

## COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

**CAT. NO.** CG5023

**LOT NO.** 276CG

**SIZE:** 12 x 1 ml

**EXPIRY:** 2020-10-28

**GTIN:** 05055273207644

### INTENDED USE

This product is intended for *in vitro* diagnostic use, and in the quality control of coagulation systems. The Coagulation Controls are for the control of accuracy and precision.

### DEVICE DESCRIPTION

The Coagulation Controls are supplied at 3 levels, level 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the values section.

### SAFETY PRECAUTIONS AND WARNINGS

The controls are intended for *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents and controls.

Human source material, which has been added, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and was found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data sheets are available on request.

### STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). APTT, TT, PT, Fibrinogen and Antithrombin III in reconstituted serum are stable for 24 hours at +2°C to +8°C, if kept capped in original container and free from contamination. Protein C, Protein S, Plasminogen, and Factors II, V, VII, VIII, IX, X, XI, XII are stable for 8 hours at +2°C to +8°C. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

### LIMITATION

The Randox Level 3 Coagulation Control may not be suitable for the control of aPTT on some analysers due to a slow clotting time.

### PREPARATION FOR USE

The Coagulation Controls are supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised control with exactly 1 ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid the formation of foam. Do not shake the vial.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix the contents of the vial thoroughly.

### MATERIALS PROVIDED

Coagulation Control - Level 3 12 x 1 ml

### MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

### ASSIGNED VALUES

Each batch of Coagulation Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd. The expected range of the mean is provided to aid laboratory, until it has established its own mean and SD for its test methods.

07 Jun '19 ne

## COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 276CG Size: 12 x 1 ml Expiry: 2020-10-28

| Range  |         |        |      |                          |                                   |
|--|---------|--------|------|--------------------------|-----------------------------------|
| Analyte  | unit    | Target | low  | high                     | methods                           |
| Activated Partial Thromboplastin Time (APTT)       | seconds | 73.8   | 59.0 | 88.6                     | Tcoag TriniCLOT aPTT S            |
|  | seconds | 65.1   | 52.1 | 78.1                     | Tcoag TriniCLOT aPTT HS           |
|  | seconds | 63.6   | 50.9 | 76.3                     | Siemens/Dade Actin                |
|  | seconds | 56.8   | 45.4 | 68.2                     | Siemens/Dade Actin FS             |
|  | seconds | 55.3   | 44.2 | 66.4                     | Siemens/Dade Actin FSL            |
|  | seconds | 112    | 89.6 | 134                      | Siemens/Dade Pathromtin SL        |
|  | seconds | 52.7   | 42.2 | 63.2                     | HemosIL APTT-SP Liquid            |
|  | seconds | 78.3   | 62.6 | 94.0                     | HemosIL Synthasil                 |
