

INTRODUCTION:

Welcome to the TRUResult twist Blood Glucose Monitoring System

Our Commitment to You

TRUResult twist is a simple, accurate way to test whole blood glucose (sugar) level, anytime, anywhere. Our goal is to provide quality healthcare products and dedicated customer service. For questions about TRUResult products, please see cover for phone number.

This booklet contains all the information needed to get the most from the TRUResult twist System. To start testing quickly, please see the Quick Reference Guide found inside the cover of this Owner's Booklet.



Please read complete Owner's Booklet and all product Instructions for Use before using the System.

SYMBOLS:	Control	Serial Number	Control Level	Caution	Keep Dry
Biological Risk	Sterile		Use By Date		
For Assistance Call	Attention! Read Instructions for Use.	Storage Temperature Range	Do Not Resterilise	Single Use Only	
Lot Number	For <i>in vitro</i> Diagnostic Testing Only	Authorised Representative	Date of Manufacture	Manufactured By	

IMPORTANCE OF BLOOD GLUCOSE MONITORING

The more you know about diabetes, the better you will be able to take care of yourself. A Doctor or Healthcare Professional will determine target ranges for blood glucose results and how often to test. Having most results within the target ranges shows how well a treatment plan is working to control glucose levels. Keeping most results within the target ranges helps slow or stop complications of diabetes.

NEVER change a treatment plan without consulting with a Doctor or Healthcare Professional.

Use of the TRUResult twist Blood Glucose Monitoring System in a manner not specified in this Owner's Booklet is not recommended and may affect your ability to determine true blood glucose levels.

The TRUResult twist System is an *in vitro* IVD (outside body) quantitative system that is used for self-testing and point-of-care testing of only human whole blood. The most accurate results come from using fresh whole blood taken from the fingertip or forearm (capillary) or from the vein (venous).

What you need to know when using the TRUResult twist System:

- **Read all product instructions for use before testing.**
- Use only TRUResult Test Strips and TRUResult Control Solution with TRUResult twist Meter.
- To help prevent false high results, wash hands before using the System to test blood, especially after handling fruit or other foods containing sugar.
- Perform Control Tests before performing a blood glucose test for the first time (see *Control Test*).
- Remove only one Test Strip at a time from vial when testing. Recap vial immediately after removing Test Strip.
- **NEVER** reuse Test Strips. **NEVER** wipe Test Strips with water, alcohol or any cleaner. **DO NOT** attempt to clean and re-use Test Strips. Reuse of Test Strips will cause inaccurate results.
- **NEVER** add a second drop of sample to Test Strip. Adding more sample to the Test Strip gives an error message.
- Venous whole blood collected into sodium or lithium heparin blood collection tubes may be used for testing by Healthcare Professionals. Use of EDTA blood collection tubes is not recommended and may cause low results. Mix tube contents gently before using.

IMPORTANT HEALTH and SAFETY INFORMATION:

The TRUeResult twist Blood Glucose Monitoring System is for one person use **ONLY. DO NOT** share your Meter or your Lancing Device with anyone, including family members. **DO NOT** use on more than one person. **ALL** parts of the TRUeResult twist Blood Glucose Monitoring System could carry blood-borne pathogens after use, even after cleaning and disinfection.^{2,3}

For cleaning and disinfecting the Meter, see *Care, Cleaning/Disinfecting*. For cleaning and disinfecting the lancing device, see the lancing device's Instructions for Use.

We suggest cleaning the Meter when visibly dirty or if blood is on the Meter. Wash your hands thoroughly with soap and warm water after handling the Meter, lancing device, or Test Strips as contact with blood presents an infection risk.

Reuse of devices labeled for single-use may result in product contamination and patient infection.

- **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):⁴
 - ~ shock
 - ~ severe hypotension
 - ~ severe dehydration
 - ~ hyperglycaemia with hyperosmolarity, with or without ketosis.
- Do not use the TRUResult twist for the diagnosis of diabetes or for testing blood glucose in neonates (newborns).
- Do not use TRUResult twist System during a xylose absorption test. This may falsely raise glucose results.⁵ Please check with your Doctor before using TRUResult twist.

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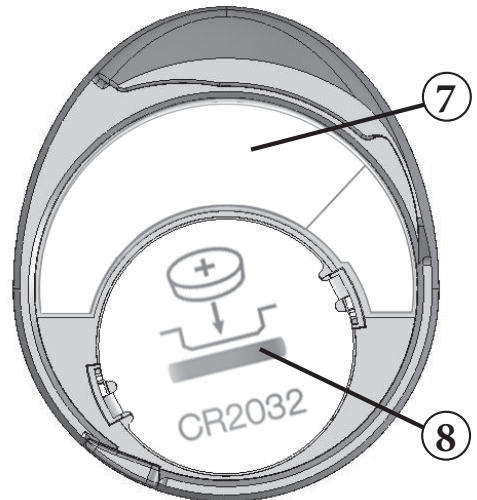
KNOW THE SYSTEM

Meter

Top of Meter

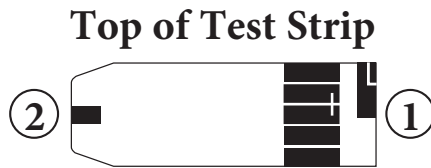


Bottom of Meter



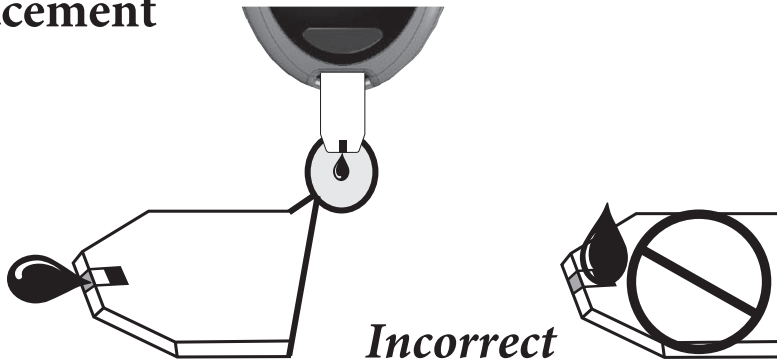
- ① **Set Button** - Turn Meter on for Memory, view/scroll results in Memory, mark result as Alternate Site.
- ② **Display** - Shows test results, messages, user prompts, other information.
- ③ **Drop Symbol** - Apply blood or Control Solution.
- ④ **Units of Measure**
(Note: Factory set, cannot be changed by user.)
- ⑤ **Strip Release Button** - Releases Test Strip after testing.
- ⑥ **Test Port** - Insert TRUEresult Test Strip here.
- ⑦ **Meter Label** - Contains serial number of Meter. Identifies Meter when calling for assistance.
- ⑧ **Battery** - Use one non-rechargeable 3V lithium battery (#CR2032), positive (“+”) side up (see *Changing Battery*).

