



## OMEGA DIAGNOSTICS

**NEW!**

### LIQUID QUALITY CONTROLS THIRD PARTY QC

2010/2011



#### MAIN CONTENTS:

Cliniqua Chemistry Controls

Forensic Controls

Calibration Verifiers

Toxicology Controls



**OMEGA**

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| Catalogue No.                                                                                                                                                                                                                                                                                                    | Product                                                         | Size          | Page         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|---------------|--------------|
| <b>CLINIQA® Liquid QC™ ALCOHOL/AMMONIA CONTROL</b>                                                                                                                                                                                                                                                               |                                                                 |               | <b>3-4</b>   |
| 95501                                                                                                                                                                                                                                                                                                            | Alcohol/Ammonia Control Level 1                                 | 6 x 3 mL      |              |
| 95502                                                                                                                                                                                                                                                                                                            | Alcohol/Ammonia Control Level 2                                 | 6 x 3 mL      |              |
| 95505                                                                                                                                                                                                                                                                                                            | Bi-Level Alcohol/Ammonia Control (Levels 1 & 2)                 | 3 x 2 x 3 mL  |              |
| Analytes: AMM, ETOH                                                                                                                                                                                                                                                                                              |                                                                 |               |              |
| <b>CLINIQA® Liquid QC™ BILIRUBIN CONTROL</b>                                                                                                                                                                                                                                                                     |                                                                 |               | <b>5-6</b>   |
| 95401                                                                                                                                                                                                                                                                                                            | Bilirubin Control Level 1                                       | 6 x 3 mL      |              |
| 95402                                                                                                                                                                                                                                                                                                            | Bilirubin Control Level 2                                       | 6 x 3 mL      |              |
| 95403                                                                                                                                                                                                                                                                                                            | Bilirubin Control Level 3                                       | 6 x 3 mL      |              |
| 95404                                                                                                                                                                                                                                                                                                            | Tri-Level Bilirubin Control (Levels 1, 2 & 3)                   | 2 x 3 x 3 mL  |              |
| Analytes: DBIL, TBIL, Bilirubin conjugated, Bilirubin unconjugated                                                                                                                                                                                                                                               |                                                                 |               |              |
| <b>CLINIQA® Liquid QC™ CARDIAC MARKER CONTROL SP</b>                                                                                                                                                                                                                                                             |                                                                 |               | <b>7-8</b>   |
| 91411                                                                                                                                                                                                                                                                                                            | Cardiac Marker Control SP Level 1                               | 6 x 3 mL      |              |
| 91412                                                                                                                                                                                                                                                                                                            | Cardiac Marker Control SP Level 2                               | 6 x 3 mL      |              |
| 91413                                                                                                                                                                                                                                                                                                            | Cardiac Marker Control SP Level 3                               | 6 x 3 mL      |              |
| 91414                                                                                                                                                                                                                                                                                                            | Tri-Level Cardiac Marker Control SP (Levels 1, 2 & 3)           | 2 x 3 x 3 mL  |              |
| Analytes: CKMB, hsCRP, DIG, MYO, NT-proBNP, TnI, TnT                                                                                                                                                                                                                                                             |                                                                 |               |              |
| <b>CLINIQA® Liquid QC™ GENERAL CHEMISTRY, UNASSAYED</b>                                                                                                                                                                                                                                                          |                                                                 |               | <b>9-10</b>  |
| 95301                                                                                                                                                                                                                                                                                                            | Unassayed General Chemistry Control Level 1                     | 12 x 10 mL    |              |
| 95302                                                                                                                                                                                                                                                                                                            | Unassayed General Chemistry Control Level 2                     | 12 x 10 mL    |              |
| 95303                                                                                                                                                                                                                                                                                                            | Unassayed General Chemistry Control Level 3                     | 12 x 10 mL    |              |
| 95304                                                                                                                                                                                                                                                                                                            | Tri-Level Unassayed General Chemistry Control (Levels 1, 2 & 3) | 4 x 3 x 10 mL |              |
| <b>CLINIQA® Liquid QC™ IMMUNOASSAY CONTROL</b>                                                                                                                                                                                                                                                                   |                                                                 |               | <b>11-12</b> |
| 94101                                                                                                                                                                                                                                                                                                            | Immunoassay Control Level 1                                     | 6 x 5 mL      |              |
| 94102                                                                                                                                                                                                                                                                                                            | Immunoassay Control Level 2                                     | 6 x 5 mL      |              |
| 94103                                                                                                                                                                                                                                                                                                            | Immunoassay Control Level 3                                     | 6 x 5 mL      |              |
| 94104                                                                                                                                                                                                                                                                                                            | Tri-Level Immunoassay Control                                   | 2 x 3 x 5 mL  |              |
| 94109                                                                                                                                                                                                                                                                                                            | Tri-Level Immunoassay Control                                   | 1 x 3 x 5 mL  |              |
| Analytes: ACTM, AFP, AMK, CARB, CEA, Cortisol, DHEA-S, DIG, DIS, E <sub>2</sub> , E <sub>3</sub> , ETHO, FE, FOL, FSH, GENT, hCG, β-hCG, hGH, IgA, IgG, IgM, INS, LH, LIDO, LI, NAPA, PHENO, PHENY, PRIM, PROC, PRG, PRL, PSA, fPSA, QUIN, SALY, fT3, T3, T3U, fT4, T4, T, THEO, TOB, TCA, TSH, VALP, VANC, VB12 |                                                                 |               |              |
| <b>CLINIQA® Liquid QC™ ImmuTROL SERUM PROTEIN CONTROL</b>                                                                                                                                                                                                                                                        |                                                                 |               | <b>13-14</b> |
| 91101                                                                                                                                                                                                                                                                                                            | ImmuTROL Serum Protein Control Level 1                          | 6 x 3 mL      |              |
| 91102                                                                                                                                                                                                                                                                                                            | ImmuTROL Serum Protein Control Level 2                          | 6 x 3 mL      |              |
| 91103                                                                                                                                                                                                                                                                                                            | ImmuTROL Serum Protein Control Level 3                          | 6 x 3 mL      |              |
| 91104                                                                                                                                                                                                                                                                                                            | Tri-Level ImmuTROL Serum Protein Control (Levels 1, 2 & 3)      | 2 x 3 x 3 mL  |              |
| 91105                                                                                                                                                                                                                                                                                                            | Bi-Level ImmuTROL Serum Protein Control (Levels 1 & 3)          | 3 x 2 x 3 mL  |              |
| Analytes: ALB, AAG, AAT, A2M, ASO, AT3, B2M, CER, C3, C4, CRP, FER, HPT, IgA, IgE, IgG, IgM, KAP, LAM, PAB, RBP, RF, TRF                                                                                                                                                                                         |                                                                 |               |              |

