

# MAS<sup>®</sup> T-Marker

## LIQUID ASSAYED TUMOR MARKER CONTROL

IVD

### INTENDED USE

**MAS<sup>®</sup> T-Marker** is intended for use in the clinical laboratory as a quantitative control for monitoring test procedures used to assay human serum for tumor markers. Include **T-Marker** with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

### PRODUCT DESCRIPTION

**T-Marker** is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various pure chemicals and preparations from human tissue or body fluids. Preservatives and stabilizers are added to maintain product integrity.

**CAUTION: T-Marker** is prepared from human source material. Components of the control which are derived from human source material have been tested using FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C (HCV), HIV-1 and HIV-2. However, no test method can offer complete assurance that products derived from human source material are free of infectious agents. This control must be handled in accordance with recommendations from Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories," 2009. The packaging of this product contains dry natural rubber.

**DANGER: T-Marker** contains  $\leq 0.2\%$  bovine serum albumin (BSA).  
H317 - May cause allergic skin reaction.  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/ face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. If INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

### STORAGE AND STABILITY

Unopened vials of **T-Marker** are stable for 90 days from receipt when stored at 2-8°C. Once opened, vials of **T-Marker** are stable for 30 days when stored tightly capped at 2-8°C. This product is stable until the expiration date on the box when stored at -25 to -15°C. **Self-defrosting freezers are not suitable.**

Bacterial contamination produces an increase in turbidity and/or a characteristic odor. Discard vial if evidence of microbial contamination is observed.

### CONTROL RANGES

The published control ranges are based upon a combination of replicate assays of representative samples by participating laboratories, instrument/reagent manufacturers and direct correlation with other analytical systems in accordance with established protocol. Instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges. All values have been assigned with instruments and reagents available at the time of assay and expected values may vary with different reagents and/or methodologies. Laboratory established means should fall within the assigned ranges although subsequent instrument, reagent or calibration modifications may invalidate assigned values.

Peer comparison data and latest QC lot specific updates are available online through LabLink<sup>®</sup> xL Quality Assurance Program at [www.maslablink.com](http://www.maslablink.com). Refer to the Technical Assistance section for contact information.

### INSTRUCTIONS FOR USE

Thaw control at room temperature (18-25°C) on a rocker or with periodic gentle inversion until liquid and then immediately store at 2-8°C. Thoroughly mix the contents of the vial before each use by gently inverting for several minutes. Once control is removed from 2-8°C use immediately. Open the vial and transfer the required quantity of control into a clean sample cup. Replace cap immediately and store the opened vial at 2-8°C.

### ONCE THAWED, DO NOT REFREEZE THE CONTROL.

Dropper tips are available to help minimize exposure of control samples to air. DO NOT use a syringe needle to withdraw sample through the control bottle cap.

### QUALITY CONTROL

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

### LIMITATIONS OF PROCEDURE

Tumor Markers included in the control are AFP, CA 125, CA 15-3, CA 19-9, CA 27-29, CA 72-4, Calcitonin, CEA,  $\beta$ -hCG, PAP, PSA and Thyroglobulin.

The following constituents are also weighed into **T-Marker**. However, no claim is made for expected values nor the stability of these constituents: NSE, ACTH and Cyfra 21-1.

Compatibility of **T-Marker** has been demonstrated only with methods shown in this insert. Caution should be employed when using these controls with methods for which values have not been printed.

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique. This product is intended for use as an assayed control for quantitative assays of listed constituents in human serum. This product is not intended for use as a calibrator. For professional use only.

### TECHNICAL ASSISTANCE

**In the USA**, for technical assistance, call 800-232-3342 or 510-979-5417. For insert updates and information, if your laboratory subscribes to LabLink xL, visit [www.maslablink.com](http://www.maslablink.com) and select LabLink Extra. Alternatively, to subscribe to LabLink xL call 800-232-3342 or 510-979-5451.

**Outside of the USA**, if your laboratory subscribes to LabLink xL, visit [www.maslablink.com](http://www.maslablink.com) select LabLink Extra. Alternatively, please contact your local sales office or authorized distributor.

| Cat. No. | Description       | Size     |
|----------|-------------------|----------|
| TUM-101  | T-Marker, Level 1 | 6 x 3 mL |
| TUM-202  | T-Marker, Level 2 | 6 x 3 mL |
| TUM-303  | T-Marker, Level 3 | 6 x 3 mL |
| 286-606  | Dropper Tips      | Pkg. 100 |

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**IVD**

| U  | CON       |             |           |             |           |             |        | SI        |             |           |             |           |             |        |
|--|-----------|-------------|-----------|-------------|-----------|-------------|--------|-----------|-------------|-----------|-------------|-----------|-------------|--------|
|  | TM24061A  |             | TM24062A  |             | TM24063A  |             | U      | TM24061A  |             | TM24062A  |             | TM24063A  |             | U      |
|  | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         |        | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         |        |
| <b>ABBOTT AEROSSET / ARCHITECT SYSTEMS</b> |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| Alpha-Fetoprotein (AFP)                    |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (3P36)                                | 3.91      | 3.13 - 4.70 | 26.5      | 21.2 - 31.9 | 122       | 97.6 - 146  | ng/mL  | 3.23      | 2.59 - 3.88 | 21.9      | 17.5 - 26.3 | 101       | 80.6 - 121  | IU/mL  |
| Beta-2-Microglobulin (B2M)                 |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| Immunoturbidimetric (6K39)                 | 0.70      | 0.56 - 0.84 | 1.60      | 1.28 - 1.92 | 4.07      | 3.26 - 4.89 | mg/L   | 59.2      | 47.4 - 71.1 | 136       | 108 - 163   | 345       | 276 - 414   | nmol/L |
| Cancer Antigen 125 (CA 125)                |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (2K45)                                | 15.2      | 12.1 - 18.2 | 52.1      | 41.7 - 62.5 | 144       | 116 - 173   | U/mL   | 15.2      | 12.1 - 18.2 | 52.1      | 41.7 - 62.5 | 144       | 116 - 173   | kU/L   |
| Cancer Antigen 15-3 (CA 15-3)              |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (2K44)                                | 11.2      | 8.69 - 13.8 | 30.5      | 24.4 - 36.6 | 58.6      | 46.8 - 70.3 | U/mL   | 11.2      | 8.69 - 13.8 | 30.5      | 24.4 - 36.6 | 58.6      | 46.8 - 70.3 | kU/L   |
| Cancer Antigen 19-9 (CA 19-9)              |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (2K91)                                | 14.0      | 10.0 - 18.0 | 31.3      | 23.1 - 39.4 | 122       | 92.4 - 152  | U/mL   | 14.0      | 10.0 - 18.0 | 31.3      | 23.1 - 39.4 | 122       | 92.4 - 152  | kU/L   |
| Carcinoembryonic Antigen (CEA)             |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (7K68)                                | 1.99      | 1.59 - 2.39 | 14.5      | 11.6 - 17.4 | 65.4      | 52.3 - 78.5 | ng/mL  | 1.99      | 1.59 - 2.39 | 14.5      | 11.6 - 17.4 | 65.4      | 52.3 - 78.5 | µg/L   |
| Cortisol                                   |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (8D15)                                | 3.26      | 2.60 - 3.91 | 13.5      | 10.8 - 16.2 | 44.1      | 35.3 - 53.0 | µg/dL  | 89.8      | 71.8 - 108  | 373       | 298 - 447   | 1218      | 974 - 1461  | nmol/L |
| Estradiol                                  |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (7K72)                                | **        |             | **        |             | **        |             | pg/mL  | **        |             | **        |             | **        |             | pmol/L |
| Ferritin                                   |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (7K59)                                | 61.0      | 48.8 - 73.2 | 205       | 164 - 246   | 311       | 249 - 374   | ng/mL  | 61.0      | 48.8 - 73.2 | 205       | 164 - 246   | 311       | 249 - 374   | µg/L   |
| Ferritin                                   |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| Immunoturbidimetric (6K41)                 | 63.4      | 50.7 - 76.1 | 207       | 166 - 248   | 317       | 254 - 380   | ng/mL  | 63.4      | 50.7 - 76.1 | 207       | 166 - 248   | 317       | 254 - 380   | µg/L   |
| Human Chorionic Gonadotropin-Beta (BhCG)   |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (Routine) (7K78)                      | **        |             | **        |             | **        |             | mIU/mL | **        |             | **        |             | **        |             | IU/L   |
| Human Chorionic Gonadotropin-Beta (BhCG)   |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (STAT) (7K78)                         | 16.0      | 12.6 - 19.3 | 250       | 200 - 300   | 337       | 270 - 405   | mIU/mL | 16.0      | 12.6 - 19.3 | 250       | 200 - 300   | 337       | 270 - 405   | IU/L   |
| Insulin                                    |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (8K41)                                | **        |             | **        |             | **        |             | µU/mL  | **        |             | **        |             | **        |             | pmol/L |
| Prolactin                                  |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (7K76)                                | 3.87      | 3.09 - 4.64 | 11.0      | 8.76 - 13.1 | 27.8      | 22.3 - 33.4 | ng/mL  | 0.17      | 0.13 - 0.20 | 0.48      | 0.38 - 0.57 | 1.21      | 0.97 - 1.45 | nmol/L |
| Prostate Specific Antigen (PSA)            |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (6C06)                                | 0.50      | 0.40 - 0.59 | 5.91      | 4.73 - 7.10 | 19.3      | 15.5 - 23.2 | ng/mL  | 0.50      | 0.40 - 0.59 | 5.91      | 4.73 - 7.10 | 19.3      | 15.5 - 23.2 | µg/L   |
| Prostate Specific Antigen (PSA)            |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (7K70) (Non U.S.)                     | 0.49      | 0.39 - 0.59 | 5.82      | 4.65 - 6.98 | 19.2      | 15.4 - 23.0 | ng/mL  | 0.49      | 0.39 - 0.59 | 5.82      | 4.65 - 6.98 | 19.2      | 15.4 - 23.0 | µg/L   |
| Prostate Specific Antigen, Free (fPSA)     |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (6C07)                                | **        |             | **        |             | **        |             | ng/mL  | **        |             | **        |             | **        |             | µg/L   |
| Prostate Specific Antigen, Free (fPSA)     |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| CMIA (7K71) (Non U.S.)                     | 0.52      | 0.41 - 0.62 | 6.20      | 4.96 - 7.44 | 21.9      | 17.5 - 26.3 | ng/mL  | 0.52      | 0.41 - 0.62 | 6.20      | 4.96 - 7.44 | 21.9      | 17.5 - 26.3 | µg/L   |

