

NOTE : reconstitution, preparation, calibration and controls, expression of results: usual cautions and realization according to the specific technical insert D.750.02/BI/1304.

Reagents are reconstituted as per the insert, well equilibrated, and preheated at 37°C

| PHASE | CONDITION | OPERATION | PARAMETERS |
|---|--------------|---|--------------|
| 1 st loading step | YES | Reagent loading (pos 18) R2 (Thromboplastin) | 25µl |
| | | Washing after reagent loading (pos 18) | 2 |
| | | Diluent (pos DIL) | 0µL |
| | | Specimen (working dilution : prediluted 1 : 1000 in R4 buffer) | 25µl |
| | | Reagent (nacelle 2) Reagent R1 FX | 50µL |
| | | Washing between specimen | 2 |
| | | Optical ref. (cycle abs.) Diluent (pos DIL) Reagent (nacelle 2) | 80µL 80µL |
| | | Washing (at the end of loading) | 1 |
| | | Incubation time (T1) | 420 s |
| | | 2 nd loading step | YES |
| Specimen | 0µL | | |
| Washing between specimen | 0 | | |
| Reagent (nacelle 3) Reagent R3 substrate | 50µL | | |
| Washing after reagent loading | 1 | | |
| Mix time (T2) | 300 s | | |
| Activation time (T3) | 0 s | | |
| 3 rd loading step | NO | Reagent (pos 17) | 0µL |
| | | Washing after reagent loading | 0 |
| | | Mix time (T4) | 0 s |
| | | Activation time (T5) | 0 s |
| Washing | NO | Reagent (pos 1) | 0µL |
| | | Reagent (pos 16) | 0µL |
| | | Cycles number | 1 |
| | | Washing at the end of loading | 1 |
| Levels detection | NO | | |
| Acquisition parameters | YES | Ramp | yes |
| | | Inter-ramp interval (T6) | 1s |
| | | Delay before acquisition (T7) | 5s |
| | | Acquisition time (T8) | 300s |
| | | Canal used | 405nm |
| | | Rotation speed | 1200 rpm |

Example of calibration curve obtained:

| | Acquisition 300 sec |
|---------------------------|---------------------|
| % FVII | A405 |
| 200% (1 :500 dil) | 0.524 |
| 100% (1 :1000 dil) | 0.326 |
| 50% (1 :2000 dil) | 0.160 |
| 25% (1 :4000 dil) | 0.071 |
| 12.5% (1 :8000 dil) | 0.028 |
| r^2 (logA405-log conc) | 0.988 |

Note: The stability at 2-8°C and at room temperature (18-25°C) claimed are validated on reconstituted vials kept closed, protected from any evaporation or contamination. Stabilities of reagents on each automate must be controlled, adjusted and validated under each exact laboratory working conditions.

NOTE : reconstitution, préparation, calibration et contrôle, expression des résultats : précautions d'usage, et à réaliser selon les indications de la notice technique correspondante D.750.01/BI/1304

Réactifs repris selon notice, équilibrés et préchauffés à 37°C

| PHASE | CONDITION | OPERATION | PARAMETRES |
|--|-----------|--|--------------|
| 1ere étape de chargement | OUI | Chargement réactif (pos 18) R2 (Thromboplastin) | 25µl |
| | | Cycle nettoyage après réactif (pos 18) | 2 |
| | | Diluant (pos DIL) | 0µL |
| | | Specimen (dilution de travail : 1/1000 en tampon R4) | 25µl |
| | | Réactif (nacelle 2) Réactif R1 FX | 50µL |
| | | Nettoyage entre échantillons | 2 |
| | | Ref Optique (cycle abs.) Diluant (pos DIL) Réactif (nacelle 2) | 80µL 80µL |
| | | Nettoyage (fin de chargement) | 1 |
| | | Temps d'Incubation (T1) | 420 s |
| | | 2eme étape de chargement | OUI |
| Specimen | 0µL | | |
| Nettoyage entre specimens | 0 | | |
| Réactif (nacelle 3) Réactif R3 substrat | 50µL | | |
| Nettoyage (fin de chargement) | 1 | | |
| Temps de mélange (T2) | 300 s | | |
| Temps d'Activation (T3) | 0 s | | |
| 3eme étape de chargement | NON | Réactif (pos 17) | 0µL |
| | | Nettoyage (fin de chargement) | 0 |
| | | Temps de mélange (T4) | 0 s |
| | | Temps d'activation (T5) | 0 s |
| Nettoyage | NON | Réactif (pos 1) | 0µL |
| | | Réactif (pos 16) | 0µL |
| | | Nombre de Cycles | 1 |
| | | Nettoyage (fin de chargement) | 1 |
| Détection de niveaux | NON | | |
| Paramètres d'acquisition | OUI | Rampe | yes |
| | | Intervalle Inter-rampe (T6) | 1s |
| | | Délai avant acquisition (T7) | 5s |
| | | Temps d'Acquisition (T8) | 300s |
| | | Canal utilisé | 405nm |
| | | Vitesse de Rotation | 1200 rpm |

Exemple de calibration obtenue :

| | Acquisition 300 sec |
|---------------------------|---------------------|
| % FVII | A405 |
| 200% (1 / 500 dil) | 0.524 |
| 100% (1 / 1000 dil) | 0.326 |
| 50% (1 / 2000 dil) | 0.160 |
| 25% (1 / 4000 dil) | 0.071 |
| 12.5% (1 / 8000 dil) | 0.028 |
| r^2 (logA405-log conc) | 0.988 |

Nota: Les stabilités à 2-8°C et à TA ont été obtenues sur des flacons reconstitués, conservés fermés, exempts de tout risque d'évaporation ou de contamination. Chaque laboratoire doit contrôler, ajuster et valider selon ses conditions exactes de travail, la stabilité à bord de chaque automate.