

**ATTENTION: RISK MANAGEMENT AND CHIEF MEDICAL OFFICER**



**TRUEresult®**

## **QUALITY ASSURANCE AND QUALITY CONTROL REFERENCE GUIDE FOR MULTI-PATIENT USE FACILITIES**

Information in This Manual is Specific for Healthcare Providers

### **ATTENTION:**

TRUEtest™ Strips contain GDH-PQQ enzyme. Please carefully review all critical safety information and instructional materials prior to performing patient blood glucose testing.

**[www.homediagnostics.com](http://www.homediagnostics.com)**

**1-800-803-6025 or 1-954-677-4599.**

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**TRUEresult®**

**MCKESSON**

**TRUEresult** QUALITY ASSURANCE AND  
QUALITY CONTROL REFERENCE GUIDE  
FOR MULTI-PATIENT USE FACILITIES

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## ***Safety Notice***

### **ATTENTION: Pharmacy Staff, Nursing Staff, Laboratory Staff, and Central Supply Staff – Reminder of Potential for Falsely Elevated Blood Glucose Results due to Drug Interferences**

This Safety Notice is for personnel involved in the issuance of point-of-care blood glucose testing systems and personnel involved in actual point-of-care blood glucose testing. Parenterally administered drugs containing or metabolizing to maltose or galactose, and orally administered xylose can cause falsely high blood glucose results with certain point-of-care blood glucose monitoring systems that utilize the enzyme glucose dehydrogenase-PQQ (GDH-PQQ) for the measuring of a blood glucose result.

***Please note: The interferences described in this Notice may be seen with all blood glucose monitoring systems that use GDH-PQQ methodology, regardless of the manufacturer of the system.***

The information regarding the limitations of using GDH-PQQ methodology may or may not be included in the labeling of drugs containing or metabolizing maltose, galactose, or xylose. It is important that **all staff** are aware of this interference in order to prevent inappropriate treatment based on falsely elevated blood glucose results. Staff must advise at-risk patients who use blood glucose monitoring systems with GDH-PQQ methodology of these risks and the consequences of inappropriate treatment.

#### ***Who is at risk?***

Patients at risk for falsely elevated blood glucose results include those using blood glucose monitoring systems utilizing glucose dehydrogenase-PQQ, and who are:

- Peritoneal dialysis patients receiving dialysis solutions containing icodextrin (e.g. Extraneal®, Icodial®) that is metabolized to maltose;
- Receiving injections or infusions of solutions containing galactose or maltose (including some human immunoglobulin preparations (e.g. Octagam®, WinRho®, SDF Liquid, HepaGam B™);
- Patients undergoing xylose absorption testing;
- Patients receiving intravenous solutions containing maltose as a substitute for glucose or as a means for patient hydration;
- Patients receiving any drugs, including any investigational drugs and those made by compounding pharmacies, which contain or metabolize to maltose, galactose, or xylose (Orencia®, Adept®, Bexxar®).

***Note: An At-Risk Patient Identification Notice located under Forms, Section 10, in this Manual may be used for easy identification of at-risk patients.***

## **TRUEresult® Quality Assurance / Quality Control Manual**

### **Home Diagnostics, Inc Blood Glucose Monitoring Systems Using GDH-PQQ**

- TRUEresult® / TRUEtest™ Blood Glucose Test Strips
- TRUE2go™ / TRUEtest™ Blood Glucose Test Strips

#### ***What causes these interferences?***

The GDH-PQQ methodology does not distinguish between maltose, galactose, xylose, and glucose when measuring blood glucose. Maltose, galactose, and xylose are not normally found in the blood, but can be found with the administration of certain drugs. When present in the blood, these substances can falsely increase the blood glucose result to a clinically significant level. A false high glucose result may lead to inappropriate treatment, such as the injection of insulin, which could lead to a hypoglycemic coma and death.

#### ***Actions required:***

- Be aware of the drugs used (including any investigational drugs and those made by compounding pharmacies) that contain or metabolize maltose, galactose, or xylose,
- At patient admission/presentation and periodically throughout the patient's stay at the facility, assess the presence and use of therapies containing interfering drugs,
- Consult with the pharmacist for more information on which drugs have been or will be administered to the patient,
- Identify and flag files or records of at-risk patients,
- If there are pre-print orders sets for patients receiving interfering drugs, include a prescription to test blood glucose using laboratory methods,
- Use only laboratory methods for monitoring blood glucose levels in patients receiving interfering drugs,
- Establish facility protocols to verify point-of-care (bedside) blood glucose results with laboratory results for patients who are unresponsive or unable to communicate,
- Ensure that protocols for testing adequately address the issue when the patient history is unknown,
- If your facility provides a blood glucose monitoring system for use at home for an at-risk patient, instruct the patient not to use a blood glucose monitoring system that utilizes GDH-PQQ, including the TRUE2go and TRUEresult Systems,
- After drug treatment is completed, ensure that use of a blood glucose monitoring system that utilizes GDH-PQQ is cleared by the Doctor or Healthcare Professional before use.

#### **File this Safety Notice for future reference.**

#### ***Questions?***

If you have any questions regarding the information contained in this Safety Notice, please go to

[www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm154213.htm](http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm154213.htm), or call for assistance using the number on the front cover of the Manual.

# **TRUEresult® Quality Assurance / Quality Control Manual**

## **Introduction**

Home Diagnostics, Inc (HDI) is proud to present the TRUEresult Blood Glucose Monitoring System, a no-coding system which means the Meter does not have to be coded to each lot of test strips. The Quality Assurance/Quality Control Manual is designed for use specifically by the Healthcare Professional for point-of-care testing in a multi-patient, multi-user setting. Healthcare Professionals in your facility now have a very simple and accurate way to safely test blood glucose levels in your patients.

Home Diagnostics, Inc. recognizes the importance of practicing safe and reliable testing using the TRUEresult Blood Glucose Monitoring System. Therefore, this Manual has been designed to provide the following:

- A basic understanding of the TRUEresult System,
- A detailed testing guide,
- Quality Control Program recommendations for the TRUEresult System in your facility,
- A complete guide to troubleshooting issues and concerns that may arise with using with the TRUEresult System in patient care,
- A comprehensive HDI certified training program for Healthcare Professionals that will be using the TRUEresult System.

### ***CAUTION!***

***Please read this entire Manual and all product Instructions for Use before testing. Operators of the TRUEresult Blood Glucose Monitoring System must be trained per the HDI Training Certification Program, Section 9, prior to using the product.***

### ***CAUTION!***

***DO NOT change patient medication, diet, or exercise routine without consulting the patient's Doctor or Diabetes Healthcare Professional.***

***Use of TRUEresult in a manner not specified in this Manual is not recommended and may affect the ability to determine true blood glucose levels.***

Our goal is to provide quality healthcare products and dedicated customer service. For questions about the TRUEresult products, visit our website at **[www.homediagnostics.com](http://www.homediagnostics.com)**.

# TRUEresult® Quality Assurance / Quality Control Manual

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# **Section 1:**

## **Using TRUEresult® in a Clinical Setting**



# TRUEresult® Quality Assurance / Quality Control Manual

## Critical Safety Information / Important Information / Limitations /

### Expected Results

#### **WARNING!**

*TRUEtest Blood Glucose Test Strips utilize glucose dehydrogenase-PQQ (GDH-PQQ). The TRUEresult System **MUST NOT** be used for the following patient conditions:*

- *Peritoneal dialysis patients receiving dialysis solutions containing icodextrin (e.g. Extraneal®, Icodial®) that is metabolized to maltose,*
- *Injection or infusion of solutions containing galactose or maltose, including some human immunoglobulin preparations (e.g. Octagam®, WinRho®, SDF Liquid, HepaGam B™),*
- *Patients undergoing xylose absorption testing,*
- *Patients receiving intravenous solutions containing maltose as a substitute for glucose or as a means for patient hydration,,*
- *Any drugs, including any investigational drugs and those made by compounding pharmacies, which contain or metabolize to maltose, galactose, or xylose (Orencia®, Adept®, Bexxar®).*

*Using the TRUEresult System for testing patients with the above conditions may result in falsely high glucose results. A falsely elevated glucose result may cause a patient or healthcare professional to take inappropriate steps to bring the blood glucose in normal range, including giving insulin. The inappropriate use of insulin could lead to unconsciousness, severe hypoglycemic coma and possible death. More information may be found in the TRUEtest Test Strip Instructions for Use or at*

*[www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm154213.htm](http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm154213.htm)*<sup>1</sup>

#### **Limitations**

- Please read all product Instructions for Use carefully before referencing or using this Manual.
- Use only TRUEtest Blood Glucose Test Strips and TRUEtest Glucose Control Solution when testing with the TRUEresult Meter.
- Perform Glucose Control Tests ***before*** performing a blood glucose test (See *Quality Control Testing, Section 3*), when using the System for the first time. Three levels of TRUEtest Glucose Control Solution are available for Quality Control Testing. Contact your distributor to order different levels of Glucose Control Solution. We recommend testing at least 2 levels of Control. For testing frequency and the number of Control levels to test, refer to your facility quality control procedure/policy.
- TRUEresult is an *in vitro* quantitative system that is used for self testing and point-of-care testing of human whole blood only.



