ATTENTION: RISK MANAGEMENT AND CHIEF MEDICAL OFFICER

TRUE2go

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.niprodiagnostics.com

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

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IMPORTANT HEALTH AND SAFETY INFORMATION

WARNING!
Healthcare Professionals should adhere to Standard Precautions and disinfection procedures when handling or using this device for testing. ALL parts of the TRUE2go Blood Glucose Monitoring System are considered potentially infectious, and capable of transmitting blood-borne pathogens. Only auto-disabling, single-use lancing devices may be used with this device. For more information on Standard Precautions and practices please refer to http://www.cdc.gov/biosafety/publications/bmbl5.

WARNING!
• NEVER reuse Test Strips. NEVER wipe Test Strips with water, alcohol, or any cleaner. DO NOT attempt to remove blood or control sample from Test Strips or clean Test Strips and re-use. Reuse of Test Strips will cause inaccurate results.
• NEVER add a second drop of sample to Strip. Adding more sample gives an error message.

CAUTION!
Point-of-care blood testing devices such as blood glucose meters should be used only on one patient and not shared. If dedicating blood glucose meters to a single patient is not possible, the meters must be properly cleaned and disinfected after every use following the guidelines found in Meter Care, Cleaning/Disinfection.

We suggest cleaning and disinfecting the Meter after each use to prevent the transmission of blood-borne pathogens. Healthcare Professionals should wear gloves when cleaning and disinfecting the Meter. Wash hands after taking off gloves. Contact with blood presents a potential infection risk. A new pair of gloves should be worn before testing each patient.

We recommend one meter per patient. We suggest to clean and disinfect Meter between patients when Meter is used on multiple patients.

Note: Clean to remove blood or soil from the surface of your Meter and disinfect to destroy infectious agents on the surface of Meter after each use.

• To clean and disinfect Meter, use PDI Super Sani-Cloth Germicidal Disposable wipes (active ingredients - 55% Isopropyl alcohol/Isopropanol, 5,000 ppm (Parts Per Million) quaternary ammonium chlorides) Viraguard/Virahold wipes (active ingredient - 70% Isopropyl alcohol/Isopropanol) or disinfectants with identical active ingredients from www.epa.gov/oppad001/list_d_hepatitisbhiv.pdf. Please follow the prepared wipes product label manufacturer’s instructions for cleaning and disinfecting the Meter.
• Never put Meter in liquids or allow any liquids to enter the Test Ports.
• Let Meter air dry thoroughly before testing.
• Please dispose of wipes after cleaning/disinfecting.
• Wash hands after taking off gloves.
• Use a new pair of gloves before testing each patient.

Note: For more information on the PDI wipes, visit www.pdipdi.com or for information on Viraguard wipes, visit www.veridien.com.
TRUE2go® Quality Assurance / Quality Control Manual

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.*
TRUE2go® Quality Assurance / Quality Control Manual

Nipro 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 in 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, or call for assistance using the number on the front cover of the Manual.
TRUE2go® Quality Assurance / Quality Control Manual

Introduction

Nipro Diagnostics, Inc. is proud to present the TRUE2go Blood Glucose Monitoring System. The TRUE2go is 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.

Nipro Diagnostics, Inc. recognizes the importance of practicing safe and reliable testing using the TRUE2go Blood Glucose Monitoring System. Therefore, this Manual has been designed to provide the following:

- A basic understanding of the TRUE2go System,
- A detailed testing guide,
- Quality Control Program recommendations for the TRUE2go System in your facility,
- A complete guide to troubleshooting issues and concerns that may arise with using with the TRUE2go System in patient care,
- A comprehensive certified training program for Healthcare Professionals that will be using the TRUE2go System.

CAUTION!

Please read this entire Manual and all product Instructions for Use before testing. Operators of the TRUE2go Blood Glucose Monitoring System must be trained per the Training Certification Program, Section 8, 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 TRUE2go 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 TRUE2go products, visit our website at www.niprodiagnostics.com.
## TRUE2go® Quality Assurance / Quality Control Manual

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Section 1:

Using TRUE2go®
in a Clinical Setting
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Critical Safety Information / Important Information / Limitations / Expected Results

WARNING!
TRUEtest Blood Glucose Test Strips utilize glucose dehydrogenase-PQQ (GDH-PQQ). The TRUE2go 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 TRUE2go 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

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 TRUE2go Meter.
- Do not leave Test Strips where the storage temperature printed on vial label may be exceeded (car, trunk, briefcase, etc.).
- 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.
- TRUE2go 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 TRUE2go 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.4

- For evaluation or Quality Control procedures where TRUE2go 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 TRUE2go 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 TRUE2go System are considered accurate if within ± 20% of laboratory results.5 If patient has recently eaten, finger results from the TRUE2go System can be up to 70 mg/dL higher than venous laboratory results.6

- The TRUE2go System cannot be used in the diagnosis of diabetes or to test blood glucose in newborns.