| Catalogue No.                                                                                                                                                    | Product                                           | Size                    | Page                                                                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-------------------------|--------------------------------------------------------------------------------------------------------------------|
| <b>CLINIQA® Liquid QC™ LIPID CONTROL</b>                                                                                                                         |                                                   |                         | <b>15-16</b>                                                                                                       |
| 91501-S                                                                                                                                                          | Lipid Control Level 1                             | 6 x 3 mL                |                                                                                                                    |
| 91502-S                                                                                                                                                          | Lipid Control Level 2                             | 6 x 3 mL                |                                                                                                                    |
| 91505-S                                                                                                                                                          | Bi-Level Lipid Controls (Levels 1 & 2)            | 3 x 2 x 3 mL            |                                                                                                                    |
| Analytes: Apo, A1, ApoB, CHOL, HDL, LDL, TG                                                                                                                      |                                                   |                         |                                                                                                                    |
| <b>CLINIQA® Liquid QC™ TUMOUR MARKER CONTROL</b>                                                                                                                 |                                                   |                         | <b>17-18</b>                                                                                                       |
| 91301                                                                                                                                                            | Tumour Marker Control Level 1                     | 6 x 3 mL                |                                                                                                                    |
| 91302                                                                                                                                                            | Tumour Marker Control Level 2                     | 6 x 3 mL                |                                                                                                                    |
| 91302                                                                                                                                                            | Tumour Marker Control Level 3                     | 6 x 3 mL                |                                                                                                                    |
| 91304                                                                                                                                                            | Tri-Level Tumour Marker Control (Levels 1, 2 & 3) | 2 x 2 x 3 mL            |                                                                                                                    |
| Analytes: 12 Tumour markers: AFP, CEA, CA15-3, CA19-9, CA125, CA72-4, CA 27-29, CYFRA 21-1, NSE, PSA, fPSA, Thyroglobulin, and serum proteins: B2M, FER, and hCG |                                                   |                         |                                                                                                                    |
| <b>CLINIQA® Liquid QC™ URINE CHEMISTRY CONTROL</b>                                                                                                               |                                                   |                         | <b>19</b>                                                                                                          |
| 97105                                                                                                                                                            | Urine Chemistry Control Bi-Level                  | 6 x 2 x 10 mL           |                                                                                                                    |
| 97109                                                                                                                                                            | Urine Chemistry Control Bi-Level                  | 1 x 2 x 10 mL           |                                                                                                                    |
| <b>CLINIQA® Liquid QC™ DIABETES CONTROL SP</b>                                                                                                                   |                                                   |                         | <b>20</b>                                                                                                          |
| 91805                                                                                                                                                            | Urine Chemistry Control Bi-Level                  | 3 x 2 x 1 mL            |                                                                                                                    |
| 91815                                                                                                                                                            | Urine Chemistry Control Bi-Level                  | 3 x 2 x 0.5 mL          |                                                                                                                    |
| <b>CLINIQA® Liquid QC™ URINALYSIS CONTROL</b>                                                                                                                    |                                                   |                         | <b>21-22</b>                                                                                                       |
| 97201                                                                                                                                                            | DipStrip Bi-Level                                 | 3 x 2 x 15 mL           |                                                                                                                    |
| 97202                                                                                                                                                            | DropStrip Bi-Level                                | 2 x 2 x 25 mL           |                                                                                                                    |
| 97203                                                                                                                                                            | MicroStrip Bi-Level                               | 5 x 2 x 5 mL            |                                                                                                                    |
| 97204                                                                                                                                                            | DipScopics Bi-Level                               | 2 x 2 x 120 mL          |                                                                                                                    |
| 91505-S                                                                                                                                                          | Bi-Level Lipid Controls (Levels 1 & 2)            | 3 x 2 x 3 mL            |                                                                                                                    |
| Analytes: Apo, A1, ApoB, CHOL, HDL, LDL, TG                                                                                                                      |                                                   |                         |                                                                                                                    |
| <b>CLINIQA® CALIBRATORS</b>                                                                                                                                      |                                                   | See:<br>or email us at: | <a href="http://www.omegairl.com">www.omegairl.com</a><br><a href="mailto:info@omegairl.com">info@omegairl.com</a> |
| <b>LiquiSPx Forensic Controls<br/>(Whole Blood Ethanol, Volatiles)</b>                                                                                           |                                                   | See:<br>or email us at: | <a href="http://www.omegairl.com">www.omegairl.com</a><br><a href="mailto:info@omegairl.com">info@omegairl.com</a> |
| <b>LiniCAL Calibration Verifiers</b>                                                                                                                             |                                                   | See:<br>or email us at: | <a href="http://www.omegairl.com">www.omegairl.com</a><br><a href="mailto:info@omegairl.com">info@omegairl.com</a> |

CLINIQA® Liquid QC Alcohol/Ammonia Control is a true ready-to-use control that eliminates pre-analytical error. With long product stability at 2-8°C, the performance is guaranteed and provides maximum convenience. Two distinct analyte levels cover critical decision points for Alcohol/Ammonia.

- Alcohol

- Ammonia



Value assignment for the following analysers:

- Beckman Coulter Synchron® Systems
- Roche Integra®/ Hitachi® Systems
- Ortho Vitros® Systems
- Siemens Dade Behring Dimension® Series
- Olympus AU® Systems



The Quality Alliance of CLINIQA and VITRO is a partnership providing InterQC™, an advanced web based Quality Assurance Application available for the management of internal quality control data and external peer review. Call CLINIQA for more details on this exciting addition to our product line of Controls and Calibration Verifiers. Visit [www.cliniqa.com](http://www.cliniqa.com) for complete information on all CLINIQA products and services.