|  | seconds | 69.3   | 55.4 | 83.2                     | Pacific Hemostasis APTT-XL        |
|  | seconds | 66.4   | 53.1 | 79.7                     | Stago aPTT                        |
|  | seconds | 58.2   | 46.6 | 69.8                     | Stago Cephascreen                 |
|  | seconds | 70.7   | 56.6 | 84.8                     | Stago CK-Prest                    |
|  | seconds | 69.1   | 55.3 | 82.9                     | Stago PTT Automate                |
|  | seconds | 70.7   | 56.6 | 84.8                     | Teco TEClot APTT                  |
|  | seconds | 61.2   | 49.0 | 73.4                     | Human Hemostat APTT               |
|  | seconds | 57.3   | 45.8 | 68.8                     | Bio-Ksel System APTTs             |
|  | seconds | 80.4   | 64.3 | 96.5                     | Diagon Dia-PTT                    |
|  | seconds | 51.5   | 41.2 | 61.8                     | Weiner Lab APTT                   |
|  | seconds | 64.2   | 51.4 | 77.0                     | Biolabo Bio-CK APTT               |
|  | seconds | 68.2   | 54.6 | 81.8                     | Spinreact APTT                    |
|  | seconds | 68.6   | 54.9 | 82.3                     | Tcoag TriniCLOT Automated aPTT    |
|  | seconds | 66.0   | 52.8 | 79.2                     | Media IVD aPTT                    |
|  | seconds | 58.8   | 47.0 | 70.6                     | Biomedica QuikCoag aPTT           |
|  | seconds | 64.6   | 51.7 | 77.5                     | Siemens Dade Actin Cephaloplastin |
|  | seconds | 57.8   | 46.2 | 69.4                     | Labitec aPTT                      |
|  | seconds | 66.4   | 53.1 | 79.7                     | Sclavo APTT-S                     |
| seconds  | 65.8    | 52.6   | 79.0 | HemoDiagnostica aPTT     |                                   |
| seconds  | 62.4    | 49.9   | 74.9 | Cypress Diagnostics aPTT |                                   |
| seconds  | 74.2    | 59.4   | 89.0 | Tokra Medikal APTT       |                                   |
| seconds  | 53.2    | 42.6   | 63.8 | Coagpia APTT-N           |                                   |
| seconds  | 106     | 84.8   | 127  | Cobas aPTT MedS          |                                   |
| Activated Partial Thromboplastin Time (APTT) Ratio | ratio   | 2.12   | 1.70 | 2.54                     | Siemens/Dade Actin FSL            |
|  | ratio   | 3.34   | 2.67 | 4.01                     | Siemens/Dade Actin SL             |
|  | ratio   | 1.96   | 1.57 | 2.35                     | Stago Cephascreen                 |
|  | ratio   | 2.07   | 1.66 | 2.48                     | Stago PTT Automate                |
|  | ratio   | 2.14   | 1.71 | 2.57                     | Stago aPTT                        |
|  | ratio   | 3.48   | 2.78 | 4.18                     | Siemens/Dade Pathromtin SL        |
|  | ratio   | 1.73   | 1.38 | 2.08                     | HemosIL APTT-SP Liquid            |
|  | ratio   | 2.66   | 2.13 | 3.19                     | HemosIL Synthasil                 |
|  | ratio   | 2.37   | 1.90 | 2.84                     | Stago CK-Prest                    |
|  | ratio   | 2.38   | 1.90 | 2.86                     | Human Hemostat APTT               |
|  | ratio   | 1.71   | 1.37 | 2.05                     | Bio-Ksel System APTTs             |

## COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 276CG Size: 12 x 1 ml Expiry: 2020-10-28

| Analyte  | unit  | Target | Range |                                    | methods                                 |
|--|-------|--------|-------|------------------------------------|---|
|  |       |        | low   | high                               |   |
| Activated Partial Thromboplastin Time (APTT) Ratio | ratio | 2.19   | 1.75  | 2.63                               | Siemens/Dade Actin FS                   |
|  | ratio | 2.48   | 1.98  | 2.98                               | Diagon Dia-PTT                          |
|  | ratio | 2.29   | 1.83  | 2.75                               | Media IVD aPTT                          |
|  | ratio | 1.87   | 1.50  | 2.24                               | Biodevice aPTT                          |
|  | ratio | 1.95   | 1.56  | 2.34                               | Labitec aPTT                            |
|  | ratio | 2.31   | 1.85  | 2.77                               | Sclavo APTT-S                           |
|  | ratio | 1.63   | 1.30  | 1.96                               | Coagpia APTT-N                          |
| Antithrombin III activity                          | %     | 57.8   | 46.2  | 69.4                               | Siemens/Dade Berichrom ATIII            |
|  | %     | 54.5   | 43.6  | 65.4                               | HemosIL Liquid Antithrombin             |
|  | %     | 58.6   | 46.9  | 70.3                               | Roche Chronogenic Thrombin              |
|  | %     | 57.0   | 45.6  | 68.4                               | Hemosil Lyophilised Antithrombin III    |
|  | %     | 60.0   | 48.0  | 72.0                               | STACHrom ATIII                          |
|  | %     | 61.2   | 49.0  | 73.4                               | Siemens/Dade Antithrombin III           |
|  | %     | 63.1   | 50.5  | 75.7                               | Diagon ATIII                            |
|  | %     | 57.3   | 45.8  | 68.8                               | Siemens Innovance Antithrombin III      |
| Factor II activity                                 | %     | 57.4   | 45.9  | 68.9                               | Dade Innovin                            |
|  | %     | 62.4   | 49.9  | 74.9                               | Siemens/Dade Thromborel S               |
|  | %     | 63.6   | 50.9  | 76.3                               | Stago Neoplastine CI Plus               |
|  | %     | 57.5   | 46.0  | 69.0                               | HemosIL PT-Fibrinogen HS Plus           |
|  | %     | 55.6   | 44.5  | 66.7                               | HemosIL PT-Fibrinogen Recombiplastin 2G |
| Factor IX activity                                 | %     | 64.3   | 51.4  | 77.2                               | Stago PTT Automate                      |
|  | %     | 50.7   | 40.6  | 60.8                               | Siemens/Dade Actin FS                   |
|  | %     | 57.0   | 45.6  | 68.4                               | Siemens/Dade Pathromtin SL              |
|  | %     | 49.1   | 39.3  | 58.9                               | HemosIL Synthasil                       |
|  | %     | 56.0   | 44.8  | 67.2                               | Stago CK-Prest                          |
|  | %     | 51.3   | 41.0  | 61.6                               | Siemens/Dade Actin FSL                  |
|  | %     | 48.8   | 39.0  | 58.6                               | HemosIL APTT-SP Liquid                  |
|  | %     | 46.0   | 36.8  | 55.2                               | Siemens/Dade Actin                      |
|  | %     | 63.3   | 50.6  | 76.0                               | Stago Deficient / ImmunoDef IX          |
| %  | 47.6  | 38.1   | 57.1  | HemosIL Factor IX deficient plasma |   |
| Factor V activity                                  | %     | 41.0   | 32.8  | 49.2                               | Stago Neoplastine CI Plus               |
|  | %     | 43.3   | 34.6  | 52.0                               | Siemens/Dade Thromborel S               |
|  | %     | 37.4   | 29.9  | 44.9                               | Dade Innovin                            |
|  | %     | 35.6   | 28.5  | 42.7                               | HemosIL PT-Fibrinogen HS Plus           |
|  | %     | 41.6   | 33.3  | 49.9                               | HemosIL PT-Fibrinogen Recombiplastin 2G |
|  | %     | 36.0   | 28.8  | 43.2                               | Stago Neoplastin R                      |
|  | %     | 38.0   | 30.4  | 45.6                               | HemosIL Factor V deficient plasma       |
| Factor VII activity                                | %     | 78.7   | 63.0  | 94.4                               | Stago Neoplastine CI Plus               |
|  | %     | 83.2   | 66.6  | 100                                | Siemens/Dade Thromborel S               |
|  | %     | 91.9   | 73.5  | 110                                | Dade Innovin                            |
|  | %     | 83.5   | 66.8  | 100                                | HemosIL PT-Fibrinogen HS Plus           |
|  | %     | 108    | 86.4  | 130                                | HemosIL PT-Fibrinogen Recombiplastin 2G |
|  | %     | 79.3   | 63.4  | 95.2                               | Stago Neoplastin R                      |
| Factor VIII activity                               | %     | 102    | 81.6  | 122                                | HemosIL Factor VIII deficient plasma    |
|  | %     | 29.2   | 23.4  | 35.0                               | Stago CK-Prest                          |

## COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 276CG Size: 12 x 1 ml Expiry: 2020-10-28

| Range                |       |        |       |                                |   |
|----------------------|-------|--------|-------|--------------------------------|---|
| Analyte              | unit  | Target | low   | high                           | methods                                 |
| Factor VIII activity | %     | 32.9   | 26.3  | 39.5                           | Siemens/Dade Actin FS                   |
|                      | %     | 29.2   | 23.4  | 35.0                           | Siemens/Dade Pathromtin SL              |
|                      | %     | 28.1   | 22.5  | 33.7                           | Siemens/Dade Actin FSL                  |
|                      | %     | 29.5   | 23.6  | 35.4                           | HemosIL Synthasil                       |
|                      | %     | 28.6   | 22.9  | 34.3                           | HemosIL Factor VIII deficient plasma    |
| Factor X activity    | %     | 65.6   | 52.5  | 78.7                           | Siemens/Dade Thromborel S               |
|                      | %     | 62.1   | 49.7  | 74.5                           | Dade Innovin                            |
|                      | %     | 60.8   | 48.6  | 73.0                           | HemosIL PT-Fibrinogen HS Plus           |
|                      | %     | 59.2   | 47.4  | 71.0                           | Stago Neoplastine CI Plus               |
|                      | %     | 64.7   | 51.8  | 77.6                           | HemosIL PT-Fibrinogen Recombiplastin 2G |
| Factor XI activity   | %     | 27.0   | 21.6  | 32.4                           | Siemens/Dade Actin FS                   |
|                      | %     | 33.0   | 26.4  | 39.6                           | Siemens/Dade Pathromtin SL              |
|                      | %     | 26.3   | 21.0  | 31.6                           | HemosIL Synthasil                       |
|                      | %     | 27.4   | 21.9  | 32.9                           | HemosIL Factor XI Deficient Plasma      |
| Factor XII activity  | %     | 55.8   | 44.6  | 67.0                           | Siemens/Dade Actin FS                   |
|                      | %     | 57.1   | 45.7  | 68.5                           | Siemens/Dade Pathromtin SL              |
|                      | %     | 53.1   | 42.5  | 63.7                           | HemosIL Synthasil                       |
|                      | %     | 48.5   | 38.8  | 58.2                           | Siemens/Dade Actin FSL                  |
| Fibrinogen           | g/L   | 1.62   | 1.30  | 1.94                           | HemosIL PT-Fibrinogen HS Plus           |
|                      | mg/dL | 162    | 130   | 194                            |   |
|                      | g/L   | 1.74   | 1.39  | 2.09                           | Helena Fibrinogen                       |
|                      | mg/dL | 174    | 139   | 209                            |   |
|                      | g/L   | 1.60   | 1.28  | 1.92                           | Stago Fibrinogen / Liquid-Fib           |
|                      | mg/dL | 160    | 128   | 192                            |   |
|                      | g/L   | 1.07   | 0.856 | 1.28                           | Siemens/Dade Multifibren U              |
|                      | mg/dL | 107    | 85.6  | 128                            |   |
|                      | g/L   | 1.48   | 1.18  | 1.78                           | HemosIL Fibrinogen C                    |
|                      | mg/dL | 148    | 118   | 178                            |   |
|                      | g/L   | 1.28   | 1.02  | 1.54                           | Dade Thrombin                           |
|                      | mg/dL | 128    | 102   | 154                            |   |
|                      | g/L   | 1.47   | 1.18  | 1.76                           | Tcoag TriniCLOT Fibrinogen              |
|                      | mg/dL | 147    | 118   | 176                            |   |
|                      | g/L   | 1.42   | 1.14  | 1.70                           | Biolabo Bio-Fibri                       |
|                      | mg/dL | 142    | 114   | 170                            |   |
|                      | g/L   | 1.44   | 1.15  | 1.73                           | HemosIL QFA (bovine thrombin)           |
|                      | mg/dL | 144    | 115   | 173                            |   |
|                      | g/L   | 2.01   | 1.61  | 2.41                           | Pacific Hemostasis Fibrinogen           |
|                      | mg/dL | 201    | 161   | 241                            |   |
| g/L                  | 1.50  | 1.20   | 1.80  | Human Fibrinogen               |   |
| mg/dL                | 150   | 120    | 180   |                                |   |
| g/L                  | 1.58  | 1.26   | 1.90  | Stago STA Fibri-Prest Automate |   |
| mg/dL                | 158   | 126    | 190   |                                |   |
| g/L                  | 1.64  | 1.31   | 1.97  | Bio-Ksel Fibrinogen            |   |
| mg/dL                | 164   | 131    | 197   |                                |   |
| g/L                  | 1.42  | 1.14   | 1.70  | Diagon Dia-F                   |   |
| mg/dL                | 142   | 114    | 170   |                                |   |

## COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 276CG Size: 12 x 1 ml Expiry: 2020-10-28

| Analyte               | unit    | Target | Range |                              | methods  |
|-----------------------|---------|--------|-------|------------------------------|--|
|                       |         |        | low   | high                         |  |
| Fibrinogen            | g/L     | 1.09   | 0.872 | 1.31                         | Dade Innovin Derived Fibrinogen                |
|                       | mg/dL   | 109    | 87.2  | 131                          |  |
|                       | g/L     | 1.12   | 0.896 | 1.34                         | Siemens/Dade Thromboplastin Derived Fibrinogen |
|                       | mg/dL   | 112    | 89.6  | 134                          |  |
|                       | g/L     | 1.50   | 1.20  | 1.80                         | Technology-Standard Fibrinogen                 |
|                       | mg/dL   | 150    | 120   | 180                          |  |
|                       | g/L     | 0.986  | 0.789 | 1.18                         | HemosIL PT-Fibrinogen Recombiplastin 2G        |
|                       | mg/dL   | 98.6   | 78.9  | 118                          |  |
|                       | g/L     | 1.41   | 1.13  | 1.69                         | Sclavo Fibrinogen                              |
|                       | mg/dL   | 141    | 113   | 169                          |  |
|                       | g/L     | 1.52   | 1.22  | 1.82                         | Labitec Fibrinogen                             |
|                       | mg/dL   | 152    | 122   | 182                          |  |
|                       | g/L     | 1.64   | 1.31  | 1.97                         | Helena Clauss Fibrinogen 100                   |
|                       | mg/dL   | 164    | 131   | 197                          |  |
|                       | g/L     | 1.14   | 0.912 | 1.37                         | Coagpia Fibrinogen                             |
|                       | mg/dL   | 114    | 91.2  | 137                          |  |
| g/L                   | 1.47    | 1.18   | 1.76  | HemosIL PT-Fibrinogen        |  |
| mg/dL                 | 147     | 118    | 176   |                              |  |
| g/L                   | 1.45    | 1.16   | 1.74  | Beijing Succeeder Fibrinogen |  |
| mg/dL                 | 145     | 116    | 174   |                              |  |
| g/L                   | 1.44    | 1.15   | 1.73  | Cobas Fibrinogen             |  |
| mg/dL                 | 144     | 115    | 173   |                              |  |
| Plasminogen activity  | %       | 58.6   | 46.9  | 70.3                         | Stago Stachrom Plasminogen                     |
|                       | %       | 58.0   | 46.4  | 69.6                         | HemosIL Plasminogen                            |
|                       | %       | 60.7   | 48.6  | 72.8                         | Siemens/Dade Berichrom Plasminogen             |
| Protein C activity    | %       | 57.9   | 46.3  | 69.5                         | Siemens/Dade Berichrom Protein C               |
|                       | %       | 64.0   | 51.2  | 76.8                         | Stago StaClot                                  |
|                       | %       | 52.0   | 41.6  | 62.4                         | Biomerieux VIDAS Protein C                     |
|                       | %       | 54.3   | 43.4  | 65.2                         | IL HemosIL Protein C                           |
|                       | %       | 61.4   | 49.1  | 73.7                         | Siemens  |
|                       | %       | 62.0   | 49.6  | 74.4                         | STACHrom Protein C                             |
| Protein S activity    | %       | 53.2   | 37.2  | 69.2                         | STA Liatest                                    |
|                       | %       | 57.4   | 40.2  | 74.6                         | Stago StaClot                                  |
|                       | %       | 55.5   | 38.9  | 72.2                         | IL HemosIL Free Protein S                      |
|                       | %       | 37.6   | 26.3  | 48.9                         | Dade Protein S Ac                              |
|                       | %       | 55.3   | 38.7  | 71.9                         | Siemens Innovance Free PS Ag                   |
|                       | %       | 38.7   | 27.1  | 50.3                         | IL HemosIL Protein S Activity                  |
| Prothrombin Time (PT) | Seconds | 27.2   | 21.8  | 32.6                         | Dade Innovin                                   |
|                       | Seconds | 18.8   | 15.0  | 22.6                         | Siemens/Dade Thromborel IS                     |
|                       | Seconds | 18.9   | 15.1  | 22.7                         | Siemens/Dade Thromborel S                      |
|                       | Seconds | 28.4   | 22.7  | 34.1                         | HemosIL PT-Fibrinogen HS Plus                  |
|                       | Seconds | 22.0   | 17.6  | 26.4                         | Stago Neoplastine CI                           |
|                       | Seconds | 24.7   | 19.8  | 29.6                         | Stago Neoplastine CI Plus                      |
|                       | Seconds | 24.9   | 19.9  | 29.9                         | Teco TEClot PT-S                               |
|                       | Seconds | 28.8   | 23.0  | 34.6                         | Biolabo Bio-TP                                 |
|                       | Seconds | 19.7   | 15.8  | 23.6                         | Stago Neoplastin R                             |

## COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 276CG Size: 12 x 1 ml Expiry: 2020-10-28

| Range                          |         |        |      |             |   |
|--------------------------------|---------|--------|------|-------------|---|
| Analyte                        | unit    | Target | low  | high        | methods                                 |
| Prothrombin Time (PT)          | Seconds | 15.8   | 12.6 | 19.0        | Bio-Ksel System PT                      |
|                                | Seconds | 22.7   | 18.2 | 27.2        | Human Thromboplastin                    |
|                                | Seconds | 25.9   | 20.7 | 31.1        | Diagon PT                               |
|                                | Seconds | 26.7   | 21.4 | 32.0        | Spinreact PT                            |
|                                | Seconds | 46.8   | 37.4 | 56.2        | TCoag TriniCLOT PT Excel S              |
|                                | Seconds | 19.3   | 15.4 | 23.2        | Biodevice PT                            |
|                                | Seconds | 27.8   | 22.2 | 33.4        | Biomedica QuikCoag PT-HS                |
|                                | Seconds | 16.2   | 13.0 | 19.4        | HemosIL PT-Fibrinogen Recombiplastin 2G |
|                                | Seconds | 30.6   | 24.5 | 36.7        | Helena Thromboplastin                   |
|                                | Seconds | 21.0   | 16.8 | 25.2        | Cypress Diagnostics PT                  |
|                                | Seconds | 24.8   | 19.8 | 29.8        | Tokra Medikal PT                        |
|                                | Seconds | 15.6   | 12.5 | 18.7        | Bio-Ksel PT Plus                        |
|                                | Seconds | 29.3   | 23.4 | 35.2        | Beijing Succeeder PT                    |
|                                | Seconds | 19.7   | 15.8 | 23.6        | Diagon PT R                             |
|                                | Seconds | 19.0   | 15.2 | 22.8        | Cobas PT Screen                         |
| Prothrombin Time (PT) activity | %       | 21.5   | 17.2 | 25.8        | Dade Innovin                            |
|                                | %       | 44.8   | 35.8 | 53.8        | Siemens/Dade Thromborel S               |
|                                | %       | 38.6   | 30.9 | 46.3        | Stago Neoplastine CI                    |
|                                | %       | 35.9   | 28.7 | 43.1        | Stago Neoplastine CI Plus               |
|                                | %       | 32.6   | 26.1 | 39.1        | HemosIL PT-Fibrinogen HS Plus           |
|                                | %       | 27.2   | 21.8 | 32.6        | Biolabo Bio-TP                          |
|                                | %       | 54.7   | 43.8 | 65.6        | Stago Neoplastin R                      |
|                                | %       | 36.9   | 29.5 | 44.3        | Human Thromboplastin                    |
|                                | %       | 15.6   | 12.5 | 18.7        | TCoag TriniCLOT PT Excel S              |
|                                | %       | 40.2   | 32.2 | 48.2        | Biodevice PT                            |
|                                | %       | 57.8   | 46.2 | 69.4        | HemosIL PT-Fibrinogen Recombiplastin 2G |
|                                | %       | 25.7   | 20.6 | 30.8        | Helena Thromboplastin                   |
|                                | %       | 26.8   | 21.4 | 32.2        | Tokra Medikal PT                        |
|                                | %       | 70.2   | 56.2 | 84.2        | Bio-Ksel PT Plus                        |
|                                | %       | 27.5   | 22.0 | 33.0        | Beijing Succeeder PT                    |
| %                              | 33.3    | 26.6   | 40.0 | Diagon PT R |   |
| Prothrombin Time (PT) INR      | INR     | 2.65   | 2.12 | 3.18        | Dade Innovin                            |
|                                | INR     | 1.61   | 1.29 | 1.93        | Siemens/Dade Thromborel IS              |
|                                | INR     | 1.66   | 1.33 | 1.99        | Siemens/Dade Thromborel S               |
|                                | INR     | 2.24   | 1.79 | 2.69        | HemosIL PT-Fibrinogen HS Plus           |
|                                | INR     | 2.07   | 1.66 | 2.48        | Stago Neoplastine CI                    |
|                                | INR     | 2.15   | 1.72 | 2.58        | Stago Neoplastine CI Plus               |
|                                | INR     | 1.96   | 1.57 | 2.35        | Human Thromboplastin                    |
|                                | INR     | 1.89   | 1.51 | 2.27        | Teco TEClot PT-S                        |
|                                | INR     | 1.40   | 1.12 | 1.68        | Stago Neoplastin R                      |
|                                | INR     | 1.43   | 1.14 | 1.72        | Bio-Ksel System PT                      |
|                                | INR     | 2.09   | 1.67 | 2.51        | Diagon PT                               |
|                                | INR     | 2.29   | 1.83 | 2.75        | Spinreact PT                            |
|                                | INR     | 4.74   | 3.79 | 5.69        | TCoag TriniCLOT PT Excel S              |
|                                | INR     | 1.84   | 1.47 | 2.21        | Biodevice PT                            |
|                                | INR     | 2.12   | 1.70 | 2.54        | Biomedica QuikCoag PT-HS                |

## COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 276CG

Size: 12 x 1 ml Expiry: 2020-10-28

| Range                          |         |        |      |      |   |
|--------------------------------|---------|--------|------|------|---|
| Analyte                        | unit    | Target | low  | high | methods                                 |
| Prothrombin Time (PT)<br>INR   | INR     | 1.42   | 1.14 | 1.70 | HemosIL PT-Fibrinogen Recombiplastin 2G |
|                                | INR     | 1.86   | 1.49 | 2.23 | Technoclone Technoplastin HIS           |
|                                | INR     | 2.58   | 2.06 | 3.10 | Helena Thromboplastin                   |
|                                | INR     | 2.43   | 1.94 | 2.92 | Labitec PT                              |
|                                | INR     | 1.96   | 1.57 | 2.35 | Tokra Medikal PT                        |
|                                | INR     | 1.40   | 1.12 | 1.68 | Bio-Ksel PT Plus                        |
|                                | INR     | 2.28   | 1.82 | 2.74 | Beijing Succeeder PT                    |
|                                | INR     | 1.91   | 1.53 | 2.29 | Diagon PT R                             |
|                                | INR     | 1.85   | 1.48 | 2.22 | Cobas PT Screen                         |
| Prothrombin Time (PT)<br>ratio | ratio   | 2.65   | 2.12 | 3.18 | Dade Innovin                            |
|                                | ratio   | 1.65   | 1.32 | 1.98 | Siemens/Dade Thromborel S               |
|                                | ratio   | 1.66   | 1.33 | 1.99 | Stago Neoplastine CI                    |
|                                | ratio   | 2.01   | 1.61 | 2.41 | Stago Neoplastine CI Plus               |
|                                | ratio   | 1.41   | 1.13 | 1.69 | Stago Neoplastin R                      |
|                                | ratio   | 1.96   | 1.57 | 2.35 | HemosIL PT-Fibrinogen HS Plus           |
|                                | ratio   | 1.42   | 1.14 | 1.70 | HemosIL PT-Fibrinogen Recombiplastin 2G |
| Thrombin Time (TT)             | Seconds | 35.1   | 28.1 | 42.1 | Dade Thrombin                           |
|                                | Seconds | 30.8   | 24.6 | 37.0 | Siemens/Dade Thromboclotin              |
|                                | Seconds | 38.4   | 30.7 | 46.1 | Stago Thrombin                          |
|                                | Seconds | 32.7   | 26.2 | 39.2 | Sysmex Thrombin Time                    |
|                                | Seconds | 30.9   | 24.7 | 37.1 | HemosIL Thrombin Time 5ml               |
|                                | Seconds | 42.2   | 33.8 | 50.6 | HemosIL Thrombin Time 8ml               |