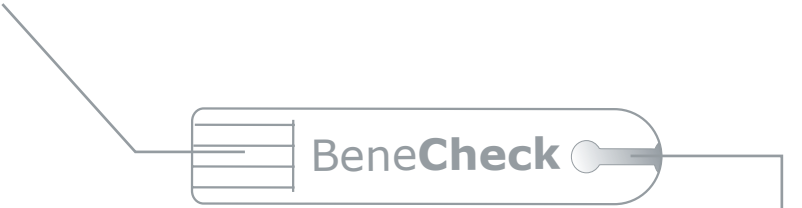
Reaction Zone :
Reaction zone of Total Cholesterol

Sample Inlet :
The inlet where the whole blood or control solution is drawn in. When a blood sample or control solution touches this end, the sample will be sucked into the reaction zone automatically.

* **The reaction zone of total cholesterol strip has to be filled up with control solution or a blood sample (at least 10 µL is essential).**

Glucose Strip

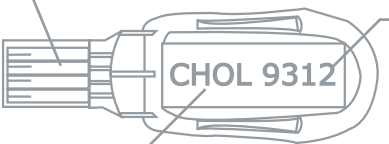
Electronic Contact Bars :
Insert this end of the test strip into the test Port of the meter to activate it.



Sample Inlet :
The inlet where the whole blood or control solution is drawn in. When a blood sample or control solution touches this end, the sample will be sucked into the reaction zone automatically.

Code Strip (Front View)

Contact Bar :
Insert this end into the Test Port of the meter.



Code Number

Test Mode

Test Mode :
CHOL - Total Cholesterol
GLUC - Glucose

Chapter 2 Setting-up the Meter

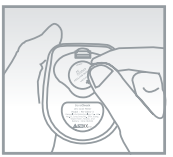
2.1 Installing/Replacing the Batteries

A 3-volt lithium battery (CR2032) is included in the meter package. Use only 3V lithium batteries. Do not use or replace the battery with different types of batteries. Doing so will damage the electronics of the meter.

Instructions :

1. 

Hold the meter with one hand, slightly lift the back cover lid to open the back cover.

2. 

Insert a new battery in the meter with the "+" side facing up, you will hear a "beep" sound which indicates that meter is on.

3.  Place back the cover onto the meter.

2.2 Set the Year/Month/Day/Hour/Minute/Measurement unit

The directions to setting mode.

Open the battery cover (on the back of the meter), press the setting button then a number such "2008" will blink on screen, which means Year.

Set the Year

1. Press the front button to advance one year until you get a correct year number.
2. After you set the desired year number, press the back setting button again then the meter enters into month setting.

Set the Month

1. Press and release the front button until the correct month appears.
2. Press the setting button and the day segment will start blinking.

Set the Day

1. Press and release the front button until the correct day appears.
2. Press the setting button and hour segment starts blinking.

Set the Hour

1. Press and release the front button until the correct hour appears.
2. Press the setting button and minute segment start blinking.

Set the Minute

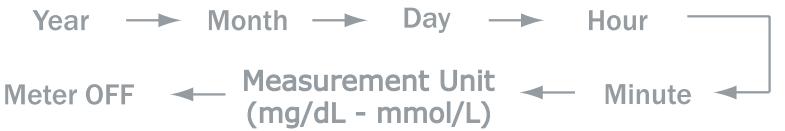
1. Press and release the front button until the correct minute appears.
2. Press the setting button and Measurement unit (mg/dL or mmol/L) starts blinking.

Set the Measurement Unit

1. Press and release the front button until to select the unit of **mg/dL** or **mmol/L** .
2. Press the setting button once will finish the setting and turns off automatically.

Note :

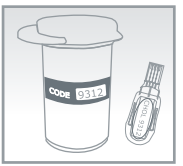
- The setting items of the meter is listed as follows. **Please be careful to set the desired measurement unit.**



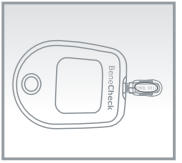
2.3 Coding the Meter

The BeneCheck CHOL.GLU Meter should be coded before testing with BeneCheck Total Cholesterol or Glucose Test Strips for the first time, or every time a new box of BeneCheck Total Cholesterol or Glucose Test Strips is used. Each vial of test strips has an assigned code number. The code strip is packaged with the test strip in order to calibrate/code the meter. Every time a test strip is inserted, please be sure to check the code number appearing on the screen is the same as the code number and test mode marked on the test strip vial.