Test Strip



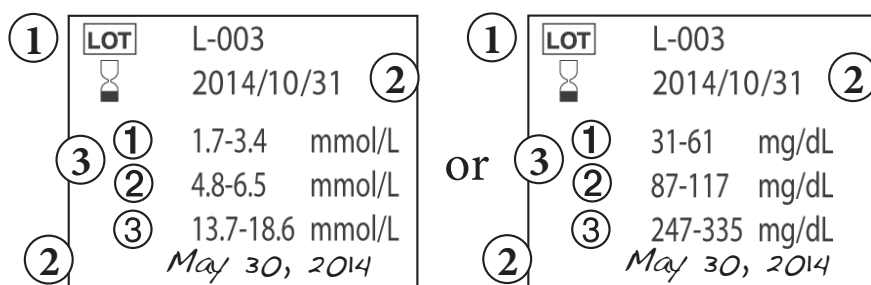
- ① **Contact End** - Insert into Test Port with blocks (contacts) facing up.
- ② **Sample Tip** - Touch to top of sample (fresh, capillary or venous blood or Control Solution) *after* inserting Contact End into Meter.



Sample Placement



- Do not touch Sample Tip to drop of sample unless Contact End is inserted into Meter.
- Do not apply blood or Control Solution to top of Test Strip.
- Do not smear or scrape drop with Test Strip.
- Do not apply more sample to the Test Strip after testing begins.
- Do not insert Sample Tip with sample into Meter for testing. May damage Meter.

Test Strip Vial Label



- ① **Lot Number (**LOT**)** - Used for identification when calling for assistance.
- ② **Use By Dates ()** - Write date first opened on vial label. Discard vial and unused Test Strips if either 4 months after first opening or date printed next to  on vial label has passed , whichever comes first.

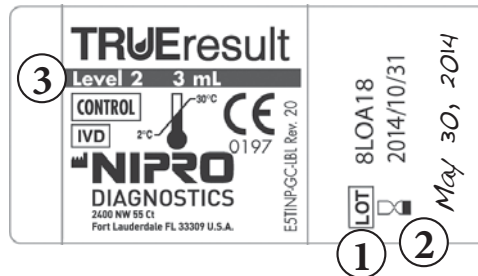




Use of Test Strips or Control Solution past the Use By Dates may give incorrect test results. Discard out-of-date products and test with new products.

- ③ **Control Test Range** - Range of numbers in which Control Test result must fall to assure System is working properly.

Control Solution **CONTROL**

Control Solution Bottle Label



- ① **Lot Number (**LOT**)** - Used for identification when calling for assistance.
- ② **Use By Dates ()** - Write date first opened on bottle label. Discard bottle if either 3 months after first opening or date printed next to  on bottle label has passed, whichever comes first.
- ③ **Control Solution Level (1, 2 or 3)** - Testing at least 2 levels of Control Solution is recommended. Call the number on the cover of this Booklet for information on how to obtain different levels of Control Solution.

Attach / Remove TRUEresult twist Meter to TRUEresult Test Strip Vial

The TRUEresult twist Meter is made to attach to the top of the TRUEresult Test Strip vial cap.

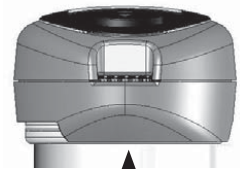
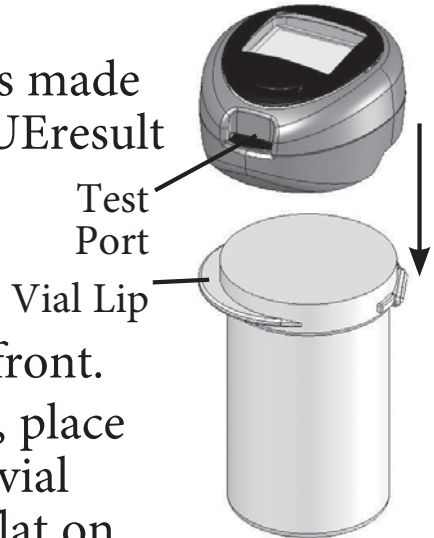
To attach:

1. Set Test Strip vial on flat surface with vial lip facing front.
2. With Test Port facing right, place bottom of Meter firmly on vial top. Meter must be seated flat on top of vial cap.
3. Holding the vial, twist the Meter 1/4 turn clockwise. The Test Port area on the Meter should cover the vial lip if attached properly.
4. To open the vial, lift up on the Meter under the Test Port.

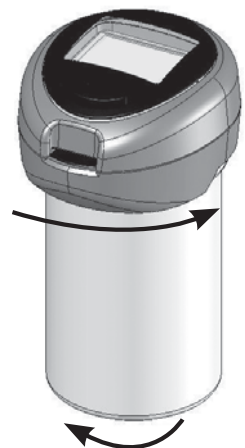
To remove:

1. Holding the vial, twist the Meter 1/4 turn counterclockwise.
2. Lift off Meter from vial top.

The Meter may also be used for testing without attaching to the vial.



Lift Up To
Open



GETTING STARTED

The Meter turns on when a Test Strip is inserted into the Test Port or when Set Button is pressed and released (see *Memory*). Meter turns off when the Test Strip is released from the Meter, Set Button is pressed and held for 20 seconds, or after 2 minutes of non-use.