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- The most accurate results are obtained using fresh, capillary whole blood from the fingertip. Venous whole blood drawn in EDTA (purple top tube) or heparin (green top tube) may be used for testing. Mix tube contents gently before using. Use venous blood within 30 minutes after drawing. Serum, clotted blood, or plasma cannot be used with the TRUEresult System.
- Capillary blood from the forearm may be used. Check with the Doctor or Healthcare Professional to see if forearm testing may be used for glucose testing on the patient. Results from the forearm are not always the same as results from the fingertip. Use fingertip instead of forearm:
  - Within 2 hours of eating, exercise, or taking insulin,
  - If the patient's blood glucose may be rising or falling rapidly or their results often fluctuate,
  - If the patient is ill or under stress,
  - If the glucose result may be low or high,
  - If symptoms of low or high glucose levels are not evident.<sup>2</sup>
- For evaluation or Quality Control procedures where TRUEresult blood glucose values are compared to blood glucose values given by a laboratory, it is recommended that capillary or venous whole blood obtained from the same site be used for both the laboratory instrument as well as the TRUEresult System. Laboratory tests should be performed within 30 minutes of a blood glucose meter test to minimize the changes in glucose values due to glycolysis. Results from the TRUEresult System are considered accurate if within  $\pm 20\%$  of laboratory results. If patient has recently eaten, finger results from the TRUEresult System can be up to 70 mg/dL higher than venous laboratory results.<sup>3</sup>
- The TRUEresult System cannot be used in the diagnosis of diabetes or to test blood glucose in neonates.
- Inaccurate results may occur in severely hypotensive patients or patients in shock. Inaccurate results may occur for patients experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with a blood glucose meter.<sup>4</sup>
- Testing at altitudes up to and including 10,150 feet will not affect accurate results.<sup>5</sup>
- Hematocrit levels between 20% and 60% will not affect accurate results.<sup>5</sup>

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### Expected Results

Each patient should have specific blood glucose target ranges that are determined by the Doctor or Diabetes Healthcare Professional. Having most blood glucose results within the patient's target range shows how well a treatment plan is working to control glucose levels. Keeping results within the patient's target range helps slow or stop complications from diabetes.

Expected Results for people without diabetes<sup>6</sup>:

#### Plasma Blood Glucose Result

Before eating	<126 mg/dL
Two hours after meals	<200 mg/dL

- Low blood glucose (hypoglycemia) symptoms may include trembling, sweating, intense hunger, nervousness, weakness or trouble speaking.
- High blood glucose (hyperglycemia) symptoms may include intense thirst, a need to urinate often, a dry mouth, vomiting, or headache.

If the patient is showing any of these symptoms, check their blood glucose. If any result seems higher or lower than expected, repeat the test with a new Test Strip. Contact the Doctor or Diabetes Healthcare Professional with any unusual results.

## **TRUEresult® Quality Assurance / Quality Control Manual**

### **Regulatory Requirements - CLIA**

Self-testing and point-of-care testing of blood glucose has been classified by the Clinical Laboratory Improvement Amendments (CLIA) as a waived test. CLIA requires all entities that perform even one test, including waived tests, [on materials derived for the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings] to meet certain Federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program.

Waived laboratories must meet the following requirements:

- Complete the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Application for Certification, Form CMS-116. The form and instructions on completing and mailing the form are found on [http://www.cms.hhs.gov/CLIA/06\\_How\\_to\\_Apply\\_for\\_a\\_CLIA\\_Certificate\\_Including\\_Foreign\\_Laboratories.asp#TopOfPage](http://www.cms.hhs.gov/CLIA/06_How_to_Apply_for_a_CLIA_Certificate_Including_Foreign_Laboratories.asp#TopOfPage).
- Pay applicable certificate fees biennially.
- Follow manufacturer's test instructions, including instructions for Quality Control, maintenance, and storage instructions.

Upon approval of Form CMS-116, a Certificate of Waiver is forwarded to the laboratory.

For more information on the CLIA program, see <http://www.cms.hhs.gov/CLIA/>.

For a comprehensive look at waived testing, see <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm>.

# **TRUEresult® Quality Assurance / Quality Control Manual**

## **TRUEresult Blood Glucose Monitoring System**

### **Proficiency Testing Information**

The objective of proficiency testing is to qualitatively determine the skill of the user of a specific product and the accuracy of the results obtained using the product. Participating laboratories receive specimens from a distributor, test the specimens and report the results back to the distributor. The results of all participants are summarized in a report that is sent to the participating laboratories. The report contains an evaluation of the individual laboratory performance as well as a comparison to a summary of results from other participating labs.

It is important to be aware that proficiency samples are not fresh blood and may behave differently on different glucose test systems. The accuracy of the result from a proficiency sample is not an indicator of the accuracy of your system when tested with fresh whole blood obtained from a patient. The proficiency testing only serves to show how your results compare to other TRUEresult system users. If your proficiency sample results are not within acceptable limits of other TRUEresult users' results, then you should investigate possible sources of testing error such as expiration date and storage conditions for the test strips. Always perform quality control testing per your facility's procedures and policies to make sure your system is working properly. The Owner's Booklet or QA Manual will assist you with this process.

The TRUEresult system is optimized to give accurate results with fresh, capillary whole blood and venous whole blood samples. Venous whole blood samples must be tested immediately or preserved in a vacutainer tube containing EDTA (purple top) or heparin (green top). This will preserve the sample for approximately 30 minutes. Refer to the TRUEresult Owners Booklet and TRUEtest Strip Instructions for Use for further information.

Resources to learn about and obtain Proficiency Samples:

College of American Pathology (CAP) [www.cap.org](http://www.cap.org)

American Association of Bioanalysts [www.aab.org](http://www.aab.org)

# **TRUEresult® Quality Assurance / Quality Control Manual**

## **Meter Specifications**

**Result Range:** 20 - 600 mg/dL

**Sample Size:** Minimum 0.5 microliters (0.5 µL)

**Sample Type:** Fresh capillary whole blood from the finger or forearm,  
venous blood drawn in EDTA (purple top tube) or heparin  
(green top tube) within 30 minutes of collection

**Test Time:** As little as 4 seconds

**Result Value:** Plasma calibrated

**Assay Method:** Electrochemical

**Reference Method:** Yellow Springs Instrument (YSI)

**Power Supply:** One 3V lithium battery #CR2032 (non-rechargeable)  
Total power when active at full battery = 8.6 mW

**Battery Life:** Approximately 2146 tests or 1.5 years

**Automatic Shut-off:** After 2 minutes of non-use

**Weight:** 1.66 ounces

**Size:** 3.44" x 2.16" x 0.69"

**Memory Size:** 500 results

### **System Operating Range (Meter and Test Strips):**

Relative Humidity: 10 - 90% (non-condensing)

Temperature: 50° - 104°F

Hematocrit: 20 - 60%

***Note:** Use within specified environmental conditions only.*

### **Chemical Composition**

**TRUEtest Test Strips:** Glucose dehydrogenase - PQQ (*Acinetobacter calcoaceticus*), mediators, buffers and stabilizers

**TRUEtest Glucose Control Solution:** Water, d-glucose, buffers,  
viscosity enhancing agent, salts, dye and preservatives

# **TRUEresult® Quality Assurance / Quality Control Manual**

## **Material Safety Data Sheet**

### **Section 1 : Product Information**

**Product Name :** TRUEtest Blood Glucose Test Strips

**Date Prepared :** 16 April 2008

**Revision Number :** 0

### **Section 2 : Composition / Information on Ingredients**

**Vial:** Silica Gel, polypropylene, polyethylene

**Test Strips:** Glucose dehydrogenase-PQQ, mediators, buffers and stabilizers

**Test Strip Box and Package Insert:** Paper

### **Section 3 : Hazard Identification**

No significant immediate hazards for emergency response are known.

### **Section 4 : Emergency First Aid Procedures**

**Eye:** No first aid required.

**Skin:** No first aid required for contact with skin.

**Ingestion:** No first aid required from ingestion.

**Inhalation:** No first aid required.

### **Section 5 : Fire and Explosion Hazard Data**

**Flash Point (Method Used):** Vial - > 450°F (estimated), Test Strips - N/A

**Flammable Limits:** N/A

**General Hazard:** Solid material may burn at or above the flashpoint. If thermally decomposed, flammable/toxic gases may be released. Toxic gases will form upon combustion. Hazardous combustion products may include and are not limited to: carbon monoxide, carbon dioxide.

**Special Fire Fighting Procedures:** Use water spray to cool fire exposed surfaces and to protect personnel. Isolate “fuel” supply to fire. Extinguish the fire by cooling with water spray. Respiratory and eye protection required for fire fighting personnel.

**Unusual Fire and Explosion Hazards:** None determined.

# **TRUEresult® Quality Assurance / Quality Control Manual**

## **Section 6 : Spill or Leak Procedures**

**Steps to be taken in case material is released or spilled:** Contain material to prevent contamination of soil, surface water and ground water. May be slipping hazard.

## **Section 7 : Handling and Storage**

Store at temperatures and conditions as indicated on the product label. Store in original container and keep vial closed.

## **Section 8 : Personal Protection**

**Ventilation:** Use general room ventilation.

**Respiratory Equipment:** None.

**Protective Gloves:** None

**Eye Protection:** None

**Other Protective Equipment/Clothing:** None

## **Section 9 : Physical Data**

**Appearance and odor:** Vial - Vial with desiccant liner, Test Strips - Plastic strip with reaction area.

**pH:** N/A

**Specific Gravity:** N/A

**Boiling Point:** N/A

**Melting Point:** N/A

**Vapor Pressure:** N/A

**Evaporation Rate:** N/A

**Solubility in Water:** N/A

## **Section 10 : Reactivity Data**

**Stability:** Stable if at storage temperature and original vial closed.

**Conditions to Avoid:** Product can oxidize and decompose at elevated temperatures. Avoid putting water inside of vial, exothermic reaction will occur. Temperatures above 300°F may cause product degradation and self combustion.