### SPECIFICATIONS

#### Typical Assay Values<sup>®</sup>

| Analyte | Conv Units | Level 1 Mean | Level 2 Mean | SI Units | Level 1 Mean | Level 2 Mean |
|---------|------------|--------------|--------------|----------|--------------|--------------|
| Alcohol | mg/dL      | 44           | 149          | mmol/L   | 9.59         | 32.48        |
| Ammonia | μmol/L     | 47           | 190          | μmol/L   | 47           | 190          |

### ORDER INFORMATION

#### CLINIQA<sup>®</sup> Liquid QC<sup>™</sup> ALCOHOL/AMMONIA

|       |                                         |              |
|-------|-----------------------------------------|--------------|
| 95501 | Alcohol/Ammonia Control Level 1         | 6 x 3mL      |
| 95502 | Alcohol/Ammonia Control Level 2         | 6 x 3mL      |
| 95505 | Alcohol/Ammonia Controls (Levels 1 & 2) | 3 x 2 x 3 mL |

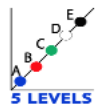
#### Companion Products<sup>®</sup>

#### GET LINEAR

#### GET COMPLIANT

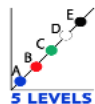
### LiniCAL CALIBRATION VERIFIER/LINEARITY SETS FOR BECKMAN COULTER SYNCHRON

|       |                    |                           |          |
|-------|--------------------|---------------------------|----------|
| 98226 | Esoteric Chemistry | AMM, ETOH, MA, M-TP, SALY | 5 x 1 mL |
|-------|--------------------|---------------------------|----------|



### LiniCAL CALIBRATION VERIFIER/LINEARITY SETS FOR OLYMPUS AU SYSTEMS

|       |                    |                           |          |
|-------|--------------------|---------------------------|----------|
| 98306 | Esoteric Chemistry | AMM, ETOH, MA, M-TP, SALY | 5 x 3 mL |
|-------|--------------------|---------------------------|----------|



LiniCAL calibration verifier/linearity sets are designed for use with specific instrument platforms in order to challenge the low and high limits of the analyzer's reportable range. They are ready to use and conveniently stored at 2-8°C with an open vial stability of 30 days. LiniCAL sets meet CLIA requirements for 3rd party calibration verification while also being very useful for troubleshooting after preventative maintenance or a new installation.

Assay values may change from batch to batch. Please refer to product pack insert for actual values.

CLINIQA® Liquid QC Bilirubin Control is a true ready-to-use control that eliminates pre-analytical error. With long product stability at 2-8°C, the performance is guaranteed and provides maximum convenience. Three distinct analyte levels cover critical decision points.

- Bilirubin, Conjugated
- Bilirubin, Unconjugated
- Bilirubin, Total



Value assignment for the following analysers:

- Beckman Coulter Synchron® Systems
- Roche Integra® / Hitachi® Systems
- Ortho Vitros® Systems
- Siemens Dade Behring Dimension® Series
- Olympus AU® Systems



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## SPECIFICATIONS

### Typical Assay Values®

| Analyte                 | Conv Units | Level 1 Mean | Level 2 Mean | Level 3 Mean | SI Units | Level 1 Mean | Level 2 Mean | Level 3 Mean |
|-------------------------|------------|--------------|--------------|--------------|----------|--------------|--------------|--------------|
| Bilirubin, Conjugated   | mg/dL      | 0.35         | 2.25         | 6.5          | μmol/L   | 5.98         | 38.48        | 111.18       |
| Bilirubin, Unconjugated | mg/dL      | As Found     | As Found     | As Found     | μmol/L   | As Found     | As Found     | As Found     |
| Bilirubin, Total        | mg/dL      | 0.80         | 6.95         | 23           | μmol/L   | 13.68        | 118.87       | 393.39       |

## ORDER INFORMATION

### CLINIQA® Liquid QC™ BILIRUBIN CONTROL

|       |                                               |             |
|-------|-----------------------------------------------|-------------|
| 95401 | Bilirubin Control Level 1                     | 6 x 3mL     |
| 95402 | Bilirubin Control Level 2                     | 6 x 3mL     |
| 95403 | Bilirubin Control Level 3                     | 6 x 3 mL    |
| 95404 | Tri-Level Bilirubin Controls (Levels 1,2 & 3) | 2 x 3 x 3mL |

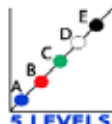
### Companion Products

### GET LINEAR

### GET COMPLIANT

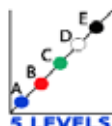
## LiniCAL CALIBRATION VERIFIER/LINEARITY SETS FOR BECKMAN COULTER SYNCHRON

|       |           |            |          |
|-------|-----------|------------|----------|
| 98224 | Bilirubin | DBIL, TBIL | 5 x 1 mL |
|-------|-----------|------------|----------|



## LiniCAL CALIBRATION VERIFIER/LINEARITY SETS FOR OLYMPUS AU SYSTEMS

|       |           |            |          |
|-------|-----------|------------|----------|
| 98304 | Bilirubin | DBIL, TBIL | 5 x 3 mL |
|-------|-----------|------------|----------|



LiniCAL calibration verifier/linearity sets are designed for use with specific instrument platforms in order to challenge the low and high limits of the analyser's reportable range. They are ready to use and conveniently stored at 2-8°C with an open vial stability of 30 days. LiniCAL sets meet CLIA requirements for 3rd party calibration verification while also being very useful for troubleshooting after preventative maintenance or a new installation.

Assay values may change from batch to batch. Please refer to product pack insert for actual values.

CLINIQA has channeled its proprietary liquid stabilisation technology into producing the first "True Liquid" Cardiac Marker Control that is stored at 2-8°C and has a 2-year shelf life from date of manufacture. This unique, true liquid stable control covers 8 analytes in 3 levels to suit instrument system requirements. With an open vial stability of 30 days when stored chilled, Liquid QC Cardiac Marker Control SP is intended for use in the clinical laboratory as a quantitative control for monitoring test procedures used to assay human specimens for determination of cardiac markers.