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|---|-----------|--------------|-----------|-------------|-----------|-------------|-----------|--------------|-----------|-------------|-----------|-------------|--------|
|   | TM24061A  |              | TM24062A  |             | TM24063A  |             | TM24061A  |              | TM24062A  |             | TM24063A  |             | U      |
|   | $\bar{x}$ | <R>          | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         | $\bar{x}$ | <R>          | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         |        |
| <b>ABBOTT ALINITY SYSTEMS</b>           |           |              |           |             |           |             |           |              |           |             |           |             |        |
| Alpha-Fetoprotein (AFP)                 |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (07P90)                            | **        |              | **        |             | **        |             | **        |              | **        |             | **        |             | IU/mL  |
| Beta-2-Microglobulin (B2M)              |           |              |           |             |           |             |           |              |           |             |           |             |        |
| Immunoturbidimetric (01R09)             | 0.73      | 0.59 - 0.88  | 1.63      | 1.30 - 1.96 | 4.08      | 3.26 - 4.89 | 62.1      | 49.7 - 74.5  | 138       | 111 - 166   | 345       | 276 - 414   | nmol/L |
| Cancer Antigen 125 (CA 125)             |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (08P49)                            | 16.3      | 13.0 - 19.6  | 54.8      | 43.8 - 65.7 | 151       | 121 - 181   | 16.3      | 13.0 - 19.6  | 54.8      | 43.8 - 65.7 | 151       | 121 - 181   | kU/L   |
| Cancer Antigen 15-3 (CA 15-3)           |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (08P51)                            | 11.1      | 8.84 - 13.3  | 30.4      | 24.3 - 36.5 | 58.4      | 46.7 - 70.1 | 11.1      | 8.84 - 13.3  | 30.4      | 24.3 - 36.5 | 58.4      | 46.7 - 70.1 | kU/L   |
| Cancer Antigen 19-9 (CA 19-9)           |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (08P32)                            | 14.8      | 11.9 - 17.8  | 33.6      | 26.9 - 40.3 | 135       | 108 - 162   | 14.8      | 11.9 - 17.8  | 33.6      | 26.9 - 40.3 | 135       | 108 - 162   | kU/L   |
| Carcinoembryonic Antigen (CEA)          |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (07P62)                            | 1.81      | <1.73 - 2.17 | 14.0      | 11.2 - 16.8 | 65.0      | 52.0 - 78.0 | 1.81      | <1.73 - 2.17 | 14.0      | 11.2 - 16.8 | 65.0      | 52.0 - 78.0 | µg/L   |
| Cortisol                                |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (08P33)                            | 3.48      | 2.60 - 4.36  | 13.9      | 11.1 - 16.7 | 44.2      | 35.3 - 53.0 | 96.0      | 71.7 - 120   | 383       | 307 - 460   | 1218      | 975 - 1462  | nmol/L |
| Estradiol                               |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (07P50)                            | 209       | 168 - 251    | 316       | 253 - 379   | 622       | 497 - 746   | 769       | 615 - 922    | 1159      | 927 - 1391  | 2282      | 1826 - 2738 | pmol/L |
| Ferritin                                |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CIMA (07P65)                            | **        |              | **        |             | **        |             | **        |              | **        |             | **        |             | µg/L   |
| Human Chorionic Gonadotropin-Beta (hCG) |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (07P51)                            | 18.7      | 15.0 - 22.5  | 273       | 219 - 328   | 365       | 292 - 438   | 18.7      | 15.0 - 22.5  | 273       | 219 - 328   | 365       | 292 - 438   | IU/L   |
| Insulin                                 |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (04T75)                            | 8.37      | 6.70 - 10.0  | 65.7      | 52.6 - 78.9 | 121       | 96.8 - 145  | 58.1      | 46.5 - 69.8  | 456       | 365 - 548   | 840       | 672 - 1008  | pmol/L |
| Prolactin                               |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (07P66)                            | 3.46      | 2.77 - 4.15  | 10.2      | 8.13 - 12.2 | 26.5      | 21.2 - 31.7 | 0.15      | 0.12 - 0.18  | 0.44      | 0.35 - 0.53 | 1.15      | 0.92 - 1.38 | nmol/L |
| Prostate Specific Antigen (PSA)         |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (07P92)                            | 0.48      | 0.39 - 0.58  | 5.87      | 4.70 - 7.05 | 18.6      | 14.9 - 22.3 | 0.48      | 0.39 - 0.58  | 5.87      | 4.70 - 7.05 | 18.6      | 14.9 - 22.3 | µg/L   |
| Prostate Specific Antigen, Free (fPSA)  |           |              |           |             |           |             |           |              |           |             |           |             |        |
| CMIA (07P93)                            | 0.53      | 0.42 - 0.64  | 6.16      | 4.93 - 7.39 | 21.3      | 17.1 - 25.6 | 0.53      | 0.42 - 0.64  | 6.16      | 4.93 - 7.39 | 21.3      | 17.1 - 25.6 | µg/L   |

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|---|-----------|-------------|-----------|-------------|-----------|--------------|--------|-----------|-------------|-----------|-------------|-----------|--------------|--------|
|   | TM24061A  |             | TM24062A  |             | TM24063A  |              | U      | TM24061A  |             | TM24062A  |             | TM24063A  |              | U      |
|   | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         | $\bar{x}$ | <R>          |        | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         | $\bar{x}$ | <R>          |        |
| <b>BECKMAN COULTER ACCESS / DxI SYSTEMS</b> |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Alpha-Fetoprotein (AFP)                     |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence                           | 4.49      | 3.59 - 5.39 | 28.3      | 22.6 - 33.9 | 122       | 97.3 - 146   | ng/mL  | 3.71      | 2.97 - 4.45 | 23.4      | 18.7 - 28.0 | 100       | 80.4 - 121   | IU/mL  |
| Cancer Antigen 125 (CA 125)                 |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence                           | 7.40      | 5.61 - 9.19 | 29.0      | 23.2 - 34.7 | 86.7      | 69.4 - 104   | U/mL   | 7.40      | 5.61 - 9.19 | 29.0      | 23.2 - 34.7 | 86.7      | 69.4 - 104   | kU/L   |
| Cancer Antigen 15-3 (CA 15-3)               |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence                           | 6.12      | 4.90 - 7.34 | 14.6      | 11.6 - 17.5 | 25.0      | 20.0 - 30.1  | U/mL   | 6.12      | 4.90 - 7.34 | 14.6      | 11.6 - 17.5 | 25.0      | 20.0 - 30.1  | kU/L   |
| Cancer Antigen 19-9 (CA 19-9)               |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence                           | 16.0      | 12.8 - 19.1 | 34.1      | 27.3 - 41.0 | 136       | 109 - 163    | U/mL   | 16.0      | 12.8 - 19.1 | 34.1      | 27.3 - 41.0 | 136       | 109 - 163    | kU/L   |
| Carcinoembryonic Antigen (CEA)              |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence (CEA2)                    | 1.54      | 1.23 - 1.85 | 10.1      | 7.87 - 12.2 | 42.7      | 33.8 - 51.5  | ng/mL  | 1.54      | 1.23 - 1.85 | 10.1      | 7.87 - 12.2 | 42.7      | 33.8 - 51.5  | µg/L   |
| Cortisol                                    | 5.14      | 4.11 - 6.16 | 19.8      | 15.8 - 23.8 | 57.7      | 46.1 - >60.0 | µg/dL  | 142       | 113 - 170   | 546       | 437 - 656   | 1592      | 1273 - >1655 | nmol/L |
| Estradiol                                   | **        |             | **        |             | 1391      | 884 - 1899   | pg/mL  | **        |             | **        |             | 5107      | 3244 - 6970  | pmol/L |
| Estradiol (SNSE2)                           | 33.4      | 23.8 - 43.1 | 354       | 283 - 425   | 1319      | 1055 - 1583  | pg/mL  | 123       | 87.3 - 158  | 1300      | 1040 - 1560 | 4843      | 3874 - 5812  | pmol/L |
| Ferritin                                    | 43.9      | 28.0 - 59.8 | 156       | 92.3 - 219  | 241       | 144 - 339    | ng/mL  | 43.9      | 28.0 - 59.8 | 156       | 92.3 - 219  | 241       | 144 - 339    | µg/L   |
| Human Chorionic Gonadotropin-Beta (BhCG)    |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence (5th IS)                  | 19.2      | 14.4 - 24.0 | 254       | 203 - 305   | 339       | 271 - 407    | mIU/mL | 19.2      | 14.4 - 24.0 | 254       | 203 - 305   | 339       | 271 - 407    | IU/L   |
| Insulin                                     |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence (Ultrasensitive)          | 7.22      | 5.07 - 9.36 | 59.0      | 47.2 - 70.8 | 93.5      | 74.8 - 112   | µU/mL  | 50.1      | 35.2 - 65.0 | 410       | 328 - 492   | 650       | 520 - 780    | pmol/L |
| Prolactin                                   | 2.55      | 2.04 - 3.06 | 6.96      | 5.57 - 8.35 | 18.3      | 14.7 - 22.0  | ng/mL  | 0.11      | 0.09 - 0.13 | 0.30      | 0.24 - 0.36 | 0.80      | 0.64 - 0.96  | nmol/L |
| Prostate Specific Antigen (PSA)             |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence (Hybritech)               | 0.61      | 0.49 - 0.73 | 6.71      | 4.95 - 8.47 | 22.5      | 18.0 - 27.0  | ng/mL  | 0.61      | 0.49 - 0.73 | 6.71      | 4.95 - 8.47 | 22.5      | 18.0 - 27.0  | µg/L   |
| Prostate Specific Antigen (PSA)             |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence (Hybritech) (p2PSA)       | **        |             | **        |             | **        |              | ng/mL  | **        |             | **        |             | **        |              | µg/L   |
| Prostate Specific Antigen (PSA)             |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence (WHO)                     | **        |             | **        |             | **        |              | ng/mL  | **        |             | **        |             | **        |              | µg/L   |
| Prostate Specific Antigen, Free (fPSA)      |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence (Hybritech)               | **        |             | **        |             | **        |              | ng/mL  | **        |             | **        |             | **        |              | µg/L   |
| Prostate Specific Antigen, Free (fPSA)      |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence (WHO)                     | **        |             | **        |             | **        |              | ng/mL  | **        |             | **        |             | **        |              | µg/L   |
| Thyroglobulin <sup>(a)</sup>                |           |             |           |             |           |              |        |           |             |           |             |           |              |        |
| Chemiluminescence (33860)                   | 6.11      | 4.89 - 7.33 | 25.4      | 19.8 - 30.9 | 51.7      | 41.3 - 62.0  | ng/mL  | 6.11      | 4.89 - 7.33 | 25.4      | 19.8 - 30.9 | 51.7      | 41.3 - 62.0  | µg/L   |

