|  |  |
| --- | --- |
| **Purpose** | This document provides instructions for the operation of the Abbott Precision Xtra monitor, performing whole blood ketone measurement and reporting results. |
| **Intended Use** | The Abbott Precision Xtra monitor uses fresh whole blood to measure the amount of *B*-hydroxybutyrate (ketone) circulating in the bloodstream.  **Note:** This monitor may also be used to measure glucose in whole blood. For laboratory purposes, the meter will be used only for *B* – ketone testing. |
| **Principle** | The Precision Xtra monitor is used in conjunction with Precision Xtra *B*- ketone strips to measure the amount of *B* -ketone in the blood stream. When a blood sample is applied to the strip, *B*- ketone reacts with chemicals on the test strip, producing a small electrical current. The amount of current is measured by the monitor and the result is displayed in the monitor’s window. |
| **Specimen Requirements** | Capillary blood obtained by fingerstick  Venous whole blood collected in sodium or lithium heparin tubes or EDTA tubes.   * **Venous blood must be tested within 30 minutes of collection.** * **Do not use tubes containing anticoagulants other than those listed above.** |
| **Materials, Storage Requirements and Precautions** | Lancets, single use auto-disabling for fingerstick  Precison Xtra Monitor  Precision Xtra Blood *B*-ketone test strips   * Store between 4 and 30°C. * Keep away from direct sunlight and heat * Do not use expired strips. * Do not use a strip that is wet, bent, scratched or damaged. * Do not use the test strips if the foil packet has a tear or puncture in it.   Medisense Glucose and Ketone control solutions.   * Store solutions between 4 and 30 °C. * Solutions are stable 90 days after opening. Date each bottle with the date opened. * Discard unused solution after 90 days. * Do not use solutions if they are expired. Check the expiration date printed on each bottle. * If control solutions have been refrigerated, allow them to reach toom temperature **before** performing control testing. |
| **Monitor Configuration Settings** | Before initial use, configure the monitor time and date settings following instructions in the Precision Xtra user’s guide. |

|  |  |
| --- | --- |
| **Monitor Features** | * **Strip port**   Insertion point for test strips and ketone calibrator.   * **Mode Button**   Turn monitor on and off  Access monitor setup options  Access and save monitor settings  Access previous results   * **Forward and Backward button**   Review and select monitor settings  Review results   * **Backlight button**   Turn backlight on and off   * **Battery Compartment** * **Display Window**   Displays results, calibration code, previous test results and error messages.  **Important** Each time the monitor is turned on, a display check shows. The display check must match the display pictured in the user’s guide. Please refer to this picture before using the monitor. Do not use the monitor if the full display does not match. |
| **Calibration** | No calibration is necessary for testing with *B*-hydroxybutyrate strips. |
| **Quality Control (QC)** | One low and one high quality control solution must be performed each day of use.  1. Wash hands with warm soapy water and dry completely.  2. Remove a test strip from its foil packet.  3. Insert the three black lines at the end of the test strip into the foil port.  4. Push the test strip until it stops.   * The monitor turns on automatically * These items show on the display window, on after the other:   Display Check  Time, Month and Date  LOT number for the box of strips being used  Apply Sample and **KETONE** will also show in the display.   1. Mark the test as a control by pressing and selecting the middle button once. A blue icon shows on screen. **Important:** Remember to mark the sample as a control or it will be saved to memory as a patient test. |
| **Quality Control (QC) (cont.)** | 6. Mix the Low control solution by inverting 3 or 4 times.  7. Remove the cap and apply a drop to the white area on the end of the strip.  8. Continue to touch the control solution to the test strip until the monitor begins the test. The test has begun when:   * The monitor beeps * The display window shows the status bar. * The display window shows the countdown.   9. **Do not** remove the test strip from the monitor or disturb it during the countdown.  10. At the end of the countdown, the monitor will beep and display the result.  **Note:** If the countdown does not start, enough control solution may not have been applied to the strip. Apply a second drop to the strip.  If the countdown does not start after application of the second drop, discard the test strip, turn off the monitor and repeat the test.  11. Repeat the procedure for the High control.  12. Record results in the QC control log.  **Note:** Quality control values for each lot number of test strips are found on the package insert included in the test strip box.  13. Control results must be verified as acceptable before proceeding with patient testing. |
|  | **Control Results Outside of Control Range**  Patient results cannot be reported if QC results are outside of the stated range.  If QC results are not within the expected range:   * Verify the QC ranges on the *B-*ketone strip package insert. * Check the expiration date on the QC solution vials and the test strips. * Retest the control level that is out of range using the same control vial and a new strip.  1. If the control is within acceptable limits, patient results may be reported. 2. If the control is outside acceptable limits, retest using a new vial of control solution. 3. If the controls is still outside of acceptable limits, notify the Point of Care Department at 4652 or 4108. **Do not use the monitor for patient testing.** |

