

InteliQ Immunoassay Plus Control

Levels 1, 2 and 3



12009948 Level 1 12 x 4 mL
12009949 Level 2 12 x 4 mL
12009950 Level 3 12 x 4 mL
12009951 Trilevel MiniPak 3 x 4 mL



Level 1 85301T
Level 2 85302T
Level 3 85303T



<http://www.myeinserts.com/85300T>

INTENDED USE

InteliQ Immunoassay Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Multiple levels of control are available to allow monitoring of the test system's reliability.

For customers in Germany: Quality control materials are required for assessment of laboratory performance as described in the "Guideline for Quality Assurance of Medical Laboratory Examinations following the German Medical Association" (Rili-BÄK regulation).

REAGENT

This product is prepared from human serum with added chemicals, constituents of human and animal origin, therapeutic drugs, stabilizers and preservatives. This product is provided in liquid form for convenience.

STORAGE AND STABILITY

This product will be stable until the expiration date when stored unopened at -20 to -70°C.

Thawed Unopened:

When thawed and stored unopened at 2 to 8°C, this product will be stable as follows:

- All Analytes: 30 days

Except:

- Androstenedione: 25 days

- Prolactin, PSA (Free) and PSA (Total): 14 days

- Estradiol: 8 days

- Folate: 4 days

Refrigerator Storage (All Instruments, Off-Board, 2 to 8°C):

This product will be stable as follows:

- All analytes: 10 days

Except:

- Estradiol: 5 days

- Folate: 4 days

Instrument Storage (Siemens Atellica, On-Board, 2 to 8°C):

This product will be stable as follows:

- All analytes: 14 days

Except:

- Estradiol: 5 days

- Folate: 4 days

Do not refreeze this product after opening the tubes.

This product is shipped under frozen conditions.

PROCEDURE

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used.

This product can only be used following either instrument storage or refrigerator storage procedure, but not a combination of both.

To Thaw the Product:

Allow the frozen product to thaw at room temperature (18 to 25°C) for approximately 60 minutes or until completely thawed prior to use. Once thawed, gently invert the tube several times to ensure homogeneity.

Refrigerator Storage (All Instruments, Off-Board, 2 to 8°C):

Before use, gently swirl the tube several times to ensure homogeneity. Remove the cap and place the product in the instrument for testing. Once testing is completed, promptly replace the cap and return the product to refrigerator storage. For optimal analyte stability, minimize the time on-board the instrument and exposure to room temperature.

Instrument Storage (Siemens Atellica, On-Board, 2 to 8°C):

Remove the cap and place the product in the instrument for testing. Store the product opened for the duration of the on-board stability claim.

Safety Precautions

- Caution should be used when handling this product to prevent splashing. Wear appropriate eye/face protection when using this product to protect from splashes.
- Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

LIMITATIONS

1. This product should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the product, discard the tube.
3. This product is not intended for use as a standard.
4. Values may gradually decrease over the product shelf life for the following analytes: Folate and Progesterone. Individual laboratory means may eventually fall outside of the corresponding ranges printed in the data charts.

WARNING



Biological source material. Treat as potentially infectious.

Each human donor unit used to manufacture this product was tested as required by FDA accepted methods. Tests results were non-reactive or negative for evidence of infection due to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). This product may also contain other human source materials for which there are no approved tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens. Safety Data Sheet (SDS) available for professional users on www.bio-rad.com.

SPECIFIC PERFORMANCE CHARACTERISTICS

This product is a stabilized liquid product manufactured under rigid quality control standards. To obtain consistent assay values, the control requires proper storage and handling as described.

ASSIGNMENT OF VALUES

The mean values and corresponding $\pm 3SD$ ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product. Data from Unity™ Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. [Customers in Germany have to follow the requirements as described in the Rili-BÄK regulation.] Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

Unity™ Interlaboratory Program is a proprietary Bio-Rad software program holding more than 2 billion QC data points from thousands of laboratories.

INSTRUCTIONS FOR OBTAINING THE DATA CHARTS

To obtain the Data Charts use the checkboxes on the Customize My elnserts page to select your chart items. You can View & Print your selections or Save Selections. Follow the directions on this website to receive email notifications of insert updates. Alternate methods for receiving data charts are available by contacting your local Bio-Rad Laboratories Office.

BARCODE LABELS

For some instruments, supplemental barcode labels may be available at <https://blg.qcnet.com>. Ensure the product tube is clean and dry prior to applying the label.