Always check your supplies before using.

- Check Meter for damage (cracked Display, missing buttons, etc.). If damage is seen, do not use Meter. Call for assistance.
- Check Test Strip vial for damage (cracked vial, broken vial, etc.). Discard damaged vial and all contents (Test Strips) and use a new vial of Test Strips for testing.
- Write date first opened on Test Strip vial. Check Use By Dates (written and printed) before using any Test Strips from the vial. Do not use if 4 months after first opening (written date) or if printed Use By Date has passed.
- Check Control Solution bottle for any leaks or broken cap. Discard bottle and open a new one for testing.
- Write date first opened on Control Solution bottle label. Check Use By Dates (written and printed) before using. Do not use if 3 months after first opening (written date) or if printed Use By Date has passed.

Quality Control Testing

To assure you are getting accurate and reliable results, TRUEresult twist offers two kinds of quality control tests. These tests let you know that your TRUEresult twist System is working properly and your testing technique is good.

Automatic Self-Test

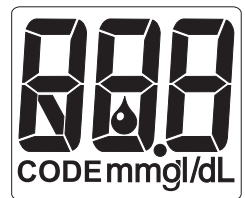
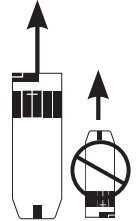
An Automatic Self-Test ensures that the Meter is working correctly.

1. Wash hands and dry thoroughly.
2. Remove one Test Strip from the Test Strip vial and insert Test Strip into the Meter.
3. Meter turns on. The full Display appears and is replaced by the blinking Drop Symbol. The Meter is working correctly and is ready to perform a Control or blood test.

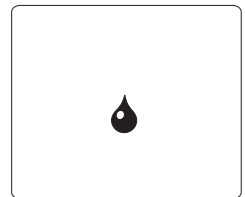
Do not use Meter if:

- The full Display does not appear (segments are missing),
- The blinking Drop Symbol does not appear, or
- An error message appears in the Display.

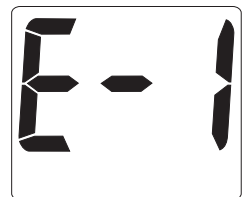
See *Troubleshooting* or call for assistance (see cover of this Booklet for phone number).



Full Display



Drop Symbol



Control Test

The Control Test checks that the System is working correctly and testing technique is good. Use **ONLY** TRUEresult Control Solution to perform Control Tests. Perform Control Tests:

- For practice before using the System for the first time,
- When opening a new vial of Test Strips,
- Occasionally as a vial of Test Strips is used,
- If a Test Strip vial has been left opened or left in extreme heat, cold, or humidity,
- Whenever a check on performance of the System is needed,
- If results seem unusually high or low,
- If Meter damage is suspected (Meter was dropped, crushed, wet, etc.).

Performing Control Tests with more than one level of Control Solution is recommended to ensure that the System is working properly. Three levels of TRUEresult Control Solution are available. Contact place of purchase or use the number on the cover of this Booklet for more information on how to obtain different levels of Control Solution.



*Ranges printed on Test Strip vial label are for Control Test results only and **are not** suggested levels for your blood glucose. Do not drink Control Solution.*

How to Test Control Solution

Use **ONLY** TRUEresult Control Solution with the TRUEresult twist Meter.

1. Check supplies. See *Getting Started*.
2. Allow Control Solution, vial of Test Strips and Meter to adjust to room temperature (20°C-25°C).

Note: *Running a Control Test at temperatures outside the range listed above may cause Control Solution to read as a blood test.*

3. Wash hands. Dry thoroughly.
4. Gently swirl or invert Control Solution bottle to mix. **DO NOT SHAKE!**
5. Remove one Test Strip from vial. Close Test Strip vial immediately. Use Test Strip quickly after removal from vial.

Note: *If Test Strip has been out of the vial too long before testing, an error message appears upon insertion of the Test Strip into the Meter. Release and discard old Test Strip. Use new Test Strip for testing.*

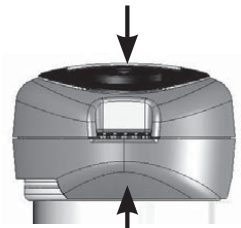
6. Insert Test Strip into Meter. Meter turns on and shows blinking Drop Symbol. Do not remove Test Strip.

LOT	8LOA18
	2014/10/31

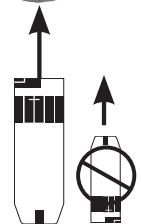
LOT	L-003
	2014/10/31
①	1.7-3.4 mmol/L
②	4.8-6.5 mmol/L
③	13.7-18.6 mmol/L
<i>May 30, 2014</i>	

LOT	L-003
	2014/10/31
①	31-61 mg/dL
②	87-117 mg/dL
③	247-335 mg/dL
<i>May 30, 2014</i>	

Press Down
To Close

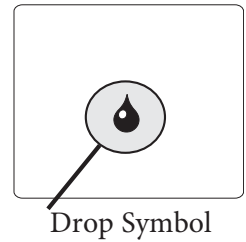


Lift Up
To Open



Contacts
face up

7. With cap removed, turn Control Solution bottle upside down. Gently squeeze one drop of Control Solution onto a clean tissue. Wipe off bottle tip with the tissue.



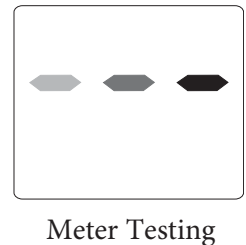
Note: *If Test Strip is removed before testing is finished, an error message appears. Release and discard old Test Strip. Use new Test Strip for testing.*

8. Gently squeeze a drop of Control Solution onto a small piece of unused aluminum foil or clear plastic wrap. Discard foil or plastic wrap after use.



Note: *Do not put drop on top of the Test Strip.*

9. With Test Strip still in Meter, touch Sample Tip to top of the drop of Control Solution. Allow drop to be drawn into Test Strip. Remove Test Strip from drop when dashes appear across Meter Display. Meter is testing.