**Substances to Avoid:** Avoid contact with strong acids and oxidizing materials.

**Hazardous Decomposition Products:** Flammable hydrocarbons.

**Hazardous Polymerization:** Will not occur.

# **TRUEresult® Quality Assurance / Quality Control Manual**

## **Section 11 : Toxicological Information**

**Chronic Effects of Overexposure:** None currently known.

**Carcinogen or Suspected Carcinogen:** None of the compounds present are listed as a carcinogen or suspected carcinogen.

**Medical Conditions Aggravated by Exposure:** None currently known.

**Acute Toxicity Values:** Not applicable.

## **Section 12 : Ecological Information**

Ecological effects of this product have not been determined.

## **Section 13 : Disposal**

**Primary Container Type:** Vial with 50 test strips.

**Waste Disposal Method:** Each disposal facility must determine proper disposal methods to comply with local, state, and federal environmental regulations.



# **TRUEresult® Quality Assurance / Quality Control Manual**

## **Material Safety Data Sheet**

### **Section 1 : Product Information**

**Product Name :** TRUEtest Glucose Control Solution - Levels 1, 2, and 3

**Date Prepared :** 16 April 2008

**Revision Number :** 0

### **Section 2 : Composition / Information on Ingredients**

**Bottle:** Polypropylene, polyethylene

**Control Solution:** Water, d-glucose, buffers, viscosity enhancing agents, salts, dyes, and preservatives.

**Control Solution Box and Package Insert:** Paper

### **Section 3 : Hazard Identification**

No significant immediate hazards for emergency response are known.

### **Section 4 : Emergency First Aid Procedures**

**Eye:** Flush with copious amounts of water

**Skin:** Flush with water

**Ingestion:** Contact physician

**Inhalation:** Contact physician

### **Section 5 : Fire and Explosion Hazard Data**

**Flash Point (Method Used):** Bottle - N/A, Control Solution - N/A

**Flammable Limits:** N/A

**General Hazard:** N/A

**Special Fire Fighting Procedures:** N/A

**Unusual Fire and Explosion Hazards:** None determined.

### **Section 6 : Spill or Leak Procedures**

**Steps to be taken in case material is released or spilled:** Contain material to prevent contamination of soil, surface water and ground water. May be slipping hazard.

# **TRUEresult® Quality Assurance / Quality Control Manual**

## **Section 7 : Handling and Storage**

Store at temperatures and conditions as indicated on the product label. Keep bottle tightly closed when not in use.

## **Section 8 : Personal Protection**

**Ventilation:** Use general room ventilation.

**Respiratory Equipment:** None.

**Protective Gloves:** None

**Eye Protection:** None

**Other Protective Equipment/Clothing:** None

## **Section 9 : Physical Data**

**Appearance and odor:** Bottle - plastic bottle with cap, Control Solution - Red liquid

**pH:** N/A

**Specific Gravity:** N/A

**Boiling Point:** N/A

**Melting Point:** N/A

**Vapor Pressure:** N/A

**Evaporation Rate:** N/A

**Solubility in Water:** N/A

## **Section 10 : Reactivity Data**

**Stability:** Stable at storage temperature. Keep bottle closed when not in use.

**Conditions to Avoid:** N/A

**Substances to Avoid:** Avoid contact with strong acids and oxidizing materials.

**Hazardous Decomposition Products:** Flammable hydrocarbons.

**Hazardous Polymerization:** Will not occur.

## **Section 11 : Toxicological Information**

**Chronic Effects of Overexposure:** None currently known.

**Carcinogen or Suspected Carcinogen:** None of the compounds present greater than 0.1% are listed as a carcinogen or suspected carcinogen.

**Medical Conditions Aggravated by Exposure:** None currently known.

**Acute Toxicity Values:** Not applicable.

## **TRUEresult® Quality Assurance / Quality Control Manual**

### **Section 12 : Ecological Information**

Ecological effects of this product have not been determined.

### **Section 13 : Disposal**

**Primary Container Type:** Bottle with 3 mL Glucose Control Solution.

**Waste Disposal Method:** Each disposal facility must determine proper disposal methods to comply with local, state, and federal environmental regulations.



## **Section 2:**

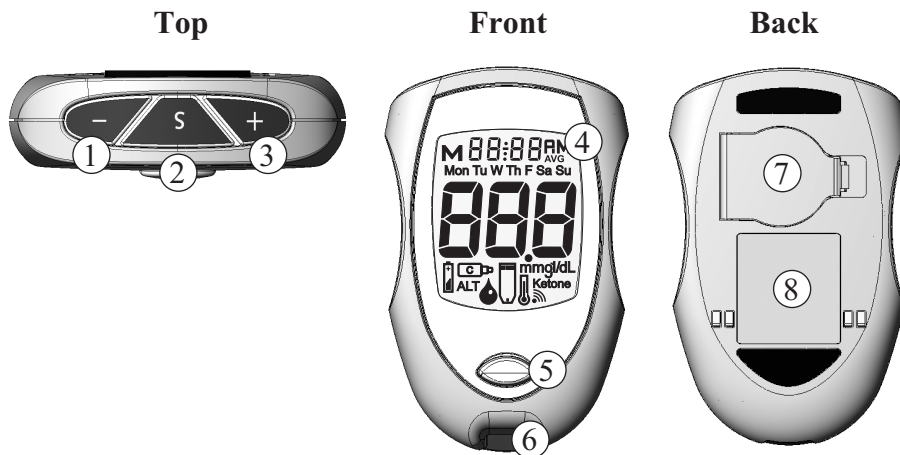
# **Description of System**



# TRUEresult® Quality Assurance / Quality Control Manual

## Description of System

### Meter



#### Top:

1. **“+” Button** – Adds Alternate Site Symbol, increases numbers in Set Up, moves forward by time / date when viewing results in Memory.

*Note: Use of Memory function is not recommended in a multi-patient setting.*

2. **“S” Button** – Turns Meter on/off for Memory/Set Up, views / scrolls results in Memory.
3. **“-” Button** – Removes Alternate Site Symbol, decreases numbers in Set Up, moves backwards by time / date when viewing results in Memory.

#### Front:

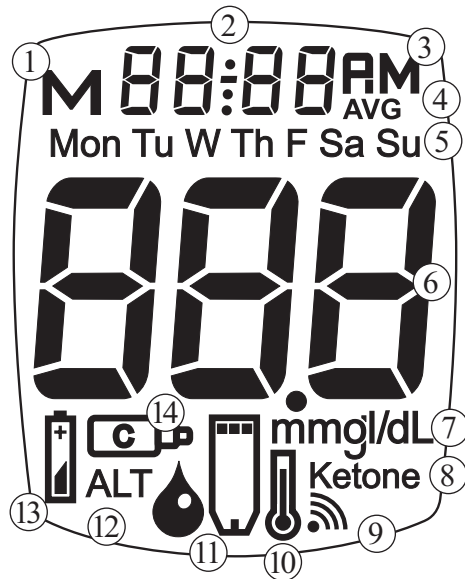
4. **Display Screen** – Shows results, messages, user prompts, information (see next page for full explanation).
5. **Strip Release Button** – Releases Test Strip after testing is finished.
6. **Test Port** – Place to insert TRUEtest Test Strip

#### Back:

7. **Battery Door** – Open to replace battery. Use one non-rechargeable 3V lithium battery (#CR2032), positive (“+”) side up (see Battery Replacement, Section 7, for more details).
8. **Meter Label** – Contains Serial Number of the Meter and phone number to call for assistance.

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### Full Display



### Full Display Components:

1. Result is from Memory.
2. Time, date
3. Time is AM/PM
4. Result is from 7, 14, or 30 day Average
5. Day of the week
6. Test result
7. Units of measure (*Note: Factory set, cannot be changed by user.*)
8. Ketone Symbol (*see Ketone Alert, Section 5*)
9. Alert Symbol (*See Testing Reminders, Section 5*)
10. Temperature Symbol
11. Drop Symbol
12. Alternate Site Symbol
13. Battery Symbol
14. Control Symbol

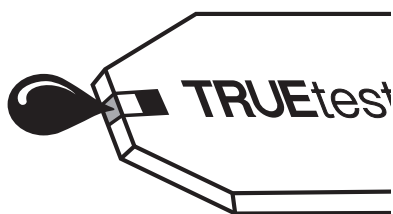
### Test Strip



15. **Contact End** - Insert into Test Port with TRUEtest name facing up.
16. **Sample Tip** - Bring sample (fresh, capillary or venous blood or Glucose Control Solution) to edge of Tip. Capillary action draws sample into Test Strip for testing.

# TRUEresult® Quality Assurance / Quality Control Manual

## Sample Placement



Correct Placement

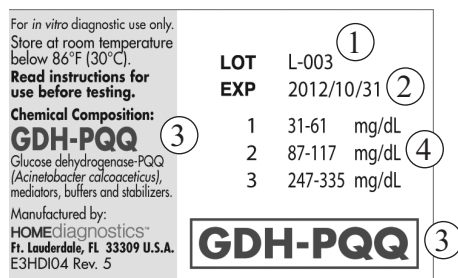


Incorrect Placement

- Allow sample (blood or Control) to be drawn into Sample Tip.
- Do not smear or scrape sample with Tip of Test Strip.
- Do not apply more sample to the Test Strip after removing the Test Strip from the sample drop.
- Do not apply blood or Control to top of Test Strip.
- Do not insert Sample Tip into the Meter.

**Note:** Inserting the Test Strip backwards (Sample Tip into Test Port) after sampling may cause the Meter not to turn on. If Meter does not turn on, see Troubleshooting, Section 8.