ANALYTES

Acetaminophen	Ferritin	Luteinizing Hormone (LH)	T3 (Total)
AFP	Folate	N-Acetyl Procainamide (NAPA)	T3 Uptake/T Uptake
Amikacin	Follicle Stimulating Hormone (FSH)	Phenobarbital	T4 (Free)
Androstenedione	Gentamicin	Phenytoin	T4 (Total)
Caffeine	hCG	Primidone	Testosterone
Carbamazepine	Human Growth Hormone (hGH)	Procainamide	Theophylline
CEA	Immunoglobulin A (IgA) ◆	Progesterone	Thyroid Stimulating Hormone (TSH)
CK-MB Isoenzyme	Immunoglobulin E (IgE)	Prolactin	Thyroxine Binding Globulin (TBG)
Cortisol	Immunoglobulin G (IgG) ◆	PSA (Free)	Tobramycin
Dehydroepiandrosterone-Sulfate (DHEA-Sulfate)	Immunoglobulin M (IgM) ◆	PSA (Total)	Tricyclic Antidepressants (TCA)
Digoxin	Insulin	Quinidine	Valproic Acid
Estradiol	Iron ◆	Salicylate	Vancocycin
Estriol (Free)	Lidocaine	Sex Hormone Binding Globulin (SHBG) ◆	Vitamin B12
	Lithium	T3 (Free)	

NOTES

◆ Endogenous levels only.



UNITED STATES, Bio-Rad Laboratories
9500 Jeronimo Road, Irvine, CA 92618

EC REP

FRANCE, Bio-Rad
3 boulevard Raymond Poincare, 92430 Marnes-la-Coquette
Phone:(33) 1-4795-6000 / Fax:(33) 1-4741-9133

Clinical Diagnostics Group

9500 Jeronimo Road
Irvine, California 92618
(800) 854-6737
FAX (949) 598-1550
bio-rad.com/qualitycontrol

Technical Service:
(800) 854-6737

United States Customer Service: 4000 Alfred Nobel Drive • Hercules, California 94547 • Phone (510) 724-7000 • FAX (510) 741-6373
Also in: **Gladesville, Australia,** Phone +61 (2) 9914 2800 • Fax +61 (2) 9914 2888 **Vienna, Austria,** Phone +43 (0) 1 877 89 01 9 • Fax +43 (0) 1 876 56 29 **Temse, Belgium,** Phone +32 (0) 3 710 53 00 • Fax +32 (0) 3 710 53 01 **São Paulo, Brazil,** Phone +55 11 3065-7500 **Montréal, Canada,** Phone +1 514.334 4372 • Fax +1 514.334 0872 **Shanghai, China,** Phone +86 21 6169 8500 • Fax +86 21 6169 8599 **Prague, Czech Republic,** Phone +420 241 431 660 **Symbion Science Park, Denmark,** Phone +45 44 52 10 00 • Fax +45 44 52 10 01 **Helsinki, Finland,** Phone +358 9 804 22 00 **Marnes-la-Coquette, France,** Phone +33 (0)1 47 95 60 00 • Fax +33 (0)1 47 41 91 33 **Munich, Germany,** Phone +49 (0) 89 31884 393 • Fax +49 (0) 89 31884 136 **Athens, Greece,** Phone +30 210 7774396 • Fax +30 210 7774376 **Quarry Bay, Hong Kong,** Phone +85 2 2789 3300 • Fax +85 2 2789 1257 **Budapest, Hungary,** Phone +36 1 459 6190 • Fax +36 1 459 6101 **Haryana, India,** Phone +91 124 4029300 • Fax +91 124 2398115 **Rishon Le Zion, Israel,** Phone +972 03 963 6025 • Fax +972 03 951 4129 **Milan, Italy,** Phone +39 024 94 86 600 • Fax +39 02 21609399 **Tokyo, Japan,** Phone +81 3 6361 7070 • Fax +81 3 5463 8481 **Seoul, Korea,** Phone +82 080 007 7373 • Fax +82 (2) 3472 7003 **Mexico D.F., Mexico,** Phone +52 (55) 5488 7670 • Fax +52 (55) 1107 7246 **Veenendaal, The Netherlands,** Phone +31 (0)318 540 666 • Fax +31 (0)318 542 216 **Auckland, New Zealand,** Phone +64 (9)415 2280 • Fax +64 (9)415 2284 **Oslo, Norway,** Phone +47 23 38 41 30 • Fax +47 23 38 41 39 **Warsaw, Poland,** Phone +48 22 331 99 99 • Fax +48 22 331 99 88 **Amadora, Portugal,** Phone +351 21 47 27 700 • Fax +351 21 472 7777 **Moscow, Russia,** Phone +7 495 721 1404 • Fax +7 495 721 1412 **Singapore,** Phone +65 6415 3170 • Fax +65 6415 3189 **Johannesburg, South Africa,** Phone +27 11 442 8508 • Fax +27 11 442 8525 **Madrid, Spain,** Phone +34 91 490 6580 • Fax +34 91 590 5211 **Sundbyberg, Sweden,** Phone +46 844 98053 • Fax +46 8 55 51 27 80 **Cressier, Switzerland,** Phone +41 (0) 61 717 9555 • Fax +41 (0) 61 717 9550 **Taipei, Taiwan,** Phone +886 (2) 2578-7189 • Fax +886 (2) 2578-6890 **Bangkok, Thailand,** Phone (662) 651 8311 • Fax (662) 651 8312 **Hertfordshire, United Kingdom,** Phone +44 (0)1923 471301 • Fax +44 (0)1923 471340

