**CERTIFICATE OF ANALYSIS**

CHROMOGENIX

| | | | |
|---|---|---|---|
| PRODUCT: | Factor V Deficient Plasma | PRODUCT # : | 82314663 |
| EXP. DATE: | 2005-01 | LOT # : | N0934907 |
| VENDOR: | INSTRUMENTATION LABORATORY | ASSAYED PER QCM: | H01450 |

| TEST DESCRIPTION | SPECIFICATIONS | | | RESULTS | DISPOSITION |
|---|---|---|---|---|---|
| **APC ratio on ACL** | **MIN** | **MAX** | **UNITS** | | **PASS/FAIL** |
| (1 part Control Plasma Level 1 + 4 parts V-Def plasma) | | | | | |
| APT Time | -- | 38 | seconds | 35 | PASS |
| APC Ratio | 2.3 | 3.0 | -- | 3 | PASS |
| (1 part heterozygous plasma @ 1IU Heparin/ml + 4 parts V-Def plasma) | | | | | |
| APT Time | -- | 38 | seconds | 37 | PASS |
| APC Ratio | 1.4 | 1.9 | | 1.8 | PASS |
| (1 part homozygous plasma + 4 parts V-Def plasma) | | | | | |
| APT Time | -- | 38 | seconds | 36 | PASS |
| APC Ratio | -- | 1.4 | | 1.3 | PASS |
| **Factor V Content (on ST-4)** | | | | | |
| Factor V Content | -- | 4.5 | % | 0.3 | PASS |
| **Residual Moisture** | | | | | |
| $H_2O$ Content | -- | 5 | % | 2 | PASS |

| DESCRIPTION | LOT NUMBER | EXP.DATE | VOLUME |
|---|---|---|---|
| Factor V Deficient Plasma | N0934907 | 2005-01 | 4 ml (x 5) |

We hereby certify that the above product(s):
- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY: *M. Brunswick* DATE: 10/28/03

APPROVAL SIGNATURE: *J. Facciola* DATE: 10/28/03

Form QCM H01450, Rev. 10/03

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