XIII. Waived INR Testing			
A. Purpose/Clinical Usage, B. Policy, C. Test Principal and D. Specimen			
Effective: 12/08	Revised: 3/5/2014	Review Month: May	*Discontinue Date:*

A. Purpose/ Clinical Usage
The INRatio Monitor is used to perform waived PT/INR testing for patients on warfarin therapy in the clinical setting. This test is for quantitative PT/INR testing using fresh capillary whole blood with the INRatio system. Quality care of patients on oral anticoagulant therapy is best ensured when INR tests are performed correctly, testing equipment is maintained, and staff is thoroughly trained.

B. Policy
A Provider's order is required to perform this test. When the clinical indication or department protocol suggests confirmatory testing, the specimen may be sent STAT to the reference laboratory.

C. Test Principle
The INRatio System uses a modified version of the one stage PT test. After a drop of blood is applied to the test strip, it is drawn into the test area and mixed with reagents that initiate coagulation. Changes in impedance are detected by the monitor when the blood sample clots. The monitor calculates the PT and INR results from this impedance change and reports them on the display.

D. Specimen:
Patient Preparation:

- The operator must verify the patient identification using two patient identifiers: correct name and birth date. Rusk State Hospital staff achieves this by checking the patient's name on the request against the patient's verbal identification statement of name and date of birth.
- Prior to testing the patient should be informed of the purpose of the test and the steps involved in the procedure.

Specimen Collection

- Fresh fingerstick whole blood is the acceptable specimen.
- Perform a finger stick. Collect a large hanging drop.
- Minimum sample size is 9.5.

Specimen Rejection

- Plasma or serum cannot be used as a testing sample.
- Additional sample must not be added to the test strip once testing has begun. The monitor will beep to indicate that sufficient blood has been applied.
- Glass tubes or syringes cannot be used.
- This test should not be used for patients on heparin therapy.

XIII. Waived INR Testing			
E. Equipment, F. Reagents and Storage, G. Calibration and H. Quality Control Rationale			
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E. Equipment and Supplies
- INRatio Monitor
- Prothrombin/INR test strips
- Lancets
- Sterile Gauze
- Alcohol pad

F. Reagents Storage and Stability
- Store strips at room temperature 10-32 degrees Centigrade.
- Store strips in their original foil pouch until ready to use.
- Use the test strip within 10 minutes of opening the foil pouch.
- Dispose of any test strips that are past their expiration date or out of the pouch longer than 10 minutes.

G. Calibration

No calibration is required by the manufacturer.

H. Quality Control Rationale
- Rusk State Hospital Lab adheres to the manufacturer's quality control guidelines.
- The quality control performed for each test performed ensures the user's technique, integrity of the test strip and performance of the monitor.
- Each INR test strip incorporates two control channels that automatically test a low and high control each time a sample is tested.
- As an important safety feature, the monitor will not display the patient test result if either of the quality controls has failed. In this case, repeat the test.
- If the monitor still gives a warning an error, contact the laboratory supervisor. If unavailable contact Alere Technical Services at 1-877-866-5313. The two levels of Quality control will be reported with each patient test performed and will be monitored by the laboratory supervisor for trending patterns.
- Instrument and test evaluations will be performed annually by a correlations study of three test results for accuracy.

XIII. Waived INR Testing			
I. Testing Procedure			
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I. Testing Procedure: Follow the manufacturer's Instructions for testing.

