UltraTRAK™ ULTIMATE

SAMPLE POLICY AND PROCEDURES

The UltraTRAK ULTIMATE is intended for multi-patient use in a long term care setting. Please note that the following Sample Policy and Procedures is provided only as a model to help your facility establish its own policy and procedures. Your own policy may differ depending upon the existing procedures. Please consult with the Director of Nursing for further guidance.

Policy: Performing a Blood Glucose Test with the UltraTRAK ULTIMATE Meter

Patients requiring daily administration of insulin or oral hypoglycemic agents will have:

- Glucose levels monitored using the UltraTRAK ULTIMATE Blood Glucose Meter in accordance with a physician's orders. When no physician's order is available, a registered nurse should monitor at least weekly.
- Fasting serum blood glucose test performed as ordered by the physician.

Patients with diet-controlled diabetes mellitus will have:

- Glucose levels monitored using the UltraTRAK ULTIMATE Blood Glucose Meter in accordance with a physician's order. When no physician's order is available, a registered nurse should monitor at least monthly.
- Fasting serum blood glucose test performed as ordered by the physician.

Level of Responsibility: RN/LPN

Equipment Needed:

- UltraTRAK ULTIMATE Blood Glucose Meter
- UltraTRAK ULTIMATE Test Strips
- Safety Lancet
- Gloves
- Alcohol Wipe

Procedure: Consult manufacturer's instructions for additional information regarding the use of the UltraTRAK ULTIMATE Blood Glucose Meter.

1. Verify physician's order
2. Assemble equipment
3. Identify the patient
4. Explain procedure
5. Provide privacy
6. Wash hands
7. Put on non-sterile gloves.
8. Cleanse area that is to be punctured (side of fingertip) with an alcohol swab. Allow area to dry.

9. Obtain blood sample. Follow the manufacturer's instructions for preparing the lancet. Do not touch the sterile tip. Lightly hold lancet device against skin and lance the area. Obtain a blood sample (a hanging drop of blood). Following the puncture, immediately remove lancet from skin and dispose of it according to facility procedure.
10. Apply blood to test strip. Verify that the bottle of test strips has not expired and/or that the vial has not been opened for longer than 45 days. Discard the vial of test strips if it has expired an/or has been opened for more than 45 days.
11. Remove gloves.
12. Wash hands.

Aftercare:

- Clean the UltraTRAK ULTIMATE Blood Glucose Meter between patient tests.
- Return Blood Glucose Meter and Test Strip vial to the proper place.
- Dispose of lancet into a sharps (puncture resistant) container for soiled needles/syringes. Do not recap or reuse needle.
- Place used alcohol swab, test strip and gloves in infectious waste container.

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Policy: Quality Control Testing on UltraTRAK ULTIMATE Meter

Quality control testing using the UltraTRAK ULTIMATE Control Solution is required to check the performance of the UltraTRAK ULTIMATE Blood Glucose Monitoring System.
The UltraTRAK ULTIMATE Control Solution checks if the meter and test strips are working correctly as a system and if the system is being utilized correctly.

Perform a Control Solution Test:

- Before testing with the UltraTRAK ULTIMATE System for the first time.
- When you open a new bottle of test strips.
- Whenever you suspect the meter or test strips may not be functioning properly.
- If test results appear to be unusually high or low or are inconsistent with clinical symptoms.
- If the test strip vial has been left open or has been exposed to light or temperatures below above 86°F (30°C), or humidity levels above 85%
- To check your technique
- When the UltraTRAK ULTIMATE meter has been dropped or stored below 14°F (-10 °C) or above 140°F (60°C).

Important: Depending on different state regulations, control solution testing may be required on a daily basis. Please check with your local inspector's regulations or facility procedures.

Please note:

- UltraTRAK ULTIMATE Control Solution is not intended for human consumption. Do not drink.
- Only use with UltraTRAK ULTIMATE Blood Glucose Meter with Test Strips.
- Store the control solution between 66-77°F (20-25°C).
- Keep away from direct sunlight and heat. Do not freeze or refrigerate.
- Use before the expiration date printed on bottle.
- Use the control solution within 45 days of first opening. It is recommended that you write the date of opening on the control solution bottle label ("Date Opened") as a reminder to dispose of the opened solution after 45 days.
- Always replace the cap immediately after use.
- To avoid contamination never touch the tip of the bottle to the test strip.
- UltraTRAK ULTIMATE Control Solution is not a cleaning solution. Do not clean your meter with control solution.