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|  | <b>CON</b> |          |           |     |           | <b>SI</b> |           |          |           |     |          |
|---|------------|----------|-----------|-----|-----------|-----------|-----------|----------|-----------|-----|----------|
|   | TM24061A   | TM24062A | TM24063A  |     |           | TM24061A  | TM24062A  | TM24063A |           |     |          |
|   | $\bar{x}$  | <R>      | $\bar{x}$ | <R> | $\bar{x}$ | <R>       | $\bar{x}$ | <R>      | $\bar{x}$ | <R> | <b>U</b> |
| <b>BECKMAN COULTER RIA DSL</b>  |            |          |           |     |           |           |           |          |           |     |          |
| Aldosterone RIA   | **         |          | **        |     | **        |           |           | **       |           | **  | ng/dL    |
| Cancer Antigen 125 (CA 125) RIA   | **         |          | **        |     | **        |           |           | **       |           | **  | U/mL     |
|   |            |          |           |     |           |           |           |          |           |     | nmol/L   |
|   |            |          |           |     |           |           |           |          |           |     | kU/L     |

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|---|------------|-----|-----------|-----|-----------|-----|-----------|-----|-----------|-----|-----------|-----|----------|----------|
|   | TM24061A   |     | TM24062A  |     | TM24063A  |     | TM24061A  |     | TM24062A  |     | TM24063A  |     | <b>U</b> |          |
|   | $\bar{x}$  | <R> | $\bar{x}$ | <R> | $\bar{x}$ | <R> | $\bar{x}$ | <R> | $\bar{x}$ | <R> | $\bar{x}$ | <R> |          | <b>U</b> |
| <b>BIOMERIEUX VIDAS</b>   |            |     |           |     |           |     |           |     |           |     |           |     |          |          |
| Alpha-Fetoprotein (AFP)<br>ELFA   | **         |     | **        |     | **        |     | ng/mL     | **  |           | **  |           | **  |          | µg/L     |
| Beta-2-Microglobulin (B2M)<br>ELFA  | **         |     | **        |     | **        |     | mg/L      | **  |           | **  |           | **  |          | nmol/L   |
| Cortisol<br>ELFA  | **         |     | **        |     | **        |     | µg/dL     | **  |           | **  |           | **  |          | nmol/L   |
| Estradiol (E2)<br>ELFA (E2 II)  | **         |     | **        |     | **        |     | pg/mL     | **  |           | **  |           | **  |          | pmol/L   |
| Human Chorionic Gonadotropin (hCG)<br>ELFA  | **         |     | **        |     | **        |     | mIU/mL    | **  |           | **  |           | **  |          | IU/L     |
| Prolactin<br>ELFA   | **         |     | **        |     | **        |     | ng/mL     | **  |           | **  |           | **  |          | nmol/L   |

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|---|------------|-----|-----------|-----|----------|-----------|-----|-----------|-----|-----------|-------|
|   | TM24061A   |     | TM24062A  |     | <b>U</b> | TM24061A  |     | TM24062A  |     | TM24063A  |       |
|   | $\bar{x}$  | <R> | $\bar{x}$ | <R> |          | $\bar{x}$ | <R> | $\bar{x}$ | <R> | $\bar{x}$ | <R>   |
| <b>BRAHMS KRYPTOR SYSTEMS</b>   |            |     |           |     |          |           |     |           |     |           |       |
| Alpha-Fetoprotein (AFP)<br>TRACE-Technology (Non U.S.)                            | **         | **  | **        | **  | ng/mL    | **        | **  | **        | **  | **        | IU/mL |
| Cancer Antigen 125 (CA 125)<br>TRACE-Technology (Non U.S.)                        | **         | **  | **        | **  | U/mL     | **        | **  | **        | **  | **        | kU/L  |
| Cancer Antigen 15-3 (CA 15-3)<br>TRACE-Technology (Non U.S.)                      | **         | **  | **        | **  | U/mL     | **        | **  | **        | **  | **        | kU/L  |
| Cancer Antigen 19-9 (CA 19-9)<br>TRACE-Technology (Non U.S.)                      | **         | **  | **        | **  | U/mL     | **        | **  | **        | **  | **        | kU/L  |
| Carcinoembryonic Antigen (CEA)<br>TRACE-Technology (Non U.S.)                     | **         | **  | **        | **  | ng/mL    | **        | **  | **        | **  | **        | µg/L  |
| Prostate Specific Antigen (PSA)<br>TRACE-Technology (Non U.S.)                    | **         | **  | **        | **  | ng/mL    | **        | **  | **        | **  | **        | µg/L  |
| Prostate Specific Antigen, Free (fPSA)<br>TRACE-Technology (Non U.S.)             | **         | **  | **        | **  | ng/mL    | **        | **  | **        | **  | **        | µg/L  |

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|---|-----------|--------------|-----------|-------------|-----------|-------------|-----------|------|--------------|------|-------------|-------|---------------|--------|
|   | TM24061A  |              | TM24062A  |             | TM24063A  |             | TM24061A  |      | TM24062A     |      | TM24063A    |       | U             |        |
|   | $\bar{x}$ | <R>          | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         | $\bar{x}$ | <R>  | $\bar{x}$    | <R>  | $\bar{x}$   | <R>   |               |        |
| <b>ORTHO-VITROS EGi SYSTEMS</b>         |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Alpha-Fetoprotein (AFP)                 |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | **        |              | **        |             | **        |             | ng/mL     | **   |              | **   |             | **    | IU/mL         |        |
| Cancer Antigen 125 (CA 125)             |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | 6.33      | <5.50 - 7.59 | 34.4      | 27.5 - 41.3 | 103       | 82.3 - 123  | U/mL      | 6.33 | <5.50 - 7.59 | 34.4 | 27.5 - 41.3 | 103   | 82.3 - 123    | kU/L   |
| Cancer Antigen 15-3 (CA 15-3)           |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | 10.1      | 8.05 - 12.1  | 27.5      | 22.0 - 33.0 | 54.8      | 43.8 - 65.7 | U/mL      | 10.1 | 8.05 - 12.1  | 27.5 | 22.0 - 33.0 | 54.8  | 43.8 - 65.7   | kU/L   |
| Cancer Antigen 19-9 (CA 19-9)           |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | 15.2      | 12.1 - 18.2  | 34.4      | 27.5 - 41.3 | 131       | 105 - 157   | U/mL      | 15.2 | 12.1 - 18.2  | 34.4 | 27.5 - 41.3 | 131   | 105 - 157     | kU/L   |
| Carcinoembryonic Antigen (CEA)          |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | 0.46      | <0.31 - 0.79 | 11.5      | 9.22 - 13.8 | 59.7      | 47.8 - 71.7 | ng/mL     | 0.46 | <0.31 - 0.79 | 11.5 | 9.22 - 13.8 | 59.7  | 47.8 - 71.7   | µg/L   |
| Cortisol                                |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | 4.82      | 3.86 - 5.79  | 20.4      | 16.3 - 24.5 | >61.6     |             | µg/dL     | 133  | 106 - 160    | 563  | 450 - 676   | >1700 |               | nmol/L |
| Estradiol                               |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | 236       | 134 - 338    | 718       | 368 - 1069  | 2635      | 978 - >3814 | pg/mL     | 867  | 494 - 1240   | 2637 | 1350 - 3924 | 9674  | 3590 - >14000 | pmol/L |
| Ferritin                                |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | 36.7      | 29.3 - 44.0  | 118       | 94.4 - 142  | 184       | 147 - 221   | ng/mL     | 36.7 | 29.3 - 44.0  | 118  | 94.4 - 142  | 184   | 147 - 221     | µg/L   |
| Human Chorionic Gonadotropin-Beta (hCG) |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | 21.6      | 17.3 - 26.0  | 372       | 298 - 447   | 556       | 445 - 667   | mIU/mL    | 21.6 | 17.3 - 26.0  | 372  | 298 - 447   | 556   | 445 - 667     | IU/L   |
| Insulin                                 |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | **        |              | **        |             | **        |             | µIU/mL    | **   |              | **   |             | **    |               | pmol/L |
| Prolactin                               |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | 2.84      | 1.52 - 4.16  | 7.00      | 5.60 - 8.40 | 18.1      | 14.5 - 21.8 | ng/mL     | 0.12 | 0.07 - 0.18  | 0.30 | 0.24 - 0.37 | 0.79  | 0.63 - 0.95   | nmol/L |
| Prostate Specific Antigen (PSA)         |           |              |           |             |           |             |           |      |              |      |             |       |               |        |
| Chemiluminescence                       | 0.30      | 0.23 - 0.37  | 4.37      | 3.50 - 5.25 | 13.6      | 10.9 - 16.3 | ng/mL     | 0.30 | 0.23 - 0.37  | 4.37 | 3.50 - 5.25 | 13.6  | 10.9 - 16.3   | µg/L   |