Revision Date 2022-04-19 → Indicates Revised Information
INSTRUMENT (1)

	Units	Level 1 - 85301T		Level 2 - 85302T		Level 3 - 85303T		
		Mean	Range	Mean	Range	Mean	Range	
Abbott Alinity c Analyzer								
Amikacin	µg/mL	5.04	3.44 – 6.64	14.9	10.4 – 19.4	29.0	22.0 – 36.0	
Carbamazepine	µg/mL	2.86	2.22 – 3.49	8.43	6.97 – 9.89	11.8	9.82 – 13.7	
Digoxin	ng/mL	1.18	0.900 – 1.46	1.75	1.39 – 2.10	3.07	2.54 – 3.61	
Gentamicin	µg/mL	2.82	2.28 – 3.35	4.88	4.10 – 5.66	6.93	5.91 – 7.96	
Lithium	mmol/L	0.484	0.390 – 0.578	1.26	1.12 – 1.40	1.88	1.70 – 2.06	
Phenobarbital	µg/mL	8.92	6.87 – 11.0	23.0	18.6 – 27.3	50.8	42.7 – 58.8	
Phenytoin	µg/mL	5.04	4.04 – 6.04	12.1	9.97 – 14.2	20.0	16.6 – 23.3	
Salicylate	mg/dL	7.24	5.42 – 9.06	16.5	14.0 – 19.0	36.2	32.3 – 40.1	
Theophylline	µg/mL	3.88	2.93 – 4.83	12.5	10.0 – 15.1	25.9	20.7 – 31.0	
Valproic Acid	µg/mL	34.6	28.1 – 41.2	74.4	65.6 – 83.1	108	96.9 – 118	
Vancomycin →	µg/mL	5.70	4.46 – 6.94	19.2	15.8 – 22.6	34.1	28.3 – 40.0	
Abbott Alinity i Analyzer								
AFP	ng/mL	26.9	23.8 – 30.1	110	98.3 – 122	220	196 – 244	
CEA	ng/mL	2.95	2.43 – 3.47	20.7	18.2 – 23.2	42.1	37.2 – 47.1	
Cortisol	µg/dL	3.90	3.09 – 4.72	21.4	18.5 – 24.2	31.7	27.7 – 35.8	
Dehydroepiandrosterone-Sulfate (DHEA-Sulfate)	µg/dL	94.0	80.7 – 107	168	143 – 193	673	570 – 776	
Ferritin	ng/mL	37.0	30.8 – 43.2	277	227 – 326	750	643 – 856	
Folate	ng/mL	5.00	3.08 – 6.92	13.1	8.83 – 17.4	>20.0		
Follicle Stimulating Hormone (FSH)	mIU/mL	6.74	5.71 – 7.77	16.8	14.1 – 19.4	40.8	34.3 – 47.2	
hCG	mIU/mL	7.36	5.34 – 9.39	24.9	20.7 – 29.1	414	361 – 467	
Luteinizing Hormone (LH)	mIU/mL	2.81	2.47 – 3.16	16.6	14.6 – 18.7	50.0	43.6 – 56.3	
Progesterone	ng/mL	0.656	<0.500 – 0.816	8.29	6.51 – 10.1	20.5	16.1 – 24.8	
Prolactin	ng/mL	8.65	7.59 – 9.70	20.7	18.0 – 23.4	52.2	45.1 – 59.3	
PSA (Free)	ng/mL	0.207	0.180 – 0.235	3.08	2.55 – 3.61	17.6	14.5 – 20.7	
PSA (Total)	ng/mL	0.374	0.287 – 0.462	4.03	3.24 – 4.82	20.7	16.7 – 24.7	
Sex Hormone Binding Globulin (SHBG)	nmol/L	20.1	15.9 – 24.3	39.1	30.9 – 47.4	36.2	28.6 – 43.9	
T3 (Free)	pg/mL	1.98	<1.50 – 2.46	5.93	4.96 – 6.89	11.9	10.3 – 13.6	
T3 Uptake/T Uptake	T Uptake Unit	1.67	1.40 – >1.89	0.924	0.775 – 1.07	0.903	0.757 – 1.05	
T4 (Total)	µg/dL	7.69	6.67 – 8.71	11.0	9.34 – 12.7	14.1	11.8 – 16.5	
Testosterone →	ng/dL	125	96.5 – 154	397	317 – 478	821	660 – 981	
Thyroid Stimulating Hormone (TSH)	µIU/mL	0.704	0.505 – 0.902	4.87	4.02 – 5.71	25.5	21.3 – 29.6	
Vitamin B12	pg/mL	208	<148 – 284	494	383 – 604	636	505 – 767	
ROCHE / HITACHI COBAS C SYSTEMS								
Acetaminophen (ACET2) (REF 06769942190)	µg/mL	10.3	7.83 – 12.8	34.5	28.8 – 40.3	104	88.3 – 119	
Amikacin	µg/mL	§		§		§		
Carbamazepine (CARB4)	µg/mL	2.71	<2.00 – 3.56	9.29	7.40 – 11.2	13.5	10.9 – 16.0	
Digoxin	ng/mL	1.31	0.991 – 1.63	1.89	1.53 – 2.25	3.37	2.91 – 3.83	
Ferritin	ng/mL	40.5	34.7 – 46.2	180	155 – 206	396	340 – 453	
Gentamicin (GENT2)	µg/mL	§		§		§		
Gentamicin (QMS)	µg/mL	2.95	2.25 – 3.65	5.48	4.45 – 6.52	8.00	6.64 – 9.36	
Immunoglobulin A (IgA)	mg/dL	83.7	66.2 – 101	163	138 – 187	159	135 – 183	
Immunoglobulin G (IgG)	mg/dL	420	365 – 474	796	686 – 906	855	737 – 973	
Immunoglobulin M (IgM)	mg/dL	29.9	<25.0 – 38.1	69.1	58.5 – 79.7	68.2	57.7 – 78.7	
Iron	µg/dL	192	171 – 214	194	172 – 216	192	170 – 214	
Lithium	mg/dL	0.341	0.220 – 0.461	0.891	0.747 – 1.04	1.35	1.17 – 1.52	
Phenobarbital	µg/mL	9.42	7.35 – 11.5	25.6	22.0 – 29.1	51.0	45.1 – 56.9	
Phenytoin	µg/mL	4.38	3.24 – 5.52	12.4	10.1 – 14.7	19.4	16.1 – 22.7	
Salicylate	mg/dL	7.30	5.72 – 8.89	16.1	13.7 – 18.4	36.3	32.1 – 40.5	
Theophylline	µg/mL	5.00	4.27 – 5.73	15.5	13.7 – 17.4	29.6	26.2 – 32.9	
Tobramycin	µg/mL	0.948	0.632 – 1.27	3.51	2.94 – 4.08	6.41	5.54 – 7.28	
Valproic Acid	µg/mL	38.2	31.1 – 45.2	78.9	65.8 – 92.0	110	91.9 – 127	
Vancomycin (VAN3)	µg/mL	7.11	5.09 – 9.14	19.6	16.0 – 23.3	34.2	28.7 – 39.7	

