



**ProTime<sup>®</sup>**  
**Microcoagulation System**

**Prothrombin Time Whole Blood Test**  
NCCLS Formatted Procedure

# Procedure: ProTime® Microcoagulation System Prothrombin Time Whole Blood Test

Prepared by	Date Adopted	Supersedes Procedure#

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Director's Signature

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## I. PRINCIPLE

The ProTime® Microcoagulation System measures the PT using fibrin clot formation and detection. The ProTime® cuvette is a self-contained, microvolume reaction cell constructed of precision molded plastic.

There are two user options within the ProTime® Microcoagulation System: the standard ProTime cuvette and the ProTime3 cuvette. The ProTime instrument has been updated to allow it to read either the ProTime or ProTime 3 cuvette. These cuvettes differ from each other only in the amount of blood collected and tested.

The standard ProTime cuvette has five micro-channels which contain the dried reagents required to perform triplicate testing of the prothrombin time assay and two levels of controls. The ProTime3 cuvette has three functional micro-channels. Two micro-channels perform the controls, and one micro-channel performs the prothrombin time assay test. The standard ProTime uses the Tenderlett® Plus device for performing the fingerstick and it is designed to hold 65 µl of blood (approximately 3 drops) needed to fill all five micro-channels. The ProTime3 uses the Tenderlett Plus LV (lower volume) device for performing the fingerstick and it collects the 27 µl of blood (approximately 1 large drop) needed to fill the three micro-channels of the ProTime3 cuvette.

The instrument draws the precise volume of blood into the micro-channel of either cuvette, which contains thromboplastin and other reagents. An array of LEDs detects the motion of sample/reagent mixtures as they move through a precision restriction in the channel. The blood is pumped back and forth until a clot forms, obstructing the channels and slowing the flow of blood. The instrument detects the clot when the blood movement decreases below a predetermined rate.

## II. SPECIMEN

Patient Preparation:

Either the Tenderlett Plus (ProTime) or Tenderlett Plus LV (ProTime3) is supplied for finger incision and blood collection. The Tenderlett Plus collects approximately 65 µl of blood, while the Tenderlett Plus LV collects approximately 27 µl of blood. Samples should be analyzed immediately after collection. No additional sample preparation is required. Refer to the Test Procedure in the package insert for full instructions on hand preparation, finger lancing and blood collection. (Based on NCCLS Document H4-A3, Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture.)

For venous samples, collect venous whole blood (approximately 100µl) into an anticoagulant-free plastic syringe. (Refer to NCCLS Document H3-A3, Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture) Follow these steps in place of step 3 and 4 of the fingerstick test procedure. Immediately dispense sample into the Tenderlett® Plus collection cup. Fill the Tenderlett® Plus collection cup to the line (to top for Tenderlett Plus LV). Follow instructions from step 5 of the fingerstick test procedure.

### A. Type:

Fingerstick whole blood is the recommended specimen. Anticoagulant-free venous whole blood may be used if the sample is collected into a plastic syringe. (Glass activates the clotting process and will therefore interfere with the results.)

***NOTE: Whole blood collected with citrate, heparin, oxalate or EDTA anticoagulants are NOT suitable for use with the ProTime Microcoagulation System. Serum or plasma samples are not appropriate samples.***

**B. Handling Conditions:**

Patient specimens and used cuvettes are potentially infectious. Handle with appropriate care and dispose of cuvettes and blood collection materials in accordance with standard methods of biohazard control. Based on NCCLS Document H4-A3, Vol. 11, No. 11, July 1991- Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture and NCCLS Document H3-A3, Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture.

**C. Sensitivity**

ProTime is sensitive to deficiencies in vitamin K-dependent coagulation factors known to influence the PT test (i.e., factors II, VII and X.) Hematocrit levels between 20% to 60% do not significantly affect test results.

**III. EQUIPMENT AND MATERIALS****A. Equipment:**

No extra equipment is needed.

**B. Materials:**

## 1. Materials Provided

ProTime Instrument

Charger

ProTime Cuvette

Tenderlett incision device

Program Plug

## 2. Materials needed, but not supplied

Alcohol pad

Gauze

**C. Preparation:**

ProTime cuvettes are ready-to-use. No additional preparation is required. Remove cuvette from refrigeration and allow to come to room temperature prior to testing. This could be as long as 60 minutes.