- Abbott AxSYM®
- Beckman Coulter
  - Access®
  - CX/LX/DxC®
- bioMérieux Vidas
- OrthoVitros® Eci
- Roche
  - Elecsys®
  - Hitachi®
  - Integra®
- Siemens
  - BayerAdvia Centaur®
  - Dade Behring Dimension®
  - Dade Behring Stratus®
  - DPC Immulite®
- Tosoh AIA® Systems



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| SPECIFICATIONS |          |              |              |              |                  |
|----------------|----------|--------------|--------------|--------------|------------------|
| Analyte        | SI Units | Level 1 Mean | Level 2 Mean | Level 3 Mean | Assay Platform   |
| BNP            | µg/L     | 94.6         | 1535         | 4401         | Access           |
| CK-MB          | µg/L     | 1.63         | 9.13         | 36.6         | Ortho Vitros Eci |
| Digoxin        | nmol/L   | 1.47         | 2.49         | 3.91         | Roche Integra    |
| hsCRP          | mg/dL    | 0.900        | 4.53         | 7.41         | Roche Integra    |
| Homocysteine   | µmol/L   | 9.94         | 33.8         | 46.5         | Olympus AU       |
| Myoglobin      | µg/L     | 80.4         | 219          | 483          | BCI Access       |
| NT-proBNP      | pmol/L   | 9.57         | 53.8         | 424          | Ortho Vitros Eci |
| Troponin I     | µg/L     | 0.556        | 2.75         | 65.0         | Ortho Vitros Eci |
| Troponin T     | µg/L     | 0.064        | 0.381        | 2.20         | Roche Elecsys    |

### ORDER INFORMATION

#### CLINIQA<sup>®</sup> Liquid QC<sup>™</sup> CARDIAC MARKER CONTROL SP

|       |                                                      |              |
|-------|------------------------------------------------------|--------------|
| 91411 | Cardiac Marker Control SP Level 1                    | 6 x 3mL      |
| 91412 | Cardiac Marker Control SP Level 2                    | 6 x 3mL      |
| 91413 | Cardiac Marker Control SP Level 3                    | 6 x 3mL      |
| 91414 | Tri-Level Cardiac Marker Control SP (Levels 1,2 & 3) | 2 x 3 x 3 mL |

Assay values may change from batch to batch. Please refer to product pack insert for actual values.

CLINIQA® Liquid QC Unassayed General Chemistry Control, available in 3 levels, is liquid, human serum based and intended for use as unassayed quality control material for the constituents featured on the following page. Most analytes have a 14 day open vial stability.



## interQC™

*InterQC is a cost effective single module web accessed data management solution for 3rd party Statistical QC of control and linearity data as well as global Peer Review. It is designed to complement CLINIQA Liquid QC™ Controls and LiniCAL® Calibration Verifiers to enable laboratories to monitor and compare their performance directly with laboratories worldwide*

| ANALYTES |          |       |      |
|----------|----------|-------|------|
| ACTM     | APT      | ALT   | ALB  |
| ALP      | AMIK     | AAT   | AMY  |
| PAMY     | Apo A1   | Apo B | AST  |
| BICARB   | DBIL     | TBIL  | C3   |
| C4       | CA       | CARB  | CER  |
| CL       | HDL      | LDL   | CHOL |
| CHE      | Cortisol | CK    | CKMB |
| CREA     | DIG      | ETHO  | FE   |
| GGT      | GENT     | GLUC  | HPT  |
| HCG-B    | IGA      | IGG   | IGM  |
| Iron     | UIBC     | LAC   | LDH  |
| LIP      | LI       | MG    | OSMO |
| PHENO    | PHENY    | PHOS  | K    |
| PAB      | TP       | SALY  | NA   |
| T3U      | FT3      | T3    | FT4  |
| T4       | THEO     | TSH   | TOB  |
| TRF      | TRIG     | UREA  | UA   |
| VALP     | B12      |       |      |

## ORDER INFORMATION

### CLINIQA® Liquid QC™ Unassayed General Chemistry Control

|       |                                                                   |               |
|-------|-------------------------------------------------------------------|---------------|
| 95301 | Unsassayed General Chemistry Control Level 1                      | 12 x 10 mL    |
| 95302 | Unsassayed General Chemistry Control Level 2                      | 12 x 10 mL    |
| 95303 | Unsassayed General Chemistry Control Level 3                      | 12 x 10 mL    |
| 95304 | Tri-Level Unsassayed General Chemistry Controls (Levels 1, 2 & 3) | 4 x 3 x 10 mL |

CLINIQA<sup>®</sup> Liquid QC<sup>™</sup> Immunoassay Control is a true ready-to-use liquid control. With long product stability at  $\leq 20^{\circ}\text{C}$ , performance is guaranteed and provides maximum convenience. Three distinct analyte levels cover critical decision points the constituents listed below. Its non-azide formula ensures no interference with IESs. Most analytes have a 30 day open vial stability; and 90 day closed vial stability at  $2-8^{\circ}\text{C}$ .



## Typical Value Assignments

- Abbott
  - Architect<sup>®</sup>
  - AxSYM<sup>®</sup>
- Beckman Coulter
  - Access<sup>®</sup>
  - Immage<sup>®</sup>
  - SynchronCX/LX/DXC/DXI<sup>®</sup>
- bioMérieux VIDAS Systems
- Roche Systems
  - Elecsys<sup>®</sup>
  - Integra<sup>®</sup>
  - Hitachi<sup>®</sup>
  - Modular<sup>®</sup>
- Orthos Vitros<sup>®</sup> Systems
- Olympus AU<sup>®</sup> Systems
- Siemens
  - Centaur<sup>®</sup>
  - Dimension<sup>®</sup>
  - Immulite<sup>®</sup>



The Quality Alliance of CLINIQA and VITRO is a partnership providing InterQC<sup>™</sup>, an advanced web based Quality Assurance Application available for the management of internal quality control data and external peer review. Call CLINIQA for more details on this exciting addition to our product line of Controls and Calibration Verifiers. Visit [www.cliniqa.com](http://www.cliniqa.com) for complete information on all CLINIQA products and services.