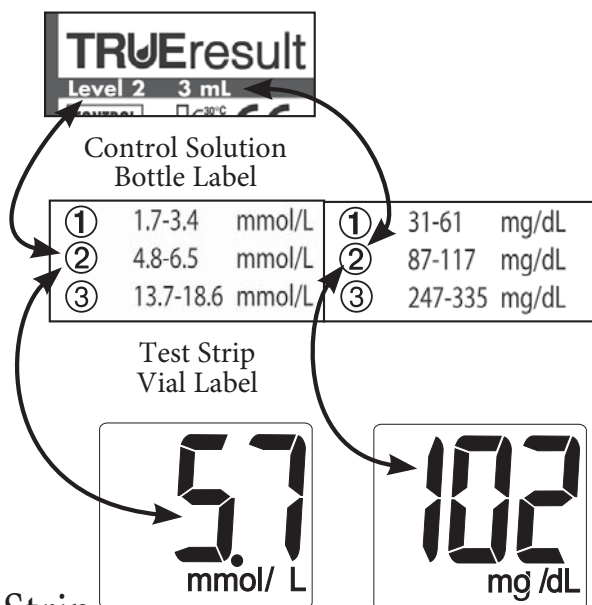


Note: *If Meter does not begin testing soon after drawing up sample, release and discard Test Strip. Repeat test with new Test Strip. If problem persists, see Troubleshooting.*

10. After testing is finished, the result appears in the Display.

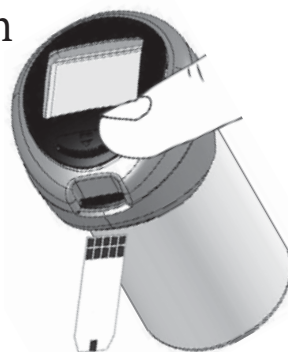
11. Compare result to Control Test Range printed on Test Strip vial label for Control Solution Level you are using.

If result is in range, System can be used for testing blood. If result does not fall within range, repeat test using a new Test Strip.



If result is still outside range after a second Control Test, System should not be used for testing blood. Call for assistance (see cover for phone number).

12. After result is shown, hold Meter with Test Strip pointing down. Press Strip Release Button to release and discard Test Strip in appropriate container. Meter turns off. Recap Control Solution bottle tightly.



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

TESTING YOUR BLOOD

Obtaining a Blood Sample

Refer to lancing device's Instructions for Use for detailed instructions.

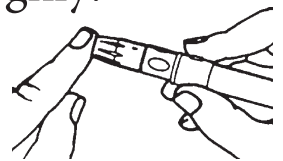


The lancing device is for single patient use ONLY. For cleaning/disinfecting your lancing device see Lancing Device Care in the lancing device's Instructions for Use. Wash your hands thoroughly with soap and warm water after handling the Meter, lancing device, or Test Strips. Contact with blood presents an infection risk.

- **NEVER** share lancets or lancing device.
- Lancets are for single use only. Do not reuse lancets.
- To help prevent false high results, wash hands before using the System to test blood, especially after handling fruit or other foods containing sugar.

From Fingertip

1. Prepare fingertip by washing hands in warm, soapy water. Rinse well. Dry thoroughly.
2. Place end of lancing device equipped with lancet against tip of finger. Lance fingertip.
3. Set lancing device aside. To help blood drop form, lower hand to waist level, gently massage finger from palm to fingertip. Allow blood drop to form before attempting to apply to Test Strip.
4. Recap and remove used lancet from lancing device. Discard used lancet into appropriate container.



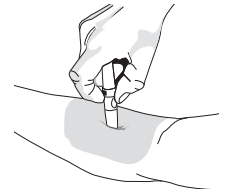
Note: *Treat used Test Strips and lancets as a biological risk. Dispose used Test Strips and lancets in approved container.*



From Forearm

Note: *Some lancing devices include a special end cap for alternate site testing. Check lancing device's Instructions for Use.*

1. Select area to be lanced. Wash with soap and warm water, rinse and dry thoroughly.
2. Rub area vigorously or apply a warm dry compress to increase blood flow.
3. Place end of lancing device equipped with lancet firmly against forearm. Press trigger button. Apply firm pressure on lancing device for 10 seconds. Allow blood drop to form before attempting to apply to the Test Strip.
4. Recap and remove lancet from lancing device. Discard used lancet into appropriate container.

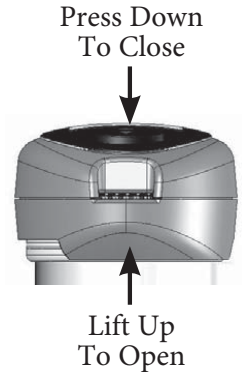


Important Notes Regarding Forearm Testing⁶

- Check with your Doctor or Healthcare Professional to see if forearm testing is right for you.
- Results from forearm are not always the same as results from fingertip.
- Use fingertip instead of forearm for more accurate results:
 - Within 2 hours of eating, exercise, or taking insulin,
 - If your blood sugar may be rising or falling rapidly or your routine results are often fluctuating,
 - If you are ill or under stress,
 - If your forearm test results do not match how you feel,
 - If your blood sugar may be low or high,
 - If you do not notice symptoms when blood sugar is low or high.

How to Test Blood Glucose

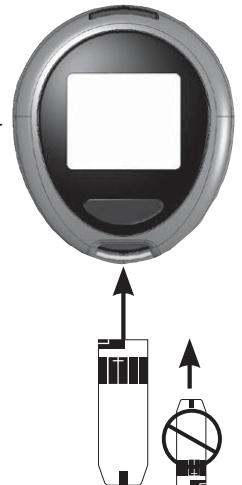
1. Check supplies. See *Getting Started*.
2. Wash hands (and forearm for alternate site testing). Rinse well and dry thoroughly.
3. Remove one Test Strip from vial. Close vial immediately. Use Test Strips quickly after removal from vial.
4. With Meter off, insert Test Strip Contact End (blocks facing up) into Meter. Meter turns on. Keep Test Strip in Meter until testing is finished.



