

ASSESSMENT OF SINGLE-FACTOR DEFICIENCY SENSITIVITY OF THREE THROMBOPLASTIN REAGENTS

Magalie Lubineau¹, Pierre-Olivier Sevenet¹, Nadine Masset², Vincent Juif²

¹Diagnostica Stago, Asnières-sur-Seine, France; ²Diagnostica Stago, Gennevilliers, France

INTRODUCTION

Prothrombin time (PT) is a routine clotting assay that is used as a coagulation screening test. Beside the use of PT (expressed as international normalised ratio) for vitamin K antagonist follow-up, an abnormal PT may trigger the measurement of clotting factors II, V, VII and X to investigate a possible inherited or acquired factor defect.

PT sensitivity for detecting isolated factor deficiency can vary according to different reagents, due to thromboplastin origin, composition and concentration in phospholipids. Performances of single-factor deficiency sensitivity of three thromboplastin reagents from Stago were assessed, including **STA[®]-NeoPTimal**, the new Stago thromboplastin from rabbit brain origin with an ISI close to 1.0.

Agreement with H47-A2 CLSI recommendations were evaluated for each reagent, following guideline's procedure (1).

MATERIALS & METHODS

For each exogenous coagulation factor (II, V, VII, X), 8 serial dilutions to achieve ranges between 10 and 100% were prepared from normal pool plasma containing normal level of factors and respective deficient-factor plasma. Each sample was tested on STA[®]-R analyser with

- **STA[®]-NeoPTimal**, rabbit brain origin (1 lot for each packaging: 5, 10 and 20mL)
- **STA[®]-Neoplastine[®] R**, recombinant (2 lots of 15mL)
- **STA[®]-Neoplastine[®] CI PLUS**, rabbit brain origin (2 lots of 10mL)

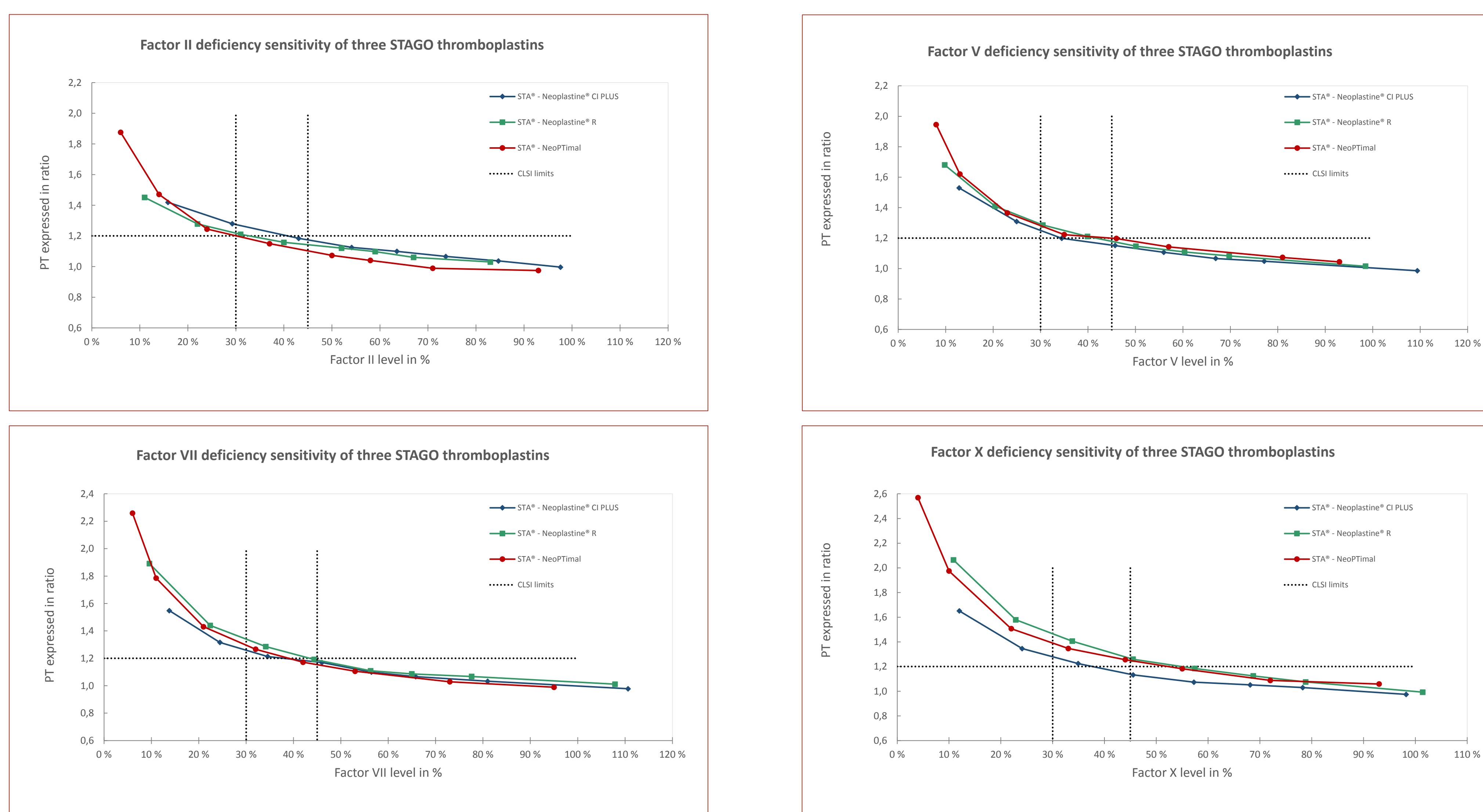
Ratios were expressed by dividing PT result in seconds by the mean of normal PT (MNPT) defined with 20 fresh plasma samples from healthy donor. Factor level of each sample was tested using one-stage clotting assay from Stago.

The sensitivity is defined as the maximum factor level producing a PT ratio result out of the reference range, *i.e.* > 1.2.

RESULTS

For each factor/thromboplastin combination, the sensitivity obtained with different lots of reagents are consistent from one lot to each other.

All the 3 reagents reached H47-A2 CLSI recommendations (factor sensitivity between 30% and 45%) except for factor X with STA[®]-Neoplastine[®] R and STA[®]-NeoPTimal where factor sensitivity is slightly higher than 45%.



STAGO Thromboplastins	Factor II Sensitivity	Factor V Sensitivity	Factor VII Sensitivity	Factor X Sensitivity
STA [®] -NeoPTimal	30%	43%	39%	51%
STA [®] -Neoplastine [®] R	33%	41%	44%	54%
STA [®] -Neoplastine [®] CI PLUS	40%	35%	36%	38%

CONCLUSION

Results show a very good lot-to-lot consistency for single factor deficiency sensitivity with the 3 reagents from Stago, STA[®]-Neoplastine[®] CI PLUS, STA[®]-Neoplastine[®] R, and STA[®]-NeoPTimal. All reagent demonstrated adequate sensitivity to single factor deficiency, according to H47-A2 CLSI guideline. A slightly higher responsiveness for FX defect is observed with two reagents, but does not overlap with FX normal ranges.

This study confirms the reliability of these reagents to CLSI guideline, in particular for STA[®]-NeoPTimal which is a new reagent*.