|  |  |
| --- | --- |
| **Patient Test Procedure** | 1. Prepare lancing device. 2. Wash hands using warm soapy water and dry completely. 3. Open the test strip packet by tearing at the notch and remove the strip. 4. Insert the three black lines at the end of the test strip into the strip port. 5. Push the test strip in until it stops.  * The monitor turns on automatically. * The Display Check, Time, Month and Day and LOT number of the strip in use display on the monitor window, one after another, then **KETONE B** and Apply Sample.  1. When **Apply Sample** appears, the monitor is ready for testing. 2. Obtain a blood droplet by fingerstick.  * **NOTE:** Venous blood may be used for testing. Collect a venous sample in sodium or lithium heparin or EDTA. Do not use tubes containing fluoride or oxalate. **Testing must take place within 30 minutes**  1. Touch the blood drop to the white area at the end of the test strip. The blood will be drawn into the test strip.  * **NOTE**: If the monitor shuts off before blood is applied, remove the test strip from the monitor and reinsert strip.  1. Continue to touch the blood drop to the white area st the end of the test strip until monitor begins the test. The monitor begins the test when:  * The monitor beeps. * The display window shows the status bar * The display window shows the countdown. **NOTE: Do not remove the test strip from the monitor or disturb it during the countdown.**  1. At the end of the countdown, the beeper will sound. The result will show in the window with the word **KETONE**. 2. Remove the test strip from the monitor. The monitor will shut off when strip is removed. Discard the test strip in the appropriate biohazard container. |
| **Results** | Record the patient result in Meditech and on the Occult Blood Log at the Urinalysis bench  Results higher than 1.5 mmol/L indicates a risk of developing diabetic ketoacidosis.  If the monitor displays a “HI” result, this indicates a ketone level of > 8.0 mmol/L **OR there may be a problem with the test strip.** Repeat the test immediately with a new test strip. |
| **Results (cont.)** | Blood ketone may be higher when a person is ill, exercises vigorously or if blood glucose levels are not controlled. |
| **Reference Ranges** | Normal - <0.6 mmol/L |
| **Assay Range** | 0.0 – 8.0 mmol/L |
| **Error Messages** | **E-1** Temperature is too hot or cold for the system to function properly.  **E-2** Monitor error.  **E-3** There may be a problem with thetest strip.  **E-4** There may be a problem with the test strip  **E-5** Blood applied to the test strip too soon.  **E-6** Calibration/test strip error.  **E-7** Test strip error. Strip is damaged, used or monitor does not recognize it.  **E-8** Monitor error  **E-9** Monitor error |
| **Limitations** | 1. Venous whole blood may be collected in sodium or lithium heparin or EDTA. Test must be performed within 30 minutes of collection. Do not use fluoride or oxalate. 2. The test strip has not been evaluated for alternate site testing. 3. The test strip is not designed for arterial, neonatal, serum or plasma samples. 4. Test results are valid in hematocrit range is 30 – 60 %. 5. Test results may be erroneously low if patient is dehydrated, severely hypotensive, in shock or in a hyperglycemic-hyperosmolar state. |
| **Interfering Substances** | The following substances have no effect on blood ketone results.   * Captopril up to 500 ug/dl * Dopamine up to 90 ug/dl * Acetaminophen up to 25 mg/dl * Ascorbic acid up to 4 mg/dl * Cholesterol up to 500 mg/dl * L-DOPA up to 600 ug/dl * Gentisic acid up to 1.8 mg/dl * Uric acid up to 24 mg/dl * Unconjugated bilirubin up to 20 mg/dl |
| **Interfering Substances (cont.)** | * Trigylcerides up to 1875 mg/dl |
| **Safety** | Meters must be cleaned between each patient with a hospital approved disinfectant.  Lancets used for fingersticks must be single use, auto-disabling. |
| **Proficiency Testing** | Proficiency testing samples are obtained from the College of American Pathologists.  Samples must be tested within the time limit stated by the CAP proficiency kit instructions.  Samples are tested in the same manner as patient samples. |
| **References** | Precision Xtra User’s Guide. Abbott Diabetes Care Inc. 11/2009.  Precision Xtra Blood *B* ***–*** Ketone Test Strips package insert. Abbott Diabetes Care Inc. 6/2012.  MediSense Glucose and Ketone Control Solutions package insert. Abbott Diabetes Care Inc. 11/2010. |

**Document History**

|  |  |  |
| --- | --- | --- |
| Document Author: | Sherilyn Solanick MS MT(ASCP) | Date: 12/1//2012 |
| Approved by: | Jess U Socrates MD | Date: 12/1/2012 |
| Revised by: |  | Date: |
| Approved by: |  |  |
| Reviewed by: |  | Date: |