Step mechanism, 07797826160

Casual. For in vitro diagnostic use. For USA, Casual use only. Call this device to sale by or on the order of a physician.

Storing the test strips Store the test strips in their original container, with the cap tightly closed. You can store the test strips at room temperature or in the refrigerator (23°C to 36°C or 68°F to 97°F). When stored properly, the test strips can be used until the expiration date printed on the test strip container. Discard the test strips if any of the expiration date on the container.

Handling the test strips When you are ready to test, open the test strip container and remove one test strip. Immediately close the container. Make sure it seals tightly. IAP®/AHT® can be used with or without gloves. This may damage the test strips. You must use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message, and you will have to repeat the test.

Sample collection and preparation The steps that follow apply to collecting a blood sample for the Cassette or Cassette-XS® test. Optional use of anticoagulated blood or capillary to collect the fingerstick blood sample. You may also use the Cassette-XS® Warfarin Strip test for venous blood. A Cassette-XS® Warfarin Test Strip System User Manual for more information. When collecting any type of sample, follow all the instructions that are applicable and that are specified in the test kit.

Step 1: Getting ready to test Gather supplies:
- Cassette-XS® Plus Meter
- Cassette-XS® XT Test strip and strip code chip
- Lancing device (Follow the manufacturer’s instructions for use.)
- If you are using the Cassette-XS® XT test, you must change the test strip code chip.
- The three-number code on the test strip container must match the test strip code chip. To install the code chip, follow the instructions in the Code Chip section of the Cassette-XS® Plus System User Manual. Place the meter on a flat surface (like a table or countertop) or hold it upright with one hand while using the other hand to hold the test strip and press the test button. Failure to follow these instructions may result in an error message.

Step 2: Getting the test blood

Winterization. You may need to wait a few minutes before you can perform the test. If the test does not start within 30 seconds, 15 seconds of lancing the finger and 0.969 correlation. If the meter displays an error message, check the following:

- Changes in the patient’s diet can cause unusually low or high results. It is important that the patient should be followed up to determine the cause of the unusual result. It does not match the clinical symptoms of the patient test to rule out procedural error.

Performance characteristics Measuring range: The Cassette-XS® Plus System has a reportable range of 0.8 to 8.0 INR.

Accuracy: 811 venous sample results were collected from 412 patients at three external sites. The INR of each sample was compared to the INR of a venous sample tested with the Cassette-XS® Plus System. The results were analyzed using the Pearson correlation coefficient (r = 0.969). The patient clinical characteristics included (number of patients): not on warfarin (81), atrial fibrillation (163), valve repair/replacement (44), stroke/TIA (5), DVT (1), PE (1), postpartum (1), and various other conditions. 822 capillary samples were then tested using 3 representative lots of Cassette-XS® XT test strips across 16 Cassette-XS® meters. The results, shown in the graph, represent the typical Cassette-XS® XT test sensitivity to Factors V, II, VII, and X.

Built-in controls and diagnostics The Cassette-XS® Plus System has quality control functions integrated into the meter and test strips, so you do not have to perform additional quality control tests. A two-level, on-board quality control test is performed within the test chamber as part of every blood test. For more information about built-in quality control refer to the Cassette-XS® Warfarin Strip System User Manual. Roche Diagnostics has available optional liquid quality control reagent (1045S382916) for the Cassette-XS® Plus System. These controls are used to assist with monitoring compliance requirements, as applicable to your facility. Frequency and necessity of liquid quality control tests are at the discretion of each individual facility.

Additional information The user manuals for Cassette-XS® XT System and Cassette-XS® Plus System contain more information. If you need technical support, call Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week. 365 days a year.

If there are any problems with the Cassette-XS® Plus meter, notify CMS at http://www.cms.hhs.gov/nto/aip/nto.htm for symptoms, report policy, and limited warranty, refer to the other side of this method sheet.

References