INSTRUMENT (1)

	Units	Level 1 - 85301T		Level 2 - 85302T		Level 3 - 85303T		
		Mean	Range	Mean	Range	Mean	Range	
ROCHE ELECSYS / E 170 / COBAS e SYSTEMS								
AFP	ng/mL	32.1	27.5 – 36.7	127	110 – 145	255	220 – 290	
CEA	ng/mL	2.92	2.44 – 3.41	16.4	14.5 – 18.2	31.8	28.3 – 35.3	
CK-MB Isoenzyme (mass) (2)	ng/mL	§		§		§		
CK-MB Isoenzyme (mass) (STAT) (2)	ng/mL	§		§		§		
Cortisol (II)	µg/dL	3.68	3.12 – 4.23	21.2	18.0 – 24.4	30.6	26.0 – 35.3	
Dehydroepiandrosterone-Sulfate (DHEA-Sulfate) (DHEA-Sulfate)	µg/dL	104	83.4 – 124	174	143 – 205	661	552 – 770	
Digoxin (cobas e801)	ng/mL	1.24	1.01 – 1.48	1.85	1.55 – 2.16	3.37	2.89 – 3.85	
Estradiol (III)	pg/mL	74.1	57.9 – 90.2	267	236 – 298	669	607 – 731	
Estradiol (III, cobas e801)	pg/mL	71.7	55.8 – 87.5	262	232 – 292	674	612 – 736	
Ferritin	ng/mL	34.1	29.8 – 38.3	180	158 – 203	400	350 – 449	
Folate (cobas e801)	ng/mL	3.09	2.00 – 4.18	8.08	5.66 – 10.5	12.6	8.95 – 16.2	
Folate (III) (E170/e601/e602/e411) (Ref. 07559992) restand.	ng/mL	3.07	<2.00 – 4.15	7.61	5.29 – 9.92	12.2	8.61 – 15.7	
Follicle Stimulating Hormone (FSH)	mIU/mL	6.72	5.88 – 7.56	17.4	15.4 – 19.5	38.4	33.9 – 42.9	
hCG (hCG STAT)	mIU/mL	5.10	4.07 – 6.14	19.2	13.9 – 24.5	359	250 – 468	
hCG (hCG+B)	mIU/mL	5.40	4.28 – 6.51	21.1	15.2 – 27.0	399	277 – 520	
Human Chorionic Gonadotropin (hCG) (cobas e801)	mIU/mL	5.35	4.26 – 6.45	20.4	14.7 – 26.0	377	263 – 492	
Human Growth Hormone (hGH)	ng/mL	4.83	4.25 – 5.41	12.7	11.2 – 14.2	24.8	22.0 – 27.6	
Immunoglobulin E (IgE)	ng/mL	181	159 – 203	252	222 – 283	822	727 – 916	
Insulin	µU/mL	§		§		§		
Luteinizing Hormone (LH)	mIU/mL	4.72	4.15 – 5.28	24.0	21.3 – 26.7	68.0	60.3 – 75.7	
Progesterone (III)	ng/mL	0.886	0.633 – 1.14	12.2	10.2 – 14.3	26.4	22.1 – 30.7	
Prolactin	µIU/mL	9.70	8.43 – 11.0	23.6	20.7 – 26.4	60.6	53.5 – 67.6	
PSA (Free)	ng/mL	0.163	0.136 – 0.190	2.24	1.93 – 2.54	11.9	10.3 – 13.5	
PSA (Total)	ng/mL	0.468	0.386 – 0.551	4.99	4.34 – 5.64	26.9	23.5 – 30.3	
Sex Hormone Binding Globulin (SHBG)	µg/mL	1.76	1.43 – 2.08	3.48	2.96 – 4.00	3.11	2.63 – 3.59	
T3 (Free)	pg/mL	2.37	1.99 – 2.75	7.18	6.35 – 8.02	13.7	12.3 – 15.2	