**D. Performance Parameters:**

- For in vitro diagnostic use.
- The ProTime instrument is designed for use only with ProTime cuvettes.
- ProTime will not produce a result if the cuvette is past its expiration date.
- DO NOT expose the ProTime to extremes in temperature (above 35°C, 95°F). Such exposure could affect the performance of any type of electronic instrumentation.
- Patient specimens and used cuvettes are potentially infectious. Handle with appropriate care and dispose of cuvettes and blood collection materials in accordance with standard methods of biohazard control.
- Leaving cuvettes unpacked on counter top or on paper may cause lint/debris to adhere to cuvette.

**E. Storage Requirements:**

Store the foil-pouched cuvettes refrigerated (2-8°C, 35-46°F). An unopened cuvette is stable until the date printed on the pouch when stored at 2-8°C. Unopened cuvettes may be stored at room temperature for 30 days. Once the pouch has been opened, the cuvette must be used within 8 hours.

## IV. CALIBRATION

### A. Standard Preparation:

The ProTime instrument and cuvettes are pre-calibrated. No additional calibration is required.

### B. Quality Control:

The ProTime instrument has been designed with multiple systems to ensure proper instrument function. The instrument self-check at start-up checks temperature and timing functions, battery level, and optical, electrical and mechanical functions. The instrument does not require further calibration. Each ProTime cuvette has two integral reagent controls which ensure assay reliability and performance. Both levels of control produce quantifiable clotting endpoints which are compared to pre-set acceptance limits programmed in the instrument. Other in process instrument QC features and the integral reagent controls function together to ensure correct sample size and collection technique, correct test procedure, instrument functionality and reagent integrity. A fault message is displayed instead of PT results when any instrument or reagent quality criterion is not met. When a fault message is displayed, the user should review the product instructions and repeat the test.

Additional control materials may be used to check instrument function, reagent integrity and user technique in addition to the built-in controls of the ProTime System when results are inconsistent with the patient's clinical history. Each institution should establish a quality assurance program for prothrombin time testing which complies with existing local, state and federal regulations as applicable. (Add your institution's policy here, if applicable.)

The built-in safety features of the ProTime instrument and integral reagent controls work together to ensure that the instrument and reagent system are working properly and that the test procedure was performed correctly. Quality control is performed with each and every test.

#### 1. External Quality Controls

##### a. Introduction

The PT Whole Blood Control is intended for use with the ProTime Microcoagulation System, which has been designed with redundant systems to ensure proper function. The instrument self-check at start-up checks battery level, temperature, timing, optical, electrical and mechanical functions. No additional calibration of functional procedures are required. Each ProTime cuvette has two levels of built-in controls which indicate proper sample collection, correct test procedure and ensure assay reliability and performance. The use of external quality control materials is not required.

##### b. Intended Use

The ProTime Whole Blood Control is designed for institutions which prefer to supplement the ProTime internal control features with the use of external quality control materials. Lyophilized control materials are useful to check instrument function, reagent integrity and user technique in addition to the built-in controls of the ProTime System.

##### c. Specifications

The PT Whole Blood Control consists of lyophilized fixed bovine red blood cells and buffered sheep and horse plasma.

***CAUTION: No human product is used in this product. However, all blood products should be handled with care, and should be discarded in accordance with your institution's policy on disposal of medical waste.***

d. Handling and Storage

When refrigerated (2–8°C) the vials are stable until the marked expiration date. The quality control product should never be exposed to temperatures in excess of 37°C. Reconstituted vials should be used immediately. *directCHECK* Quality Control products may also be stored at room temperature for up to 4 weeks. (The marked expiration date must not be exceeded.) A redating label is provided and should be marked with 4 weeks dating if room temperature storage is selected.

e. Materials

*directCHECK* quality control product kits for use with the HEMOCHRON Jr. and ProTime Microcoagulation Systems contain the following:

i. Materials Provided

15 dropper vials of dried whole blood control (0.5 cc) in a glass ampule provided with 0.7 cc of diluent

4 reusable protective sleeves, for use in crushing ampules

ii. Materials Required But Not Provided

ProTime Microcoagulation instrument

ProTime Microcoagulation PT test cuvette

f. Preparation of Control Material

i. HEMOCHRON Jr. or ProTime Microcoagulation Assays

Remove the appropriate test cuvettes from the refrigerator and allow them to come to room temperature (15-30°C) prior to testing. This could require up to 60 minutes.