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|--|-----------|-------------|-----------|-------------|-----------|-------------|--------|-----------|-------------|-----------|-------------|-----------|-------------|--------|
|  | TM24061A  |             | TM24062A  |             | TM24063A  |             | U      | TM24061A  |             | TM24062A  |             | TM24063A  |             | U      |
|  | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         |        | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         |        |
| <b>ROCHE COBAS C / E / MODULAR SYSTEMS</b> |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| Alpha-Fetoprotein (AFP)                    |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA                                      | 4.81      | 3.85 - 5.77 | 31.5      | 25.2 - 37.8 | 143       | 114 - 171   | ng/mL  | 3.97      | 3.18 - 4.77 | 26.0      | 20.8 - 31.2 | 118       | 94.3 - 141  | IU/mL  |
| Beta-2-Microglobulin (B2M)                 |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| Immunoturbidimetric                        |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| Cancer Antigen 125 (CA125)                 | 0.72      | 0.57 - 0.86 | 1.61      | 1.29 - 1.94 | 4.01      | 3.20 - 4.81 | mg/L   | 60.6      | 48.4 - 72.7 | 137       | 109 - 164   | 339       | 271 - 407   | nmol/L |
| ECLIA (CA 125 II)                          | 10.8      | 8.65 - 13.0 | 35.4      | 28.3 - 42.4 | 96.0      | 76.8 - 115  | U/mL   | 10.8      | 8.65 - 13.0 | 35.4      | 28.3 - 42.4 | 96.0      | 76.8 - 115  | kU/L   |
| Cancer Antigen 15-3 (CA 15-3)              |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA (CA 15-3 II)                         | 9.39      | 7.51 - 11.3 | 26.2      | 21.0 - 31.5 | 48.7      | 39.0 - 58.5 | U/mL   | 9.39      | 7.51 - 11.3 | 26.2      | 21.0 - 31.5 | 48.7      | 39.0 - 58.5 | kU/L   |
| Cancer Antigen 19-9 (CA 19-9)              |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA                                      | 14.3      | 11.4 - 17.2 | 28.6      | 22.9 - 34.3 | 100       | 80.4 - 121  | U/mL   | 14.3      | 11.4 - 17.2 | 28.6      | 22.9 - 34.3 | 100       | 80.4 - 121  | kU/L   |
| Cancer Antigen 72-4 (CA 72-4)              |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA                                      | **        |             | **        |             | **        |             | U/mL   | **        |             | **        |             | **        |             | kU/L   |
| Carcinoembryonic Antigen (CEA)             |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA                                      | 1.28      | 1.02 - 1.53 | 10.5      | 8.43 - 12.6 | 46.5      | 37.2 - 55.7 | ng/mL  | 1.28      | 1.02 - 1.53 | 10.5      | 8.43 - 12.6 | 46.5      | 37.2 - 55.7 | µg/L   |
| Cortisol                                   | 3.06      | 2.45 - 3.67 | 13.1      | 10.5 - 15.8 | 45.3      | 36.3 - 54.4 | µg/dL  | 84.4      | 67.5 - 101  | 362       | 290 - 435   | 1251      | 1001 - 1501 | nmol/L |
| ECLIA (Cortisol III)                       | 99.6      | 79.7 - 120  | 310       | 248 - 372   | 1235      | 988 - 1482  | pg/mL  | 366       | 293 - 439   | 1139      | 911 - 1367  | 4534      | 3627 - 5441 | pmol/L |
| Estradiol                                  | **        |             | **        |             | **        |             | ng/mL  | **        |             | **        |             | **        |             | µg/L   |
| Ferritin                                   | 66.5      | 53.2 - 79.8 | 211       | 169 - 254   | 298       | 238 - 357   | ng/mL  | 66.5      | 53.2 - 79.8 | 211       | 169 - 254   | 298       | 238 - 357   | µg/L   |
| Immunoturbidimetric (FERR4)                |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| Human Chorionic Gonadotropin (hCG)         |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA (STAT)                               | **        |             | **        |             | **        |             | mIU/mL | **        |             | **        |             | **        |             | IU/L   |
| Human Chorionic Gonadotropin-Beta (hCG)    |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA                                      | 15.8      | 12.6 - 18.9 | 248       | 198 - 297   | 344       | 275 - 412   | mIU/mL | 15.8      | 12.6 - 18.9 | 248       | 198 - 297   | 344       | 275 - 412   | IU/L   |
| Insulin                                    | 9.84      | 7.87 - 11.8 | 78.3      | 62.6 - 93.9 | 132       | 106 - 159   | µU/mL  | 68.3      | 54.6 - 82.0 | 544       | 435 - 652   | 918       | 734 - 1102  | pmol/L |
| ECLIA                                      | 3.31      | 2.65 - 3.97 | 9.57      | 7.66 - 11.5 | 24.6      | 19.7 - 29.5 | ng/mL  | 0.14      | 0.12 - 0.17 | 0.42      | 0.33 - 0.50 | 1.07      | 0.86 - 1.29 | nmol/L |
| Prolactin                                  |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA (Prolactin II)                       | 0.65      | 0.52 - 0.78 | 7.17      | 5.73 - 8.60 | 23.3      | 18.7 - 28.0 | ng/mL  | 0.65      | 0.52 - 0.78 | 7.17      | 5.73 - 8.60 | 23.3      | 18.7 - 28.0 | µg/L   |
| Prostate Specific Antigen (PSA)            |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA                                      | 0.53      | 0.43 - 0.64 | 5.52      | 4.41 - 6.62 | 17.9      | 14.3 - 21.5 | ng/mL  | 0.53      | 0.43 - 0.64 | 5.52      | 4.41 - 6.62 | 17.9      | 14.3 - 21.5 | µg/L   |
| Prostate Specific Antigen, Free (fPSA)     |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA                                      | 8.63      | 6.90 - 10.4 | 33.1      | 26.5 - 39.8 | 66.5      | 53.2 - 79.7 | ng/mL  | 8.63      | 6.90 - 10.4 | 33.1      | 26.5 - 39.8 | 66.5      | 53.2 - 79.7 | µg/L   |
| Thyroglobulin (a)                          |           |             |           |             |           |             |        |           |             |           |             |           |             |        |
| ECLIA                                      | 8.63      | 6.90 - 10.4 | 33.1      | 26.5 - 39.8 | 66.5      | 53.2 - 79.7 | ng/mL  | 8.63      | 6.90 - 10.4 | 33.1      | 26.5 - 39.8 | 66.5      | 53.2 - 79.7 | µg/L   |

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|------------------------------|--|------------|-----|-----------|-----|-----------|-----------|-----------|-----|-----------|-----|-----------|------|
|                              |  | TM24061A   |     | TM24062A  |     | TM24063A  |           | TM24061A  |     | TM24062A  |     | TM24063A  |      |
|                              |  | $\bar{x}$  | <R> | $\bar{x}$ | <R> | $\bar{x}$ | <R>       | $\bar{x}$ | <R> | $\bar{x}$ | <R> | $\bar{x}$ | <R>  |
| <b>U</b>                     |  |            |     |           |     |           |           |           |     |           |     |           |      |
| <b>ROCHE INTEGRA SYSTEMS</b> |  |            |     |           |     |           |           |           |     |           |     |           |      |
| Ferritin                     | Particle Enhanced<br>Immunoturbidimetric | **         |     | **        |     | **        |           | ng/mL     | **  |           | **  |           | µg/L |

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| U                                      | CON       |              |           |             |           |             |        | SI        |              |           |             |           |             |        |
|--|-----------|--------------|-----------|-------------|-----------|-------------|--------|-----------|--------------|-----------|-------------|-----------|-------------|--------|
|  | TM24061A  |              | TM24062A  |             | TM24063A  |             | U      | TM24061A  |              | TM24062A  |             | TM24063A  |             | U      |
|  | $\bar{x}$ | <R>          | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         |        | $\bar{x}$ | <R>          | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         |        |
| <b>SIEMENS ATELICA SYSTEMS</b>         |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Alpha-Fetoprotein (AFP)                |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence                      | 5.55      | 4.21 - 6.90  | 32.4      | 25.9 - 38.9 | 141       | 113 - 170   | ng/mL  | 4.59      | 3.47 - 5.70  | 26.7      | 21.4 - 32.1 | 117       | 93.4 - 140  | IU/mL  |
| Beta-2-Microglobulin (B2M)             |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Latex-enhanced<br>Immunoturbidimetric  | 0.70      | 0.56 - 0.83  | 1.53      | 1.22 - 1.84 | 4.02      | 3.21 - 4.82 | mg/L   | 58.9      | 47.1 - 70.6  | 130       | 104 - 156   | 340       | 272 - 408   | nmol/L |
| Cancer Antigen 125 (CA 125)            |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence<br>CA 125(I)         | 15.0      | 12.0 - 18.0  | 53.9      | 43.1 - 64.7 | 150       | 120 - 180   | U/mL   | 15.0      | 12.0 - 18.0  | 53.9      | 43.1 - 64.7 | 150       | 120 - 180   | kU/L   |
| Cancer Antigen 15-3 (CA 15-3)          |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence                      | 14.2      | 11.3 - 17.0  | 31.3      | 25.0 - 37.5 | 56.2      | 45.0 - 67.5 | U/mL   | 14.2      | 11.3 - 17.0  | 31.3      | 25.0 - 37.5 | 56.2      | 45.0 - 67.5 | kU/L   |
| Cancer Antigen 19-9 (CA 19-9)          |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence                      | 14.2      | 9.87 - 18.4  | 27.8      | 22.2 - 33.4 | 110       | 88.1 - 132  | U/mL   | 14.2      | 9.87 - 18.4  | 27.8      | 22.2 - 33.4 | 110       | 88.1 - 132  | kU/L   |
| Carcinoembryonic Antigen (CEA)         |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence                      | 1.36      | 1.09 - 1.63  | 10.2      | 8.13 - 12.2 | 47.1      | 37.7 - 56.5 | ng/mL  | 1.36      | 1.09 - 1.63  | 10.2      | 8.13 - 12.2 | 47.1      | 37.7 - 56.5 | µg/L   |
| Cortisol                               |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence<br>(Cor)             | 5.08      | 4.06 - 6.09  | 20.9      | 16.7 - 25.1 | 55.9      | 44.7 - 67.0 | µg/dL  | 140       | 112 - 168    | 577       | 462 - 693   | 1541      | 1233 - 1850 | nmol/L |
| Estradiol                              |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence<br>(Enhanced)(eE2)   | 134       | 107 - 160    | 461       | 369 - 553   | 1750      | 1400 - 2099 | pg/mL  | 491       | 392 - 589    | 1693      | 1355 - 2032 | 6423      | 5138 - 7707 | pmol/L |
| Ferritin                               |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence<br>(Fer)             | 38.7      | 31.0 - 46.4  | 136       | 109 - 163   | 209       | 167 - 250   | ng/mL  | 38.7      | 31.0 - 46.4  | 136       | 109 - 163   | 209       | 167 - 250   | µg/L   |
| Human Chorionic Gonadotropin (hCG)     |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence<br>(ThCG)            | 16.6      | 13.3 - 19.9  | 232       | 185 - 278   | 304       | 243 - 365   | mIU/mL | 16.6      | 13.3 - 19.9  | 232       | 185 - 278   | 304       | 243 - 365   | IU/L   |
| Insulin                                |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence<br>(IRI)             | 8.68      | 6.94 - 10.4  | 65.6      | 52.5 - 78.7 | 106       | 85.0 - 127  | µU/mL  | 60.3      | 48.2 - 72.3  | 456       | 365 - 547   | 738       | 590 - 885   | pmol/L |
| Prolactin                              |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence<br>(PRL)             | 3.23      | 2.58 - 3.87  | 8.54      | 6.83 - 10.2 | 21.7      | 17.3 - 26.0 | ng/mL  | 0.14      | 0.11 - 0.17  | 0.37      | 0.30 - 0.45 | 0.94      | 0.75 - 1.13 | nmol/L |
| Prostate Specific Antigen (PSA)        |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence                      | 0.60      | 0.48 - 0.72  | 6.79      | 5.43 - 8.15 | 23.4      | 18.7 - 28.0 | ng/mL  | 0.60      | 0.48 - 0.72  | 6.79      | 5.43 - 8.15 | 23.4      | 18.7 - 28.0 | µg/L   |
| Prostate Specific Antigen (PSA)        |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence<br>(cPSA)            | 0.04      | <0.03 - 0.06 | 0.40      | 0.32 - 0.48 | 1.20      | 0.96 - 1.44 | ng/mL  | 0.04      | <0.03 - 0.06 | 0.40      | 0.32 - 0.48 | 1.20      | 0.96 - 1.44 | µg/L   |
| Prostate Specific Antigen, Free (fPSA) |           |              |           |             |           |             |        |           |              |           |             |           |             |        |
| Chemiluminescence                      | 0.54      | 0.43 - 0.65  | 6.31      | 5.05 - 7.58 | 20.7      | 16.5 - 24.8 | ng/mL  | 0.54      | 0.43 - 0.65  | 6.31      | 5.05 - 7.58 | 20.7      | 16.5 - 24.8 | µg/L   |