Level of Responsibility: RN/LPN
Equipment Needed:

- UltraTRAK ULTIMATE Control Solution (High and Low levels)
- UltraTRAK ULTIMATE Test Strips
- UltraTRAK ULTIMATE Meter
- Record Sheet

Procedure: Consult manufacturer's instructions for additional information regarding the use of the UltraTRAK ULTIMATE Meter.

1. **Wash hands.**

2. **Insert the Test Strip.** Insert a test strip into the test slot to turn on the meter. Wait for the meter to display the test strip and blood drop symbols in the following sequence:

- "CHK" and strip symbol
- Strip symbol and flashing drop sign

3. **Enter QC Mode.** While the drop symbol is flashing, press the main button and you will see the "QC" appear, which means that the meter is in the "Control Solution Testing Mode". If you decide not to perform a control solution test, press the main button again and the "QC" sign will disappear.

4. **Obtain Control Solution.** Shake the control solution vial well. Remove the cap from the control solution bottle. Place cap on flat surface. Squeeze the vial, discard the first drop, and wipe off the dispenser tip to prevent contamination. Squeeze the vial again to get another drop and apply the drop to the top of the cap.

5. **Apply Control Solution.** While holding the meter, move the absorbent hole of the test strip to touch the drop of control solution. Once the confirmation window fills completely, the meter will begin counting down. To avoid contaminating the control solution with the content of the test strip, you have to place a drop of control solution on a clean surface.
***Do not directly apply control solution into a test strip.**

6. **Read and Compare Result.** After counting to 0, the test result of control solution is shown on the screen. Compare this result with the range printed on the test strip vial. It should fall within this range.

Out-of-range results

If test results fall outside the range printed on the test strip vial, check the section of "Problem in Operation" in trouble-shooting guide and repeat the test. If you continue to get out-of-range results, it means that the system may not be working properly. Do NOT test your blood. Please contact the Customer Care Line at 1.888.90.VERTEX.

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Policy: Maintaining the UltraTRAK ULTIMATE Meter

Level of Responsibility: RN/LPN/CNA

Cleaning: The UltraTRAK ULTIMATE should be cleaned and disinfected between each patient test.

Equipment Needed:

- Lint-free dampened cloth
- EPA registered germicidal or bleach wipes; must be approved for use in healthcare settings and for surface cleaning; must be effective against the Human Immunodeficiency Virus (HIV), the Hepatitis B Virus (HBV), and the Hepatitis C Virus (HCV)
- Isopropyl Alcohol pads; or a solution of soap and water

Please note that there are EPA registered products on the market that can both clean and disinfect the meter with one wipe. These can be used; however, if there is any visual traces of blood on the meter, two wipes must be used - one to clean the meter, and another to disinfect the meter as per the manufacturer's instructions.

Procedure: Consult the manufacturer's instructions for additional information regarding the use of disinfecting wipes.

1. Put on non-sterile gloves.

2. To clean the meter, take an alcohol pad or cleaning wipe and wipe down the body of the meter. Be careful not to allow any liquid inside the battery compartment, strip port, or screen.

3. To disinfect the meter, refer to the product label of the disinfectant wipes to determine how long the liquid from the wipes needs to be on the body of the meter for full disinfecting (also known as "contact time").

4. Take a pre-moistened disinfecting wipe and squeeze out any excess liquid in order to prevent damage to the meter. Wipe down the body of the meter, being careful not to allow any liquid to get inside the battery compartment, strip port, or screen.

5. According to CMS Tag F441, ensure that the meter has been both cleaned and disinfected between each use.

6. Inspect for any damage to the meter. If the meter is damaged, contact Vertex Diagnostics at 1.888.908.3783.

7. Remove gloves and wash hands.

Replacing the Battery

Each UltraTRAK ULTIMATE meter comes with two 1.5V AAA alkaline batteries. The meter will alert you when the power is getting low by displaying two different messages:

1. When the battery symbol appears on the display: the meter is functional and the result remains accurate, but it is time to change the battery.