---Alternate Site Testing---

To mark test as alternate site (forearm) result, press Set Button. Result is marked as alternate site in Memory.

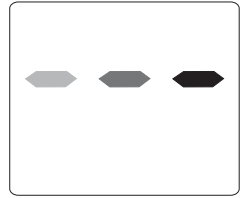
- Note:** *If Test Strip has been out of the vial too long before testing, an error message appears upon insertion of the Test Strip into the Meter. Release and discard Test Strip. Use new Test Strip for testing.*
5. Lance fingertip or forearm. Allow drop to form. (see *Obtaining a Blood Sample*).



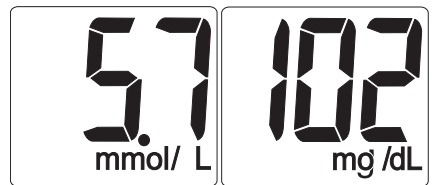
6. With Test Strip still in Meter, touch Sample Tip to top of blood drop and allow blood to be drawn into Test Strip. Remove from blood drop immediately after the dashes appear across Meter Display.



Note: *If Meter does not begin testing soon after touching blood drop to Sample Tip, discard Test Strip. Repeat test with new Test Strip and new blood drop. If problem persists, see Troubleshooting.*



7. After the test is finished, result is displayed. Record result in log book.



8. Hold Meter with Test Strip pointing down. Press Strip Release Button to discard Test Strip in the appropriate container.



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

9. Meter turns off. Result is stored in Memory.

Note: *Treat used Test Strips and lancets as a biological risk. Dispose used Test Strips and lancets in approved container.*



Unusual Blood Glucose Test Results

If you have symptoms of low or high glucose, check your blood glucose immediately. If your result does not match the way you feel, repeat test. If your results still do not match the way you feel, call your Doctor or Healthcare Professional.

- Low blood glucose (hypoglycaemia) symptoms may be trembling, sweating, intense hunger, nervousness, weakness, and trouble speaking.
- High blood glucose (hyperglycaemia) symptoms may be intense thirst, a need to urinate often, a dry mouth, vomiting and headache.

Meter reads blood glucose levels from 1.1-33.3 mmol/L (20-600 mg/dL).

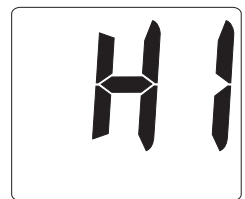
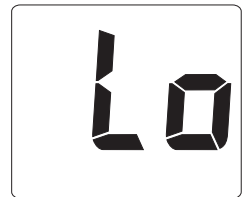


If blood test result is less than 1.1 mmol/L (20 mg/dL), “Lo” appears in Meter Display.

If blood test result is greater than 33.3 mmol/L (600 mg/dL), “HI” appears in Meter Display.

ALWAYS repeat test to confirm Low (“Lo”) and High (“HI”) results. If results still display “Lo” or “HI”, call your Doctor or Healthcare Professional *immediately*.

Note: “Lo” results are included in the Average as 1.1 mmol/L (20 mg/dL). “HI” results are included as 33.3 mmol/L (600 mg/dL).



TRUResult twist System and Laboratory Testing

The most accurate results come from using fresh, capillary whole blood from the fingertip or forearm. Venous whole blood collected into sodium or lithium heparin blood collection tubes may be used for testing by Healthcare Professionals. Use of EDTA blood collection tubes is not recommended and may cause low results. Mix tube contents gently before using.

When comparing results between TRUResult twist and a laboratory system, perform a TRUResult twist blood test within 30 minutes of laboratory test. Diabetes experts have suggested that 95% of glucose meter results should agree within 0.83 mmol/L (15 mg/dL) of a laboratory method when the glucose concentration is less than 5.55 mmol/L (100 mg/dL), and within 15% of a laboratory method when the glucose concentration is 5.55 mmol/L (100 mg/dL) or higher.⁷ If the patient has recently eaten, fingerstick results from the TRUResult twist System can be up to 3.9 mmol/L (70 mg/dL) higher than venous laboratory results.⁸

MEMORY

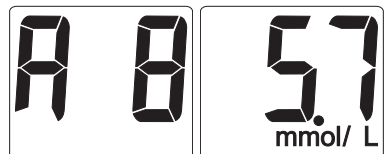
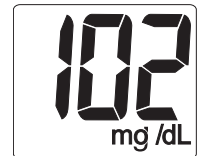
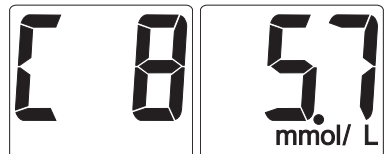
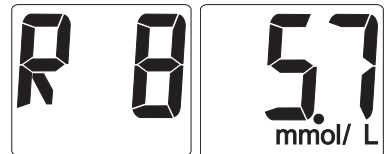
View Results

Memory holds 99 total blood and Control Test results, which are displayed from most recent to oldest. When Memory is full, the oldest result is replaced with the newest result.

1. Press and release Set Button. Meter turns on to view results in Memory. The last result is shown first.

2. Press and release Set Button again to view most recent result in Memory. Continue to press and release Set Button to scroll through results. Holding the Set Button scrolls through the results quickly. If there are no results in Memory, dashes appear across the Display.

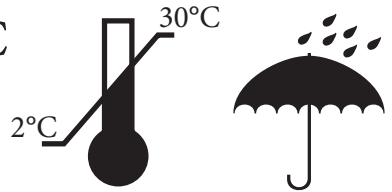
- Blood Test results are shown as “R 1” followed by the result, “R 2” followed by the result, and so on (R3, result; R4, result; ...).
- Control Test results are shown as “C 1” followed by the result, “C 2” followed by the result, and so on (C3, result; C4, result; ...).
- Alternate site Blood Test results are shown as “A 1” followed by the result, “A 2” followed by the result, and so on (A3, result; A4, result; ...).