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| <b>SIEMENS CENTAUR SYSTEMS</b>         |            |             |           |             |           |             |           |             |           |             |           |             |
| Alpha-Fetoprotein (AFP)                |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | **         |             | **        |             | **        |             | **        |             | **        |             | **        |             |
| Cancer Antigen 125 (CA 125)            |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 13.6       | 10.9 - 16.3 | 49.0      | 39.2 - 58.8 | 135       | 108 - 162   | 13.6      | 10.9 - 16.3 | 49.0      | 39.2 - 58.8 | 135       | 108 - 162   |
| Cancer Antigen 15-3 (CA 15-3)          |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 10.3       | 7.12 - 13.5 | 29.5      | 23.6 - 35.4 | 56.5      | 45.2 - 67.8 | 10.3      | 7.12 - 13.5 | 29.5      | 23.6 - 35.4 | 56.5      | 45.2 - 67.8 |
| Cancer Antigen 19-9 (CA 19-9)          |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 8.79       | 5.23 - 12.4 | 20.9      | 16.0 - 25.7 | 72.3      | 55.4 - 89.2 | 8.79      | 5.23 - 12.4 | 20.9      | 16.0 - 25.7 | 72.3      | 55.4 - 89.2 |
| Cancer Antigen 27.29 (CA 27.29)        |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | **         |             | **        |             | **        |             | **        |             | **        |             | **        |             |
| Carcinoembryonic Antigen (CEA)         |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 1.54       | 1.09 - 2.00 | 10.1      | 8.06 - 12.1 | 47.3      | 37.8 - 56.8 | 1.54      | 1.09 - 2.00 | 10.1      | 8.06 - 12.1 | 47.3      | 37.8 - 56.8 |
| Cortisol                               |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 4.20       | 3.36 - 5.04 | 18.1      | 14.5 - 21.7 | 51.6      | 41.2 - 61.9 | 116       | 92.7 - 139  | 499       | 399 - 599   | 1422      | 1138 - 1707 |
| Estradiol                              |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 125        | 79.7 - 170  | 473       | 378 - 568   | 1803      | 1443 - 2164 | 458       | 293 - 623   | 1737      | 1389 - 2084 | 6620      | 5296 - 7943 |
| Ferritin                               |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 39.9       | 31.9 - 47.8 | 138       | 111 - 166   | 215       | 172 - 258   | 39.9      | 31.9 - 47.8 | 138       | 111 - 166   | 215       | 172 - 258   |
| Human Chorionic Gonadotropin (hCG)     |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 17.4       | 13.9 - 20.9 | 237       | 190 - 284   | 315       | 252 - 378   | 17.4      | 13.9 - 20.9 | 237       | 190 - 284   | 315       | 252 - 378   |
| Insulin                                |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 9.39       | 7.51 - 11.3 | 69.1      | 55.3 - 82.9 | 111       | 89.0 - 133  | 65.2      | 52.1 - 78.2 | 480       | 384 - 576   | 772       | 618 - 927   |
| Prolactin                              |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 3.47       | 2.78 - 4.17 | 8.85      | 7.08 - 10.6 | 22.7      | 18.1 - 27.2 | 0.15      | 0.12 - 0.18 | 0.39      | 0.31 - 0.46 | 0.99      | 0.79 - 1.18 |
| Prostate Specific Antigen (PSA)        |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 0.60       | 0.48 - 0.72 | 6.20      | 4.96 - 7.44 | 21.4      | 17.1 - 25.6 | 0.60      | 0.48 - 0.72 | 6.20      | 4.96 - 7.44 | 21.4      | 17.1 - 25.6 |
| Prostate Specific Antigen (PSA)        |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | **         |             | **        |             | **        |             | **        |             | **        |             | **        |             |
| Prostate Specific Antigen, Free (fPSA) |            |             |           |             |           |             |           |             |           |             |           |             |
| Chemiluminescence                      | 0.49       | 0.39 - 0.59 | 5.64      | 4.51 - 6.77 | 19.0      | 15.2 - 22.8 | 0.49      | 0.39 - 0.59 | 5.64      | 4.51 - 6.77 | 19.0      | 15.2 - 22.8 |

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| <b>SIEMENS DIMENSION SYSTEMS</b>                  |   |            |             |           |             |           |             |           |      |             |      |             |      |             |      |
| Ferritin EIA (FERR)                               |   | 58.1       | 46.5 - 69.7 | 182       | 145 - 218   | 272       | 218 - 327   | ng/mL     | 58.1 | 46.5 - 69.7 | 182  | 145 - 218   | 272  | 218 - 327   | µg/L |
| Prostate Specific Antigen (PSA) EIA (TPSA)        |   | 0.57       | 0.45 - 0.68 | 7.08      | 5.66 - 8.49 | 23.2      | 18.6 - 27.9 | ng/mL     | 0.57 | 0.45 - 0.68 | 7.08 | 5.66 - 8.49 | 23.2 | 18.6 - 27.9 | µg/L |
| Prostate Specific Antigen, Free (fPSA) EIA (FPSA) |   | **         |             | **        |             | **        |             | ng/mL     | **   |             | **   |             | **   |             | µg/L |

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|   | $\bar{x}$  | <R>         | $\bar{x}$ | <R>         | $\bar{x}$ | <R>          | $\bar{x}$ | <R>  | $\bar{x}$   | <R>  | $\bar{x}$   | <R>  |              | <b>U</b> |
| <b>SIEMENS DIMENSION VISTA SYSTEMS</b>  |            |             |           |             |           |              |           |      |             |      |             |      |              |          |
| Alpha-Fetoprotein (AFP)<br>LOC <sup>®</sup>                                       | 5.17       | 4.14 - 6.20 | 32.2      | 25.7 - 38.6 | 143       | 115 - 172    | ng/mL     | 4.27 | 3.42 - 5.12 | 26.6 | 21.3 - 31.9 | 118  | 94.7 - 142   | IU/mL    |
| Beta-2-Microglobulin (B2M)<br>Nephelometric (B2MIC)                               | **         |             | **        |             | **        |              | mg/L      | **   |             | **   |             | **   |              | nmol/L   |
| Cancer Antigen 125 (CA 125)<br>LOC <sup>®</sup>                                   | 13.9       | 11.1 - 16.6 | 49.9      | 39.9 - 59.9 | 131       | 105 - 157    | U/mL      | 13.9 | 11.1 - 16.6 | 49.9 | 39.9 - 59.9 | 131  | 105 - 157    | kU/L     |
| Cancer Antigen 15-3 (CA 15-3)<br>LOC <sup>®</sup>                                 | **         |             | **        |             | **        |              | U/mL      | **   |             | **   |             | **   |              | kU/L     |
| Cancer Antigen 19-9 (CA 19-9)<br>LOC <sup>®</sup>                                 | **         |             | **        |             | **        |              | U/mL      | **   |             | **   |             | **   |              | kU/L     |
| Carcinoembryonic Antigen (CEA)<br>LOC <sup>®</sup>                                | 0.94       | 0.75 - 1.13 | 8.55      | 6.48 - 10.6 | 41.2      | 32.9 - 49.4  | ng/mL     | 0.94 | 0.75 - 1.13 | 8.55 | 6.48 - 10.6 | 41.2 | 32.9 - 49.4  | µg/L     |
| Estradiol<br>LOC <sup>®</sup>   | **         |             | **        |             | **        |              | pg/mL     | **   |             | **   |             | **   |              | pmol/L   |
| Ferritin<br>LOC <sup>®</sup>  | **         |             | **        |             | **        |              | ng/mL     | **   |             | **   |             | **   |              | µg/L     |
| Human Chorionic Gonadotropin-Beta (hCG)<br>LOC <sup>®</sup>                       | 23.7       | 19.0 - 28.4 | 385       | 308 - 462   | 559       | 447 - 671    | mIU/mL    | 23.7 | 19.0 - 28.4 | 385  | 308 - 462   | 559  | 447 - 671    | IU/L     |
| Prolactin<br>LOC <sup>®</sup>   | 2.95       | 2.36 - 3.54 | 9.07      | 7.26 - 10.9 | 24.9      | 19.9 - 29.8  | ng/mL     | 0.13 | 0.10 - 0.15 | 0.39 | 0.32 - 0.47 | 1.08 | 0.86 - 1.30  | nmol/L   |
| Prostate Specific Antigen (PSA)<br>LOC <sup>®</sup> (TPSA)                        | **         |             | **        |             | **        |              | ng/mL     | **   |             | **   |             | **   |              | µg/L     |
| Prostate Specific Antigen, Free (fPSA)<br>LOC <sup>®</sup> (fPSA)                 | 0.49       | 0.37 - 0.62 | 5.69      | 4.16 - 7.21 | 18.5      | 14.8 - >20.0 | ng/mL     | 0.49 | 0.37 - 0.62 | 5.69 | 4.16 - 7.21 | 18.5 | 14.8 - >20.0 | µg/L     |