## Test Strip Vial Label



1. **Lot Number (LOT)** - Used for identification of lot for QC Form, used as a reference if calling for assistance.
2. **Expiration Dates (EXP)** - The printed Expiration Date is located on the Test Strip vial next to **EXP**. Write the date first opened on vial label. Discard vial and unused Test Strips if either date printed after **EXP** on Test Strip vial label or 4 months after date written on vial label has passed.
3. **GDH - PQQ** - Enzyme used for glucose testing is glucose dehydrogenase-PQQ. See **Critical Safety Information / Important Information / Limitations / Expected Results, Section 1** for limitations of use with patient.

**CAUTION!** Use of Test Strips or Glucose Control Solution past the Expiration Dates may give incorrect test results. Discard out-of-date products and test with new products.

4. **Control Range** - Range of numbers in which Control Test result must fall to assure the System is working properly.

# TRUEresult® Quality Assurance / Quality Control Manual

## Glucose Control Solution Bottle Label



1. **Lot Number (LOT)** - Used for identification of lot for QC Form, used as a reference if calling for assistance.
2. **Expiration Dates (EXP)** - The printed Expiration Date is located on the Control bottle label next to **EXP**. Write the date first opened on bottle label. Discard bottle and unused Control Solution if either date printed after **EXP** on Control bottle label or 3 months after date written on bottle label has passed.
3. **Control Level** - Three levels of TRUEtest Glucose Control Solution are available, Levels 1, 2, and 3. We recommend testing at least 2 levels of Control. For testing frequency and the number of Control levels tested, refer to your facility quality control procedure/policy to test.





## **Section 3:**

# **Quality Control Testing**



# TRUEresult® Quality Assurance / Quality Control Manual

## Quality Control Testing

Quality Control procedures are used to detect errors that may occur due to test system errors, product defects, adverse environmental conditions and variance in operator performance. Ongoing QC procedures are also used to detect any performance issues of the System over time. Facility Quality Control Testing Policy and Procedure should adhere to the manufacturer's instructions for use and regulatory guidelines set forth by appropriate state, regional or national licensing or accrediting agencies.

TRUEresult is a no-coding system, which means the Meter does not have to be coded to each lot of Test Strips. To assure accurate and reliable results, TRUEresult offers two kinds of Quality Control Tests. These tests ensure that TRUEresult is working properly and testing technique is good.

### Automatic Self-Test

An automatic self-test is performed by the Meter each time a TRUEtest Strip is inserted correctly into the Test Port. After inserting the Strip into the Test Port, if the full Display (showing no missing segments, see Description of System, Section 2) followed by the Drop Symbol appears, the Meter is working properly. If an error message (E-1, E-2 etc.) appears in the Display after inserting a Test Strip, the Meter will not perform a glucose test. See Display Messages, Section 8 for more information on error messages.

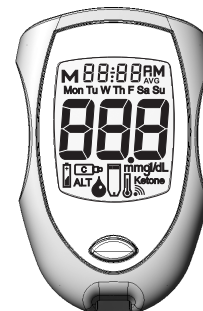
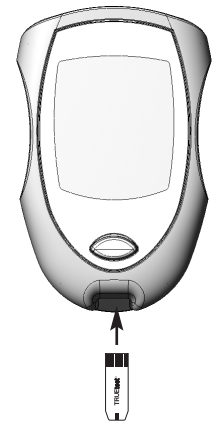
**CAUTION!** *If any segments are missing in the Display when the Test Strip is inserted into the Test Port, do not use the Meter for testing. Call for assistance using the phone number on the QA/QC Manual cover.*

### Control Test

Use **ONLY** TRUEtest Glucose Control Solution to check the performance of the System. It is important to perform Control Tests with more than one level of Control to assure that the System is working properly and testing technique is good. Three levels of TRUEtest Glucose Control Solution (Levels 1-3) containing known amounts of glucose are available. Call the phone number on the QA/QC Manual cover or contact your supplier to order different levels of Control Solution. Control Test(s) should be performed:

- Before using the System for the first time,
- For practice to ensure that testing technique is good,
- When opening a new vial of Strips,
- If results seem unusually high or low based on the patient's condition,
- If Strip vial has been left open or exposed to extreme heat, cold or humidity,
- Whenever a check on the performance of the System is needed, or
- If Meter damage is suspected (Meter dropped, crushed, wet, etc.).

**CAUTION!** *Glucose Control ranges printed on the Test Strip vial are ranges for Control Tests results only. These ranges are not to be used by patients for blood glucose management. Contact a Doctor or Diabetes Healthcare Professional for individualized blood glucose target ranges. DO NOT consume Glucose Control.*



Drop Symbol



# TRUEresult® Quality Assurance / Quality Control Manual

## How to Perform a Control Test

Use the Quality Control Log located in *Forms, Section 10* to record Control Test results.

1. Allow Control bottle, vial of Test Strips and Meter to adjust to room temperature (59° - 86°F).

**Note:** *Performing a Control Test at temperatures above or below room temperature may cause the Control to read as a blood test.*

2. Check dates on Control bottle label and Test Strip vial label.
  - Do not use Control if 3 months past written opened date *or* after **EXP** date printed on Control bottle label.
  - Do not use Test Strips 4 months past written opened date *or* after **EXP** date printed on Test Strip vial label.

Discard out of date products and use new products if either date has passed.

3. Swirl or invert Control bottle gently to mix Control. **DO NOT SHAKE!**
4. Open Test Strip vial by pushing up under the lip of the vial cap. Remove one Test Strip. Close vial immediately by firmly pressing down on the top of the vial cap.

**Note:** *Use Test Strip quickly after removal from vial. Test Strips that have been left outside the vial too long will give an error message. If an error message appears in the Display, release and discard the old Test Strip and test with a new Test Strip.*

5. With Meter off, insert the Test Strip Contact End (TRUEtest name facing up) into the Test Port. Meter turns on. Keep the Test Strip in the Meter until testing is complete.

6. Wait until the **Drop Symbol** appears in the Display.

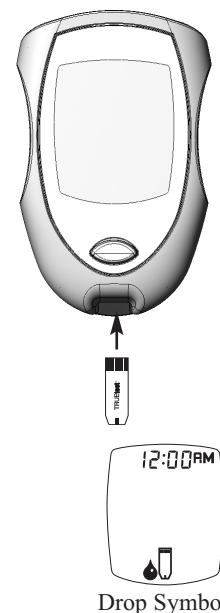
**Note:** *If Test Strip is removed before testing is finished, an error message appears. Release and discard old Test Strip. Test with new Test Strip.*

7. Remove cap from Control bottle. Turn Control bottle upside down. Squeeze one drop of Control onto a clean tissue. Wipe off bottle tip.
8. Gently squeeze another drop of Control onto a small piece of unused aluminum foil, clear plastic wrap, or a clean, non porous surface. (Discard foil/wrap or clean area after use.)

LOT	L-003
EXP	2012/10/31
1	31-61 mg/dL
2	87-117 mg/dL
3	247-335 mg/dL

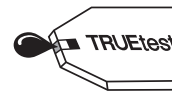
**GDH-PQQ**

<b>TRUEtest</b> Control/Control de Glucosa Level 1 3 mL Manufactured for/Fabricado para: diagnostics Jale, FL 33309 USA diagnostic use only, use at room temperature between C. DO NOT REFRIGERATE	LOT 8LOA18 EXP 2012/10/31
--	------------------------------

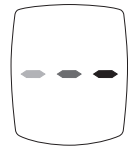


## TRUEresult® Quality Assurance / Quality Control Manual

9. While Test Strip is still in the Meter, touch edge of Test Strip Sample Tip to drop of Control and allow drop to be drawn into Test Strip. Remove Test Strip from the drop when dashes appear across the Meter Display. Meter is testing.



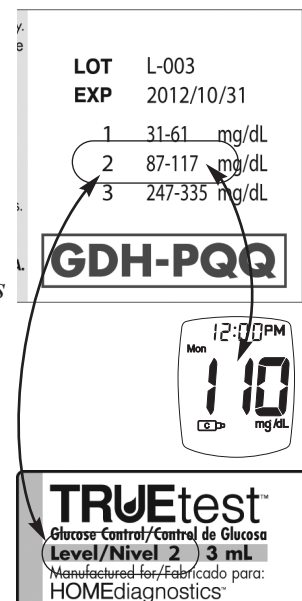
**Note:** If Meter does not begin testing soon after drawing up sample (dashes appear in the Display), release and discard Test Strip. Repeat the test with a new Test Strip. If problem persists, See Troubleshooting, Section 7.



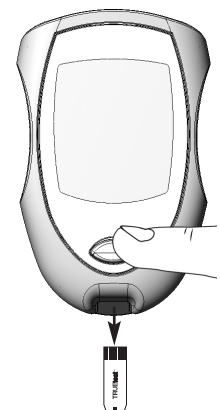
10. Control Test result is displayed. Compare the Meter result to the Control Range printed on the Test Strip vial label for the Control level that is being tested. If the result is in range, the System can be used for testing blood. If the result is not within range, repeat the test using a new Test Strip.

**Note:** Performing a Control Test at temperatures above or below room temperature (59° - 86°F) may cause the Control to read as a blood test. Control Symbol does not show in Display with test result if the Control is not detected.

**CAUTION!** If Control Test is outside of the correct range, perform test again using a new Test Strip and a new drop of Control. If the result is still outside the correct range, the System should not be used for testing blood. Call for assistance (see cover for phone number).