CARE, CLEANING/DISINFECTING

Caring for TRUEresult twist

- Store System (Meter, Control Solution, Test Strips) in Carrying Case to protect from liquids, dust and dirt.
- Store in a dry place at 2°C-30°C (room temperature).
- **DO NOT REFRIGERATE OR FREEZE.**



Meter Care

- Do not keep meter in an area where it may be crushed (i.e. back pocket, drawer, bottom of bag, etc.).


Cleaning removes blood and soil, disinfecting removes infectious agents.

To Clean the Meter:

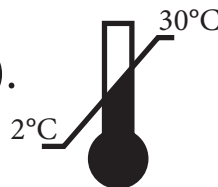
- Clean the Meter when visibly dirty or if blood is on the Meter.
- Never put Meter in liquids or allow any liquids to enter the Test Port.
- Wipe Meter with a clean, lint-free cloth dampened with 70% Isopropyl alcohol.
- Let Meter air dry thoroughly before using to test.
- Do not use bleach to clean the Meter.

For assistance call the phone number on the cover of the Owner's Booklet.

Control Solution Care


- Write date opened on Control Solution label. Discard if either 3 months after first opening or after date printed next to  on bottle label has passed, whichever comes first.
- Store at 2°C-30°C (room temperature).

**DO NOT REFRIGERATE
OR FREEZE.**

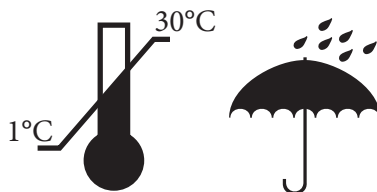


- After use, wipe bottle tip clean and close tightly.

Test Strip Care

- Store Test Strips in original vial only. Do not transfer old Test Strips to new vial or store Test Strips outside of vial.
- Write date opened on Test Strip vial. Discard unused Test Strips from vial if either 4 months after first opening or after date printed next to  on vial label has passed, whichever comes first. Use of Test Strips past either date may give incorrect results.
- Close vial immediately after removing Test Strip.
- Store in a dry place below 30°C (room temperature).

**DO NOT REFRIGERATE
OR FREEZE.**

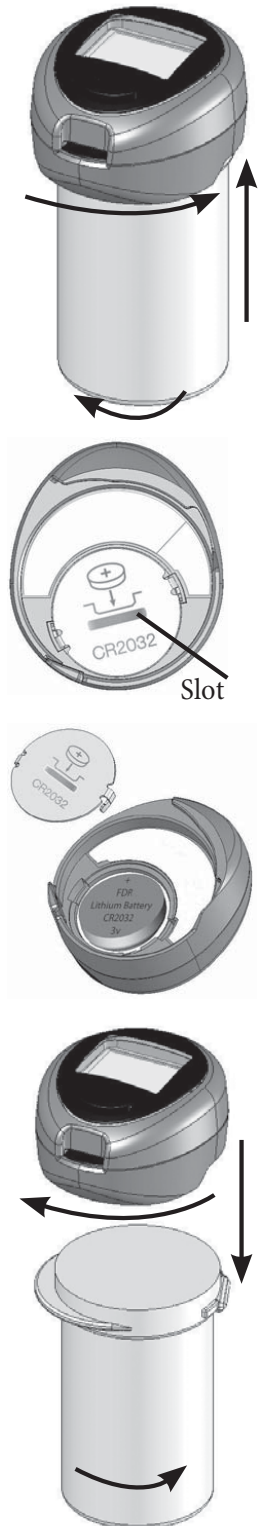


- Do not reuse Test Strip. **NEVER** wipe Test Strips with water, alcohol or any cleaner. **DO NOT** attempt to clean and re-use Test Strips. Reuse of Test Strips will cause inaccurate results.
- Do not bend, cut or alter Test Strips in any way.

Changing Battery

If “Lb” or “db” appears in Display, change battery. To replace battery:

1. Remove Meter from vial (see *Attach/Remove TRUEresult twist Meter to TRUEresult Test Strip Vial*).
2. Turn Meter over to show Meter label and Battery Cover.
3. Place edge of a coin in slot in center of Battery Cover. Twist coin slightly counterclockwise until Battery Cover is loose. Remove coin.
4. Holding the Meter over your other hand, turn the Meter over. Battery Cover and battery drops out.
5. Turn Meter back over. Replace battery with new 3V non-rechargeable lithium battery (#CR2032), positive (“+”) side facing up.
6. Replace Battery Cover, with slot facing up and metal tips in notches. Firmly push Battery Cover down using edge of coin. Turn coin slightly clockwise to close.
7. Re-attach Meter to vial (see *Attach/Remove TRUEresult twist Meter to TRUEresult Test Strip Vial*).



8. Press Set Button to turn Meter on. If Meter does not turn on, check that battery was installed properly with “ + ” facing up. If not, remove and reinsert battery and try again. Call for assistance if problem persists.



Batteries might 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 specific regulations.

TROUBLESHOOTING

1) After inserting Test Strip, Meter does not turn on.

Reason	Action
Test Strip inserted upside down or backwards	Remove Test Strip. Re-insert correctly.
Test Strip not fully inserted	Remove Test Strip. Re-insert Test Strip fully into Meter.
Test Strip Error	Repeat with new Test Strip.
Dead or no battery	Replace battery.
Battery in backwards	Battery positive (“+”) side must face up.
Meter Error	Call for assistance.

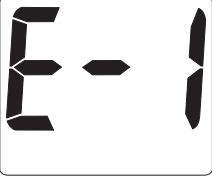
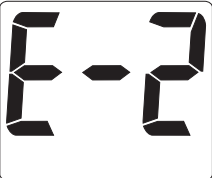
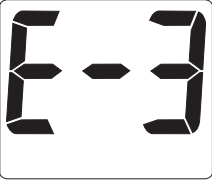
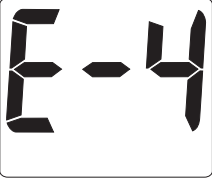
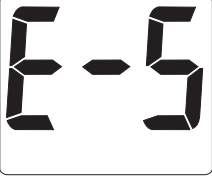
2) After applying sample, test does not start/ Meter does not begin testing.