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| <b>SIEMENS IMMULITE SYSTEMS</b>                 |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Alpha-Fetoprotein (AFP)                         |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence (AF)                          | **        |     | **        |     | **        |     | ng/mL     | **  | **        | **  |           |     | IU/mL  |
| Beta-2-Microglobulin (B2M)                      |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | mg/L      | **  | **        | **  |           |     | nmol/L |
| Calcitonin                                      |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | pg/mL     | **  | **        | **  |           |     | pmol/L |
| Cancer Antigen 125 (CA 125)                     |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence (OV)                          | **        |     | **        |     | **        |     | U/mL      | **  | **        | **  |           |     | kU/L   |
| Cancer Antigen 15-3 (CA 15-3)                   |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence (BRM)                         | **        |     | **        |     | **        |     | U/mL      | **  | **        | **  |           |     | kU/L   |
| Cancer Antigen 19-9 (CA 19-9)                   |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence (GIM)                         | **        |     | **        |     | **        |     | U/mL      | **  | **        | **  |           |     | kU/L   |
| Carcinoembryonic Antigen (CEA)                  |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | ng/mL     | **  | **        | **  |           |     | µg/L   |
| Cortisol  |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | µg/dL     | **  | **        | **  |           |     | nmol/L |
| Estradiol                                       |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence (Non U.S.)                    | **        |     | **        |     | **        |     | pg/mL     | **  | **        | **  |           |     | pmol/L |
| Ferritin  |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | ng/mL     | **  | **        | **  |           |     | µg/L   |
| Gastrin   |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | pg/mL     | **  | **        | **  |           |     | pmol/L |
| Human Chorionic Gonadotropin (hCG)              |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | mIU/mL    | **  | **        | **  |           |     | IU/L   |
| Human Chorionic Gonadotropin (hCG) (STAT/Turbo) |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | mU/mL     | **  | **        | **  |           |     | IU/L   |
| Insulin   |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | µU/mL     | **  | **        | **  |           |     | pmol/L |
| Prolactin                                       |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | ng/mL     | **  | **        | **  |           |     | nmol/L |
| Prostate Specific Antigen (PSA) (3PS)           |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | ng/mL     | **  | **        | **  |           |     | µg/L   |
| Prostate Specific Antigen (PSA) (PTS)           |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | ng/mL     | **  | **        | **  |           |     | µg/L   |
| Prostate Specific Antigen, Free (fPSA) (fPS)    |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | ng/mL     | **  | **        | **  |           |     | µg/L   |
| Prostatic Acid Phosphatase (PAP) (PAP)          |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | ng/mL     | **  | **        | **  |           |     | µg/L   |
| Thyroglobulin (a)                               |           |     |           |     |           |     |           |     |           |     |           |     |        |
| Chemiluminescence                               | **        |     | **        |     | **        |     | ng/mL     | **  | **        | **  |           |     | µg/L   |

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| U  | CON       |             |           |             |           |              | SI        |      |             |      |             |       |               |        |
|--|-----------|-------------|-----------|-------------|-----------|--------------|-----------|------|-------------|------|-------------|-------|---------------|--------|
|  | TM24061A  |             | TM24062A  |             | TM24063A  |              | TM24061A  |      | TM24062A    |      | TM24063A    |       | U             |        |
|  | $\bar{x}$ | <R>         | $\bar{x}$ | <R>         | $\bar{x}$ | <R>          | $\bar{x}$ | <R>  | $\bar{x}$   | <R>  | $\bar{x}$   | <R>   |               |        |
| <b>TOSOH AIA SYSTEMS</b>                       |           |             |           |             |           |              |           |      |             |      |             |       |               |        |
| Adrenocorticotrophic Hormone (ACTH)<br>EIA     | 17.6      | 12.3 - 22.9 | 25.2      | 17.7 - 32.8 | 28.2      | 19.7 - 36.7  | pg/mL     | 3.91 | 2.74 - 5.09 | 5.60 | 3.92 - 7.28 | 6.26  | 4.38 - 8.14   | pmol/L |
| Alpha-Fetoprotein (AFP)<br>EIA                 | 4.70      | 3.30 - 6.10 | 29.1      | 20.4 - 37.8 | 124       | 86.8 - 161   | ng/mL     | 3.88 | 2.73 - 5.04 | 24.0 | 16.9 - 31.2 | 102   | 71.7 - 133    | IU/mL  |
| Beta-2-Microglobulin (B2M)<br>EIA              | 0.67      | 0.47 - 0.87 | 1.52      | 1.06 - 1.98 | 3.83      | 2.68 - 4.98  | mg/L      | 56.6 | 39.6 - 73.6 | 129  | 90.1 - 167  | 325   | 227 - 422     | nmol/L |
| Cancer Antigen 125 (CA 125)<br>EIA             | 12.8      | 9.00 - 16.6 | 49.4      | 34.6 - 64.2 | 149       | 104 - 193    | U/mL      | 12.8 | 9.00 - 16.6 | 49.4 | 34.6 - 64.2 | 149   | 104 - 193     | kU/L   |
| Cancer Antigen 19-9 (CA 19-9)<br>EIA           | 6.30      | 4.40 - 8.20 | 13.2      | 9.20 - 17.2 | 41.8      | 29.3 - 54.3  | U/mL      | 6.30 | 4.40 - 8.20 | 13.2 | 9.20 - 17.2 | 41.8  | 29.3 - 54.3   | kU/L   |
| Cancer Antigen 27.29 (CA 27.29)<br>EIA         | 10.5      | 7.35 - 13.7 | 26.0      | 18.2 - 33.8 | 47.6      | 33.3 - 61.9  | U/mL      | 10.5 | 7.35 - 13.7 | 26.0 | 18.2 - 33.8 | 47.6  | 33.3 - 61.9   | kU/L   |
| Carcinoembryonic Antigen (CEA)<br>EIA          | 1.60      | 1.10 - 2.10 | 14.9      | 10.4 - 19.4 | 68.0      | 47.6 - 88.4  | ng/mL     | 1.60 | 1.10 - 2.10 | 14.9 | 10.4 - 19.4 | 68.0  | 47.6 - 88.4   | µg/L   |
| Cortisol<br>EIA                                | 3.80      | 2.70 - 4.90 | 15.5      | 10.9 - 20.2 | 51.9      | 36.3 - >60.0 | µg/dL     | 105  | 74.5 - 135  | 428  | 301 - 557   | 1432  | 1002 - >1655  | nmol/L |
| Estradiol<br>EIA (E2)                          | 318       | 223 - 413   | 737       | 516 - 958   | 2336      | 1636 - >3000 | pg/mL     | 1167 | 817 - 1516  | 2705 | 1894 - 3517 | 8577  | 6004 - >11013 | pmol/L |
| Estradiol<br>EIA (hsE2)                        | 43.2      | 30.2 - 56.2 | 337       | 236 - 438   | >1000     |              | pg/mL     | 159  | 111 - 206   | 1235 | 865 - 1606  | >3671 |               | pmol/L |
| Estradiol<br>EIA (iE2)                         |           |             |           |             |           |              | pg/mL     |      |             |      |             |       |               | pmol/L |
| Ferritin<br>EIA                                | 39.3      | 27.5 - 51.1 | 138       | 96.7 - 180  | 214       | 150 - 279    | ng/mL     | 39.3 | 27.5 - 51.1 | 138  | 96.7 - 180  | 214   | 150 - 279     | µg/L   |
| Human Chorionic Gonadotropin-Beta (hCG)<br>EIA | 25.2      | 17.6 - 32.8 | 346       | 242 - >400  | >400      |              | mIU/mL    | 25.2 | 17.6 - 32.8 | 346  | 242 - >400  | >400  |               | IU/L   |
| Insulin<br>EIA                                 | 8.80      | 6.20 - 11.4 | 75.2      | 52.6 - 97.8 | 127       | 88.9 - 165   | µU/mL     | 61.1 | 43.1 - 79.2 | 522  | 365 - 679   | 882   | 617 - 1147    | pmol/L |
| Prolactin<br>EIA                               | 2.80      | 1.30 - 4.30 | 8.20      | 5.70 - 10.7 | 20.4      | 14.3 - 26.5  | ng/mL     | 0.12 | 0.06 - 0.19 | 0.36 | 0.25 - 0.47 | 0.89  | 0.62 - 1.15   | nmol/L |
| Prostate Specific Antigen (PSA)<br>EIA         | 0.58      | 0.41 - 0.75 | 6.10      | 4.27 - 7.93 | 19.2      | 13.4 - 25.0  | ng/mL     | 0.58 | 0.41 - 0.75 | 6.10 | 4.27 - 7.93 | 19.2  | 13.4 - 25.0   | µg/L   |
| Prostatic Acid Phosphatase (PAP)<br>EIA        | 1.60      | 1.10 - 2.10 | 16.7      | 11.7 - 21.7 | 38.4      | 26.9 - >40.0 | ng/mL     | 1.60 | 1.10 - 2.10 | 16.7 | 11.7 - 21.7 | 38.4  | 26.9 - >40.0  | µg/L   |



**AxSYM**®, **IMx**®, **Architect**®, **Aerosep**®, Reg. TM: Abbott Laboratories, Inc., Abbott Park, IL  
**Centaur**®, **Immulite**®, Reg. TM: Siemens Healthcare Diagnostics, Tarrytown, NY  
**Access**®, **Dxl**®, Reg. TM: Beckman-Coulter Inc., Brea, CA  
**Dimension**®, Reg. TM: Siemens Healthcare Diagnostics, Glasgow, DE  
**DSL RIA**®, Reg. TM: Diagnostic Systems Laboratories, Inc., Webster, TX  
**Vitros ECI**®, Reg. TM: Ortho Clinical Diagnostics, Rochester, NY  
**Elecsys**®, **Integra**®, **Modular E-170**®, **Cobas 'o' Systems**, Reg. TM: Roche Diagnostics, Inc, Indianapolis, IN  
**AIA Systems**, Reg. TM: Tosoh Medics Inc., S. San Francisco, CA

\*\* **Data not available. If interested in participating in our value assignment process, please fax or email your contact information to our Value Assignment group at 510-771-1539, or [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).**

\*\* Keine Daten verfügbar. Wenn Sie an unserem Wertzuweisungsprozess teilnehmen möchten, senden Sie Ihre Kontaktdaten bitte per Fax oder E-Mail an unsere Wertzuweisungsgruppe unter 510-771-1539 oder [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

\*\* Données non disponibles. Si vous souhaitez participer à notre processus d'affectation des valeurs, veuillez nous faire parvenir vos coordonnées par fax ou par e-mail au groupe Value Assignment au 510-771-1539 ou à l'adresse [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

\*\* Dati non disponibili. Per partecipare al processo di assegnazione dei valori, inviare tramite fax o e-mail le proprie informazioni di contatto al gruppo Value Assignment al numero 510-771-1539 o all'indirizzo [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

\*\* Datos no disponibles. Si está interesado en participar en nuestro proceso de asignación de valor, envíe su información de contacto a nuestro grupo de asignación de valor por fax al 510-771-1539 o por correo electrónico a [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

\*\* Data er ikke tilgængelige. Hvis du er interesseret i at deltage i vores værditildelingsproces, kan du sende dine kontaktoplysninger via fax eller e-mail til vores værditildelingsafdeling på 510-771-1539 eller [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

