Xprecia™ System

PT/INR TEST STRIPS

Xprecia™ Systems PT/INR Strips are designed for use only with the Siemens Xprecia Stride™ Coagulation Analyzer (hereafter referred to as analyzer).

OTHER TEST STRIPS

Other test strips won't work with the analyzer.

INTENDED USE

The Xprecia Stride™ Coagulation System, which includes the Xprecia Stride™ Coagulation Analyzer and the Xprecia™ System PT/INR Strips, is intended for use by professional healthcare providers to provide an INR (International Normalized Ratio) based on a prothrombin time (PT) response for the monitoring of oral anticoagulation therapy with warfarin, a vitamin K antagonist. The Xprecia Stride™ Coagulation Analyzer is intended to be used with only the Xprecia™ System PT/INR Strips and the Xprecia™ System PT Controls. The analyzer uses fresh capillary (fingerstick) whole blood applied to an Xprecia™ System PT/INR Strip. It is intended for in vitro diagnostic use at the point-of-care.

Xprecia™ System PT/INR Strips are for use only with the Xprecia Stride™ Coagulation Analyzer for PT/INR determinations by professional healthcare providers. This product is for in vitro diagnostic use. The Xprecia Stride™ Coagulation System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

CLEANING AND DISINFECTING

You must clean and disinfect the exterior of the analyzer, and the test strip port protective cap, after patient and quality control tests using a Siemens recommended germicidal wipe. For detailed cleaning instructions, see the User Guide.

SUMMARY AND EXPLANATION

Quick, 1935

Quick1 reported the first PT test in 1935. It has become one of the most useful tests for evaluating the extrinsic and common pathways of the coagulation process. The application for this test is a method for monitoring oral anticoagulant drug therapy, such as warfarin. Warfarin is a vitamin K antagonist that reduces the activity of Factors II (prothrombin), VII, IX, and X.2

PRINCIPLES OF THE PROCEDURE

Warfarin is prescribed to prevent blood clots from forming or growing larger in blood or blood vessels. When using anticoagulation medication, patients have to stay within a specific therapeutic range, as determined by their doctor. The doctor needs to monitor the warfarin activity to ensure that the medication dosage is correct. To monitor the activity, the doctor orders a PT test. A PT test is a blood test that measures the time it takes for blood to clot, reporting results using International Normalized Ratio (INR). The INR was developed to standardize the PT results.

The analyzer measures PT values in whole blood. To begin testing, the contact end of the test strip is inserted into the test strip port on the analyzer. Then, a blood sample is applied to the test strip target area. The blood sample is automatically drawn by capillary action into the reaction chamber of the strip where the blood mixes with reagents and activates the coagulation cascade. When the analyzer senses that the blood has clotted, the testing stops. A PT response is determined and appears on the analyzer as INR.

For complete instructions, see the User Guide that came with your Xprecia System. If you have questions, contact your local technical support provider.

REAGENTS

The test strips are packaged in 1 vial with 23 test strips. Each test strip contains the reagent Dade® Innovin®, which is a preparation of purified recombinant human tissue factor (0.1–0.2 mg/l) combined with synthetic phospholipids (≤ 30 mg/l), calcium chloride (1.2–2.0 g/l), and stabilizers (1.5–2.5 g/l).

WARNINGS AND CAUTIONS

– Federal Law restricts this device to sale by or on the order of a licensed practitioner.
– Always follow the safety procedures and precautions listed here and throughout the User Guide when using the analyzer.
– You must clean and disinfect the device after each patient use. You can only use the analyzer for testing multiple patients when all standard precautions and the recommended cleaning and disinfection procedures are followed.
– Only auto-disabling, single use lancing devices may be used with Analyzer.
– Don't take test strips internally or drink control solutions.
– Don't run a patient test or quality control (QC) test when holding the analyzer at extreme angles.
– Fingerstick DevicesBGM.html.

TEST STRIP STORAGE AND STABILITY

– Always store the test strips as packaged and use within the expiration date printed on the test strip vial.
– Unopened Storage: 5–30°C (41–86°F) @ up to 75% RH, use before the 24 month lot expiration date.
– Opened Storage: 5–30°C (41–86°F) @ up to 75% RH, use within 2 months after first opening vial

LIQUID QUALITY CONTROL

For quality control information, see the Xprecia System PT Controls Instructions for Use.