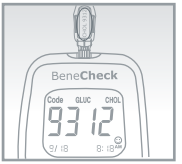
Directions :

1. 

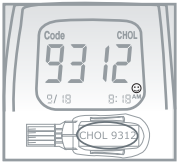
Check the code number on the code strip is the same as the code number on the test strip vial.

2. 

Insert code strip into the test port of the meter.

3. 

Wait for the code number to appear on the screen.

4. 

Make sure the code number on the screen is the same as the code number on the code strip.
Remove the code strip. "☺" should appear on the screen, indicating that the meter has been coded.

Cautions :
If "E-0" appears on the screen after removing the code strip, there may be a problem with the code strip. Perform the coding again, and if "E-0" continues to appear, please contact the original dealer or supplier for service.

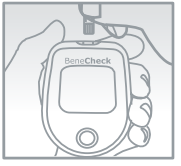
2.4 Control Test

A control solution is used to check the performance of the BeneCheck CHOL.GLU Dual Monitoring System, including BeneCheck CHOL.GLU Meter, BeneCheck Test Strip, and the user's operating skill. The system performs adequately if the control test result falls within the indicated control range listed on the test strip vial.

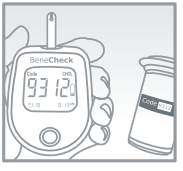
The system should be checked

- When you get the meter for the first time or begin using a new vial of test strip.
- When you suspect that the meter or the test strips are not working properly.
- Any time the total cholesterol or blood glucose test results are not consistent with how you feel, or any time you think your results are not accurate.
- Any time you drop or bump the meter.
- Upon the advice of the healthcare professional.

Directions :

1. 

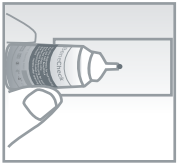
Insert a test strip and immediately cover the vial to keep the other test strips in dry condition. The meter will turn on automatically.

2. 

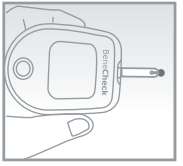
After "CH" and "  " appear on the screen, the code number will follow. Be careful to make sure the code number is the same as the code number marked on test strip vial.

3. 

A blood drop symbol "  " blinking on the screen means the system is ready for sample loading.

4. 

Please shake well and discard the first three drops of control solution, then drop some control solution onto a clean surface.

5. 

Touch the sample inlet of the total cholesterol or glucose test strip to the drop of control solution until the meter sounds a "beep". The screen will display a countdown.

∗The reaction zone of total cholestrol has to be filled up control solution.

6.

After count down and the screen will display the control test results. Compare the results to the control range listed on the test strip vial.

Note :

- Do not reuse test strips.
- Newly opened vials of control solution and test strips must be marked with the opening date.
- Close the test strip vial cap immediately after taking out the strip.
- Do not use BeneCheck CHOL.GLU Dual Monitoring System to do any test until you can get the control test result falls within the range listed on the test strip vial.
- If the test results fall outside the control range, please refer to Chapter 7 for trouble shooting.

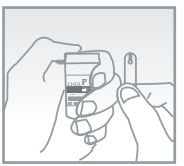
Chapter 3 How to perform a Test

3.1 Before Testing

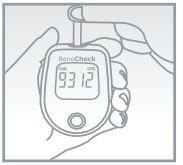
Please follow the step-by-step instructions to ensure accurate test results.
Materials required to perform a total cholesterol or blood glucose test include :

- BeneCheck CHOL.GLU Meter
- BeneCheck Total Cholesterol or Glucose Test Strip
- Lancing Device / Lancet
- Tissue or cotton ball with 75% ethanol for wiping blood sampling area before test, or simply wash hands with soap and water thoroughly before and after test for disinfection.