Step	Action
1.	Gather the necessary phlebotomy materials, wash hands, apply gloves and gown. a. Lancets b. Alcohol swabs c. Gauze d. INR test strips at room temperature for 5 minutes. ~~Do not use past the expiration date.~~ e. INR monitor
2.	Identify the patient using two patient identifiers, following the policy on Good Laboratory Practices pg. 11 of Lab Manual.
3.	Make sure the patient's hand is warm. If not, warm the hand by washing in warm water. Hold the arm down for about 30 sec. to increase blood flow.
4.	Place the monitor on a flat surface, free of vibrations. Turn the monitor on by pressing the OK button for 2 seconds. After the electronic self-test, the insert strip display will appear on the monitor as a strip with an arrow.
5.	Open the test strip foil pouch and remove the strip. Insert the strip into the monitor with the INRatio readable at the bottom of the test strip.
6.	Check that the strip code matches the one on the foil pouch when STRIP CODE #####? appears on the display. If it does press OK. If it does not press the UP/Down button to change the first digit. Press OK to enter a new digit. Repeat for each digit to select the correct code. Press OK to enter the new code.
7.	Wait while the monitor warms up. The monitor will be ready when you SEE the display show a flashing drop of blood above a test strip, HEAR the monitor beep, and SEE the green light under the test strip well.
8.	Perform the fingerstick following the lancet's instructions and the directions in the INRatio User's Guidebook.
9.	Collect a large, hanging drop of blood on the finger using gentle, continuous pressure. Apply the sample to the test strip immediately (within 15 seconds) after collection. Failure to apply blood immediately may cause blood to begin clotting.
	Do not use strong repetitive pressure to collect the blood. This could affect results by introducing thromboplastin interstitial fluid into the sample.
10.	Wait while the monitor performs the test and calculates the results.
11.	The monitor will beep and the results will appear. If an error message appears, see the INRatio User's Guidebook for proper action.
12.	Remove strip and discard in laboratory waste. Press the OK button for two (2) seconds to turn the monitor off. Remove gloves, discard, and wash hands.

XIII. Waived INR Testing			
J. Results reporting			
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J. Reporting Results
The INRatio system reports results as International Normalized Ratio and PT seconds. The INRatio system calculates the 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 results.

Document the patient's INR and PT results and the two controls in the INR results log.

The INRatio system reportable INR range is 0.7 to 7.5.

Normal Range:
The normal range for patients not on anticoagulant therapy is:
INR 0.7 to 1.2
PT is 6.5-11.9

Therapeutic Range:
2.3 – 3.5 (Prosthetic valves)
2.0 -3.0 (AFIB, PE, CV)

Critical values:
INR >5.0
PT > 42.0 sec

Procedure for Abnormal Results and Confirmatory Testing

Patients who are on anticoagulant therapy
For results >4.0, confirm with PT/INR sent to the stat lab.
Report the result to the provider.

Critical results $\geq$ 5.0 will be confirmed by the stat laboratory, and should always be followed up by immediately contacting the provider. Any unexpected results should always be followed up immediately by contacting the provider.

As with all diagnostic tests, the INRatio system results should be correlated with the patient's condition and anticoagulant therapy.

XIII. Waived INR Testing			
K. Interfering Substances, L. Limitations, M. Instrument Maintenance, and N. References.			
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K. Interfering substances:

- In vitro studies show the INRatio System to be sensitive to levels of heparin and low molecular weight heparin of 4 U/mL or greater. This test should not be used for patients on heparin therapy.
- Hematocrit ranges between 35-55% will not affect test results.
- In vitro studies show no significant effect in samples containing up to 20 mg/dL of bilirubin or up to 500 mg/dL of hemoglobin (hemolysis). No significant effect was seen in samples containing up to 1500 mg/dL of triglycerides (lipemia).

L. Limitations of the Procedure:

- The INRatio System uses only fresh capillary blood.
- Running a test with an incorrect strip code may cause inaccurate results. Confirm the strip code in the monitor each time a test strip is inserted.
- The INRatio System has an INR range of 0.7 to 7.5. Results outside this range should be confirmed with an alternative method.
- Results may be affected in patients receiving heparin therapy or who have an abnormal response to heparin.
- Poor fingerstick blood collection technique may affect results.

M. Instrument Maintenance:

- Disinfection of the monitor is required after each patient test.
- Clean the monitor before disinfection and when it is visibly dirty.
- Per manufacturer's instructions, wipe the monitor with a pre-moistened towel for cleaning and disinfection. Allow 1 minute of drying time.
- Do not immerse the monitor in any liquid.
- Do not use any abrasive cleaner.

N. Citation(s):

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