11. Record the result in the TRUEresult Quality Control Log (see Forms, Section 10).
12. Hold the Test Strip vial with Test Strip pointing down. Press the Strip Release Button to release and discard the Test Strip into an appropriate container. The Meter turns off.





## **Section 4:**

# **Blood Glucose Testing**



# TRUEresult® Quality Assurance / Quality Control Manual

## Blood Glucose Testing

### Sample Information

Fresh, capillary whole blood from the finger or forearm is the recommended sample to be used for testing blood glucose. Always check with the Doctor or Diabetes Healthcare Professional before using a sample from the forearm. Results from the forearm are not always the same as results from the fingertip. Use fingertip instead of forearm:

- Within 2 hours of eating, exercise, or taking insulin,
- If the patient's blood glucose may be rising or falling rapidly or their results often fluctuate,
- If the patient is ill or under stress,
- If the glucose result may be low or high,
- If symptoms of low or high glucose levels may not be evident.<sup>2</sup>

**Note:** *Venous whole blood drawn in EDTA (purple top tube) or heparin (green top tube) may be used for testing. Use venous blood within 30 minutes of collecting for best results. Mix tube contents gently before using. Serum, clotted blood, and plasma cannot be used with the TRUEresult System.*

For evaluation where TRUEresult blood glucose results are compared to blood glucose results given by a laboratory instrument, it is recommended that capillary or venous whole blood obtained from the same sampling site be used for both the laboratory instrument as well as the TRUEresult System. Laboratory tests should be performed within 30 minutes of a blood glucose meter test to minimize the changes in glucose values due to glycolysis. Results from the TRUEresult System are considered accurate if within  $\pm 20\%$  of laboratory results. If patient has recently eaten, finger results from the TRUEresult System can be up to 70 mg/dL higher than venous laboratory results.<sup>3</sup>

The TRUEresult System cannot be used on neonates. Perform laboratory glucose tests on critically ill patients.

### **WARNING!**

**TRUEtest Blood Glucose Test Strips utilize glucose dehydrogenase-PQQ (GDH-PQQ). The TRUEresult System MUST NOT be used for the following patient conditions:**

- *Peritoneal dialysis patients receiving dialysis solutions containing icodextrin (e.g. Extraneal®, Icodial®) that is metabolized to maltose,*
- *Injection or infusion of solutions containing galactose or maltose, including some human immunoglobulin preparations (e.g. Octagam®, WinRho®, SDF Liquid, HepaGam B™),*
- *Patients undergoing xylose absorption testing,*
- *Patients receiving intravenous solutions containing maltose as a substitute for glucose or as a means for patient hydration,*

## TRUEresult® Quality Assurance / Quality Control Manual

- *Any drugs, including any investigational drugs and those made by compounding pharmacies, which contain or metabolize to maltose, galactose, or xylose (Orencia®, Adept®, Bexxar®).*

*Using the TRUEresult System for testing patients with the above situations may result in falsely high glucose results. A falsely elevated glucose result may cause a patient or healthcare professional to take appropriate steps to bring the blood glucose in normal range, including giving insulin. The inappropriate use of insulin could lead to unconsciousness, severe hypoglycemic coma and possible death. More information may be found in the TRUEtest Test Strip Instructions for Use or at [www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm154213.htm](http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm154213.htm).<sup>1</sup>*

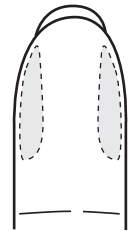
### Obtaining a Blood Sample for Blood Glucose Testing

Refer to your facility approved method for lancing to obtain a blood sample for blood glucose testing. Follow OSHA precautions for blood-borne pathogens.

*Note: Lancets are for single use only.*

### Tips for Fingertip Sampling

1. Select fingertip. Clean area with soap and warm water, rinse or use an approved disinfectant to clean the area. Dry thoroughly.
2. Lance finger.
3. To help blood drop form, lower the hand to a level below the heart and gently massage the finger from palm to fingertip. Allow the blood drop to form before attempting to apply the Test Strip.
4. Discard all biohazard materials into appropriate container.

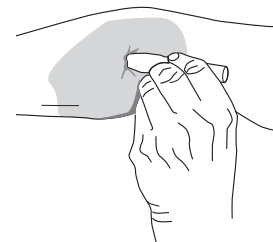


### Tips for Forearm Sampling

- *Check with your Doctor or Diabetes Healthcare Professional to see if forearm testing is appropriate for the patient.*
- *Results from the forearm are not always the same as results from the finger.*
- *Use finger for testing instead of forearm for more accurate results;*
  - *Within 2 hours of eating, exercise, or taking insulin,*
  - *If the patient's blood glucose may be rising or falling rapidly or their results often fluctuate,*
  - *If the patient is ill or under stress,*
  - *If the glucose result may be low or high,*
  - *If symptoms of low or high glucose levels are not evident.<sup>2</sup>*

## TRUEresult® Quality Assurance / Quality Control Manual

1. Select area. Clean the area with soap and warm water, rinse or use an approved disinfectant. Dry thoroughly.
2. Rub area vigorously or apply a warm, dry compress to increase blood flow.
3. Lance forearm.
4. Discard all biohazard materials into appropriate container.



<b>LOT</b>	L-003
<b>EXP</b>	2012/10/31
1	31-61 mg/dL
2	87-117 mg/dL
3	247-335 mg/dL

**GDH-PQQ**

### How to Perform a Blood Glucose Test

1. Check dates on Test Strip vial label.
  - Do not use Test Strips 4 months past written opened date *or* after **EXP** date printed on Test Strip vial label.
2. Clean the area to be lanced with an approved disinfectant. Dry thoroughly.
3. Remove one Test Strip from Test Strip vial by pressing up under the lip of the vial cap. Close Test Strip vial immediately by pressing firmly down on the top of the vial cap.

**Note:** *The TRUEresult is a no-coding system, which means the Meter does not have to be coded to each lot of test strips.*

**Note:** *Use Test Strips quickly after removal from Test Strip vial. Test Strips that have been left out of the vial too long will give an error message. If error message displays, release and discard the old Test Strip and test with a new Test Strip.*

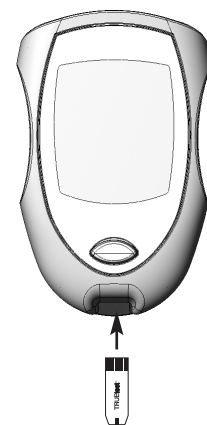
4. With Meter off, insert the Test Strip Contact End (TRUEtest name facing up) into the Test Port. The Meter turns on. Keep the Test Strip in the Meter until the test is complete.

**Note:** *Removing the Test Strip before the result is displayed cancels the test. An error message appears. Retest with a new Test Strip and do not remove the Test Strip from the Meter before the result is displayed.*

5. Wait until the **Drop Symbol** appears in the Display.

**Note:** *To mark the test as an alternate site, press the “+ ” Button.*

6. Obtain the blood sample. Allow blood drop to form (*see Obtaining a Blood Sample, Section 4*).



Drop Symbol



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7. With Test Strip still in Meter, touch edge of Test Strip Sample Tip to sample and hold. Allow blood to be drawn into Test Strip. Remove Test Strip from sample when dashes appear across the Display. Meter is testing.

**Note:** If Meter does not show dashes in the Display soon after touching the sample to the Sample Tip, release and discard the Test Strip. Repeat the test with a new Test Strip and a new sample. If problem persists, see Troubleshooting, Section 8.

8. After the test is finished, the blood glucose result is displayed.
9. Hold the Test Strip vial with the Test Strip pointing down. Press the Strip Release Button to release and discard the Test Strip into the appropriate container. The Meter turns off.
10. Record the result as required by your facility.

**Note:** If blood glucose test result is greater than 240 mg/dL and the Ketone Alert is turned on, the Ketone Symbol appears in the Display with the result. The Ketone Alert may be turned on or off during Set Up, Section 5.

### System Out of Range Warning Messages

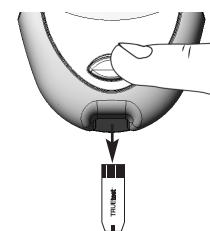
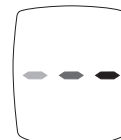
#### WARNING!

The TRUEresult System accurately reads blood glucose levels from 20 - 600 mg/dL.

If test result is less than 20 mg/dL, “Lo” appears in the Meter Display.

If the test result is greater than 600 mg/dL, “HI” appears in the Meter Display.

**ALWAYS** repeat the test to confirm low (“Lo”) or high (“HI”) results. If results still display “Lo” or “HI”, contact the Doctor or Diabetes Healthcare Professional immediately.





## **Section 5:**

### **Set Up of Time, Date, Ketone Alert and Testing Reminders**



# TRUEresult® Quality Assurance / Quality Control Manual

## Set Up of Time, Date, Ketone Alert, Testing Reminders

**Note:** Setting up the time, date, Ketone Alert and Testing Reminders may not be suitable for a multi-patient use of the System. Check with the facility procedures and policies before performing Set Up.

**Note:** If the Meter turns off at any time during the Set Up, go back to Step #1 under Time/Date and begin again.

### Time/Date

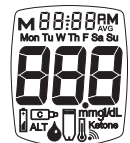
1. Press and hold the “S” Button until tone sounds (around 30 seconds). Release “S” Button. The Full Display appears and the Meter goes into Set Up.
2. The hour flashes. To change, press “+” or “-“ Buttons on the top of the Meter to select the hour. Like many alarm clocks, to set “AM” or “PM”, scroll through the hours until “AM” or “PM” appears in the Display next to the time. Press the “S” Button to set.

