Reconstituted plasmas can be frozen and thawed once. Rapid freezing and thawing in a tightly sealed container is essential to ensure the quality of the product. Once frozen, reconstituted plasmas should be thawed rapidly in a 37°C water bath for less than ten (10) minutes. Allow to stand at room temperature for at least fifteen (15) minutes prior to use. Mix reconstituted calibrators gently before use.

Stability is dependent upon environmental conditions and reagent handling, and can vary between laboratories. Determination of stability under usual operating conditions is recommended.

### PROCEDURE

#### WARNINGS AND PRECAUTIONS

Normal precautions exercised in handling products of human origin and laboratory reagents should be followed. Dispose of waste observing all local, state, and federal laws.

TriniCAL INR & Quick calibrator Set is a POTENTIALLY BIOHAZARDOUS MATERIAL. Source materials from which this product was derived were found negative for HBsAg and for antibodies against HIV, HIV-1 and HIV-2 by approved test methods. However, since no test method can offer complete assurance that infectious agents are absent, this product should be handled observing the same safety precautions employed when handling any potentially infectious material. Lack of vacuum upon opening a vial or inability to obtain reproducible values are signs of product deterioration.

#### TEST PROCEDURE

See lot specific document for the assured values.

TriniCAL INR & Quick calibrator set should be used in the same manner as freshly drawn citrated patient plasma using the same test procedures, instrument(s), and reagents. Calibration of the system is recommended with each new lot of thromboplastin and, if the controls are out of range, or after each major service intervention. It is recommended that a composite curve be prepared using the average of the PT times obtained from multiple runs.

### Determination of Patient INR using an INR Calibration Curve

An INR calibration curve is established from the relationship between the log of the mean PT of each calibrator versus the log of its assigned INR. Patient INRs may be calculated from the slope and intercept obtained from a linear regression of log PT versus log INR of the calibrators. Alternatively a graphical curve is determined by fitting a straight line on a log/log plot of calibrator PT versus calibrator INR. Patient INRs may then be read off this curve by locating the corresponding PT result and determining the associated INR (See Figure 1 for an example).

### Local ISI

The local ISI of the thromboplastin may be calculated by mathematically rearranging the formula for INR and solving for ISI using the mean PT of each calibrator, its assigned INR, and the laboratory’s MNPT (See Table 1 for an example):
Determination of Patient Results in Percent Activity

Percent Activity calibration curves may be calculated from a linear regression of the mean PTs of the calibrators and the reciprocal of their assigned Percent Activity.

The calibration curve may also be determined graphically. The vertical axis is a linear scale of PT times, and the horizontal axis is a linear scale of the reciprocal of the Percent Activity assignments (1/%PNP). Each calibrator is located on the graph, and a straight line is fitted to the four data points. Patient results in % PT are then read off this curve (See Figure 3 for an example).

Figure 3: Percent of Standard Curve (Example Curve ONLY)

Percent Activity assignments of the calibrants are reagent specific, and may be used only with the thromboplastins listed in the lot specific document.

PROCEDURAL NOTES AND PRECAUTIONS

Local ISI = Mean of the calculated ISI of the system using calibrator levels 2, 3, and 4.

LIMITATIONS

All test results are subject to the limitations of the test system. Follow all instrument and reagent manufacturer’s applications and guidelines for installation, maintenance, calibration, stability, and operation. Pre-analytic and analytic variables may influence the results of the test system and should be minimized. Collect, process, and test samples according to current revisions of the appropriate national guidelines (e.g. DIN 58 910 part 1, “Haemostaseology; determination of Thromboplastin (prothrombin) time; determination in plasma from citrated venous blood” and DIN58 905 part 1, “Haemostaseology; blood collection; preparation of plasma from citrated blood for coagulation testing”).

Determination of a valid INR by calculation using the MNPT, the sample PT, and the system ISI requires an accurately calibrated ISI and the laboratory’s determination of a valid system specific MNPT. The MNPT should be determined from the geometric mean of a minimum of twenty (20) normal donors collected and tested using the same methods and reagent/instrument system as patient samples. The use of a pooled normal plasma PT or a normal control plasma PT in place of the true MNPT is not acceptable and may cause incorrect results in the INR.

The validity of the calibration curves should be assessed by the use of appropriate controls, e.g. TriniCHECK Controls 1, 2 and 3 equivalent.

REFERENCES