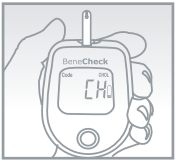
Directions :

1. 

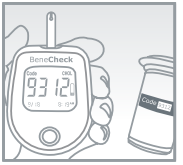
Take a test strip and immediately cover the vial cap to keep the other test strips in dry condition.

2. 

Fully insert the contact bar of the test strip into the test port of the meter. The meter will turn on automatically.

3. 

After " CH " and "  " appear on the screen, the code number will follow.

4. 

Check the test mode and code number on the screen is the same as the one on the test strip vial. Icon "CHOL" and "GLUC" indicate measuring mode of total cholesterol and glucose repectively. If not, remove the test strip and recode the meter.

Note :

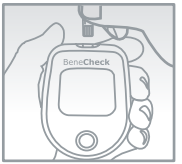
- The measurement test must be performed within 3 minutes, otherwise the meter will be turned off automatically. If turned off, remove and re-insert the test strip to do the test again.
- Test strips cannot be reused. If a used test strip is inserted, a warning message " E-U " will display on the screen. Always use new test strips.
- If the wrong end of the test strip is inserted, or if the test Strip is inserted backwards the Meter will not activate.

Warning :

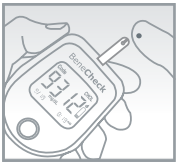
- Lancet cannot be reused.
- Please always use certified lancets to ensure safety.

3.2 Perform the Total Cholesterol Test

Directions :

1. 

Insert the BeneCheck Total Cholesterol Test Strip and take a blood sample according to the instructions for lancing device in the system.

2. 

Touch the sample inlet of the strip blood sample until **the reaction zone has been full of enough amount of blood sample**. A "beep" sound that means the sample is drawn into the strip successfully.

3. 

The screen will display a countdown then display the test results after the countdown.

3.3 Perform the Blood Glucose Test

1. Insert the BeneCheck Glucose Test Strip and take a blood sample according to the instructions for lancing device in the system.
2. Touch the sample Inlet of the strip to the drop of blood sample until the meter sounds a "beep", which means the sample has drawn into strip successfully.
3. The screen will display a countdown. After few seconds the screen will display the blood glucose results.

Note :

- Please complete the test procedures within 3 minutes or the meter will automatically turn off.
- Do not apply the blood sample on the test strip anywhere other than the sample inlet.
- Do not apply the blood sample to a same test strip twice, it will cause inaccurate test results.

3.4 Care after the Test

Directions :

1. Follow the instructions for lancing device to treat and discard the used

disposable lancet into an appropriate sharps or biohazard container.

2. After performing a test, remove the test strip and meter will automatically turned off.
3. Record the test result and date in your personal record diary.

Note :

- Please check your system performance regularly or when you suspect your test result is inaccurate.
- Dropping, bumping or other violent impact may damage the meter or cause malfunction.
- Do not use the meter in an environment with possible magnetic, electromagnetic, and radioactive interferences.

Warning :

- Do not disassemble the meter for any reason.
- Please follows local regulations to discard used test strips and lancets.
- Used test strips, lancets and any other materials which have been in contact with blood should be treated as potential biohazards. If a user has an infectious disease, the used test strips and other materials could be sources of infection.

Chapter 4 Meter Memory Function

The BeneCheck CHOL.GLU Meter automatically stores up to 410 records, which includes 50 total cholesterol, 360 blood glucose test results or control test results, each time a test is performed. The memory counts up from M01 through M50 or M360. Please follow these directions to recall stored test results.

Directions :

1. Make sure that no test strip is inserted in the meter.
2. Press the "Front Button" once to turn the meter on. A full display will appear on screen after a short "beep" sound.
3. Press the "Front Button" once again after the code number appears .The latest stored result M01 appears on the screen. The memory number increases progressively each time the button is pressed till M50 total cholesterol mode for and M360 for blood glucose mode.
4. Press and hold the "Front Button" will appear the stored memory continuously.
5. To turn the meter off, press the "Setting Button" of back side for over 5 seconds and the meter will make a long "beep" sound. The meter will also automatically shut down after 1 minutes.