**Note:** “AM” or “PM” will not display if the Meter is factory set to a 24-hour clock.

3. The minutes flash. To change, press “+” or “-“ Buttons on the top of the Meter to select the minutes. Press the “S” Button to set.
4. The month (number) flashes. To change, press “+” or “-“ Buttons to on the top of the Meter to select the month. Press the “S” Button to set.
5. The day (number) flashes. To change, press “+” or “-“ Buttons to on the top of the Meter to select the day. Press the “S” Button to set.
6. The year flashes. To change, press “+” or “-“ Buttons to on the top of the Meter to select the year. Press “S” Button to set.

**Note:** The day of the week (Mon, Tue, Wed, Thu, Fri, Sat, Sun) self-adjusts when the month, day or year are changed.

**Note:** The Meter beeps every time a setting is confirmed (when the “S” Button is pressed).



Full Display



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## Ketone Alert

**Note:** If the Meter turns off at any time during the Set Up, go back to Step #1 under Time/Date and begin again.

When a blood glucose result is over 240 mg/dL, the Ketone Alert is a reminder to check the patient's ketones per their treatment plan prescribed by Doctor or Healthcare Professional.

1. After setting year, the option to turn the Ketone Alert is shown.  
Press the "+" or "-" Buttons to turn Alert on or off. Press "S" Button to set.

**Caution!** When a Ketone Alert sounds, it does not mean that ketones have been detected in patient's blood. The Ketone Alert is a reminder to perform a ketone test as prescribed by the Doctor or Healthcare Professional.



## Testing Reminders

Up to four Testing Reminders may be set. When turned on, a Testing Reminder sounds at the indicated time for 10 seconds. The Testing Reminder turns off when Strip is inserted for testing.

**Note:** If the Meter turns off at any time during the Set Up, go back to Step #1 under Time/Date and begin again.

1. After pressing the "S" Button to set Ketone Alert, the Display shows the first Testing Reminder setting (A-1). Press "+" (on) or "-" (off) to turn Reminder on or off.
2. If "on" is chosen, press the "S" Button. The hour flashes. To change, press "+" or "-" Buttons on the top of the Meter to select the hour. To set "AM" or "PM", scroll through the hours until "AM" or "PM" appears in the Display next to the time. Press "S" Button to set.



**Note:** "AM" or "PM" will not display if the Meter is factory set to a 24-hour clock.

3. The minutes flash. To change, press "+" or "-" Buttons on the top of the Meter to select the minutes. Press "S" Button to set.



## TRUEresult® Quality Assurance / Quality Control Manual

- After the time is set by pressing the “S” Button, the Meter goes to the next Testing Reminder set-up (A-2). Repeat turning on and setting the time (*see Steps 1 - 3*) for the next 3 Reminders (if needed).



Alert Symbol

**Note:** *If any Testing Reminders are set, the Alert Symbol appears in all Displays.*

**Note:** *If battery dies or is replaced, the Ketone Alert and the Testing Reminders may have to be reset.*

### Exit Set-Up

Press and hold “S” Button until Meter turns off. Set-up choices are saved. The Meter also turns off after 2 minutes of non-use.



## **Section 6:**

## **Memory**



# TRUEresult® Quality Assurance / Quality Control Manual

## Memory

**Note:** *The use of the Memory features (Averages, Memory) may not be suitable for a multi-patient use of the System. Check with the facility procedures / policies before use.*

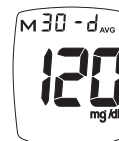
### Viewing Averages

The Averages feature allows the viewing of the average of all the blood glucose results performed on the Meter within a 7, 14 or 30 day period. Control Test results are not normally included in the averages.

**Note:** *If a Control Test is performed outside the recommended testing temperature (see How to Perform a Control Test, Section 3), the Control may read as a blood test and be included in the averages. Make sure that all Control Tests are performed within the recommended testing temperature range.*

1. Start with the Meter off. Press and release the “S” Button. The Display scrolls through the 7, 14, and 30 day Average values.
2. The Meter turns off after 2 minutes if no other buttons are pressed.

**Note:** *If there are no Average values, three dashes are displayed for the 7, 14, or 30 day Average results.*



# TRUEresult® Quality Assurance / Quality Control Manual

## Viewing Memory

**Note:** *The use of the Memory features (Averages, Memory) may not be suitable for a multi-patient use of the System. Check with the facility procedures / policies before use.*

The TRUEresult Meter's Memory stores 500 results.

The oldest glucose result is removed from the Memory when the Memory is full and a new glucose result is added.

To access the Memory:

1. Press the “S” Button for a few seconds and release. The Meter turns on and the 7, 14, and 30 day Average results are displayed. Press and release the “S” Button again to view the most recent Control Test result in Memory.

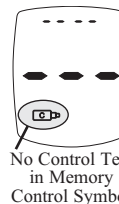
**Note:** *Only one Control Test result is stored in the Memory.*

2. Press the “+” Button and release to advance to the first blood glucose test result in Memory. Continue to press and release the “+” Button to advance through the blood glucose results. Holding the “+” Button scrolls through the results quickly. Press and release the “-” Button to go back through the results.

Test results marked as an alternate site blood glucose test (see How to Perform a Blood Test, Section 4) display the **Alternate Site Symbol (ALT)**.



Control Test results display the Control Symbol. If no Control Test has been detected, the Display shows three dashes and the Control Symbol.



**Note:** *Performing a Control Test at temperatures above or below room temperature may cause the Control to read as a blood test. Control Symbol does not show in Display with test result.*

If Ketone Alert is turned on, blood glucose test results above 240 mg/dL display the Ketone Symbol.







## **Section 7:**

# **Care and Storage of System**



# **TRUEresult® Quality Assurance / Quality Control Manual**

## **Caring for the TRUEresult System**

- Store the System (Meter, Test Strips, Glucose Control Solution) in an area protected from liquids, dust and dirt.
- Store the System in a dry place at room temperature, 36° - 86°F.  
**DO NOT REFRIGERATE OR FREEZE.**

### **Meter**

- Wipe Meter with a clean, lint-free cloth dampened with 10% bleach and water, or an OSHA approved disinfectant.
- Never put Meter in liquids or allow any liquids to enter Test Port.
- Do not use 100% Isopropyl alcohol to clean the Meter. It may result in damage to the Meter Display.

### **TRUEtest Test Strips**

- Store Test Strips in original vial only. Do not transfer old Test Strips into new vial or store Test Strips outside of vial.
- Write the date first opened on Test Strip vial label. Discard vial and unused Test Strips if either **EXP** date printed on Test Strip vial label or 4 months after date written on vial label has passed.
- Close Test Strip vial immediately after removing one Test Strip. Store in a dry place at room temperature below 86°F.  
**DO NOT REFRIGERATE OR FREEZE.**
- Do not reuse Test Strips.
- Do not bend, cut or alter Test Strips in any way.

### **TRUEtest Glucose Control Solution**

- Write the date first opened on Control bottle label. Discard bottle if either **EXP** date printed on bottle label or 3 months after date written on bottle label has passed.
- After use, wipe bottle tip clean and recap tightly.
- Store at room temperature, 36° - 86°F.  
**DO NOT REFRIGERATE OR FREEZE.**

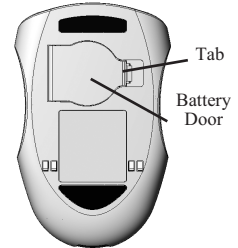
# TRUEresult® Quality Assurance / Quality Control Manual

## Battery Replacement

The Low Battery Symbol displays if the battery needs to be changed. The Meter will continue to function for about 50 more tests before Meter will not test. A dead battery displays the Battery Symbol, beeps, and then turns off. Use only a new 3V non-rechargeable lithium battery (#CR2032)




1. Lift Section on Battery Door.
2. Turn Meter over, tap gently on the palm of your other hand to loosen and remove battery.
3. Replace battery with a new non-rechargeable lithium battery (#CR2032), positive (“+”) side facing up. Close Battery Door.
4. Discard the old battery in an appropriate container.
5. Press the “S” Button to turn the Meter on. If Meter will not turn on, check that the battery was installed properly with “+” facing up. If not, remove and reinsert battery and try again. Call for assistance if problem persists.




**Caution!** *Batteries may explode if mishandled or incorrectly replaced. Do not dispose of battery in fire. Do not take apart or attempt to recharge battery. Dispose according to local/country regulations.*

**Note:** *If battery dies or is replaced, the Ketone Alert and the Testing Reminders may have to be reset. See Set Up of Time, Date, Ketone Alert, Testing Reminders, Section 5 for more information.*



# **Section 8:**

## **Troubleshooting**



# TRUEresult® Quality Assurance / Quality Control Manual

## Troubleshooting

The following is a brief guide for Troubleshooting the most common errors when using TRUEresult. If any problems arise that cannot be resolved by using the guide or the Display Messages, please call for assistance.

### **1) After inserting Test Strip into Test Port, Meter does not turn on.**

Test Strip is inserted upside down or backwards.

- Remove Test Strip. Re-insert Test Strip correctly.

Strip not fully inserted.

- Remove Test Strip. Re-insert Test Strip fully into Meter.

Strip error.

- Remove Test Strip. Repeat with new Test Strip.

Dead or no battery.

- Replace battery.

Battery in backwards.

- Check placement of battery. Battery positive (“+”) side must face up.

Meter error.

- Call for assistance.

### **2) After applying the sample to the Test Strip, test does not start / Meter does not begin testing.**

Sample too small.

- Repeat test with a new Test Strip and a larger sample drop.

Sample applied after two minute automatic shut- off of Meter.