- DO NOT perform capillary blood glucose testing on critically ill patients. Capillary blood glucose levels in critically ill patients with reduced peripheral blood flow may not reflect the true physiological state. Reduced peripheral blood flow may result from the following conditions (for example):7
  - shock
  - severe hypotension
  - severe dehydration
  - hyperglycemia with hyperosmolarity, with or without ketosis
  - Testing at altitudes up to and including 10,150 feet will not affect accurate results.5
  - Hematocrit levels between 20% and 60% will not affect accurate results.5
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:

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- 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.
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.
- 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.
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TRUE2go 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 TRUE2go system users. If your proficiency sample results are not within acceptable limits of other TRUE2go 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 TRUE2go 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 TRUE2go Owners Booklet and TRUEtest Test 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)
Meter Specifications

Result Range: 20 - 600 mg/dL

Sample Size: 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 1500 tests or 2 years

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

Weight: 0.6 ounces

Size: 1.70” x 1.46” x 0.89”

Memory Size: 99 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
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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.
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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.
P 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.
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.
TRUE2go® 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 Fighting 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.
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.
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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
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Description of System

Meter

1. Set Button - Mark result as an alternate site, turn Meter on/off for Memory, view(scroll results in Memory.
   *Note:* Use of Memory function is not recommended in a multi-patient setting.

2. Display Screen - Shows results, messages, user prompts, information

3. Drop Symbol

4. Units of Measure  *(Note: Factory set, cannot be changed by user.)*

5. Strip Release Button - Releases Test Strip after testing is complete.

6. Test Port - Place to insert TRUEtest Test Strip

7. Battery Door - Open to replace battery. Use one non-rechargeable 3V lithium battery (#CR2032), positive (“+”) side up *(See Battery Replacement, Section 6, for more details).*

8. Meter Label - Contains Serial Number of the Meter and phone number to call for assistance.

Test Strip

9. Contact End - Insert into Test Port with TRUEtest name facing up.

10. 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.
TRUE2go® Quality Assurance / Quality Control Manual

Sample Placement

- Allow sample (blood or Control) to be drawn into Sample Tip.

CAUTION! **Holding the Test Strip to blood sample too long after the Meter begins testing may cause inaccurate results.**
- 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.
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.
TRUE2go® Quality Assurance / Quality Control Manual

Attach / Remove TRUE2go Meter to TRUEtest Test Strip Vial

The TRUE2go Meter is designed to attach to the top of the TRUEtest Test Strip vial for ease of use.

Attach

1. Place Test Strip vial upright on flat surface with vial cap lip facing front.
2. With Meter Test Port facing to the right, place bottom of the Meter firmly on the vial top. Meter must be seated flat on the top of the vial cap.
3. Holding the vial, twist the Meter ¼ turn clockwise. The section of the Meter where the Test Port is located should cover the vial lip if attached properly.
4. To open the vial, lift up on the Meter under the Test Port.
5. To close the vial, press firmly on the area on the top of the Test Port.

Remove

1. Holding the vial, twist the Meter ¼ turn counterclockwise.
2. Lift off Meter from vial top.

Note: The Meter may be used for testing without attaching to the vial.
Section 3:

Quality Control Testing
**TRUE2go® 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. TRUE2go 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, TRUE2go offers two kinds of Quality Control Tests. These tests ensure that TRUE2go is working properly and testing technique is good.

**Automatic Self Test**

An automatic self-test is performed by the Meter each time a TRUEtest Test 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.
TRUE2go® Quality Assurance / Quality Control Manual

How to Perform a Control Test

Use the Quality Control Log located in Forms, Section 9 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 Test Port of the Meter attached to the vial. Remove one Test Strip. Close vial immediately by firmly pressing down on the top of the Test Port area.

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.)
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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.

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 front cover for phone number).

11. Record the result in the TRUE2go Quality Control Log (see Forms, Section 9).

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
TRUE2go® 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.¹

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 TRUE2go System.

For evaluation where TRUE2go 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 TRUE2go 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 TRUE2go System are considered accurate if within ± 20% of laboratory results.² If patient has recently eaten, finger results from the TRUE2go System can be up to 70 mg/dL higher than venous laboratory results.³

The TRUE2go System cannot be used on newborns. Perform laboratory glucose Tests on critically ill patients.