Reason	Action
Sample drop too small	Repeat test with new Test Strip and larger drop.
Sample applied after two minute shut-off	Repeat test with new Test Strip. Apply sample within 2 minutes of inserting Test Strip.
Problem with Test Strip	Repeat with new Test Strip.
Problem with Meter	Call for assistance.

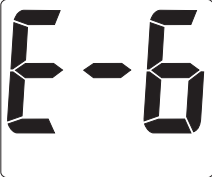
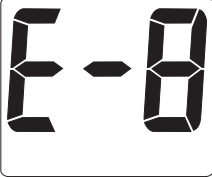




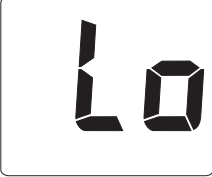


For assistance, see cover for phone number.

Messages

<u>Display</u>	<u>Reason</u>	<u>Action</u>
	Temperature Error • Too Cold/ Too Hot	Move Meter and Test Strips to area between 10°C-40°C; wait 10 minutes for System to reach room temperature before testing.
	Sample Not Detected or Using Wrong Test Strip	Retest with new Test Strip and larger sample.
	Used Test Strip, Test Strip Outside of Vial too Long	Repeat with new Test Strip. Make sure sample is touched to edge of Test Strip (not top). If error persists, call for assistance.
	Meter Error	Call for assistance.
	Test Strip Error, Very high blood glucose result (higher than 33.3 mmol/L (600 mg/dL))	Retest with new Test Strip. If error persists, call for assistance. If you have symptoms such as fatigue, excess urination, thirst, or blurry vision follow your healthcare professional's advice for high blood glucose.

Messages *(continued)*

<u>Display</u>	<u>Reason</u>	<u>Action</u>
	Test Strip Removed During Test	Retest with new Test Strip. Make sure result is displayed <u>before</u> removing Test Strip.
	Memory Error	Result was not recorded in Memory. Retest with a new Test Strip. If error persists, call for assistance.
	Low Battery	About 50 tests can be done before battery dies. Change the battery.
	Dead Battery	Battery Symbol appears before Meter turns off. Change the battery.
	Out of Range -High Results > 33.3 mmol/L (600 mg/dL)	 Retest with new Test Strip. If result is still “HI” (High) or “Lo” (Low) contact Doctor <i>immediately.</i>
	-Low Results < 1.1 mmol/L (20 mg/dL)	

If error message still appears, any other error message appears, or troubleshooting does not solve the problem, call for assistance.

Performance Characteristics⁶

Precision: Precision describes the variation between results. There are two types of precision results measured, repeatability (using blood) and intermediate precision (using control solution).

Repeatability: N=100

Mean (mmol/L)	3.5	5.2	8.7	12.6	20.2
Mean (mg/dL)	63	94	157	227	363
SD (mmol/L)	0.11	0.13	0.22	0.33	0.57
SD (mg/dL)	2.0	2.4	4.0	6.0	10.3
%CV	3.1	2.5	2.6	2.6	2.8

Intermediate Precision: N=100

Mean (mmol/L)	3.2	7.6	19.6
Mean (mg/dL)	57	137	352
SD (mmol/L)	0.09	0.21	0.67
SD (mg/dL)	1.6	3.7	12.1
%CV	2.8	2.7	3.4

System Accuracy: Diabetes experts have suggested that 95% of glucose meter results should agree within ± 0.83 mmol/L (15 mg/dL) of the medical laboratory values at glucose concentrations below 5.55 mmol/L (100 mg/dL) and within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L (100 mg/dL). The tables below show how often healthcare professionals (HCP) and users achieve these goals using capillary fingertip and forearm blood samples when glucose results are not fluctuating. The laboratory reference instrument is the Yellow Springs Instrument (YSI) Model 2300.

For Healthcare Professionals

98.8% of TRUEresult twist fingertip values performed by healthcare professionals (HCP) fell within 0.83 mmol/L (15 mg/dL) of the YSI results at glucose levels < 5.55 mmol/L (100 mg/dL) and within 15% at glucose levels \geq 5.55 mmol/L (100 mg/dL).

Fingertip Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L (100 mg/dL)

Within \pm 0.28 mmol/L (5 mg/dL)	Within \pm 0.56 mmol/L (10 mg/dL)	Within \pm 0.83 mmol/L (15 mg/dL)
53/180 (29%)	126/180 (70%)	176/180 (98%)

Fingertip Samples (HCP vs. YSI) for glucose concentrations \geq 5.55 mmol/L (100 mg/dL)

Within \pm 5%	Within \pm 10%	Within \pm 15%
255/420 (61%)	384/420 (91%)	417/420 (99%)

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L (20-600 mg/dL)

Within \pm 0.83 mmol/L (15 mg/dL) or \pm 15%
593/600 (98.8%)

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

99% of TRUEresult twist forearm values performed by healthcare professionals (HCP) fell within 0.83 mmol/L (15 mg/dL) of the YSI results at glucose levels < 5.55 mmol/L (100 mg/dL) and within 15% at glucose levels \geq 5.55 mmol/L (100 mg/dL).

Forearm Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L (100 mg/dL)

Within \pm 0.28 mmol/L (5 mg/dL)	Within \pm 0.56 mmol/L (10 mg/dL)	Within \pm 0.83 mmol/L (15 mg/dL)
14/28 (50%)	24/28 (86%)	28/28 (100%)

Forearm Samples (HCP vs. YSI) for glucose concentrations \geq 5.55 mmol/L (100 mg/dL)

Within \pm 5%	Within \pm 10%	Within \pm 15%
42/72 (58%)	67/72 (93%)	71/72 (99%)

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L (20-600 mg/dL)

Within \pm 0.83 mmol/L (15 mg/dL) or \pm 15%
99/100 (99%)

Parkes Error Grid: 100% of individual forearm glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

Venous Blood

96.6% of TRUEresult twist venous values performed by healthcare professionals (HCP) fell within 0.83 mmol/L (15 mg/dL) of the YSI results at glucose levels < 5.55 mmol/L (100 mg/dL) and within 15% at glucose levels \geq 5.55 mmol/L (100 mg/dL).