- Repeat test with a new Test Strip and apply sample within 2 minutes.

Problem with Test Strip.












- Repeat test with a new Test Strip.

Problem with Meter.

- Call for assistance.

# TRUEresult® Quality Assurance / Quality Control Manual

## Display Messages

Display	Reason	Action
	<b>Temperature Error</b> Too cold or too hot for testing.	Move System to area between 50°-104°F and wait 30 minutes for System to reach room temperature before testing.
	<b>Sample not detected or using wrong Test Strip</b>	Retest with a new TRUEtest Test Strip and a larger sample.
	<b>Used Test Strip, Test Strip outside of vial too long, sample on top of Test Strip</b>	Repeat with a new Test Strip. Make sure sample is touched to edge of Sample Tip. If error persists, call for assistance.
	<b>Meter error</b>	Call for assistance.
	<b>Test Strip error</b>	Retest with a new Test Strip. If error persists, call for assistance.
	<b>Test Strip removed during test</b>	Retest with a new Test Strip. Make sure result is displayed <i>before</i> removing Test Strip.
	<b>Memory Error</b>	Result was not recorded into Memory. Retest with a new Test Strip.
	<b>Communication Error</b>	Call for assistance.
	<b>Low or dead battery</b>	Replace battery.
	<b>Out of range high results</b> > 600 mg/dL	<b><u>WARNING!</u></b>  Retest with a new Test Strip. If result is still “HI” or “Lo”, contact Doctor <i>immediately</i> .
	<b>Out of range low results</b> < 20 mg/dL	
		<b><u>WARNING!</u></b>

*If error message still appears after action, any other error messages appear that are not shown above, or troubleshooting does not solve the problem, call for assistance.*



## **Section 9:**

# **Training Certification Program**



## **TRUEresult® Quality Assurance / Quality Control Manual**

### **TRUEresult Blood Glucose System Training Certification Program**

Trained and competent testing personnel are essential to good quality testing and patient care. Waived testing sites are subject to a high rate of personnel turnover. Personnel should be trained and competent in each test they will perform before reporting patient results. In addition, training should include aspects of safety (including Infection Control Policies) and Quality Control. The Risk Management and Chief Medical Officer, and other persons responsible for overseeing testing should ensure that testing personnel receive adequate training and are competent to perform the procedures for which they are responsible.<sup>7</sup>

#### **Certificate Information**

Home Diagnostics, Inc. (HDI) provides a training certificate for the use of the TRUEresult Blood Glucose Monitoring System for point-of-care multi-patient facilities. The Training Certificate provides a record that the person listed on the Certificate has been trained correctly in the use of the TRUEresult System and understands all procedures and limitations concerning the TRUEresult System.

##### **A. Certified Trainer**

Certified Trainers are personnel from the facility who have received a Trainer's Certificate from Home Diagnostics, Inc. To obtain a Trainer's Certificate, the person must:

1. Watch and understand the TRUEresult Clinical Training Video (if available).
2. Read and be familiar with the entire Quality Assurance/Quality Control Manual and all product Instructions for Use (Test Strip, Glucose Control Solution, Owner's Booklet).
3. Complete the Training Checklist and Post Test included in this Manual.
4. Submit completed Post Test to:

HDI/LTC Training Certification  
Attn.: Customer Care Manager  
2400 NW 55th Ct.  
Fort Lauderdale, FL 33309

Home Diagnostics, Inc. will return a Trainer's Certificate upon satisfactory completion of the Post Test (100% score required). Upon receiving the Trainer's Certificate from HDI, Certified Trainers are qualified to train appropriate personnel at their facility to be Approved Testers. Training Checklists and Certificates must be filed in the employee's file at the facility.

- **RISK MANAGEMENT AND CHIEF MEDICAL OFFICER MUST BE CERTIFIED ACCORDING TO THIS TRAINING CERTIFICATION PROGRAM.**
- **CERTIFIED TRAINERS MUST BE RE-CERTIFIED EVERY 12 MONTHS.**

**Home Diagnostics will make every effort to contact your facility to inform you of expired training certificate and the need to complete the re-certification process.**



## **TRUEresult® Quality Assurance / Quality Control Manual**

### **B. Approved Testers**

Approved Testers must be trained by Certified Trainers before they perform Control Tests or blood glucose testing using the TRUEresult System. To become an Approved Tester:

1. Watch the TRUEresult Clinical Training Video (if available).
2. Successfully complete the Training Checklist under the instruction of a Certified Trainer.
3. Demonstrate the proper technique for testing with the TRUEresult System using the appropriate blood and Control samples.
4. Identify the facility's Quality Control Policy and Procedures, including documentation of Quality Control.

Upon the person's satisfactory completion of the above, the Certified Trainer documents the training, signs the Training Checklist and files the completed Checklist in the employee's file at the facility.

**APPROVED TESTERS MUST BE RE-TRAINED EVERY 12 MONTHS BY A CERTIFIED TRAINER.**

# TRUEresult® Quality Assurance / Quality Control Manual

## TRUEresult® Blood Glucose System Training Checklist (Please print)

Name \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Title \_\_\_\_\_

Facility \_\_\_\_\_

Confirmed by Certified Trainer (print name and sign) \_\_\_\_\_

### 1. The Tester has completed the following:

- \_\_\_\_\_ Viewed the Clinical Training Video
- \_\_\_\_\_ Read the Owner's Booklet
- \_\_\_\_\_ Read the Test Strip Instructions for Use (Insert)
- \_\_\_\_\_ Read the Glucose Control Instructions for Use (Insert)
- \_\_\_\_\_ Read the QA/QC Manual

### 2. The Tester understands the following:

- \_\_\_\_\_ Use of the TRUEresult System in a clinical setting
- \_\_\_\_\_ CLIA regulations for point-of-care blood glucose testing
- \_\_\_\_\_ System specifications
- \_\_\_\_\_ Limitations and critical safety information, including that the TRUEresult System must not be used for certain patients (neonates, peritoneal dialysis patients, etc.)

### 3. Familiarization with the components of the System.

#### a. Meter

- \_\_\_\_\_ Location of serial number for the Meter
- \_\_\_\_\_ Location of phone number for assistance
- \_\_\_\_\_ Review of Meter buttons and functions

#### b. Test Strips

- \_\_\_\_\_ Identifies lot number
- \_\_\_\_\_ Writes open date on Test Strip vial label
- \_\_\_\_\_ Understands the Expiration Dates, both printed and written
- \_\_\_\_\_ Reviews proper handling of Test Strips including recapping of the Strip vial immediately after removing Test Strip
- \_\_\_\_\_ Demonstrates proper insertion of the Test Strip into the Meter

#### c. Glucose Control Solution

- \_\_\_\_\_ Identifies lot number
- \_\_\_\_\_ Writes open date on Control bottle label
- \_\_\_\_\_ Understands the Expiration Dates, both printed and written
- \_\_\_\_\_ Identifies Control level
- \_\_\_\_\_ Identifies Control ranges

# TRUEresult® Quality Assurance / Quality Control Manual

## TRUEresult® Blood Glucose System Training Checklist (Please print)

Name \_\_\_\_\_

### 4. Quality Control Tests

- \_\_\_\_\_ Understands manufacturers instructions for control testing
- \_\_\_\_\_ Understands the purpose of the automatic self-check of the Meter upon insertion of Test Strip into Test Port
- \_\_\_\_\_ Understands the purpose of Control Tests, the frequency of testing, and the number of Control levels to be tested
- \_\_\_\_\_ Understands the testing temperature range and what may result if testing temperature is out of range
- \_\_\_\_\_ Identifies correct (unopened vs. opened) Expiration Dates on the Control bottle.
- \_\_\_\_\_ Identifies the correct Control range for the Control level and understands the troubleshooting if the Control Test result is not within the acceptable range
- \_\_\_\_\_ Demonstrates the procedure using the Glucose Control Solution
- \_\_\_\_\_ Records the Control Test result on the TRUEresult Quality Control Log

### 5. Blood Collection

- \_\_\_\_\_ Understands the proper technique of capillary blood collection for both finger and forearm samples
- \_\_\_\_\_ Understands when finger should be used instead of forearm
- \_\_\_\_\_ Demonstrates the ability to obtain a sufficient amount of blood for testing from both a finger tip and forearm
- \_\_\_\_\_ Understands facility's procedure on obtaining venous blood samples and the correct tubes to use

### 6. Demonstration of Blood Glucose Testing

- \_\_\_\_\_ Demonstrates proper blood glucose testing procedure for the TRUEresult System
- \_\_\_\_\_ Understands the proper blood application to the Sample Tip and the significance of the symbols in the Display

### 7. Patient Blood Glucose Test Results

- \_\_\_\_\_ Demonstrates the proper documentation of test results
- \_\_\_\_\_ Understands the troubleshooting if test results are not within the patient target range (e.g., perform Quality Control Tests, repeat test, possible therapy change after consultation with Doctor or Diabetes Healthcare Professional, etc.)
- \_\_\_\_\_ Understands that use of Memory feature may not be appropriate for multi-patient facilities
- \_\_\_\_\_ Proper disposal of biohazardous materials per facility policy and procedures

### 8. Care and Storage

- \_\_\_\_\_ Understands proper infection control policy and procedure for cleaning and disinfecting meter
- \_\_\_\_\_ Demonstrates battery replacement
- \_\_\_\_\_ Understands proper storage of Meter, Test Strips, and Glucose Control Solution

# TRUEresult® Quality Assurance / Quality Control Manual

## TRUEresult® Blood Glucose System Certified Trainer Post Test (Please print)

Name \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Title \_\_\_\_\_

Facility \_\_\_\_\_

Does the facility corresponding to this Training Certification provide any of the following patient services? \_\_\_\_\_ Yes \_\_\_\_\_ No

- Peritoneal dialysis with solutions containing icodextrin (e.g. Extraneal, Icodial) that is metabolized to maltose,
- Injections or infusions of solutions containing galactose or maltose, including some human immunoglobulin preparations (e.g. Octagam),
- Xylose absorption testing,
- Intervenous solutions containing maltose as a substitute for glucose or as a means for patient hydration,
- Drugs, including investigational drugs and those made by compounding pharmacies, which contain or metabolize maltose, galactose, or xylose.