WARNING!
TRUEtest Blood Glucose Test Strips utilize glucose dehydrogenase-PQQ (GDH-PQQ). The TRUE2go 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,
TRUE2go® 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 TRUE2go 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).

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.

CAUTION! We suggest cleaning and disinfecting the meter after each use to prevent the transmission blood-borne pathogens. Only auto-disabling, single-use lancing devices may be used with this device.

Tips for Fingertip Sampling

Note: A new pair of gloves should be worn before obtaining a blood sample. Contact with blood presents an infection risk.

1. Select fingertip. Clean area with soap and warm water, rinse or use an approved disinfectant to clean the area. Dry thoroughly.
2. Lance fingertip.
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. Wash hands after taking off gloves.

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.
TRUE2go® Quality Assurance / Quality Control Manual

Note: A new pair of gloves should be worn before obtaining a blood sample. 
Contact with blood presents an infection risk.

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. Wash hands after 
taking off gloves.

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 Test 
Port of the Meter attached to the Test Strip vial. Close Test Strip vial 
immediately by pressing firmly down on the top of the Test Port area.

Note: The TRUE2go 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 Set Button.

6. Obtain the blood sample. Allow blood drop to form (see Obtaining a Blood 
Sample, Section 4).
TRUE2go® Quality Assurance / Quality Control Manual

7. With Test Strip still in Meter, touch edge of Sample Tip to blood drop and allow blood to be drawn into Strip. Remove Test Strip Sample Tip from sample drop immediately after dashes appear across the Meter Display.

CAUTION! Holding the Test Strip to blood sample too long after the Meter begins testing may cause inaccurate results.

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 7.

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.

System Out of Range Warning Messages

WARNING!

The TRUE2go 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:
Memory
**TRUE2go® Quality Assurance / Quality Control Manual**

**Memory**

*Note:* Use of the Memory feature may not be suitable for multi-patient use of the System. Check with the facility procedure/policy before use.

The TRUE2go Meter’s Memory holds 99 results.

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

**Viewing Memory**

1. Press the Set Button for a few seconds and release. The Meter turns on and the most recent result in Memory is displayed.

2. Press the Set Button and release to advance to the next result in Memory. Continue to press and release the Set Button to scroll through the results. Holding the Set Button scrolls through the results quickly.

Blood test results begin as “R 1” followed by the glucose result. “R 2” follows with the next glucose result, and so on. (R 3, result; R 4, result; …).

Control test results begin as “C 1” followed by the Control Test result. “C 2” follows with the next Control Test result, and so on. (C 3, result; C 4, result; …).

Alternate site blood test results begin as “A 1” followed by the glucose result. “A 2” follows with the next glucose result, and so on. (A 3, result; A 4, result; …).
Section 6:

Care, Cleaning/Disinfection and Storage of System
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CAUTION!
Point-of-care blood testing devices such as blood glucose meters should be used only on one patient and not shared. If dedicating blood glucose meters to a single patient is not possible, the meters must be properly cleaned and disinfected after every use following the guidelines found in Meter Care, Cleaning/Disinfection.

CAUTION!
Healthcare Professionals should wear gloves when cleaning and disinfecting the Meter. Wash hands after taking off gloves as contact with blood presents a risk of infection.

We recommend one meter per patient. We suggest cleaning and disinfection of Meter between patients when Meter is used on multiple patients.

Caring for the TRUE2go 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 Care, Cleaning/Disinfection

Note: Clean to remove blood or soil from the surface of your Meter and disinfect to destroy infectious agents on the surface of Meter after each use.

Remove meter from vial before cleaning to prevent deterioration of vial label.

- To clean and disinfect Meter, use PDI Super Sani-Cloth Germicidal Disposable wipes (active ingredients - 55% Isopropyl alcohol/Isopropanol, 5,000 ppm (Parts Per Million) quarternary ammonium chlorides) Viraguard/Virahold wipes (active ingredient - 70% Isopropyl alcohol/Isopropanol) or disinfectants with identical active ingredients from www.epa.gov/oppad001/list_d_hepatitisbhiv.pdf. Please follow the prepared wipes product label manufacturer’s instructions for cleaning and disinfecting the Meter.
- Never put Meter in Liquids or allow any liquids to enter the Test Ports.
- Let Meter air dry thoroughly before testing.
- Please dispose of wipes after cleaning/disinfection.
- Wash hands after taking off gloves.
- Use a new pair of gloves before testing each patient.