T3 (Total)	ng/mL	1.08	0.835 – 1.32	1.91	1.53 – 2.29	3.13	2.55 – 3.71	
T3 Uptake/T Uptake	TBI	1.16	1.03 – 1.28	0.586	0.431 – 0.741	0.315	<0.200 – 0.485	
T4 (Free) (II)	ng/dL	1.15	1.01 – 1.29	2.81	2.37 – 3.24	4.75	3.96 – 5.53	
T4 (Free) (III)	ng/dL	1.14	0.999 – 1.28	2.88	2.43 – 3.33	4.93	4.11 – 5.74	
T4 (Free) (IV) (2)	ng/dL	§		§		§		
T4 (Total)	µg/dL	8.29	7.06 – 9.51	10.5	8.92 – 12.0	13.5	11.6 – 15.5	
Testosterone (II)	ng/mL	1.27	1.02 – 1.52	4.18	3.40 – 4.97	8.27	6.74 – 9.80	
Thyroid Stimulating Hormone (TSH)	µIU/mL	0.903	0.814 – 0.991	6.13	5.49 – 6.76	33.8	30.3 – 37.3	
Vitamin B12 (II) (cobas e801)	pg/mL	263	212 – 314	572	496 – 649	734	643 – 825	
Vitamin B12 (II) (E170/e601/e602)	pg/mL	§		§		§		
Vitamin B12 (II) (e411)	pg/mL	232	180 – 283	517	444 – 589	695	607 – 784	
Siemens ADVIA Centaur Systems								
AFP (AFP)	ng/mL	32.2	26.0 – 38.4	131	107 – 156	262	213 – 311	
Androstenedione (ANDRO)	ng/mL	0.425	<0.300 – 0.645	1.15	0.698 – 1.61	2.73	1.76 – 3.70	
CEA (CEA)	ng/mL	2.70	1.88 – 3.51	18.0	14.7 – 21.3	38.1	31.5 – 44.7	
CK-MB Isoenzyme (mass) (CKMB)	ng/mL	4.35	3.33 – 5.36	14.8	12.0 – 17.7	40.5	33.8 – 47.3	
Cortisol (COR)	µg/dL	4.34	3.11 – 5.57	25.7	19.7 – 31.6	36.9	28.3 – 45.4	
Dehydroepiandrosterone-Sulfate (DHEA-Sulfate)	µg/dL	80.8	54.1 – 108	121	85.5 – 156	429	327 – 531	
Digoxin (DIG)	ng/mL	1.35	1.06 – 1.64	2.03	1.64 – 2.42	3.46	2.85 – 4.07	
Estradiol (Enhanced)	pg/mL	78.0	55.6 – 100	373	312 – 433	1127	970 – 1284	
Ferritin (FER)	ng/mL	23.0	19.2 – 26.7	146	116 – 175	359	284 – 434	
Folate (FOL)	ng/mL	1.66	0.715 – 2.60	5.78	3.27 – 8.30	9.16	5.35 – 13.0	
Follicle Stimulating Hormone (FSH)	mIU/mL	7.22	5.74 – 8.69	17.2	14.2 – 20.1	36.5	30.6 – 42.4	
hCG	mIU/mL	10.3	6.85 – 13.8	27.1	21.2 – 32.9	410	351 – 468	
Immunoglobulin E (IgE) (tigE)	IU/mL	68.6	55.3 – 82.0	90.7	72.8 – 109	323	257 – 388	
Insulin (IRI)	mIU/L	18.2	15.0 – 21.3	86.0	70.8 – 101	175	144 – 206	
Luteinizing Hormone (LH)	mIU/mL	3.67	3.04 – 4.31	24.5	19.8 – 29.3	65.7	52.8 – 78.6	
Progesterone (PRGE)	ng/mL	1.12	0.655 – 1.59	10.3	7.75 – 12.8	17.3	13.2 – 21.4	
Prolactin (PRL)	ng/mL	6.58	5.53 – 7.64	13.9	11.5 – 16.3	37.4	30.8 – 44.1	