2. With the battery symbol, low and E-b symbols on the displays: the battery can not provide enough power for a test. You must change the battery immediately.

Steps for Battery Replacement

1. Press the edge of the battery cover and lift it up to remove it.

2. Remove the old batteries and replace with two 1.5V AAA alkaline batteries.

3. Close the battery cover. If the batteries have been inserted correctly, you will hear a beep afterwards.

QUALITY CONTROL TESTING GUIDE

Please note that the procedures described in this guide may be used to contribute to the quality assurance program of the UltraTRAK ULTIMATE Blood Glucose Monitoring System.

Accuracy Study

Purpose

Performing an accuracy study helps establish how well a test system (test strip and meter) measurement agrees with the true value. The true value is determined by the use of laboratory-grade instrumentation. A true comparison of blood glucose values is a same sample analysis of blood glucose meter versus laboratory results.

Important: Accuracy studies are not necessarily designed to be conducted in your facility. All accuracy studies should be performed in a certified laboratory, with trained laboratory personnel utilizing the protocol described below. Should you have questions, please contact the Vertex Diagnostics Client Care team at 1.888.90.VERTEX.

Materials:

- UltraTRAK ULTIMATE Blood Glucose Meter
- UltraTRAK ULTIMATE Blood Glucose Test Strips (enough strips from one lot to complete the study; a minimum of 20 strips are needed)
- UltraTRAK ULTIMATE Control Solutions
- EDTA Capillary Blood Collection Tubes
- Phlebotomy Equipment
- Accuracy Study Data Record
- Laboratory Grade Instrument (plasma reference method)

Preparation:

1. Verify that the UltraTRAK ULTIMATE meter has been properly cleaned and maintained.
2. Match the code number on the meter to the code number on the vial of UltraTRAK ULTIMATE Test Strips.
3. Verify that the UltraTRAK ULTIMATE Test Strips have not expired and that the vials are unopened.
4. Examine the opened test strips and discard any discolored or damaged test strips.
5. Use the UltraTRAK ULTIMATE Control Solutions to check the system.
6. Verify that the control solutions have not expired.
7. Perform the test in triplicate.
8. All readings should fall within the stated range.

Procedure

1. Collect capillary blood samples in EDTA tubes from approximately 10-20 diabetic volunteers.

2. Promptly test each blood sample in duplicate using the UltraTRAK ULTIMATE Blood Glucose Monitoring System. Record the results on the Accuracy Study Data Record. Test the sample on the same meter using the same lot of test strips.

3. Use a laboratory glucose analyzer to test each sample in duplicate. Record the results on the Accuracy Study Data Record.

Please note: It is imperative that as little time as possible passes between the test strip/meter testing and the laboratory analysis, as the glucose level in the samples will vary over time. If the meter test is not done within 10 minutes of the laboratory test, it will result in discrepancies in the readings as blood glucose can change quickly.

Data Analysis

1. Calculate the mean for each row of duplicate readings for both the test strip/meter and laboratory analyzer methods.

2. Calculate the upper control limit by multiplying the values in the laboratory mean column by 1.15. Record the values on the Accuracy Study Data Record.

3. Calculate the lower control limit by multiplying the values in the laboratory mean column by 0.85. Record the values on the Accuracy Study Data Record.

4. Determine whether the mean values in the test strip/meter column fall within the upper and lower control limits of the laboratory mean.

UltraTRAK™

MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY INFORMATION:

Product Name: UltraTRAK ULTIMATE Blood Glucose Control Solution
Common Name: Glucose Control Solution for use with UltraTRAK ULTIMATE Blood Glucose Meter
Product Code: UTUBGS (High and Low levels)
NDC: TBD

2. COMPOSITION / INFORMATION ON INGREDIENTS:

Substance Name: Not Applicable (N/A)
CAS#: N/A
SARA 313: N/A

3. HAZARDS IDENTIFICATION:

Eye

Effect: Irritation may occur.
First Aid: Flush with ample amounts of water with the eyelid held wide open for at least 15 minutes. Seek medical attention if feeling unwell.
Protection: None required for normal conditions of use.

Skin

Effect: May cause minor irritation.
First Aid: Flush with water for at least 15 minutes. Seek medical attention if feeling unwell.
Protection: None required for normal conditions of use.