\*\* Geen gegevens beschikbaar. Als u geïnteresseerd bent in deelname aan ons waardetoewijzingsproces, kunt u uw contactgegevens faxen of e-mailen naar onze Value Assignment-groep via 510-771-1539 of via [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

\*\* Tietoja ei saatavilla. Jos olet kiinnostunut osallistumaan arvojen määrittämissä, faksa tai lähetä sähköpostilla yhteystietosi Value Assignment -osastollemme numeroon 510 771 1539 tai osoitteeseen [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

\*\* Δεν υπάρχουν διαθέσιμα δεδομένα. Εάν ενδιαφέρεστε να συμμετάσχετε στη διαδικασία καθορισμού τιμών που εφαρμόζουμε, στείλτε φάξ ή email με τις πληροφορίες επικοινωνίας σας στην ομάδα Καθορισμού τιμών της εταιρείας μας στο τηλ. 510-771-1539 ή στη διεύθυνση [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

\*\* Data ikke tilgjengelig. Hvis du er interessert i å delta i vår verditilordningsprosess, kan du sende en faks eller e-post med din kontakinformasjon til vår Value Assignment group på henholdsvis 510-771-1539 og [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

\*\* Dane nie są dostępne. W razie zainteresowania udziałem w naszym procesie przypisywania wartości należy przelać swoje dane kontaktowe do naszej grupy ds. przypisywania wartości faksem pod numer 510-771-1539 lub pocztą elektroniczną na adres [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

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\*\* Данные отсутствуют. Если вы хотите принять участие в процедуре определения числовых параметров, сообщите ваши контактные данные нашей группе специалистов по определению числовых параметров по факсу 510-771-1539 или электронной почте [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com).

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\*\* Veri mevcut değildir. Değer atama sürecimize katılmak istiyorsanız lütfen iletişim bilgilerinizi 510-771-1539 numaralı telefona faks göndererek veya [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com) adresine e-posta göndererek Değer Atama grubumuza iletin.

\*\* 无法提供数据。如果有兴趣参与我们的赋值过程，请传真或以电子邮件发送您的联系方式到我们的赋值小组。传真号码 510-771-1539，或发送邮件至 [mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com)。

\*\* ご利用になれないデータです。値付けプロセスへの参加を希望される場合は、当社の値付け担当グループまでお客様の連絡先情報を Fax (510-771-1539) または電子メール ([mgc-va@thermofisher.com](mailto:mgc-va@thermofisher.com)) にてご連絡ください。

(a) **Thyroglobulin stability may be less than general stability of other constituents. If levels fall below expected values, retest using a new kit/lot.**

(a) Die Stabilität von Thyroglobulin kann im Vergleich zur allgemeinen Stabilität der anderen Bestandteile vermindert sein. Wenn die Konzentrationen unter die erwarteten Werte fallen, den Test mit einem neuen Kit/einer neuen Charge wiederholen.

(a) La stabilité de la thyroglobuline peut être inférieure à la stabilité générale des autres constituants. Si les niveaux sont inférieurs aux valeurs attendues, effectuer un autre test en utilisant un nouveau kit/lot.

(a) La stabilità della tireoglobulina potrebbe essere inferiore alla stabilità generale di altri costituenti. Se i livelli scendono al di sotto dei valori previsti, ripetere il test utilizzando un nuovo kit/lotto.

(a) La estabilidad de la tiroglobulina puede ser inferior a la estabilidad general de otros componentes. Si los niveles están por debajo de los valores esperados, repita la prueba con un lote o kit nuevo.

(a) Holdbarheden for thyroglobulin kan være mindre end den generelle holdbarhed for andre bestanddele. Hvis niveauerne falder til under de forventede niveauer, skal testen udføres igen med et nyt kit/parti.

(a) De stabiliteit van thyroglobuline kan geringer zijn dan de algemene stabiliteit van andere bestanddelen. Als de niveaus lager zijn dan verwachte waarden, voer de test dan opnieuw uit met een nieuwe kit/partij.

(a) Thyroglobuliiniin stabiilius voi olla heikompi kuin muiden ainesosien yleinen stabiilius. Jos tasot putoavat odotettujen arvojen alapuolelle, testi on suoritettava uudelleen uudella sarjalla/erällä.

(a) Η σταθερότητα θυρεοσφαιρίνης ενδέχεται να είναι χαμηλότερη από τη γενική σταθερότητα των άλλων συστατικών. Εάν τα επίπεδα είναι χαμηλότερα από τις αναμενόμενες τιμές, επαναλάβετε την εξέταση με νέο κιτ/ νέα παρτίδα.

(a) Thyroglobuliinstabiliteten kan være lavere enn den generelle stabiliteten for andre konstituentter. Hvis et nivå faller under forventede verdier, tester du på nytt med nytt kit / ny lot.

(a) Stabiłność tyreoglobuliny może być mniejsza niż stabilność ogólna pozostałych składników. Jeśli poziomy spadną poniżej oczekiwanych wartości, należy ponownie przeprowadzić testy, używając nowego zestawu / nowej partii.

(a) A estabilidade da tiroglobulina pode ser inferior à estabilidade geral de outros componentes. Se os níveis ficarem abaixo dos valores esperados, efetue novamente o teste com um novo kit/lote.

(a) Стабильность тиреоглобулина может быть меньше общей стабильности остальных компонентов. При получении уровней ниже ожидаемых значений, повторите тест, используя новый набор/партию.

(a) Stabiliteten för tyreoglobulin kan vara lägre än den allmänna stabiliteten för andra beståndsdelar. Gör om testet med ett nytt kit/parti om nivåerna är lägre än de förväntade värdena.

(a) Tiroglobulin stabilitesi diğer bileşenlerin genel stabilitesinden daha düşük olabilir. Seviyeler beklenen değerlerin altına düşerse yeni bir kit/lot ile tekrar test edin.

(a) 甲状腺球蛋白的稳定性可能会比其他成分的一般稳定性差。如果级别低于预期值，使用一套/批新产品重新检测。

(a) サイログロブリンの安定性は、他の成分の一般的な安定性より低い場合があります。レベルが予測値未満であった場合は、新しいキット/ロットを使用して再検査してください。

**LOT**

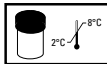
Lot Number / Chargennummer / Numéro de lot / Numero di lotto / Número de lote / Partinummer / Partijnummer / Eränumero / Αριθμός παρτίδας / Lotnummer / Numer partii / Número de lote / Номер лота / Partinummer / Lot Numarası / 批号 / ロット番号



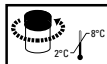
“Use By” date / Verwendbar bis / Date limite d'utilisation optimale / “Utilizzare entro” / Fecha límite de uso / “Anvendes før”-dato / Houdbaarheidsdatum / “Käyt. viim.”-päivämäärä / Ημερομηνία λήξης / Utløpsdato / Termin przydatności / Data de validade / Дата «Использовать до» / Utgångsdatum / “Son Kullanim” tarihi / 此日期前使用 / 使用期限



Shelf life: Frozen Temperature / Date limite d'utilisation optimale / Durée de conservation : température de congélation / Data di scadenza: se conservato a temperatura di congelamento / Vida útil: temperatura de congelación / Holdbarhed: Frysetemperatur / Houdbaarheidsperiode: in bevroren toestand / Käyttöikä: pakastuslämpötilassa / Διάρκεια ζωής: θερμοκρασία κατάψυξης / Holdbarhet: Frysetemperatur / Okres trwałości: temperatura zamrażania / Prazo de validade: Temperatura congelada / Срок хранения: температура замораживания / Hållbarhetstid: Fryst temperatur / Raf ömrü: Donma Sıcaklığı / 保质期: 冻结温度 / 有効期間: 凍結時温度



Unopened Vial Stability: Refrigerated Temperature / Haltbarkeit des ungeöffneten Fläschchens: Kühltemperatur / Stabilité du flacon non ouvert : température de réfrigération / Stabilità provetta non aperta: a temperatura refrigerata / Estabilidad del vial sin abrir: temperatura refrigerada / Stabilitet i uåbnet hætteglas: Nedkølet / Stabilitet van ongeopend flesje: in gekoelde toestand / Avaamattoman ampullin stabiilius: jääkaappilämpötilassa / Σταθερότητα σφραγισμένου φιαλιδίου: θερμοκρασία ψύξης / Stabilitet i uåbnet tilstand: Kjøletemperatur / Stabilność odczynników w nieotwartej fiole: temperatura chłodzenia / Estabilidade no frasco fechado: Temperatura refrigerada / Стабильность не вскрытого флакона: температура охлаждения / Hållbarhet vid öppnad flaska: kyld temperatur / Açılmamış Flakon Stabilesi: Soğutulmuş Sıcaklık / 未开封药瓶稳定性: 冷藏温度 / 未开封のバイアル安定性: 冷蔵温度



Opened Vial Stability: Refrigerated Temperature / Haltbarkeit des geöffneten Fläschchens: Kühltemperatur / Stabilité du flacon ouvert : température de réfrigération / Stabilità provetta aperta: a temperatura refrigerata / Estabilidad del vial abierto: temperatura refrigerada / Stabilitet i åbnet hætteglas: Nedkølet / Stabilitet van geopend flesje: in gekoelde toestand / Avatun ampullin stabiilius: jääkaappilämpötilassa / Σταθερότητα ανοιγμένου φιαλιδίου: θερμοκρασία ψύξης / Stabilitet i åpnet tilstand: Kjøletemperatur / Stabilność odczynników w otwartej fiole: temperatura chłodzenia / Estabilidade no frasco aberto: Temperatura refrigerada / Стабильность вскрытого флакона: температура охлаждения / Hållbarhet vid öppnad flaska: kyld temperatur / Açılmamış Flakon Stabilesi: Soğutulmuş Sıcaklık / 已开封药瓶稳定性: 冷藏温度 / 开封後のバイアル安定性: 冷蔵温度

**REF**

Catalog Number / Katalognummer / Catalogue N° / Numero di catalogo / Número de catálogo / Katalognummer / Katalognummer / Katalognummer / Tuotenumero / Αριθμός καταλόγου / Katalognummer / Numer katalogowy / Referência / Номер по каталогу / Katalognummer / Katalog Numarası / 目录编号 / カタログ番号



Manufacturer / Hersteller / Fabricant / Produttore / Fabricante / Producent / Fabrikant / Valmistaja / Κατασκευαστής / Produzent / Producent / Fabricante / Производитель / Tillverkare / Üretici / 制造商 / 製造元



Caution / Vorsicht / Attention / Attenzione / Atención / Forsigtig / Let op / Varoitus / Προσοχή / Advarsel / Przestroga / Cuidado / Осторожно / Viktigt / Dikkat / 注意 / 注意