| ANALYTES       |        |       |       |                |
|----------------|--------|-------|-------|----------------|
| ACTM           | AFP    | AMIK  | CARB  | CEA            |
| Cortisol       | DHEA-S | DIG   | DIS   | E <sub>2</sub> |
| E <sub>3</sub> | ETHO   | FER   | FOL   | FSH            |
| GENT           | hCG    | β-hCG | hGH   | IgA            |
| IgE            | IgG    | IgM   | INS   | LH             |
| LIDO           | LI     | NAPA  | PHENO | PHENY          |
| PRIM           | PROC   | PRG   | PRL   | PSA            |
| fPSA           | QUIN   | SALY  | ft3   | T3             |
| T3U            | ft4    | T4    | T     | THEO           |
| THYRO          | TOB    | TCA   | TSH   | VALP           |
| VANC           | VB12   |       |       |                |

### ORDER INFORMATION

#### CLINIQA<sup>®</sup> Liquid QC<sup>™</sup> Immunoassay Control

|       |                                        |              |
|-------|----------------------------------------|--------------|
| 94101 | Immunoassay Control Level 1            | 6 x 5 mL     |
| 94102 | Immunoassay Control Level 2            | 6 x 5 mL     |
| 94103 | Immunoassay Control Level 3            | 6 x 5 mL     |
| 94104 | Tri-Level Immunoassay Control          | 2 x 3 x 5 mL |
| 94109 | Tri-Level Immunoassay Control Minipack | 1 x 3 x 5 mL |

CLINIQA® Liquid QC ImmuTROL Serum Protein Control is a liquid stable control built on a human base matrix, free of glycerol and glycol and fortified with native serum proteins and immunoglobulins. Formulated with 23 analytes, including RF, CRP, and ASO, ImmuTROL Serum Protein Control is available in three clinically significant levels. Each kit is packaged in a convenient and user friendly configuration. Recommended for use with each assay, ImmuTROL is an important tool for monitoring the accuracy and precision of test methods and instrument performance. The controls are stable for 48 months from the date of manufacture when stored unopened at 2-8°C.

- |       |       |       |       |       |       |
|-------|-------|-------|-------|-------|-------|
| • ALB | • ASO | • C3  | • HPT | • IgM | • RBP |
| • AAG | • AT3 | • C4  | • IgA | • KAP | • RF  |
| • AAT | • B2M | • CRP | • IgE | • LAM | • TRF |
| • A2M | • CER | • FER | • IgG | • PAB |       |



Typical Value assignment for the following analysers:

- |                    |                       |                                   |
|--------------------|-----------------------|-----------------------------------|
| • Beckmann Coulter | • Olympus AU® Systems | • Siemens                         |
| - Array®           | • Roche               | - Dade Behring Dimension®         |
| - CX/LX/DxC®       | - Hitachi®            | - Dade Behring BNA®/BN® 100/BN®II |
| - Immage®          | - Integra®            |                                   |
|                    | - Modular®            |                                   |



The Quality Alliance of CLINIQA and VITRO is a partnership providing InterQC™, and advanced web based Quality Assurance Application available for the management of internal quality control data and external peer review. Call CLINIQA for more details on this exciting addition to our product line of Controls and Calibration Verifiers. Visit [www.cliniqa.com](http://www.cliniqa.com) for complete information on all CLINIQA products and services.



| SPECIFICATIONS            |            |              |              |              |
|---------------------------|------------|--------------|--------------|--------------|
| Analyte                   | Conv Units | Level 1 Mean | Level 2 Mean | Level 3 Mean |
| Albumin                   | mg/dL      | 2116         | 4111         | 5939         |
| Alpha-1-Acid Glycoprotein | mg/dL      | 47.6         | 91.8         | 134          |
| Alpha-1-Antitrypsin       | mg/dL      | 86.5         | 183          | 282          |
| Alpha-2_ Macroglobulin    | mg/dL      | 112          | 222          | 323          |
| Antistreptolysin O        | IU/mL      | 147          | 271          | 381          |
| Antithrombin III          | mg/dL      | 12.4         | 26.9         | 40.9         |
| Beta-2-Microglobulin      | mg/dL      | 0.170        | 0.316        | 0.418        |
| C-Reactive Protein        | mg/dL      | 1.79         | 3.02         | 6.84         |
| Ceruloplasmin             | mg/dL      | 12.3         | 29.4         | 43.7         |
| Complement, C3            | mg/dL      | 78.8         | 156          | 228          |
| Complement, C4            | mg/dL      | 17.6         | 34.9         | 51.3         |
| Ferritin                  | ng/dL      | 54.1         | 154          | 300          |
| Haptoglobin               | mg/dL      | 69.1         | 130          | 191          |
| Immunoglobulin A          | mg/dL      | 135          | 264          | 387          |
| Immunoglobulin E          | IU/mL      | 99.0         | 188          | 255          |
| Immunoglobulin G          | mg/dL      | 694          | 1343         | 1930         |
| Immunoglobulin M          | mg/dL      | 87.7         | 172          | 255          |
| Kappa Light Chain         | mg/dL      | 168          | 331          | 471          |
| Lambda Light Chain        | mg/dL      | 92.4         | 183          | 262          |
| Prealbumin                | mg/dL      | 18.7         | 9.7          | 53.7         |
| Retinol Binding Protein   | mg/dL      | 2.74         | 5.60         | 8.49         |
| Rheumatoid Factor         | IU/mL      | 51.5         | 100          | 136          |
| Transferrin               | mg/dL      | 113          | 220          | 309          |

## ORDER INFORMATION

### CLINIQA® Liquid QC™ ImmuTROL Serum Protein CONTROL

|       |                                                           |              |
|-------|-----------------------------------------------------------|--------------|
| 91101 | ImmuTROL Level 1 Serum Protein Control                    | 6 x 3mL      |
| 91103 | ImmuTROL Level 1 Serum Protein Control                    | 6 x 3mL      |
| 91103 | ImmuTROL Level 1 Serum Protein Control                    | 6 x 3mL      |
| 91104 | ImmuTROL Tri-Level Serum Protein Control (Levels 1,2 & 3) | 2 x 3 x 3 mL |
| 91105 | ImmuTROL Tri-Level Serum Protein Control (Levels 1&3)     | 3 x 2 x 3 mL |

Assay values may change from batch to batch. Please refer to product pack insert for actual values.