INSTRUMENT (1)

	Units	Level 1 - 85301T		Level 2 - 85302T		Level 3 - 85303T	
		Mean	Range	Mean	Range	Mean	Range
Siemens ADVIA Centaur Systems (continued)							
PSA (Free) (fPSA)	ng/mL	0.192	0.151 – 0.233	2.38	1.91 – 2.84	12.0	9.59 – 14.3
PSA (Total) (PSA)	ng/mL	0.407	0.324 – 0.489	3.78	3.09 – 4.46	20.2	16.6 – 23.8
PSA, Complexed (cPSA) (cPSA)	ng/mL	0.174	0.131 – 0.217	0.920	0.743 – 1.10	4.13	3.37 – 4.89
Sex Hormone Binding Globulin (SHBG)	µg/mL	1.75	1.25 – 2.24	3.43	2.63 – 4.23	3.02	2.31 – 3.72
T3 (Free) (FT3)	pg/mL	1.99	1.71 – 2.27	6.21	5.48 – 6.94	10.7	9.50 – 11.9
T3 (Total) (T3)	ng/mL	0.836	0.595 – 1.08	1.83	1.44 – 2.22	3.28	2.67 – 3.89
T3 Uptake/T Uptake (TUp)	T Uptake Unit	0.686	0.518 – 0.855	1.35	1.09 – 1.60	1.56	1.27 – 1.86
T4 (Free) (FT4)	ng/dL	0.901	0.702 – 1.10	2.13	1.70 – 2.55	3.22	2.58 – 3.85
T4 (Total) (T4)	µg/dL	9.33	7.20 – 11.4	11.4	8.67 – 14.1	15.2	11.4 – 19.0
Testosterone (TSTII)	ng/dL	115	81.1 – 149	410	292 – 527	769	549 – 988
Thyroid Stimulating Hormone (TSH) (3-Ultra) (TSH3-UL)	µIU/mL	0.782	0.546 – 1.02	5.45	2.86 – 8.03	30.7	15.4 – 46.1
Vitamin B12 (VB12)	pg/mL	157	79.4 – 234	475	342 – 607	675	506 – 844
Siemens ADVIA Chemistry Systems							
Acetaminophen (ACET)	mg/dL	1.12	0.753 – 1.48	3.64	2.93 – 4.35	10.9	9.11 – 12.6
Digoxin (DIG)	ng/mL	1.13	0.840 – 1.42	1.82	1.52 – 2.13	3.41	3.06 – 3.76
Immunoglobulin A (IgA) (IGA_2)	mg/dL	84.8	67.4 – 102	167	142 – 192	165	141 – 190
Immunoglobulin G (IgG) (IGG_2)	mg/dL	369	320 – 418	751	648 – 855	807	695 – 918
Immunoglobulin M (IgM) (IGM_2)	mg/dL	28.2	<21.0 – 36.4	68.5	58.0 – 79.1	68.3	57.8 – 78.8
Iron (IRON_2)	µg/dL	194	174 – 214	197	176 – 217	193	173 – 213
Lithium (LITH/LITH_2)	mmol/L	0.549	0.401 – 0.697	1.31	1.12 – 1.51	2.01	1.77 – 2.26
Salicylate (SAL)	mg/dL	8.38	5.46 – 11.3	18.2	14.1 – 22.2	40.8	34.2 – 47.3
Siemens Atellica Solution							
Acetaminophen (Acet) (CH)	mg/dL	1.08	0.912 – 1.26	3.54	3.06 – 4.02	10.7	9.31 – 12.0
AFP (AFP) (IM)	ng/mL	33.7	28.2 – 39.1	128	106 – 151	265	218 – 311
Amikacin (Amik) (CH)	µg/mL	4.81	3.71 – 5.92	14.7	11.3 – 18.0	25.9	20.0 – 31.8
Androstenedione (ANDRO) (IM)	ng/mL	0.488	<0.300 – 0.696	1.20	0.761 – 1.64	2.76	1.81 – 3.71
Caffeine (CAFF) (CH)	µg/mL	2.28	1.41 – 3.14	7.56	5.41 – 9.70	15.8	11.6 – 19.9