Consult instructions for use / Gebrauchsanweisung beachten / Se référer au mode d'emploi / Consultare le istruzioni per l'uso / Consultar las instrucciones de uso / Se brugsanvisningen / Raadpleeg de gebruiksaanwijzing / Katso käyttöohjeita / Συμβουλευτείτε τις οδηγίες χρήσης / Se i brugsanvisningen / Sprawdzić w instrukcji użytkowania / Consultar instruções de utilização / См. инструкцию по применению / Läs brugsanvisningen / Kullanım talimatlarına başvurun / 参阅使用说明 / 取扱説明書を参照

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**IVD**

For In Vitro Diagnostic Use / In-vitro-Diagnostikum / Diagnostics in vitro / Per uso diagnostico in vitro / Para uso en diagnóstico in vitro / Til in vitro-diagnostisk anvendelse / Voor diagnostisch gebruik in vitro / In Vitro -diagnostiseen käyttöön / Για In Vitro διαγνωστική χρήση / For in vitro-diagnostikk / Do stosowania w diagnostyce in vitro / Para utilização em diagnóstico in vitro / Для использования в диагностике in vitro / För in vitro-diagnostisk användning / In Vitro Diagnostik Kullanım İçin / 体外诊断用 / 体外診断用



Biological risk / Biogefährdung / Matériel à risque biologique potentiel / Rischio biologico / Material potencialmente peligroso a nivel biológico / Biologisk risiko / Biologisch risiko / Biologinen riski / Βιολογικός κίνδυνος / Biologisk risiko / Zagrożenie biologiczne / Risco biológico / Сроки хранения: температура замораживания / Биологическая опасность / Biologisk risk / Biyolojik risk / 生物风险 / 生物学的リスク

**CE 0197**

CE Marking of Conformity / CE-Konformitätszeichen / Marquage CE de conformité / Marchio di conformità CE / Marca de conformidad CE / CE-mærkning / CE-conformiteitsmerk / CE-merkintä / Σήμανση συμμόρφωσης CE / CE-samsvarsmerking / Oznakowanie zgodności CE / Marca de Conformidade CE / Маркировка соответствия стандартам CE / CE-försäkran om överensstämmelse / CE Uyumluluk İlgareti / CE 合格标志 / 適合の CE マーキング

**X̄**

Mean Value / Mittelwert / Valeur moyenne / Valore medio / Valor medio / Gennemsnitsværdi / Gemiddelde waarde / Keskiarvo / Μέση τιμή / Middelværdi / Wartość średnia / Valor médio / Среднее значение / Medelvärde / Ortalama Değer / 平均值 / 平均值

**<R>**

Expected Range / Erwarteter Bereich / Valeur attendue / Intervallo previsto / Intervallo previsto / Forventet område / Verwachte bereik / Odottettu vaihteluväli / Αναμενόμενο εύρος / Forventet område / Zakres wartości oczekiwanych / Intervallo esperado / Ожидаемый интервал / Förväntat intervall / Beklenen Aralık / 预期范围 / 予測範囲

**U**

Units / Einheiten / Unités / Unità / Unidades / Enheder / Eenheden / Yksiköt / Μονάδες / Enheter / Jednostki / Unidades / Единицы / Enheter / Birimler / 單位 / 單位

**CON**

Conventional Units / Konventionelle Einheiten / Unités conventionnelles / Unità convenzionali / Unidades convencionales / Konventionelle enheder / Conventionele eenheden / Perinteiset yksiköt / Συμβατικές μονάδες / Konvensjonelle enheter / Jednostki konwencjonalne / Unidades convencionais / Условные единицы / Konventionella enheter / Konvansiyonel Birimler / 常用單位 / 慣用單位

**SI**

System International Units / SI-Einheiten / Système international d'unités / Unità sistema internazionale / Unidades del sistema internacional / SI-systemet / System International-eeenheden / Kansainväiset yksiköt / Μονάδες διεθνούς συστήματος / SI-enheter / Jednostki w układzie SI / Unidades do Sistema Internacional / Единицы СИ / SI-enheter / Sistem Uluslararası Birimleri / 国际单位 / 國際單位系

**U**

Constituent and Method / Bestandteil und Methode / Composant et méthode / Componente e metodo / Componente y método / Bestanddel og metode / Bestanddeel en methode / Aineosa ja menetelmä / Συστατικό και μέθοδος / Konstituent og metode / Składnik i metoda / Componentes e método / Компонент и метод / Innehåll och metod / Bileşen ve Yöntem / 成分和方法 / 成分および測定法

**If you have any questions concerning this notification, in the USA please contact the Technical Support Department at 800-232-3342 or 510-979-5417. Outside the USA, please contact your local Subsidiary or Distributor.**

Falls Sie Fragen zu dieser Benachrichtigung haben, wenden Sie sich in den USA an den technischen Kundendienst unter 800-232-3342 oder 510-979-5417. Außerhalb der USA wenden Sie sich bitte an die Vertriebsniederlassung in Ihrer Nähe oder an einen autorisierten Vertriebspartner.

Aux États-Unis, pour toute question concernant cet avis, contacter le Service d'assistance technique au 800-232-3342 ou au 510-979-5417. En dehors des États-Unis, contacter la filiale locale ou le distributeur local.

Per domande relative a questa notifica e vi trovate negli Stati Uniti, rivolgersi al servizio di assistenza tecnica al numero verde 800-232-3342 o al numero 510-979-5417. Al di fuori degli Stati Uniti, rivolgersi alla filiale locale o al distributore.

Para cualquier consulta acerca de esta notificación, en EE.UU. póngase en contacto con el Departamento de Asistencia técnica en los números 800-232-3342 or 510-979-5417. Fuera de EE.UU., póngase en contacto con la subsidiaria o el distribuidor local.

Hvis du har nogle spørgsmål til denne meddelelse, kan du kontakte den tekniske supportafdeling på 800-232-3342 eller 510-979-5417, hvis du befinder dig i USA. Uden for USA kan du kontakte det lokale datterselskab eller distributøren.

Als u vragen hebt over deze kennisgeving, kunt u contact opnemen met de afdeling Technische ondersteuning op 800-232-3342 of 510-979-5417. Buiten de VS kunt u contact opnemen met de vestiging of distributeur in uw land.

Jos sinulla on kysyttävää tästä ilmoituksesta, ota Yhdysvalloissa yhteyttä tekniseen tukeen numeroon 800 232 3342 tai 510 979 5417. Ota Yhdysvaltojen ulkopuolella yhteyttä paikalliseen tytäryhtiöön tai jälleenmyyjään.

Για οποιοδήποτε ερωτήσεις αναφορικά με την παρούσα ειδοποίηση, εντός Η.Π.Α., επικοινωνήστε με το Τμήμα τεχνικής υποστήριξης στον αριθμό 800-232-3342 ή 510-979-5417. Εκτός Η.Π.Α., επικοινωνήστε με την τοπική σας θυγατρική ή τον τοπικό διανομέα.

Dersom du befinner deg i USA og har spørsmål knyttet til denne orienteringen, kontakter du avdelingen for teknisk støtte på 800-232-3342 eller 510-979-5417. Dersom du befinner deg utenfor USA, kontakter du din lokale forhandler eller distributør.

W razie jakichkolwiek pytań dotyczących tego powiadomienia, należy skontaktować się z działem wsparcia technicznego pod numerem 800-232-3342 lub 510-979-5417 (na obszarze Stanów Zjednoczonych). Poza obszarem Stanów Zjednoczonych należy skontaktować się z lokalnym oddziałem firmy lub dystrybutorem.

Se tiver quaisquer questões relativas a esta notificação, nos EUA por favor contacte o departamento de assistência técnica através do número 800-232-3342 ou 510-979-5417. Fora dos EUA, por favor contacte a filial da sua área ou o distribuidor local.

Если у вас есть вопросы относительно этого уведомления, в США обращайтесь в департамент технической поддержки по телефону 800-232-3342 или 510-979-5417. За пределами США обращайтесь в местную дочернюю компанию или к дистрибьютору.

Om du har några frågor om den här informationen och befinner dig i USA kan du kontakta vår avdelning för teknisk support på telefonnummer +1 800-232-3342 eller +1 510-979-5417. Utanför USA kan du kontakta ditt lokala avdelningskontor eller en distributör.

Bu bildirimde dair herhangi bir sorunuz varsa, ABD'de lütfen 800-232-3342 veya 510-979-5417 numaralı Teknik Destek Departmanı ile iletişim kurun. ABD'nin dışında, lütfen yerel Bayi veya Dağıtıcı ile iletişim kurun.

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本通知に関するお問い合わせについては、米国内からはお電話にて (800-232-3342 または 510-979-5417) テクニカルサポート部門までお問い合わせください。米国外の場合は、地域の子会社または代理店までお問い合わせください。

**USA**  
☎ 800-232-3342  
sales.diagnostics.fmt@thermofisher.com

**China**  
☎ +86 800-810-5118  
cdx.cn.info@thermofisher.com

**New Zealand**  
☎ 0800 933 966  
auinfo@thermofisher.com

**Switzerland & Austria**  
☎ +41 26 663 86 70  
cdx.ch.info@thermofisher.com

**Asia Pacific**  
☎ +61 1800 333 110  
cdd.asia.info@thermofisher.com

**France**  
☎ +33 1 40 86 65 20  
cdx.fr.info@thermofisher.com

**Nordic**  
☎ +47 2 325 0433  
info.nordic.cdd@thermofisher.com

**United Kingdom & Ireland**  
☎ +44 1442 868 940  
cdx.uk.info@thermofisher.com

**Australia**  
☎ +61 1800 333 110  
auinfo@thermofisher.com

**Germany**  
☎ +49 0800-40 40 771  
cdx.de.info@thermofisher.com

**South Africa**  
☎ +27117926790  
support-za.idd@thermofisher.com

**Canada**  
☎ 800-282-4075  
info.cddcanada@thermofisher.com

**Japan**  
☎ +81 (0)120-147-075  
JPYOK-CDD.QC@thermofisher.com

**Spain, Portugal & Italy**  
☎ +34 93589 8338  
cdx.es.info@thermofisher.com

**For countries not listed:**  
distributor.cdd@thermofisher.com



**Microgenics Corporation**  
46500 Kato Road  
Fremont, CA 94538 USA  
ISO 13485 Certified Company  
www.thermofisher.com/diagnostics



**B.R.A.H.M.S GmbH**  
Neuendorfstrasse 25  
16761 Hennigsdorf, Germany  
Tel: +49 (0) 800 404 077 12  
Fax: +49 (0) 800 404 077 13

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