CLINIQA® Liquid QC Lipid Control is a human serum based, ready-to-use liquid control providing maximum convenience. With long product stability at 2-8°C, performance is guaranteed with 30 day open vial stability at 2-8°C and 7 day open vial stability at 20-25°C. Two distinct analyte levels cover critical decision points for a total lipid profile.

- Apolipoprotein A1
- Apolipoprotein B
- Cholesterol (Total, HDL, LDL)
- Triglycerides



#### Typical Value assignment:

- Beckmann Coulter Synchron Systems
  - Array®
  - Image®
  - CX/LX/DxC®
- Ortho Vitros® Systems
- Olympus AU® Systems
- Roche Systems
  - Hitachi®
  - Integra®
  - Modular®
- Siemens
  - Bayer Advia Centaur®
  - Dade Behring Dimension®



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## SPECIFICATIONS

| Analyte             | Conv Units | Level 1 Mean | Level 2 Mean | SI Units | Level 1 Mean | Level 2 Mean |
|---------------------|------------|--------------|--------------|----------|--------------|--------------|
| ApoA1               | mg/dL      | 132          | 108          | g/L      | 1.32         | 1.08         |
| ApoB                | mg/dL      | 66.1         | 131          | g/L      | .00661       | 1.31         |
| Cholesterol (Total) | mg/dL      | 182          | 291          | mmol/L   | 4.71         | 7.54         |
| Cholesterol (HDL)   | mg/dL      | 55.2         | 35.4         | mmol/L   | 1.43         | 0.917        |
| Cholesterol (LDL)   | mg/dL      | 96.1         | 170          | mmol/L   | 2.49         | 4.40         |
| Triglycerides       | mg/dL      | 163          | 400          | mmol/L   | 1.84         | 4.52         |

## ORDER INFORMATION

### CLINIQA<sup>®</sup> Liquid QC<sup>™</sup> LIPID CONTROL

|         |                                        |             |
|---------|----------------------------------------|-------------|
| 91501-S | Lipid Control Level 1                  | 6 x 3mL     |
| 91502-S | Lipid Control Level 2                  | 6 x 3mL     |
| 91505-S | Bi-Level Lipid Controls (Levels 1 & 2) | 3 x 2 x 3mL |

*Assay values may change from batch to batch. Please refer to product pack insert for actual values.*

Forget about inconvenient frozen or freeze-dried tumor marker controls, CLINIQA® has channeled its proprietary liquid stabilization technology into producing the first "True Liquid" Tumor Marker Control. This tri-level human serum based control is stored at 2-8°C and is ready-to-use straight out of the refrigerator. With CLINIQA quality "Built-In", a 2-year shelf life, and no special shipping requirements, this is the ideal product for your QC Program.

- AFP
- CEA
- FER
- HCG
- NSE
- Free PSA
- CA 15-3
- CA 19-9
- PSA
- CA 72-4
- Thyroglobulin
- B2M
- CA 125
- Cyfra 21-1
- CA27-29



- Abbott AxSYM®
- Beckman Coulter
  - Access®
  - Unicel® Dxl
- bioMérieux MiniVidas®
- OrthoVitros® Eci
- Roche Elecsys®1010
- Siemens
  - BayerAdvia Centaur®
  - DPC Immulite®
- TosohAIA® Systems



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### SPECIFICATIONS

| Analyte       | Conv Units | Level 1 Mean | Level 2 Mean | Level 3 Mean | SI Units | Level 1 Mean | Level 2 Mean | Level 3 Mean |
|---------------|------------|--------------|--------------|--------------|----------|--------------|--------------|--------------|
| AFP           | IU/mL      | 12.9         | 147          | 300          | kIU/L    | 12.9         | 147          | 300          |
| CEA           | ng/mL      | 2.70         | 9.11         | 15.5         | ug/L     | 2.70         | 9.11         | 15.5         |
| FER           | ng/mL      | 18.7         | 240          | 452          | ug/L     | 18.7         | 240          | 452          |
| hCG           | mIU/mL     | 5.29         | 126          | 270          | IU/L     | 5.29         | 128          | 270          |
| PSA           | ng/mL      | 2.03         | 20.6         | 40.4         | ug/L     | 2.03         | 20.6         | 40.4         |
| Free PSA      | ng/mL      | 0.504        | 4.03         | 7.37         | ug/L     | 0.504        | 4.03         | 7.37         |
| CA 15-3       | U/mL       | 16.7         | 43.7         | 70.1         | U/mL     | 16.7         | 43.7         | 70.1         |
| CA 19-9       | U/mL       | 34.8         | 149          | 270          | U/mL     | 34.9         | 149          | 270          |
| CA 27-29      | U/mL       | 23.6         | 77.1         | 130          | U/mL     | 23.6         | 77.1         | 130          |
| CA125         | U/mL       | 26.0         | 76.4         | 127          | U/mL     | 26.0         | 76.4         | 127          |
| CA72-4*       | ng/mL      | 7.2          | 32.7         | 58.4         | U/mL     | 7.24         | 32.7         | 58.4         |
| Cyfra 21.1*   | ng/mL      | 5.14         | 41.0         | 76.8         | ug/mL    | 5.14         | 41.0         | 76.8         |
| Thyroglobulin | ng/mL      | 6.62         | 60.6         | 114          | ug/L     | 6.62         | 60.6         | 114          |
| NSE*          | ng/mL      | 0.991        | 11.0         | 21.7         | ug/L     | 0.991        | 11.0         | 21.7         |
| B2M           | mg/dL      | 0.413        | 2.02         | 3.73         | mg/L     | 0.413        | 2.02         | 3.73         |

\* These constituents have not been cleared for In Vitro Diagnostic Use by the U.S. F.D.A.  
The safety and effectiveness of these constituents have not been established.