ii. Quality Control Product

Remove the appropriate quality control dropper vials from the refrigerator and allow them to come to room temperature. This could require up to 60 minutes. Visually inspect vial to ensure that the glass ampule is intact.

g. Test Procedure

***CAUTION: All used test cuvettes and directCHECK vials should be considered as potentially infectious, handled with care and disposed of in accordance with standard medical waste disposal policy.***

***NOTE: Reconstitution and mixing of the whole blood control material should be accomplished quickly and without delay in any step. Once the dried control material has been reconstituted, the sample should be used immediately, as clotting will occur.***

1. Prior to turning on ProTime instrument, insert the program plug. Press the ● button. After self-check is completed (approximately 60 seconds), instrument will display the program menu.
2. Select “Go to Main Menu” and then select “Run QC Test”. After self-check is completed, the instrument will display “Insert Cuvette or Press ● to Go to Main Menu”.
3. Insert cuvette into slot in the front of the instrument. The printing should be face up and the bar code should be face down.
4. After the pre-warm stage (approximately 1 to 3 minutes), the instrument will signal ready with the display “1. Incise Finger 2. Fill Cup 3. Snap in Place 4. Press ●”.

5. Reconstitute the (room temperature) dropper vial contents as follows:

Remove the label from the vial. Insert vial into protective sleeve. Holding vial upright, tap the vial on a table top to settle the glass ampule to the bottom of the vial. Crush the inner glass ampule by either bending the vial over the edge of a table top or by crushing the vial between two fingers. Immediately repeat the crushing action one to two additional times to ensure complete breakage of the glass ampule.

Quickly invert the dropper vial end to end 10 times.

6. Remove and retain the vial cap. While inverting the vial (dropper tip down), use a downward snapping motion to the wrist to ensure the control material flows to dropper tip. Squeeze the vial to discard the first drop of the control material into the vial cap. Immediately dispense as many drops of control material as needed to fill the Tenderlett® Plus collection cup until it passes the line.
7. Snap the Tenderlett Plus to the ProTime: Hold the Tenderlett Plus at an angle, place cup into slot and press down to click into place.
8. Press the ● button. Wait for the beep. Remove Tenderlett Plus from ProTime.
9. Remove the control vial from the protective sleeve. Dispose of the vial and vial cap appropriately and retain the protective sleeve for reuse.
10. Record results. Press ● to shut off.

## V. PROCEDURE - STEPWISE

### A. Turn on ProTime.

Press the ● button to start. ProTime does a self-check procedure which takes 60 seconds. ProTime will prompt you through the test. Watch the screen and follow the prompts.

### B. Insert a cuvette

Wait for the prompt. Insert the cuvette into the slot with the printing face up and the bar code down. ProTime will BEEP when the cuvette is fully inserted. ProTime warms the cuvette. This will take one to three minutes.

While the cuvette is warming, prepare the finger. Wait for the prompt before incising the finger and collecting blood.

### C. Preparation for Finger Incision

It is easier to collect blood if the hands are very warm. Follow these steps to ensure a good sample:

1. Wash hands in warm water.
2. Rub hands together to warm them to stimulate blood flow.
3. Apply firm pressure to the palm and finger. Massage the hand to push blood into the fingertip.
4. Cleanse middle or ring finger with alcohol swab. Dry with gauze.

### D. Blood Collection

When this screen appears, it is time for the finger incision.

**CAUTION: Blood collection must be finished within 2 minutes to prevent early clotting of the sample. ProTime will keep time.**

1. Place the Tenderlett Plus device firmly against the side of the finger. Place your thumb on top of the device, as shown. Press the red trigger using the other thumb.
2. Wipe away the first trace of blood. (Gently massage from the base of the finger to force blood to the tip. Form a large drop of blood.
3. Touch the large drop of blood to the collection cup. Keep adding blood until the blood level passes the line on the collection cup.
4. You can not add too much blood. Add another drop if you are not sure you have enough.
5. Check to be sure there is blood in the stem of the funnel.

#### **E. Snap Tenderlett Plus to ProTime.**

Hold the device at a 45° angle and place the front end of the device into the slot in the instrument. Press down to click the Tenderlett Plus in place. You should hear a soft click.