Note :

- The day average function can be applied to glucose test mode only. Total cholesterol test mode do not have the average funation.

Chapter 5 Storage and Handling of Meter and Strips

Due to sensitive to heat and humidity, the performance of test strips may be affected by improper storage and handling. Please store the test strips and meter carefully according to the specifications listed in Chapter 8.

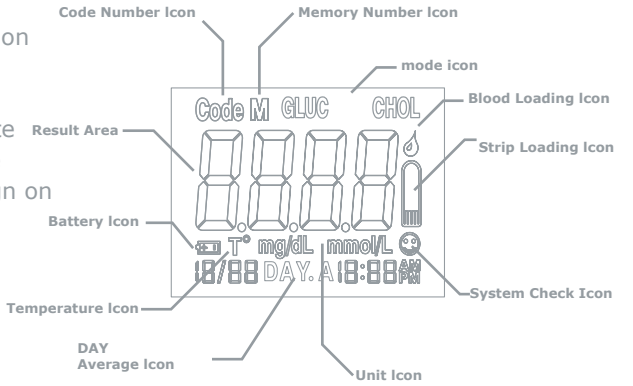
Note:

1. Store the meter, code strip, test strips and control solution at room temperature(10 - 30°C, 50 - 86°F). Do not expose them beyond the range described in Chapter 8.
2. Do not freeze or refrigerate the meter and strips.
3. Keep the meter clean by wiping the exterior of the meter with a tissue or lint-free cloth.

Chapter 6 Icon and Alert Tones

6.1 Icon on the Screen

The vivid and clear information icons on the screen are helpful and convenient. In addition to providing accurate total cholesterol and glucose test results, the icones design on the screen are easy to understand at a glance and will save you the effort of carrying the User's Manual for reference.



6.2 Alert Tones

- Normal Alert Sound : a short "beep"
- Warning Alert Sound : 3 short "beeps"
- Turning On/Off Alert Sound : a long "beep"

Message	Cause	Solution
E-0	There may be a problem with the meter or code strip.	Reload the code strip or repeat the test with a new test strip. If the problem persists, please call your local authorized supplier for service.
E-9	The test may be interrupted after applying blood to the strip.	Please don't remove the strip before the test is completed.
E-A	There is a problem with the meter.	Review the instructions and try again with a new test strip. If the problem persists,please call local authorized distributor for service.

Message	Cause	Solution
E-b	The power of the battery is too low to run a test.	Replace the battery at once.
E-1	Incompatible code strip with the meter.	Reload the code strip. If the problem persists, please contact your local supplier for service.
E-t & T^{o} Icon	The temperature was below or above the system operating range.	Repeat the test after the meter and the test strip have reached the temperature within the operating range.
E-U	It could be caused by a used test strip or a temporary or permanent electronic problem.	Repeat the test with a new test strip. If the error message appears again, please contact the dealer for service.

Message	Cause	Solution
Hi	1. Total cholesterol level is higher than 400 mg/dL (or 10.35 mmol/L) or blood glucose level is higher than 600 mg/dL (or 33.3 mmol/L). 2. A potential problem with the test strip.	1. Review the instructions and try again with a new test strip. 2. Check the test strip vial to make sure that it is not marked beyond the expiration date.
Lo	1. Total cholesterol level is lower than 100 mg/dL (or 2.59 mmol/L) or blood glucose level is lower than 18 mg/dL (or 1.0 mmol/L). 2. A potential problem with the test strip.	1. Review the instructions and try again with a new test strip. 2. Check the test strip vial to make sure that it is not marked beyond the expiration date.