### ORDER INFORMATION

#### CLINIQA<sup>®</sup> Liquid QC<sup>™</sup> TUMOUR MARKER CONTROL

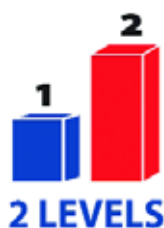
|       |                                                   |              |
|-------|---------------------------------------------------|--------------|
| 91301 | Tumour Marker Control Level 1                     | 6 x 3mL      |
| 91302 | Tumour Marker Control Level 2                     | 6 x 3mL      |
| 91303 | Tumour Marker Control Level 3                     | 6 x 3mL      |
| 91304 | Tri-Level Tumour Marker Control (Levels 1, 2 & 3) | 2 x 2 x 3 mL |

Analytes: 12 tumour markers: AFP, CEA, CA15-3, CA19-9, CA125, CA72-4, CA27-29, CYFRA 21-1, NSE, PSA, FPSA, Thyroglobulin, and 3 serum proteins: B2M, FER, and hCG.

Assay values may change from batch to batch. Please refer to product pack insert for actual values.

CLINIQA® Liquid QC Urine Chemistry Control is a ready-to-use liquid control designed to monitor the precision of laboratory testing procedures. With 36 month product stability at 2-8°C, performance is guaranteed for 36 month open vial stability at 2-8°C. Two distinct analyte levels cover critical decision points for the analytes listed below:∞

- Amylase
- Calcium
- Chloride
- Creatinine
- Cortisol
- Glucose
- hCG
- Magnesium
- Microalbumin
- Osmolality
- pH
- Phosphorus
- Potassium
- Sodium
- Specific Gravity
- Total Protein
- Urea Nitrogen
- Uric Acid



Typical value assignment:

- Abbott
  - Aeroset®
  - Architect®
- Beckman Coulter
  - Access®
  - Image®
  - SynchronCX/LX/DxC®
- Olympus AU® Systems
- Orthos Vitros® ECI Systems
- Roche Systems
  - Cobas Integra®
  - Hitachi®
- Siemens
  - Bayer Advia® 1650/Centaur®
  - Dade Behring Dimension® Series
  - DPC Immulite®

## ORDER INFORMATION

### CLINIQA® Liquid QC™ URINE CHEMISTRY CONTROL

|       |                                  |
|-------|----------------------------------|
| 97105 | Urine Chemistry Control Bi-Level |
| 97109 | Urine Chemistry Control Bi-Level |

|               |
|---------------|
| 6 x 2 x 10 mL |
| 1 x 2 x 10 mL |

Store: 2-8°C, 36 months open vial stability



CLINIQA<sup>®</sup> Liquid QC Diabetes Control is a true ready-to-use control designed to monitor hemoglobin A1c methods. With long product stability at 2-8°C, performance is guaranteed with 30 days open vial stability at 2-8°C and 7 days open vial stability at 20-25°C. Two distinct analyte levels cover critical decision points for hemoglobin A1c.



Typical Value assignment:

- Beckman Coulter Synchron<sup>®</sup> Systems
  - LX/DxC<sup>®</sup>
- Horiba ABX Pentra<sup>®</sup>
- Olympus AU<sup>®</sup> Systems
- Roche
  - Integra<sup>®</sup>
  - Cobas Mira<sup>®</sup>
  - Modular<sup>®</sup>
- Siemens
  - Dade Behring Dimension<sup>®</sup> Series
  - DCA 2000<sup>®</sup>
- Vital Diagnostics Envoy<sup>®</sup>

## ORDER INFORMATION

### CLINIQA<sup>®</sup> Liquid QC<sup>™</sup> DIABETES CONTROL SP

|       |                           |                |
|-------|---------------------------|----------------|
| 91805 | Diabetes Control Bi-Level | 3 x 2 x 1 mL   |
| 91815 | Diabetes Control Bi-Level | 3 x 2 x 0.5 mL |
| 91819 | Diabetes Control Bi-Level | 1 x 2 x 0.5 mL |

Analytes: HbA1c, Total Hemoglobin

Store: 2-8°C, 30 days open vial stability

CLINIQA® Liquid QC Urinalysis Controls are ready-to-use liquid controls designed to validate urinalysis reagent strips and to control confirmatory test reagent tablets as well as microalbumin, creatinine and hCG methods. With long product stability as 2-8°C, performance is guaranteed with up to 18 months open vial stability at 2-8°C and 30 day open vial stability at 20-25°C. Two distinct levels cover critical decision points.

∞

- |              |                |                    |                      |
|--------------|----------------|--------------------|----------------------|
| • Blood      | • Ketones      | • pH               | • Red Blood Cells*   |
| • Bilirubin  | • Leukocytes   | • Protein          | • White Blood Cells* |
| • Creatinine | • Microalbumin | • Specific Gravity | • Crystals*          |
| • Glucose    | • Nitrite      | • Urobilinogen     |                      |



Typical value assignment:

#### Reagent Strips (Visual/Analyzer):

- Roche ChemStrip®
- Siemens Clinitek®
- SiemensMultistix®Microalbumin
- Omega/Ultimed Multi Test Strips

#### Reagent Tablets:

- Siemens
- Acetest®
  - Clinitest®
  - Ictotest®

#### Slide:

- Kova® Glasstic™

#### Other Tests (non-strip):

- hCG\*
- pH paper
- Specific Gravity
- Total Protein

## ORDER INFORMATION

### CLINIQA® Liquid QC™ LIPID CONTROL

|       |                      |                |
|-------|----------------------|----------------|
| 97201 | DipStrip Bi-Level †  | 3 x 2 x 15 mL  |
| 97202 | DropStrip Bi-Level   | 2 x 2 x 15 mL  |
| 97203 | MicroStrip Bi-Level  | 5 x 2 x 5 mL   |
| 97204 | DipScopics Bi-Level* | 2 x 2 x 120 mL |

\* Only DipScopics includes red blood cells, white blood cells and crystals.