#### **F. Press ● to start test.**

This signals ProTime to draw the sample into the cuvette. It takes only a few seconds for ProTime to draw the blood into the cuvette. Watch the screen for the next prompt.

#### **G. Remove Tenderlett Plus**

Wait for the BEEP. Remove the Tenderlett Plus from ProTime.

**IMPORTANT: Remove Tenderlett Plus immediately. ProTime allows you six seconds. Failure to do so will result in a error message.**

#### **H. Read results.**

In a few minutes, the result is ready. Press ● to shut off. Press the ▼ button to go to the MAIN MENU if you want to review the data in memory, print results, transfer results to a computer or perform set up functions.

## **VI. CALCULATIONS**

$INR = (PT/PTn)ISI$  is done by the instrument.

The default parameters used to calculate PT seconds are  $ISI=1.0$ , which is the sensitivity of the thromboplastin reagent used in the ProTime cuvette, and  $PTn=13.1$  seconds, which was established in clinical trials. The  $PTn$  value used in the calculation is automatically adjusted when the  $ISI$  is changed.

## **VII. REPORTING RESULTS**

The ProTime Microcoagulation System reports results as International Normalized Ratio (INR) and PT seconds. The ProTime system calculates INR directly from whole blood clotting time based on a conversion equation that was established in clinical trials. The result in plasma equivalent seconds is then calculated from the INR result.

The ProTime system provides results in both INR and PT seconds. Since results reported in PT seconds depend on the sensitivity ( $ISI$ ) of the reagent employed, the clinician has the option of changing the  $ISI$  value in ProTime so that the ProTime results reported in PT seconds closely match the results reported by the hospital laboratory. To change the  $ISI$ , the physician simply inserts the

Program Plug into the back of the instrument, accesses the programming screens and enters the ISI of the historical laboratory reagent.

Table 1. Options for Programming ISI and Associated PTn

ISI	1.0	1.2	1.4	1.6	1.8	2.0	2.2	2.4	2.6
PTn	13.1	12.9	12.8	12.6	12.5	12.3	12.2	12.0	11.9

Table 2 shows examples of how the calculation of PT seconds is affected by changing the ISI. As the ISI increases, the plasma equivalent PT decreases at any given INR. For example, a patient with INR=3.00 would have PT seconds=39.2 if the ISI is the default ISI=1.0 or PT seconds=21.3 if the ISI is reset to ISI=2.0.

Table 2. Relationship of INR to PT seconds with Varied ISI

INR	PT seconds vs. ISI			
	ISI= 1.0	ISI= 1.6	ISI=2.0	ISI=2.4
1.00	13.1	12.6	12.3	12.0
1.50	19.6	16.2	15.1	14.2
2.00	26.1	19.4	17.4	16.0
2.50	32.6	22.3	19.5	17.6
3.00	39.2	25.0	21.3	19.0
3.50	45.7	27.6	23.0	20.2
4.00	52.2	30.0	24.6	21.4
4.50	58.7	32.3	26.1	22.5

**A. Reference Ranges:**

1 Reportable Range

In clinical trials, no significant difference was observed between fingerstick and venous specimens run on the ProTime system. ProTime measured patients with an INR range of 0.8 to 7.0. If INR>7.0, the numerical result is marked with “\*”. An error message is displayed if INR>10.0.

ProTime measures both normal and therapeutic prothrombin times in fresh whole blood. Results are displayed in plasma equivalent seconds and INR. Expected values for patients taking oral anticoagulants depend on the patient’s disease state and the target values established by the physician.

	INR	PT Seconds (ISI = 1.0)
Normal	0.8 - 1.2	10.4 - 15.7 sec
Low anticoagulation	1.5 - 2.0	19.6 - 26.1 sec
Moderate anticoagulation	2.0 - 3.0	26.1 - 39.2 sec
High anticoagulation	2.5 - 4.0	32.6 - 52.2 sec

## 2. Performance Characteristics

### a. Precision

Precision testing was conducted with two levels of standard control plasma substrate preparations (Level I and Level III).