Inhalation

Effect: May cause difficulty breathing.
First Aid: Provide victim with fresh air; give oxygen if breathing becomes difficult. If breathing stops, administer artificial respiration. Seek medical attention if feeling unwell.
Protection: None required for normal conditions of use.

Ingestion

Effect: Mild irritant.
First Aid: Drink plenty of water. Seek medical attention if feeling unwell.
Protection: None required for normal conditions of use.

4. FIRE FIGHTING MEASURES

Flash Point:	>200ºC
Flammability Limits:	N/A
Extinguishing Media:	Use media specific for site conditions.
Special Fire Fighting Procedures:	N/A
Unusual Fire Hazards:	N/A

5. ACCIDENTAL RELEASE MEASURES:

Spill or Leak: Review the "Health Hazard Data" and ventilate the area. Use an absorbent material to soak up spilled solution. Place all contaminated disposables into a suitable container, seal, label, and hold for disposal. Upon completion, flush spill area with ample amounts of water.

6. HANDLING AND STORAGE:

Handling & Storage: Keep vials tightly closed. Store in controlled room temperature area. Avoid excessive heat or cold, direct light, and high humidity.

7. EXPOSURE CONTROLS / PERSONAL PROTECTION:

Exposure Limits:	N/A
PPE:	None required for normal conditions of use.

8. PYSICAL / CHEMICAL PROPERTIES:

Boiling point (ºF):	N/A
Vapor Pressure (mmHg):	N/A
Vapor Density (Air = 1):	N/A
Solubility in Water:	Soluble
Specific Gravity (Water = 1):	N/A
Percent Volatile by Volume:	N/A
Evaporation Rate:	N/A
Appearance and Odor:	N/A

9. STABILITY AND REACTIVITY:

Stability: Product is stable under normal handling and storage conditions.

Incompatibility (Materials to Avoid):	N/A
Hazardous decomposition Products:	N/A

10. TOXICOLOGICAL INFORMATION:

Toxicity Data:NA

11. DISPOSAL CONSIDERATIONS:

Waste Disposal: Dispose of in accordance with local, state, and federal regulations.

12. TRANSPORT INFORMATION:

DOT

Proper Shipping Name: None

Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport.

IATA

Proper Shipping Name: None

Non-Hazardous for Air Transport: This substance is considered to be non-hazardous for transport.

13. REGULATORY INFORMATION:

N/A

14. OTHER INFORMATION:

This material safety data sheet and the information it details is offered in good faith as being accurate. We have reviewed all information included on this data document which was received from outside sources, and believe that the information is correct, but are unable to guarantee its accuracy or completeness. Health and safety precautions in this data sheet may not be adequate for all individuals and/or situations. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. No statement made in this data sheet shall be construed as a permission/recommendation for the use of any product in a manner that might infringe existing patents. No express or implied warranty is made.

Accuracy Study Data Record

Date: _____ **Completed By:** _____

	LABORATORY ANALYSIS						METER/TEST STRIP ANALYSIS		
	Sample Number	1	2	Mean	Lower Control Limit x 0.85	Upper Control Limit x 1.15	1	2	Mean
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									

Vertex Diagnostics
Phone1.888.90.VERTEX
Fax 1.646.415.8489
www.vertexdiagnostics.com

Daily Quality Control Record

UltraTRAK Meter Serial #_____ **Unit** _____ **Month/Year** _____

Date	Station/Shift	Operator Initials/Shift	Meter Cleaned (Y/N)	Test Strip Lot #	Code #	Test Strip Expiration Date	Level 1 Lot #	Level 1 Expiration Date	Level 1 Control Range	Level 1 Control Result	Level 2 Lot #	Level 2 Expiration Date	Level 2 Control Range	Level 2 Control Result	Corrective Action

Vertex Diagnostics
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Nurse In-Service Record of Training

The following healthcare professionals have been trained to use the UltraTRAK Blood Glucose Monitoring System

Certified Trainer's Name _____

Healthcare Professional's Name	Date	Unit/Station	Certified Trainer's Initials

Please note that this is to be used during the initial training of the UltraTRAK Blood Glucose Monitoring System by a Vertex Diagnostics Certified Trainer within the nursing home facility. This is to be kept on file in the Nursing Unit and updated by the Certified Trainer.

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