ELECTRONIC ONBOARD QUALITY CONTROL

When each test strip is inserted, the analyzer automatically conducts 2 on-strip quality control checks designed to help ensure test strip integrity. The first control checks the presence of adequate sample reagent on the test strip, and the second control detects test strip degradation due to exposure to environmental conditions.

HOLDING THE ANALYZER

Always handle the analyzer with care and don't mishandle it. Rough treatment or impact with hard objects, such as dropping, may damage parts and lead to incorrect operational results.

You can use the analyzer in the following positions:

• Flat on a tabletop or other hard surface (display side up).
• In your hand in a level position.
• Don't run a patient test or quality control (QC) test when holding the analyzer at extreme angles.
MATERIALS PROVIDED
- Xprecia System PT/INR Strips
- Xprecia Stride Coagulation Analyzer
- Alcohol wipe, cotton ball or tissue

MATERIALS REQUIRED BUT NOT PROVIDED
- Single-use lanceting device to collect capillary blood samples obtained from a finger-stick. Prepare the lanceting device according to manufacturer instructions.

PREPARING THE PATIENT SAMPLES
Prepare the patient to collect a blood sample by following your facility’s standard procedure. For example, clean the finger with an alcohol wipe, or have the patient wash his or her hands in warm, soapy water. Dry the fingertip before taking a blood sample. Only use whole blood, from a finger-stick source, with test strips.

PERFORMING A PATIENT TEST
INSTRUCTIONS
1. To turn the analyzer on, press the On/Off button.
2. If you are prompted, enter an Operator ID (OID).
4. If you are prompted, enter a Patient ID (PID).
5. Open the test strip vial and remove only 1 test strip.
6. Immediately close the vial. Make sure the vial cap seals tightly.
7. To scan the test strip barcode, aim the barcode reader at the barcode on the test strip, then tap the Scan button.
   Tip: An audible tone sounds, a check mark displays and the screen changes when the barcode is accepted.
8. Gently, but firmly, insert the test strip with the printed side up, into the test strip port until it stops.
9. (Optional) If the analyzer requests that you scan the test strip vial, aim the barcode reader at the barcode on the test strip vial, then tap the Scan button.
10. The Wait screen displays as the analyzer warms the test strip until it reaches operating temperature, in approximately 30 seconds.
11. After the Apply Sample screen displays, prepare and apply the patient blood sample.
   The test will begin when the sample is drawn into the test strip by capillary action.
   Requirement: Be sure to fill the entire target area with blood. Don’t overfill the target area.
12. After the Test in Progress screen displays, don’t touch the test strip or add more blood. The INR value, time, and date display when the test is complete.
13. Press the Test Strip Eject button to discard the test strip according to your facility’s biohazard control policies.
   Requirement: When ejecting a used test strip, always point the analyzer down facing your biohazard container before you press the Test Strip Eject button.
14. Discard the lancet according to your facility’s biohazard control policies.
15. Clean and disinfect the entire exterior surface of the analyzer, and the test strip port protective cap, with a Siemens recommended germicidal wipe.
   Requirement: You must clean and disinfect the device after each test.
16. Remove your gloves, thoroughly wash and dry your hands, and put on a new pair of gloves before performing another patient test.

COLLECTING A FINGER-STICK BLOOD SAMPLE
INSTRUCTIONS
1. To stick the finger, firmly place the lancet against the finger and press the lancet trigger.
2. Gently squeeze from the base of the finger to form a round drop of blood. If the blood smears or runs, wipe it off with a tissue and gently squeeze another round drop of blood.
   Requirement: The drop of blood should be about the same size as the test strip target area (a minimum of 6 μL in volume). Low sample volume will cause an error message.
3. Return to Performing a Patient Test to follow steps 12–16.

RESULTS
Results display as the International Normalized Ratio (INR). Desired INR values may vary depending upon the clinical practice and test methodologies, and the optimum therapeutic range for this method should be established by each user. Normal values can vary and each site should establish its own reference interval. Based on test samples from 120 non-anticoagulated subjects, the normal INR range for the Xprecia Stride PT/INR was 0.9–1.1.