#### Standard ProTime cuvette

		n	mean	SD
Level I	within day	17	0.9	0.06
	day-to-day (5 days)	4/day	1.0	0.08
Level III	within day	19	3.2	0.19
	day-to-day (5 days)	4/day	3.2	0.12

#### ProTime3 cuvette

		n	mean	SD
Level I	within day	18	0.9	0.07
	day-to-day (5 days)	4/day	0.9	0.12
Level III	within day	20	4.0	0.19
	day-to-day (5 days)	4/day	4.2	0.22

### b. Accuracy

INR results generated by the ProTime and ProTime3 cuvettes using venous and fingerstick whole blood samples were compared to INR values obtained using standard Laboratory Plasma PT Methods with samples collected in 3.2% sodium citrate tubes. The following accuracy data were obtained.

#### Standard ProTime cuvette vs Lab (Plasma)

	regression equation	r	n
fingerstick	$y=0.94x+0.38$	0.95	229
venous	$y=0.91x+0.44$	0.94	232

#### ProTime3 cuvette vs Lab (Plasma)

	regression equation	r	n
fingerstick	$y=1.05x+0.07$	0.95	229
venous	$y=0.97x+0.19$	0.95	219

### c. Sensitivity

ProTime is sensitive to deficiencies in vitamin K-dependent coagulation factors known to influence the PT test (i.e., factors II, VII and X.) Hematocrit levels between 20% to 60% do not significantly affect test results.

## **B. Procedures for Abnormal Results:**

As with all diagnostic tests, ProTime Microcoagulation System test results should be scrutinized in light of a specific patient's condition and anticoagulant therapy. Any results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional test data. (Identify your procedure for reporting abnormal results to physicians here.)

## **C. Reporting Format:**

The laboratory should report the results of the PT test to the nearest half of a second or less along with the normal reference interval and the INR. The ratio of the PT to the geometric mean of the reference interval may also be reported. It has been shown that for patients stabilized on oral anticoagulant therapy, the reporting of an INR is preferred because it reduces intermethod variability.

Conversion to an INR in effect calibrates the results of a particular reagent/instrument system to results of an international reference reagent. Despite this, INR values produced by different test systems can still vary considerably. This variability is diminished by universal use of highly responsive thromboplastin reagents, with an ISI below 1.5. (NCCLS H47-a Vol. 16 No. 3 section 8.6)

#### **D. Showing Results**

ProTime can display result history graphically or numerically.

1. Go to MAIN MENU

##### **BEFORE A TEST**

Press the ● button to turn on ProTime. Go to the MAIN MENU by pressing the ● button when the self-check is complete.

##### **AFTER A TEST:**

Press the ▼ button after the result is displayed. Press the ▼ button to move the highlight bar to SHOW RESULTS.

2. Press the ● button to view the SHOW RESULTS menu.

##### **3a. Show Result History Graphically**

Press the ● button to display GRAPHIC HISTORY.

Press the ● button to return to the previous SHOW RESULTS menu.

##### **3b. Show Result History Numerically**

Highlight the SHOW RESULTS line in the MAIN MENU. Press the ● button to view the SHOW RESULTS menu.

Press the ▼ button to move the highlight bar to DATA HISTORY. (If you viewed the graphic history of results, ProTime automatically puts you back into the SHOW RESULTS menu and highlights the DATA HISTORY line.)

Press the ● button to view the most recent result in the DATA HISTORY memory.

Press the ▼ button to scroll through individual results. The results are stored in memory from the most recent to the oldest. The memory holds 30 results. When the memory is full, the oldest result will be deleted automatically.

Press the ● button to return to the MAIN MENU.

##### **4. Print or Send Results**

Results can be sent to a printer or to another computer. Plug the cable (Cat. #WF3218X) into the ProTime instrument and to the printer or computer to access the PRINT/SEND menu.

Highlight the SHOW RESULTS line in the MAIN MENU. (See step 1 on page 24 if you need help finding the MAIN MENU.) Press the ● button to view the SHOW RESULTS menu.

Press ▼ to move the highlight bar to the PRINT/SEND DATA line. Press ● to view the PRINT/SEND DATA menu.

Press ▼ to move the highlight bar to the option you want, then press the ● button.

PRINT/SEND ALL RESULTS gives all of the results in memory.

PRINT/SEND LAST RESULT gives the last result in memory.

## VIII. PROGRAM PLUG USE (Professional use only)

### Programming Options

Insert the Program Plug into the port in the back of the instrument BEFORE TURNING IT ON in order to access the programming screens within the SET UP menu.

