

**CERTIFICATE OF ANALYSIS**

# **CHROMOGENIX**

|                                    |                                  |
|------------------------------------|----------------------------------|
| PRODUCT: COAMATIC PLASMINOGEN      | PRODUCT # : 82245263             |
| EXP. DATE: 2005-10                 | LOT # : N0448459                 |
| VENDOR: INSTRUMENTATION LABORATORY | ASSAYED PER QCM: 822452/49730505 |

| TEST DESCRIPTION  | SPECIFICATIONS      |      | UNITS              | RESULTS | DISPOSITION |
|---|---------------------|------|--------------------|---------|-------------|
|   | MIN                 | MAX  |                    |         |             |
| <b>A. STREPTOKINASE/FIBRINOGEN (H00984)</b>                 |                     |      |                    |         |             |
| VISUAL INSPECTION   | White lyoph. powder |      | --                 | PASS    | PASS        |
| RESIDUAL MOISTURE   | 0                   | 5    | % H <sub>2</sub> O | 0.24    | PASS        |
| <b>B. S-2403,8.4 mg COAMATIC PLASMIN INHIBITOR (650591)</b> |                     |      |                    |         |             |
| SUBSTRATE CONCENTRATION                                     | 7.98                | 8.82 | mg/vial            | 8.1     | PASS        |
| FREE p-NITROANILINE   | 0                   | 0.5  | mol %              | 0.2     | PASS        |
| RESIDUAL MOISTURE   | 0                   | 5    | % H <sub>2</sub> O | 0.2     | PASS        |

| <b>C. COAMATIC PLASMINOGEN KIT (822452)</b> |        |        |    |         |      |
|---|--------|--------|----|---------|------|
| SLOPE                                       | 0.0024 | 0.0032 | -- | 0.00289 | PASS |
| INTERCEPT                                   | 0      | 0.025  | -- | 0.011   | PASS |
| STANDARD CURVE(r2)                          | 0.99   | 1.000  | -- | 1.000   | PASS |
| NORMAL CONTROL PLASMA                       | 74     | 104    | %  | 88      | PASS |
| ABN. CONTROL PLASMA 1                       | 46     | 66     | %  | 54      | PASS |
| ABN. CONTROL PLASMA 2                       | 17     | 37     | %  | 23      | PASS |

**Kit Components:**

| NAME                       | LOT NUMBER | EXP. DATE | MFG. DATE |
|----------------------------|------------|-----------|-----------|
| Streptokinase / Fibrinogen | N0448458   | 2005-10   | 4/15/2004 |
| S-2403 8.4 mg              | N0348182   | 2006-03   | 3/26/2004 |

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: *VINES* DATE: 4/20/2004

APPROVAL SIGNATURE: *J FACCIOLA* DATE: 4/20/2004