† 90 day open vial stability or 20 dipstick immersions.

| Analytes         | Siemens-Bayer Multistix 10SG Urinalysis Reagent Strips |                         |                                                             |                          |
|------------------|--------------------------------------------------------|-------------------------|-------------------------------------------------------------|--------------------------|
|                  | Visual                                                 |                         | Siemens Clinitek® 50/500/Status®/<br>Atlas® Urine Analysers |                          |
|                  | Level 1                                                | Level 2                 | Level 1                                                     | Level 2                  |
| Glucose          | negative                                               | 100-1000 mg/dL or more  | negative                                                    | 100-≥1000 mg/dL          |
| Bilirubin        | negative                                               | 1+ (small) -3+ (large)  | negative                                                    | 1+ (small) -3+ (large)   |
| Ketones          | negative                                               | 5 (tr)-80 (large) mg/dL | negative                                                    | 5 (tr)-≥80 (large) mg/dL |
| Specific Gravity | 1.005-1.020                                            | 1.020-1.030             | 1.005-1.020                                                 | 1.020-≥1.030             |
| Blood            | negative                                               | 1+ (small) -3+ (large)  | negative                                                    | 1+ (small) -3+ (large)   |
| pH               | 5.0-6.0                                                | 7.0-8.5                 | 5.0-6.5                                                     | 7.0-≥9.0                 |
| Protein          | negative                                               | 30 (1+)-2000 (3+) mg/dL | negative                                                    | 30 (1+)-≥300 (3+) mg/dL  |
| Urobilinogen     | 0.1-0.3 mg/dL (normal)                                 | 1-8 mg/dL               | 0.1-0.3 mg/dL (normal)                                      | 1-≥8 mg/dL               |
| Nitrite          | negative                                               | positive                | negative                                                    | positive                 |
| Leukocytes       | negative                                               | trace-3+ (Large)        | negative                                                    | trace-3+ (large)         |
| Analytes         | Siemens Bayer Clinitex® Microalbumin Reagent Strips    |                         |                                                             |                          |
|                  | Visual                                                 |                         | Siemens Clinitek® 50/Status®/<br>Atlas® Urine Analysers     |                          |
|                  | Level 1                                                | Level 2                 | Level 1                                                     | Level 2                  |
| Microalbumin     | NA                                                     | NA                      | ≤10mg/L                                                     | ≥150 mg/dL               |
| Creatinine       | NA                                                     | NA                      | 10-50 mg/dL                                                 | 100-300 mg/dL            |

| Analytes         | Roche Chemstrip® 10 UA Urinalysis Reagent Strips |                        |                                  |                          |
|------------------|--------------------------------------------------|------------------------|----------------------------------|--------------------------|
|                  | Visual                                           |                        | Roche Urisys 1800 Urine Analyser |                          |
|                  | Level 1                                          | Level 2                | Level 1                          | Level 2                  |
| pH               | 5.0-6.0                                          | 7.0-9.0                | 6-7                              | 7.0-9.0                  |
| Leukocytes       | negative                                         | trace - 2+Leu/μL       | negative                         | 2 (tr) -500 (2+) Leu/μL  |
| Nitrite          | negative                                         | positive               | negative                         | positive                 |
| Protein          | negative                                         | 30 (1+)-500 (3+) mg/dL | negative                         | 15 (tr) -500 (3+) mg/dL  |
| Glucose          | normal                                           | 100-1000 mg/dL         | normal                           | 100 -≥1000mg/dL          |
| Ketones          | negative                                         | 1+ (small) -3+(large)  | negative                         | 15 (1+)-150 (3+) mg/dL   |
| Urobilinogen     | normal                                           | 1-8 mg/dL              | 0.2 mg/dL (normal)               | 1-8 mg/dL                |
| Bilirubin        | negative                                         | 1 (1+) -6 (3+) mg/dL   | negative                         | 1 (1+) -6 (3+) mg/dL     |
| Blood            | negative                                         | trace- 250 Ery/μL      | negative                         | 50 (2+) -250 (3+) Ery/μL |
| Specific Gravity | 1.010-1.030                                      | 1.000-1.015            | 1.000-1.015                      | 1.005-1.020              |
| Analytes         | Roche Chemstrip® Micral Reagent Strips           |                        |                                  |                          |
|                  | Visual                                           |                        | Roche Urisys 1800 Urine Analyser |                          |
|                  | Level 1                                          | Level 2                | Level 1                          | Level 2                  |
| Microalbuminn    | negative                                         | 20-100 mg/dL           | NA                               | NA                       |

| Analytes         | iChem™ 10 SG Urine Chemistry Strips |                                           | Confirmatory and Other Tests           |                          |                        |
|------------------|-------------------------------------|-------------------------------------------|----------------------------------------|--------------------------|------------------------|
|                  | iChem™ Analysers                    |                                           |                                        |                          |                        |
|                  | Level 1                             | Level 2                                   | Test                                   | Level 1                  | Level 2                |
| Bilirubin        | negative                            | 1+ -3+ (1-4 mg/dL) (17-70 μmol/L)         | Acetest*                               | negative                 | 1+ (small) -3+ (large) |
| Urobilinogen     | normal                              | 1+ -4+ (2 -12 mg/dL) (35-200 μmol/L)      | Clinitest*                             | negative                 | 1/4 -2%                |
| Ketones          | negative                            | 1+ -3+ (25 - 300 mg/dL) (2.5-30 mmol/L)   | Icotest*                               | negative                 | positive               |
| Glucose          | negative                            | 1+ -4+ (50 - ≥1000 mg/dL) (3-≥56 mmol/L)  | Specific Gravity<br>(refractometer)    | 1.000-1.015              | 1.025 -≥1.030          |
| Protein          | negative                            | 1+ -3+(30 - ≥ 500 mg/dL) (0.3-≥5g/L)      |                                        |                          |                        |
| Blood            | negative                            | 1+ -3+(0.03 - ≥ 1.0mg/dL) (5-300 RBCs/μL) | hCG<br>(Genzyme OSOM*)                 | positive<br>(~1000IU/mL) | negative<br>(~0 IU/mL) |
| pH               | ≤5.0                                | 6.0-9.0                                   |                                        |                          |                        |
| Nitrite          | negative                            | positive                                  | pH Paper                               | 5.5-6.5                  | 7.0-8.0                |
| Leukocytes       | normal                              | 1+ -3+(25-500 WBCs/μL)                    | Total Protein<br>(Sulfosalicylic acid) | negative                 | positive               |
| Specific Gravity | ≤1.000                              | 1.005-1.030                               |                                        |                          |                        |

Assay values may change from batch to batch. Please refer to product pack insert for actual values.



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