In Program Mode, you can:

- Set therapeutic limits for the graphic display
  - Change the ISI
  - Select result output preference
  - Change the month and year in the SET DATE menu
1. Insert the Program Plug before turning on ProTime.  
Press the ● button to turn on ProTime and wait for the self-check to be completed.  
Press the ▼ button to move the highlight bar to PROGRAMMING. Press the ● button.
  2. Setting INR limits.  
Set the upper limit by pressing the ▼ button until the desired limit is displayed. Press ● to set the limit. The upper limit can be set from 2.0 to 5.5.  
Set the lower limit in the same fashion. The lower limit can be set from 1.2 to 4.0.
  3. Changing ISI  
Displayed plasma equivalent values are indicative of the results obtained using a laboratory reagent with an ISI of 1.0. If the ISI of the reagent in your facility is significantly different from 1.0, you may wish to select an ISI more closely aligned with your historical lab reagent. Change the pre programmed ISI by pressing the ▼ button until the desired ISI is displayed. Press ● to set it.
  4. Choosing result format preference.  
Results are displayed as INR and PT seconds. You may choose to report results as % Quick instead of PT seconds. Press the ▼ button to highlight your format preference, then press ● to select.  
The final screen confirms all of the set up parameters now set. Press the ▼ button to return to the set up menu to make additional changes. Press ● to go to the MAIN MENU.  
Remove the Program Plug.

**NOTE: Shut off and restart ProTime before routine testing.**

## IX. SET UP OPTIONS

### SET UP OPTIONS

The SET UP menu allows you to set a language preference, set the time and set the date.

Changing pre-programmed settings is easy:

- If the option that is highlighted is your preference, simply press the ● button to select that option and move to the next menu.
- Press the ▼ button to move the highlight bar, then press the ● button to select the information that is highlighted.

#### 1. Turn on ProTime

Press the ● button. ProTime does a self-check.

#### 2. Go to the MAIN MENU

When this screen appears, press the ● button to go to the MAIN MENU.

This is the MAIN MENU.

#### 3. Go to SET UP

Press the ▼ button twice to move the highlight bar to SET UP. Press the ● button to select the SET UP menu.

#### 4. SET LANGUAGE.

This is the SET UP menu.

Press the ● button to view the SET LANGUAGE options. Press the ● button to select English, or press the ▼ button to highlight your language preference, then press the ● button to set it.

#### 5. SET TIME

Once a language has been selected, you are returned to the SET UP menu and SET TIME will be highlighted automatically.

Press the button to view the SET TIME menu.

##### Setting Time Format Preference

You may choose to display time on a 12 hour or 24 hour clock. Highlight your preference, then press the button.

##### Changing the hour

Change the hour by pressing the ▼ button until the correct hour appears in the high light bar. For example, the correct hour is 10 o'clock AM. Press the ● button when 10 AM appears in the highlight bar. TIP: You may hold down the ▼ button to scroll quickly.

##### Changing the minutes

Notice that the hour on the top line has changed to the time you just set and PM has changed to AM. Change minutes by pressing the ▼ button until the correct minute appears. Press the ● button to set the minutes.

Once time has been set, ProTime will display the time and date in its memory. ProTime also displays the upper and lower therapeutic limits that have been programmed. If no limits have been programmed, the default limits of 9.9 and 0.0 will be displayed. Press the ● button to return to the MAIN MENU.

##### SET DATE

If the date is incorrect, press the ▼ button to return to the SET UP menu. Press the ▼ button to highlight SET DATE. Press the ● button to view the SET DATE menu. NOTE: You may only change the day.

**CAUTION: The time and date will be used for future results that will be stored in memory.**

## **X. LIMITATIONS**

- ProTime uses only fresh capillary or venous whole blood. Plasma or serum cannot be used.
- In clinical trials, ProTime measured patients with an INR range of 0.8 to 7.0. If INR>7.0 the numerical result is marked with an “\*\*”. If INR>10.0, an error message is displayed. Results outside of this range must be confirmed using an alternative method.
- Glass tubes or syringes must not be used to collect venous samples. Use only plastic syringes without anticoagulants to collect venous samples.
- Results may be affected in patients receiving heparin or who have an abnormal response to heparin.
- Poor fingerstick blood collection technique may affect results.
- Correlation of results reported by ProTime to laboratory results depends on the precision of the laboratory method and on the ISI value of the laboratory reagent and instrument system.

## **XI. SUGGESTED READING**

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