Note: Prepared Isopropyl Alcohol (70%) wipes are commercially available from a variety of manufacturers. For more details on cleaning, contact our Customer Care using the phone number on the cover of the QA/QC Manual. For more information on the PDI Super Sani-Cloth wipes, visit www.pdipdi.com or for information on Viraguard wipes, visit www.veridien.com.
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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.**
Battery Replacement

If “Lb” or “db” appears in the Display, change the battery. Use only a new 3V non-rechargeable lithium battery (#CR2032).

1. Remove Meter from vial (see Attach/Remove TRUE2go Meter to TRUEtest Test Strip Vial, Section 2).

2. Turn Meter over to see the Meter label and Battery Cover.

3. Place the edge of a coin into the slot located in the center of the Battery Cover. Twist coin slightly counterclockwise until Battery Cover is loose. Remove coin from slot.

4. Holding the Meter over your other hand, turn the Meter over so the Meter Display faces up. The Battery Cover and battery drop out.

5. Turn Meter back over. Replace battery with a new 3V non-rechargeable lithium battery (#CR2032), positive (“+”) side facing up.

6. Replace Battery Cover, with slot facing up and metal tips in slots. Firmly push Battery Cover down using the edge of the coin and turn the coin slightly clockwise to close.

7. Discard the old battery in an appropriate container.

8. Press the Set 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.

9. Once Meter turns on, re-attach Meter to vial (see Attach/Remove TRUE2go Meter to TRUEtest Test Strip Vial, Section 2).

**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.**
Section 7:

Troubleshooting
TRUE2go® Quality Assurance / Quality Control Manual

Troubleshooting

The following is a brief guide for Troubleshooting the most common errors when using TRUE2go. If any problems arise that cannot be resolved by using this 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.
<table>
<thead>
<tr>
<th>Display</th>
<th>Reason</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-1</td>
<td>Temperature Error</td>
<td>Move System to area between 50°-104°F and wait 30 minutes for System to reach room temperature before testing.</td>
</tr>
<tr>
<td>E-2</td>
<td>Sample not detected or using wrong Test Strip</td>
<td>Retest with a new TRUEtest Test Strip and a larger sample.</td>
</tr>
<tr>
<td>E-3</td>
<td>Used Test Strip, Test Strip outside of vial too long, sample on top of Test Strip</td>
<td>Repeat with a new Test Strip. Make sure sample is touched to edge of Sample Tip. If error persists, call for assistance.</td>
</tr>
<tr>
<td>E-4</td>
<td>Meter error</td>
<td>Call for assistance.</td>
</tr>
<tr>
<td>E-5</td>
<td>Test Strip error</td>
<td>Retest with a new Test Strip. If error persists, call for assistance.</td>
</tr>
<tr>
<td>E-6</td>
<td>Test Strip removed during test</td>
<td>Retest with a new Test Strip. Make sure result is displayed before removing Test Strip.</td>
</tr>
<tr>
<td>E-8</td>
<td>Meter Error</td>
<td>Result was not recorded in Memory. Retest with a new strip. If error persists, call for assistance.</td>
</tr>
<tr>
<td>Lb</td>
<td>Low Battery</td>
<td>About 50 tests can be performed before battery dies. Replace battery.</td>
</tr>
<tr>
<td>db</td>
<td>Dead battery</td>
<td>Replace battery.</td>
</tr>
<tr>
<td>HI</td>
<td>Out of range high results &gt; 600 mg/dL</td>
<td>Retest with a new Test Strip. If result is still “HI” or “Lo”, contact Doctor immediately.</td>
</tr>
<tr>
<td>Lo</td>
<td>Out of range low results &lt; 20 mg/dL</td>
<td>WARNING!</td>
</tr>
</tbody>
</table>

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 8:

Training Certification Program
TRUE2go® Quality Assurance / Quality Control Manual

TRUE2go 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.

Certificate Information

Nipro Diagnostics, Inc. provides a training certificate for the use of the TRUE2go 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 TRUE2go System and understands all procedures and limitations concerning the TRUE2go System.

A. Certified Trainer

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

1. Watch and understand the TRUE2go 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:

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

Nipro 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 Nipro Diagnostics, Inc., 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.