Carbamazepine (Carb) (CH)	µg/mL	2.86	2.28 – 3.44	8.50	7.30 – 9.70	12.7	11.0 – 14.3
CEA (CEA) (IM)	ng/mL	2.70	2.18 – 3.22	18.1	15.0 – 21.2	37.3	31.0 – 43.7
CK-MB Isoenzyme (mass) (CKMB) (IM)	ng/mL	3.86	3.06 – 4.67	15.0	12.6 – 17.5	40.1	34.0 – 46.2
Cortisol (Cor) (IM)	µg/dL	4.78	3.69 – 5.88	27.1	22.0 – 32.2	39.4	32.1 – 46.7
Dehydroepiandrosterone-Sulfate (DHEA-Sulfate) (DHEAS) (IM)	µg/dL	84.0	64.9 – 103	139	109 – 170	497	392 – 603
Digoxin (Dgn) (CH)	ng/mL	1.15	0.866 – 1.42	1.74	1.43 – 2.05	3.28	2.89 – 3.68
Digoxin (Dig) (IM)	ng/mL	1.47	1.22 – 1.72	2.13	1.79 – 2.47	3.84	3.28 – 4.41
Estradiol (eE2) (IM)	pg/mL	77.0	47.7 – 106	397	301 – 494	1214	977 – 1452
Ferritin (Fer) (IM)	ng/mL	22.8	18.9 – 26.8	145	119 – 172	362	296 – 427
Folate (Fol) (IM)	ng/mL	1.89	1.04 – 2.74	6.84	4.66 – 9.02	10.1	7.04 – 13.1
Follicle Stimulating Hormone (FSH) (IM)	mIU/mL	7.03	5.80 – 8.25	17.8	14.8 – 20.9	38.8	32.2 – 45.4
Gentamicin (Gent) (CH)	µg/mL	2.48	1.96 – 3.00	5.07	4.31 – 5.82	7.08	6.14 – 8.02
hCG (ThCG) (IM)	mIU/mL	9.79	7.68 – 11.9	28.7	23.9 – 33.4	428	367 – 488
Immunoglobulin A (IgA) (IGA_2) (CH)	mg/dL	89.8	73.0 – 107	177	153 – 200	174	150 – 197
Immunoglobulin E (IgE) (tIgE) (IM)	IU/mL	67.7	52.9 – 82.6	94.9	74.7 – 115	354	284 – 425
Immunoglobulin G (IgG) (IGG_2) (CH)	mg/dL	376	330 – 422	778	677 – 879	829	721 – 937
Immunoglobulin M (IgM) (IGM_2) (CH)	mg/dL	28.0	<21.0 – 35.8	68.5	58.6 – 78.4	70.4	60.3 – 80.4
Insulin (IRI) (IM)	mIU/L	17.7	14.8 – 20.5	84.6	70.5 – 98.6	175	145 – 204
Iron (Iron_2) (CH)	µg/dL	184	166 – 202	184	166 – 202	182	164 – 200
Lidocaine (LIDO) (CH)	µg/mL	1.20	0.876 – 1.53	3.80	3.22 – 4.39	5.67	4.90 – 6.44
Lithium (Li) (CH)	mEq/L	0.504	0.425 – 0.582	1.27	1.16 – 1.39	1.92	1.77 – 2.06
Lithium (Lith/LITH_2) (CH)	mmol/L	0.475	0.340 – 0.609	1.29	1.10 – 1.47	1.97	1.74 – 2.19
Luteinizing Hormone (LH) (IM)	mIU/mL	3.92	3.28 – 4.56	23.8	19.7 – 28.0	68.3	56.4 – 80.3
N-Acetyl Procainamide (NAPA) (CH)	µg/mL	1.91	1.29 – 2.53	4.68	3.92 – 5.45	8.48	7.50 – 9.45
Phenobarbital (Phnb) (CH)	µg/mL	10.2	7.99 – 12.4	27.2	22.9 – 31.5	53.7	46.1 – 61.4
Phenytoin (Phny) (CH)	µg/mL	4.39	3.34 – 5.44	12.6	10.6 – 14.6	20.9	18.0 – 23.9
Procainamide (PROC) (CH)	µg/mL	2.24	1.54 – 2.94	7.67	6.26 – 9.08	13.2	11.0 – 15.3
Progesterone (PRGE) (IM)	ng/mL	1.09	0.741 – 1.44	11.2	8.39 – 14.0	22.3	16.8 – 27.8