PT/INR results may be affected due to variations in the type of reagents and/or instruments. Each lot of Xprecia System PT/INR test strips is calibrated to a reference lot of human recombinant thromboplastin traceable to the World Health Organization International Reference Preparation.

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INR = \left( \frac{[\text{Patient Prothrombin Time (sec)}]}{[\text{Mean Normal Prothrombin Time (sec)}]} \right)^{\text{ISI}}
\]

LIMITATIONS
The PT/INR assay measures results in patients on warfarin therapy. Don’t use this assay to analyze patients on heparin therapy. In vitro studies showed analyzer tests results are not affected by heparin levels up to 3 U/mL, low molecular weight heparin up to 2 IU anti factor Xa activity/mL, ascorbic acid levels up to 1.5 mg/dL, triglycerides up to 3270 mg/dL, hemoglobin up to 200 g/L, creatinine up to 20 mg/dL, ORTIVANTIN up to 5 mg/g, Fondaparinux up to 2.5 mg/L, Clopidogrel concentration up to 40 mg/L, Daptomycin concentration up to 300 mg/L, uric acid up to 24 mg/dL, unconjugated bilirubin up to 20 mg/dL, and conjugated bilirubin up to 29 mg/dL.

PT/INR results may be affected by many commonly administered drugs and further studies should be made to determine the source of unexpected abnormal results. If the presence of these drugs is known or suspected, consider monitoring patients for signs and symptoms of bleeding.

Hematocrit range between 22–52% doesn’t significantly affect test results.

Note: Patients with long clotting times (>4.5 INR) are outside the reporting range. Confirm results by using an alternative test method. Contact the patient’s physician.

UNUSUAL RESULTS
If an unexpected result is obtained or if you are concerned that the result doesn’t match the clinical symptoms or patient history, perform a QC test using the Xprecia System PT Controls (as described in the Xprecia System PT Controls Instructions for Use) to confirm the device is working correctly, and then repeat the patient test. If the results are confirmed, more in-depth testing may be necessary. INR results inconsistent with the patient’s clinical presentation may be an indication of improper test strip storage, interference with certain drugs, or changes in the patient’s diet.

PERFORMANCE CHARACTERISTICS
Reporting Range: 0.8–4.5 INR. Results outside this range will not be displayed.

Refer patients with INR >5.5 to laboratory testing.

Sensitivity: Factor sensitivity was assessed for coagulation factors II, V, VII, and X. The Factor Sensitivity was determined using nine (9) Xprecia Stride™ Coagulation Analyzers, three (3) lots of Xprecia™ System PT/INR test strips, and normal human red blood cells mixed with various concentrations of normal human plasma and the applicable factor deficient plasma. Each level of Factor Sensitivity was carried out twice on each analyzer. The study verifies Factor sensitivity for the Xprecia™ System PT/INR test strips at the following levels (% of normal factor level; in vitro testing): Factor II <36%; Factor V <58%; Factor VII <52%; and Factor X <68%.
Accuracy: Accuracy was evaluated using 364 subjects across 4 sites using 3 lots of test strips per site. The INR of capillary samples measured on the analyzer were compared against the INR of venous plasma samples measured on Siemens BCS XP laboratory analyzer using Dade Innovin reagent (reference device). Results are shown below:

Precision/Repeatability: Whole blood precision (Repeatability) across the measuring range was determined for fingerstick (capillary) samples by analyzing them in duplicate. Repeatability was evaluated across four (4) intended use sites using three (3) lots of PT/INR test strips per site. The table below shows the repeatability results for combined sites. The acceptance criterion of ≤10% CV across the measuring range was met.

Reproducibility/Intermediate Precision: Reproducibility was determined by analyzing three (3) lots of Xprecia™ System PT Controls (PT Control 1 and PT Control 2) for 20 operational days, with 2 runs a day and 2 replicates per run for each control across 4 intended use sites and using three (3) lots of Xprecia™ System PT/INR test strips. The study was executed by a total of twelve (12) operators – three (3) at each site - covering four (4) intended use sites that randomly performed the runs.
### Stride Reproducibility Combined Sites

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### TECHNICAL ASSISTANCE

For technical assistance, contact your local technical support provider.

### REFERENCES