

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

|            |                            |                  |          |
|------------|----------------------------|------------------|----------|
| PRODUCT:   | COAMATIC HEPARIN           | PRODUCT # :      | 82339363 |
| EXP. DATE: | 2015-06                    | LOT # :          | N0735573 |
| VENDOR:    | INSTRUMENTATION LABORATORY | ASSAYED PER QCM: | 823393   |

| TEST DESCRIPTION             | SPECIFICATIONS |       | UNITS     | RESULTS | DISPOSITION |
|------------------------------|----------------|-------|-----------|---------|-------------|
|                              | MIN            | MAX   |           |         |             |
| <b>A. FACTOR Xa (H01382)</b> |                |       |           |         |             |
| pH                           | 7.9            | 8.1   | pH        | 7.9     | PASS        |
| ACTIVITY                     | 31.5           | 38.5  | nkat/vial | 35.0    | PASS        |
| STANDARD CURVE ( $r^2$ )     | 0.990          | 1.000 | --        | 0.999   | PASS        |
| CONTROL RECOVERY             | 66.1           | 73.1  | nkat/vial | 69.0    | PASS        |

| <b>B. S-2732, FOR COAMATIC HEPARIN (H01391)</b> |      |      |         |      |      |
|---|------|------|---------|------|------|
| SUBSTRATE CONCENTRATION                         | 14.3 | 15.7 | mg/vial | 15.0 | PASS |
| FREE p-NITROANILINE                             | 0    | 0.5  | mol %   | 0    | PASS |

| <b>C. COAMATIC HEPARIN KIT (082339363) - LMW HEPARIN ON TOP</b> |        |        |    |        |      |
|---|--------|--------|----|--------|------|
| SLOPE   | -0.351 | -0.103 | -- | -0.265 | PASS |
| $r^2$   | 0.985  | --     | -- | 0.994  | PASS |

| <b>D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP</b> |        |        |    |        |      |
|--|--------|--------|----|--------|------|
| SLOPE  | -0.336 | -0.114 | -- | -0.273 | PASS |
| $r^2$  | 0.985  | --     | -- | 0.985  | PASS |

**Kit Components:**

| Name      | Lot Number | Exp. date | Volume     |
|-----------|------------|-----------|------------|
| Factor Xa | N0635053   | 2015-06   | 1 ml (x 2) |
| S-2732    | N0635156   | 2015-06   | 2 ml (x 2) |

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: WPA TEL *p.m. farey* DATE: 7-25-13  
 APPROVAL SIGNATURE: DTENCBA *[Signature]* DATE: 7/25/2013