INSTRUMENT (1)

	Units	Level 1 - 85301T		Level 2 - 85302T		Level 3 - 85303T	
		Mean	Range	Mean	Range	Mean	Range
Siemens Atellica Solution (continued)							
Prolactin (PRL) (IM)	ng/mL	6.63	5.64 – 7.62	14.3	12.1 – 16.5	37.6	31.7 – 43.5
PSA (Total) (PSA) (IM)	ng/mL	0.366	0.305 – 0.427	3.81	3.16 – 4.45	22.0	18.3 – 25.8
PSA, Complexed (cPSA) (IM)	ng/mL	0.190	0.147 – 0.232	0.965	0.792 – 1.14	4.44	3.68 – 5.20
Salicylate (Sal) (CH)	mg/dL	8.12	6.52 – 9.73	17.6	15.6 – 19.6	39.0	36.1 – 42.0
Sex Hormone Binding Globulin (SHBG) (IM)	µg/mL	1.89	1.45 – 2.34	3.81	2.99 – 4.64	3.34	2.61 – 4.07
T3 (Free) (FT3) (IM)	pg/mL	2.08	1.52 – 2.64	6.47	5.43 – 7.50	10.9	9.45 – 12.4
T3 (Total) (T3) (IM)	ng/mL	1.06	0.858 – 1.27	2.21	1.75 – 2.67	3.70	3.15 – 4.26
T3 Uptake/T Uptake (TUp) (IM)	T Uptake Unit	0.608	0.493 – 0.723	1.37	1.16 – 1.58	1.59	1.34 – 1.83
T4 (Free) (FT4) (IM)	ng/dL	0.967	0.777 – 1.16	2.27	1.92 – 2.62	3.54	3.04 – 4.04
T4 (Total) (T4) (IM)	µg/dL	10.5	8.38 – 12.6	12.9	10.3 – 15.4	16.8	13.6 – 20.1
Testosterone (TSTII) (IM)	ng/dL	105	81.4 – 129	417	343 – 491	753	625 – 880
Theophylline (Theo) (CH)	µg/mL	4.00	3.21 – 4.79	14.4	12.4 – 16.3	28.7	25.1 – 32.3
Thyroid Stimulating Hormone (TSH) (3-Ultra) (TSH3-UL) (IM)	µIU/mL	0.692	0.573 – 0.812	4.89	4.11 – 5.67	29.0	24.4 – 33.7
Tobramycin (Tob) (CH)	µg/mL	0.404	<0.300 – 0.667	2.87	2.42 – 3.32	5.79	5.12 – 6.46
Valproic Acid (VPA) (CH)	µg/mL	40.3	33.4 – 47.3	80.7	70.1 – 91.2	112	98.8 – 126
Vancomycin (Vanc) (CH)	µg/mL	6.26	4.95 – 7.58	18.6	15.9 – 21.2	31.5	27.4 – 35.5
Vitamin B12 (VB12) (IM)	pg/mL	160	116 – 203	430	335 – 525	657	519 – 795
Siemens Dimension Series							
Carbamazepine	µg/mL	2.67	2.11 – 3.23	8.52	7.33 – 9.71	12.7	11.0 – 14.3
Gentamicin (GENT)	µg/mL	2.38	1.94 – 2.82	5.14	4.48 – 5.80	7.15	6.34 – 7.96
Phenobarbital (PHNO)	µg/mL	§		§		§	
Phenytoin (PTN)	µg/mL	4.37	2.75 – 5.99	13.0	10.5 – 15.6	22.2	18.6 – 25.7
Theophylline (THEO)	µg/mL	4.60	3.68 – 5.52	14.9	12.4 – 17.3	29.2	24.6 – 33.7
Tobramycin (TOBR)	µg/mL	§		§		§	
Valproic Acid (VALP)	µg/mL	38.1	32.3 – 44.0	76.3	65.8 – 86.7	108	93.9 – 122
Vancomycin (VANC)	µg/mL	6.22	4.95 – 7.49	19.6	16.9 – 22.4	33.4	29.2 – 37.6
Siemens Dimension Vista							
Amikacin	µg/mL	4.32	3.29 – 5.34	14.4	9.21 – 19.5	26.5	16.3 – 36.7
Caffeine	µg/mL	2.37	1.28 – 3.47	7.38	4.41 – 10.4	14.4	8.76 – 20.1
Lidocaine (LIDO)	µg/mL	1.22	0.888 – 1.55	3.93	3.32 – 4.55	5.80	4.99 – 6.62
N-Acetyl Procainamide (NAPA)	µg/mL	1.73	1.09 – 2.36	4.66	3.76 – 5.56	8.64	7.38 – 9.91
Procainamide (PROC)	µg/mL	2.23	1.59 – 2.86	7.82	6.32 – 9.31	13.9	11.5 – 16.4
Tricyclic Antidepressants (TCA)	ng/mL	265	160 – 369	510	411 – 608	657	560 – 754
Siemens IMMULITE 2000/2500/XPi							
Androstenedione	ng/mL	1.42	0.878 – 1.97	3.02	1.94 – 4.11	7.63	4.98 – >10.0
Estriol (Free)	ng/mL	2.03	1.34 – 2.71	5.73	5.01 – 6.44	11.3	10.6 – >12.0
Human Growth Hormone (hGH)	ng/mL	4.39	3.48 – 5.29	10.8	8.69 – 13.0	19.4	15.6 – 23.3
Thyroxine Binding Globulin (TBG)	µg/mL	38.5	26.3 – 50.6	17.2	11.4 – 22.9	15.9	10.5 – 21.4
Siemens Viva-E							
Primidone (Syva EMIT/EMIT II)	µg/mL	2.95	<2.50 – 3.77	6.00	4.59 – 7.41	11.8	9.31 – 14.4
Quinidine (Syva EMIT 2000)	µg/mL	0.856	0.566 – 1.15	2.34	1.69 – 3.00	4.22	3.06 – 5.39

FOOTNOTES

(1) All footnotes may not apply to your custom selected data chart.

(2) Data field(s) containing inequalities (<,>), N/A, § or ▲ (where no value is assigned) are represented by a value of 0.0001 on the Roche instrument.

▲ Data is not available at this time. Please inquire.

§ The data required to establish the means and acceptable ranges for this assay were not obtained due to limited assignment participation. If your facility is interested in participating in the Value Assignment Program for this assay, please contact your local Bio-Rad office.