Venous Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L (100 mg/dL)

Within \pm 0.28 mmol/L (5 mg/dL)	Within \pm 0.56 mmol/L (10 mg/dL)	Within \pm 0.83 mmol/L (15 mg/dL)
15/68 (22%)	36/68 (53%)	62/68 (91%)

Venous Samples (HCP vs. YSI) for glucose concentrations \geq 5.55 mmol/L (100 mg/dL)

Within \pm 5%	Within \pm 10%	Within \pm 15%
130/222 (59%)	193/222 (87%)	218/222 (98%)

Venous Samples for glucose concentrations between 1.1-33.3 mmol/L (20-600 mg/dL)

Within \pm 0.83 mmol/L (15 mg/dL) or \pm 15%
280/290 (96.6%)

Parkes Error Grid: 99% of individual venous glucose measured values performed by healthcare professionals fell within Zone A and 1% within Zone B of the Parkes Error Grid (PEG).

For Consumers

100% of TRUEresult twist fingertip values performed by users fell within 0.83 mmol/L (15 mg/dL) of the YSI results at glucose levels < 5.55 mmol/L (100 mg/dL) and within 15% at glucose levels \geq 5.55 mmol/L (100 mg/dL).

Fingertip Samples (User vs. YSI) for glucose concentrations < 5.55 mmol/L (100 mg/dL)

Within \pm 0.28 mmol/L (5 mg/dL)	Within \pm 0.56 mmol/L (10 mg/dL)	Within \pm 0.83 mmol/L (15 mg/dL)
6/23 (26%)	19/23 (83%)	23/23 (100%)

Fingertip Samples (User vs. YSI) for glucose concentrations \geq 5.55 mmol/L (100 mg/dL)

Within \pm 5%	Within \pm 10%	Within \pm 15%
36/77 (47%)	69/77 (90%)	77/77 (100%)

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L (20-600 mg/dL)

Within \pm 0.83 mmol/L (15 mg/dL) or \pm 15%
100/100 (100%)

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by users fell within Zone A of the Parkes Error Grid (PEG).

99% of TRUE result twist forearm values performed by users fell within 0.83 mmol/L (15 mg/dL) of the YSI results at glucose levels < 5.55 mmol/L (100 mg/dL) and within 15% at glucose levels ≥ 5.55 mmol/L (100 mg/dL).

Forearm Samples (User vs. YSI) for glucose concentrations < 5.55 mmol/L (100 mg/dL)

Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83 mmol/L (15 mg/dL)
15/28 (54%)	23/28 (82%)	28/28 (100%)

Forearm Samples (User vs. YSI) for glucose concentrations ≥ 5.55 mmol/L (100 mg/dL)

Within ± 5%	Within ± 10%	Within ± 15%
42/72 (58%)	65/72 (90%)	71/72 (99%)

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L (20-600 mg/dL)

Within ± 0.83 mmol/L (15 mg/dL) or ± 15%
99/100 (99%)

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by users fell within Zone A of the Parkes Error Grid (PEG).

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

SYSTEM SPECIFICATIONS

Result Range: 1.1 - 33.3 mmol/L (20-600 mg/dL)

Sample Size: Minimum 0.5 microlitre (0.5 μ L)

Sample: Fresh capillary whole blood, venous blood drawn in sodium or lithium heparin blood collection tubes, or Control Solution.

Test Time: Results in as little as 4 seconds

Result Value: Plasma equivalent values

Assay Method: Electrochemical

Power Supply: One 3V Lithium Battery
#CR2032 (non-rechargeable)

Battery Life: Approximately 1,500 tests or 2 years

Automatic shut-off: After two minutes of non-use

Weight: 17 grams

Size: 4.3 cm x 3.7 cm 2.3 cm

Memory Size: 99 glucose results

Operating Range (Meter & Test Strips):

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

Temperature: 10°C-40°C

Haematocrit: 20-55%

Altitude: 3094 metres

Note: *Use within specified environmental conditions only.*

Chemical Composition

TRUEresult Test Strips: Glucose dehydrogenase-FAD (*Aspergillus sp.*), Mediators, Buffers and Stabilisers.

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

EMC Safety Information

This meter meets the electromagnetic immunity requirements as per ISO 15197:2013 Annex A. It meets the electromagnetic emissions requirements as per EN 61326 series. Interference from the meter to other electronically driven equipment is not anticipated. The electromagnetic environment should be evaluated prior to operation of the device.

Do not use the meter in a very dry environment, especially one in which synthetic materials are present. Do not use the meter close to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

REFERENCES

1. Joslin Diabetes Center. *Goals for Blood Glucose Control* [Electronic Version]. Retrieved February 16, 2012 from <http://www.joslin.org/info/Goals-for-Blood-Glucose-Control.html>.
2. FDA Public Health Notification: *Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood Borne Pathogens: Initial Communication Update 11/29/2010* [Electronic Version]. Retrieved February 22, 2012 from <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.
3. CDC Clinical Reminder: *Use of Fingerstick Devices on More than one Person Poses Risk for Transmitting Bloodborne Pathogens* [Electronic Version]. Retrieved February 22, 2012 from <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>.
4. Atkin, S.H., et. al. *Fingerstick Glucose Determination in Shock*. *Annals of Internal Medicine*, 114:1020-1024 (1991).
5. Data on file.
6. U.S. Food and Drug Administration. *Blood Glucose Meters, Getting the Most Out of Your Meter*. [Electronic Version]. Retrieved July 6, 2009: www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109371.htm.
7. International Organization for Standardization. *In vitro diagnostic test systems. Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus*. Reference number ISO 15197:2013 (E). Geneva: International Organization for Standardization; 2013.
8. Larsson-Cohn U: *Difference between capillary and venous blood glucose during oral glucose tolerance tests*. *Scand J Clin Lab Invest* 36:805-808, 1976.