Chapter 8 Specifications

System Accuracy	: ± 20% at Total Cholesterol ≥ 150 mg/dL ± 20% at Glucose level ≥75 mg/dL (4.17mmol/L)
Test Sample	: Capillary whole blood
Measuring Time	: 26 seconds (Total Cholesterol) ≤ 10 seconds (Glucose)
Measuring Range	: Total Cholesterol 100 - 400 mg/dL (2.59 - 10.35 mmol/L) Glucose 18 - 600 mg/dL (1.0 - 33.3 mmol/L)
Sample Volume	: ≥ 10 µL (Total Cholesterol), ≥ 0.7 µL (Glucose)
Strip Storage Condition	: 10 - 30°C
Operation Temperature	: 10 - 40°C
Relative Humidity	: Less than 95%
Memory	: 410 test results(50 for Total Cholesterol, 360 for Glucose)
Battery Type	: 3V (CR2032) lithium battery x 1
Battery Life	: Approximately 1,000 tests
Dimensions	: 61*77*19 mm
Weight	: About 47g (batteries not included)

Chapter 9 Limitations

1. For In-vitro diagnostic use only (External use only).

2. BeneCheck Test Strip is designed for one-time use only. Do not reuse.

3. Do not perform the test while a mobile phone is used beside; prevent the electronic signal interference.

9.1 Limitations of Total Cholesterol Test

BeneCheck Total Cholesterol Test Strips give accurate results when the following limitations are observed :

- Hematocrit (Hct) percentage may affect test result. If Hct levels less than 35% may cause incorrect high measurement results and Hct levels greater than 50% may cause incorrect low measurement results. Please consult your medical professionals if you do not know your Hct level.

- Use only fresh capillary finger whole blood. Do not use serum or plasma.

- BeneCheck Total Cholesterol Test Strips may be used at altitude up to 8,000 feet without an effect on test results.

Additional Information for Healthcare Professionals :

- Interferences : Acetaminophen, uric acid, ascorbic acid, dopamine, gentistic acid, ibuprofen, methyl DOPA, salicylate (when at physiological or therapeutical levels) do not significantly affect the results. Hemoglobin at physiological levels ≤10 mg/dL.

- In situations of decreased peripheral blood flow, examples would include but are not limited to severe dehydration, in shock, or in a hyperosmolar state (with or without ketosis), hypertension, the test results may be falsely low.

- BeneCheck Total Cholesterol Test Strips are plasma calibrated, tests with serum or plasma sample will give falsely high results.

- Lipemic samples : Glucose levels up to 476 mg/dL (13.89 mmoL/L) do not affect the results. Triglycerides and grossly lipemic patient sample have not been tested and are not recommanded for testing with the BeneCheck Total Cholesterol Test Stirps.

9.2 Limitations of Glucose Test

BeneCheck Glucose Test Strips give accurate results when the following limitations are observed :

- Hematocrit (Hct) percentage may affect test result. If Hct levels less than 30% may cause incorrect high measurement results and Hct levels greater than 55% may cause incorrect low measurement results. Please consult your medical professionals if you do not know your Hct level.

- The test strips react with only D-glucose and do not react with other sugars which may be present in blood.

- Use only fresh capillary finger whole blood. Do not use serum or plasma.

- BeneCheck Glucose Test Strips may be used at altitude up to 10,000 feet without an effect on test results.

Additional Information for Healthcare Professionals :

- When venous whole blood is used for the test, it can be collected into

heparin-containing test tubes winthin 30 minutes after drawing. The results may be 7% lower than a capillary sample.

- Interferences : Acetaminophen, uric acid, ascorbic acid, dopamine, gentistic acid, ibuprofen, methyl DOPA, salicylate, tetracycline, tolazamide, tolbutamide (when at physiological or therapeutical levels) do not significantly affect the results.

- Patients undergoing oxygen therapy may yield falsely low results.

- In situations of decreased peripheral blood flow, examples would include but are not limited to severe dehydration, in shock, or in a hyperosmolar state (with or without ketosis), hypertension, the test results may be falsely low.

- BeneCheck Glucose Test Strips are plasma calibrated, testing with serum or plasma sample will give falsely high results.

- Lipemic samples : Cholesterol levels up to 400 mg/dL (10.35 mmoL/L), and triglycerides up to 3000 mg/dL (34.88 mmoL/L) do not affect the results.

Grossly lipemic patient samples have not been tested and are not recommended for testing with the BeneCheck Glucose Test Strips.

- Critically ill patients should not be tested with blood glucose meters.