Nipro 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.
**TRUE2go® 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 TRUE2go System. To become an Approved Tester:

1. Watch the TRUE2go 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 TRUE2go 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.**
TRUE2go® Quality Assurance / Quality Control Manual
TRUE2go® 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 (if available)
   ____ 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 TRUE2go System in a clinical setting
   ____ CLIA regulations for point-of-care blood glucose testing
   ____ System specifications
   ____ Limitations and critical safety information, including that the TRUE2go System must not be
   used for certain patients (newborns, 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
TRUE2go® Quality Assurance / Quality Control Manual
TRUE2go® Blood Glucose System Training Checklist (Please print)

Name_______________________________________________________

4. Quality Control Tests

___ Understands manufacturer’s 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 TRUE2go 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 TRUE2go 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, Cleaning/Disinfection and Storage of System

___ Understands any cleaning/disinfecting procedures for Infection Control
___ Demonstrates battery replacement
___ Understands proper storage of Meter, Test Strips, and Glucose Control Solution
TRUE2go® Quality Assurance / Quality Control Manual
TRUE2go® 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,
- Intravenous 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*__________________________________________________________________

* For product updates and recertification notices. Not for promotional purposes.

True or False

1. All Healthcare Professionals performing blood glucose monitoring using the TRUE2go System
should complete the training program.

_________True _________False

2. The TRUE2go 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
TRUE2go System.

_________True _________False

4. The TRUE2go Meter may be used without attachment to the Test Strip vial.

_________True _________False
TRUE2go® Quality Assurance / Quality Control Manual
TRUE2go® Blood Glucose System Certified Trainer Post Test (Please print)

Name________________________________________________________

5. Quality Control Testing should be performed per your facility’s policies and procedures.
   __________True    __________False

6. Any control solution can be used with the TRUE2go System.
   __________True    __________False

7. Critically ill patients (shock, hyperglycemic-hyperosmolar state, with or without ketosis) should be tested with the TRUE2go System.
   __________True    __________False

8. If the Meter becomes soiled, wipe it off with Isopropyl alcohol (70%) wipes, PDI Super Sani-cloth wipes or Viraguard wipes.
   __________True    __________False

9. 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 TRUE2go System consists of reviewing the following:
   a) The Clinical Training Video (if available)
   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
TRUE2go® Quality Assurance / Quality Control Manual

TRUE2go® Blood Glucose System Certified Trainer Post Test (Please print)

Name_______________________________________________________

3. The TRUE2go System utilizes the following enzyme to test for glucose:

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

4. The TRUE2go 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 TRUE2go 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 TRUE2go 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

8. The following tests are used for Quality Control of the TRUE2go:
   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
TRUE2go® Quality Assurance / Quality Control Manual

13. Retraining of all personnel must be performed within

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

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 Nipro Diagnostics, Inc. Use Only

Score _______________________________________________________

Reviewed by ________________________________________________ Date ___/___/____

   Print name

_______________________________________________________________

   Sign name

Certificate Issued:                Yes   _________ No   Date ___/___/____
SAMPLE

NIPRO DIAGNOSTICS™

hereby certifies that

of

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

TRUE2go® 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

TRUE2go®
Section 9:

Forms
QUALITY CONTROL RECORD

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

| Date | Time | Test Strips | Glucose Control - Level | Glucose Control - Level | Initials | *
|------|------|-------------|-------------------------|-------------------------|---------|------
|      |      |LOT EXP Date Opened|LOT EXP Date Opened Acceptable Range Result|LOT EXP Date Opened Acceptable Range Result|
|      |      |              |                         |                         |         |      |
|      |      | On TRUEtest Test Strip vial label, write date vial opened. Discard vial if either 4 months after opening or after EXP date printed on the vial label has passed. | On TRUEtest Control bottle label, write date bottle opened. Discard bottle if either 3 months after opening or after EXP date printed on the label of Test Strips has passed. | On TRUEtest Control bottle label, write date bottle opened. Discard bottle if either 3 months after opening or after EXP date printed on the label of Test Strips has passed. |         |      |

*TROUBLESHOOTING

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<th>Problem</th>
<th>Action</th>
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印刷于 vial label of Test Strips being used.印刷于 vial label of Test Strips being used.
### QUALITY CONTROL RECORD

**Meter Serial Number ___________________** *(7-digit number on Meter label below the bar code)*

*Note any problems in Troubleshooting section below.*

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WARNING!

Do not use TRUE2go 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 10:

TRUE2go®
Lifetime Warranty
TRUE2go Quality Assurance / Quality Control Manual

TRUE2go Limited Lifetime Warranty

Nipro Diagnostics, Inc. provides the following Warranty to the original purchaser of the TRUE2go Blood Glucose Meter:

1) Nipro 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, Nipro 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) Nipro 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 Nipro Diagnostics, Inc. Customer Care Representative will be able to provide detailed information regarding procedures for returning your Meter, if necessary.
Section 11:

References
TRUE2go® Quality Assurance / Quality Control Manual

References