Address \_\_\_\_\_

Phone/Fax \_\_\_\_\_

E-mail Address \_\_\_\_\_

### *True or False*

1. All Healthcare Professionals performing blood glucose monitoring using the TRUEresult System should complete the training program.

\_\_\_\_\_ True \_\_\_\_\_ False

2. The TRUEresult System can be used on newborns.

\_\_\_\_\_ True \_\_\_\_\_ False

3. A patient receiving peritoneal dialysis with icodextrin (Extraneal or Icodial) or solutions containing maltose or metabolizing to maltose, or galactose (such as Octagam) can be tested using the TRUEresult System.

\_\_\_\_\_ True \_\_\_\_\_ False

4. Quality Control Testing should be performed per your facility's policies and procedures.

\_\_\_\_\_ True \_\_\_\_\_ False

## TRUEresult® Quality Assurance / Quality Control Manual

### TRUEresult® Blood Glucose System Certified Trainer Post Test (Please print)

Name \_\_\_\_\_

5. Any control solution can be used with the TRUEresult System.

\_\_\_\_\_ True      \_\_\_\_\_ False

6. Critically ill patients (shock, hyperglycemic-hyperosmolar state, with or without ketosis) should be tested with the TRUEresult System.

\_\_\_\_\_ True      \_\_\_\_\_ False

7. If the Meter becomes soiled, wipe it off with a lint free cloth dampened with an OSHA approved disinfectant.

\_\_\_\_\_ True      \_\_\_\_\_ False

8. The battery should be replaced with an AAA alkaline battery.

\_\_\_\_\_ True      \_\_\_\_\_ False

#### ***Multiple Choice (choose only one answer for each question)***

1. Training on the use of the TRUEresult System consists of reviewing the following:

- a) The Clinical Training Video
- b) The QA/QC Manual
- c) The Owner's Booklet
- d) Test Strip Instructions for Use
- e) Control Solution Instructions for Use
- f) All of the above

2. If a point-of-care blood glucose test is ordered on a patient, the tester must:

- a) Identify treatment(s) patient may be on or starting
- b) Identify drug therapy(ies) patient may be on or starting
- c) Identify and use appropriate point-of-care blood glucose testing system
- d) All of the above

3. The TRUEresult System utilizes the following enzyme to test for glucose:

- a) Glucose oxidase (GO)
- b) GDH-PQQ
- c) GDH-NAD
- d) GEH-PDQ

# **TRUEresult® Quality Assurance / Quality Control Manual**

## **TRUEresult® Blood Glucose System Certified Trainer Post Test (Please print)**

**Name** \_\_\_\_\_

4. The TRUEresult System must not be used for the following patient conditions:

- a) Peritoneal dialysis patients receiving dialysis solutions containing icodextrin (e.g. Extraneal®, Icodial®) that is metabolized to maltose
- b) Injection or infusion of solutions containing galactose or maltose, including some human immunoglobulin preparations (e.g. Octagam®)
- c) Patients undergoing xylose absorption testing
- d) Patients receiving intravenous solutions containing maltose as a substitute for glucose or as a means for patient hydration
- e) Any drugs, including any investigational drugs and those made by compounding pharmacies. which contain or metabolize to maltose, galactose, or xylose
- f) All of the above

5. Using the TRUEresult System on the above patients may cause:

- a) False low glucose results
- b) Meter to malfunction
- c) False high glucose results
- d) Control solution to read as blood
- e) Inappropriate treatment that may result in death
- f) a and d
- g) c and e
- h) b and e

6. The following sample(s) is/are appropriate for testing on the TRUEresult System:

- a) Capillary whole blood from fingertip or forearm
- b) Venous whole blood collected in a red top tube
- c) Plasma
- d) Urine
- e) Venous whole blood collected in a purple top or green top tube
- f) a and c
- g) b and d
- h) a and e

7. The phone number for assistance is located:

- a) On the Owner's Booklet cover
- b) On the cover of the QA/QC Manual
- c) On the back Meter label
- d) On the Test Strip Instructions for Use
- e) All of the above

## **TRUEresult® Quality Assurance / Quality Control Manual**

### **TRUEresult® Blood Glucose System Certified Trainer Post Test (Please print)**

**Name** \_\_\_\_\_

8. The following tests are used for Quality Control of the TRUEresult:

- a) One level of Glucose Control and a patient sample
- b) One level of Glucose Control
- c) A low level of Glucose Control and a high level of Glucose Control
- d) Meter automatic self-test and a minimum of 2 levels of Glucose Control

9. The Glucose Control open bottle expiration date is:

- a) One week after opening
- b) 120 days after opening
- c) 3 months after opening
- d) The date pre-printed on the bottle

10. If the Control Test result is out of range, it may be because:

- a) The Control has expired
- b) The Test Strip has expired or the vial was not closed
- c) The cap was left off the Control bottle
- d) The open date written on the Control bottle or Test Strip vial has passed
- e) All of the above

11. Forearm testing may not be appropriate in the following situations:

- a) Within 2 hours of exercise
- b) If the patient's glucose result often fluctuates
- c) If the patient is under stress
- d) All of the above

12. TRUEtest Test Strips open vial expiration date is:

- a) 18 months
- b) 12 months
- c) 6 months
- d) 4 months

13. Retraining of all personnel must be performed within

- a) 6 months
- b) 12 months
- c) 8 months
- d) 30 days

## TRUEresult® Quality Assurance / Quality Control Manual

14. If after inserting the Test Strip into the Test Port, the Meter does not turn on, the reason could be

- a) The Test Strip was inserted upside down
- b) The Test Strip was not fully inserted
- c) The battery is dead
- d) All of the above

**For HDI Use Only**

Score \_\_\_\_\_

Reviewed by \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_  
Print name

\_\_\_\_\_  
Sign name

Certificate Issued: \_\_\_\_\_ Yes \_\_\_\_\_ No **Date** \_\_\_\_/\_\_\_\_/\_\_\_\_



# SAMPLE

## HOMEdiagnostics™

hereby certifies that

of

Has completed an educational course in the proper use and maintenance of the

### **TRUEresult™ Blood Glucose Monitoring System**

and is therefore qualified to train blood glucose testers in the use of this system.

\_\_\_\_\_  
Customer Care Manager

\_\_\_\_\_  
Date of Issue

*Valid for one year from Certification Date*

## TRUEresult™

## HOMEdiagnostics™



# **Section 10:**

## **Forms**



**Meter Serial Number** \_\_\_\_\_ (7-digit number on Meter label below the bar code) \*Note any problems in Troubleshooting section below.

[illegible]

Date	Problem	Action	Initials

# QUALITY CONTROL RECORD

**Meter Serial Number** \_\_\_\_\_ (7-digit number on Meter label below the bar code) \***Note any problems in Troubleshooting section below.**

[illegible]

## \*TROUBLESHOOTING

Date	Problem	Action	Initials

# **WARNING!**

## **Do not use TRUEresult System for Blood Glucose Testing!**

- \_\_\_\_\_ **Patient on peritoneal dialysis**
- \_\_\_\_\_ **Patient receiving solutions containing galactose or maltose, including some human immunoglobulin preparations**
- \_\_\_\_\_ **Patient undergoing xylose absorption testing**
- \_\_\_\_\_ **Patient receiving IV solution containing maltose**
- \_\_\_\_\_ **Patient receiving drug therapies that contain or metabolize to maltose, galactose, or xylose**

# **WARNING!**



## **Section 11:**

# **TRUEresult<sup>®</sup> Lifetime Warranty**



## **TRUEresult® Quality Assurance / Quality Control Manual**

### **TRUEresult Limited Lifetime Warranty**

Home Diagnostics, Inc. provides the following Warranty to the original purchaser of the TRUEresult Blood Glucose Meter:

- 1) Home Diagnostics, Inc warrants this Meter to be free of defects in materials and workmanship at the time of purchase. If the Meter is ever inoperative, Home Diagnostics, Inc. will replace the Meter with an equivalent Meter, at its option, at no cost to the purchaser. Failure of the Meter due to abuse or use not in accordance with the instructions for use is not covered by this Warranty.
- 2) This Warranty does not include the battery supplied with the Meter.
- 3) Do not take the Meter apart. This action will void the Warranty and cause the Meter to display false results.
- 4) The duration of any implied Warranty, including any implied Warranty of merchantability or fitness for a particular purpose shall be limited to the lifetime in use with the original user in accordance with any state law to the contrary.
- 5) Home Diagnostics, Inc. disclaims liability for incidental or consequential damages for breach of any expressed or implied Warranty, including any implied Warranty of merchantability or fitness for a particular use with respect to the Meter. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusion may not apply.
- 6) This Warranty gives the user specific legal rights, and the user may also have other rights which vary state to state.

Your Home Diagnostics, Inc. Customer Care Representative will be able to provide detailed information regarding procedures for returning your Meter, if necessary.



## **Section 12:**

## **References**





# TRUEresult® Quality Assurance / Quality Control Manual

## References

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