

Assay Summary

Assay Name/ Abbreviation*	Specimens	Calibrator**	Control	Reportable (Dynamic) Range	Recommended High Sample Diluent	Methodology	Suggested Reference Interval or Cutoff	Time to First Result (Minutes)	Sensitivity (Analytical)	Sample Volume (µL)	Open Reagent Pack Stability†
AFP AFP	S, P _E , P _H , A	3 Levels, Liquid, 13 Week open stability	RE or Oncology	0-500 IU/mL 0-520 ng/mL (ng/mL = IU/mL x 1.04)	A	Immunometric	Normal Adults (upper 97.5 percentile) < 7.22 IU/mL < 7.51 ng/mL	43	0.5 IU/mL 0.5 ng/mL	25	8 weeks
Anti-HAV IgM# HAV M	S, P _C , P _E , P _H	1 Level, Liquid, 10 Week open stability	Anti-HAV IgM	Qualitative	B	Immunometric (Antibody Class Capture)	Reactive ≥ 1.20 Non-reactive < 0.80 Borderline ≥ 0.80 and < 1.20	43	Refer to Instructions for Use	10	8 weeks
Anti-HAV Total# HAV T	S, P _C , P _E , P _H	1 Level, Liquid, 13 Week open stability	Anti-HAV Total	Qualitative	B	Competitive	Reactive < 0.80 Non-reactive ≥ 1.0 and < 4.0 Borderline ≥ 0.80 and < 1.0 Retest? ≥ 4.0	53	Refer to Instructions for Use	10	12 weeks
Anti-HBc# aHBc	S, P _C , P _E , P _H	1 Level, Liquid, 13 Week open stability	Anti-HBc (CAT 680 0836)	Qualitative		Competitive	Reactive < 1.00 Non-reactive ≥ 1.20 Borderline ≥ 1.00 and < 1.20	55	Refer to Instructions for Use	50	8 weeks
Anti-HBc IgM# HBc M	S, P _C , P _E , P _H	1 Level, Liquid, 13 Week open stability	Anti-HBc IgM (CAT 680 0834)	Qualitative	B	Immunometric (Antibody Class Capture)	Reactive ≥ 1.20 Non-reactive < 0.80 Borderline ≥ 0.80 and < 1.20	43	Refer to Instructions for Use	10	8 weeks
Anti-HBe# aHBe	S	1 Level, Lyophilized 13 Week reconstituted stability	HBe	Qualitative		Competitive	Reactive ≥ 1.20 Non-reactive < 0.80 Borderline ≥ 0.80 and < 1.20	53	Refer to Instructions for Use	80	8 weeks
Anti-HBs# aHBs	S, P _C , P _H	3 Levels, Liquid, 13 Week open stability	Anti-HBs (CAT 680 0389)	0-1000 mIU/mL (IU/L) (IU/L = mIU/mL)	B	Immunometric	Antibody Positive > 12 mIU/mL Antibody Negative < 8 mIU/mL Borderline 8-12 mIU/mL	55	Refer to Instructions for Use	80	8 weeks
Anti-HCV# aHCV	S, P _C , P _E , P _H	1 Level, Liquid, 13 Week open stability	Anti-HCV (CAT 680 0731)	Qualitative		Immunometric	Reactive ≥ 1.00 Non-reactive < 0.90 Borderline ≥ 0.90 and < 1.00	55	Refer to Instructions for Use	20	8 weeks
Anti-HIV 1+2# aHIV	S, P _C , P _H	1 Level, Liquid, 13 Week open stability	Anti-HIV 1+2	Qualitative		Immunometric	Reactive ≥ 1.00 Negative < 0.90 Borderline ≥ 0.90 and < 1.00	39	Refer to Instructions for Use	80	8 weeks
CA 125 II™ CA125	S, P _E , P _H	3 Levels, Liquid, 13 Week open stability	Oncology	0-1000 U/mL	B	Immunometric	Normal Adults (98.5%) ≤ 35 U/mL	37	1.2 U/mL	25	8 weeks
CA 15-3™ CA153	S, P _E , P _H	3 Levels, Liquid, 13 Week open stability	Oncology	0-500 U/mL	B	Immunometric	Normal Adults (98%) ≤ 35 U/mL	42	0.5 U/mL	10	8 weeks
CA 19-9™ CA199	S, P _E , P _H	3 Levels, Liquid, 13 Week open stability	Oncology	0-1000 U/mL	B	Immunometric	Normal Adults (97%) ≤ 37 U/mL	42	1.0 U/mL	35	8 weeks
CEA CEA	S, P _E , P _H	2 Levels, Liquid, 13 Week open stability	Oncology	0-400 ng/mL (µg/L) (µg/L = ng/mL)	B	Immunometric	Healthy Non-Smokers (91.9%) & Healthy Smokers (67.3%) ≤ 3.0 ng/mL (µg/L)	38	< 0.45 ng/mL < 0.45 µg/L	20	8 weeks
CK-MB CK-MB	S, P _E , P _H	3 Levels, Lyophilized, 4 Week reconstituted stability	Cardiology	0-400 ng/mL (µg/L) (µg/L = ng/mL)	B	Immunometric	Apparently Healthy (upper 97.5 percentile) Serum 3.38 ng/mL (µg/L) Heparin Plasma 2.37 ng/mL (µg/L) EDTA Plasma 2.03 ng/mL (µg/L)	16	0.3 ng/mL 0.3 µg/L	40	8 weeks
Cortisol Cort	S, P _E , P _H , U†	3 Levels, Lyophilized, 13 Week reconstituted stability	Metabolism	0-1700 nmol/L 0-61.6 µg/dL (µg/dL = nmol/L x 0.03625)	B	Competitive	Before 10:00 am 123-626 nmol/L 4.46-22.7 µg/dL After 5:00 pm 46.2-389 nmol/L 1.7-14.1 µg/dL Urinary Free 59.2-413 nmol cortisol/24 hours 21.5-150 µg cortisol/24 hours	38	< 3 nmol/L < 0.11 µg/dL	25	8 weeks
Estradiol E2	S, P _E , P _H	2 Levels, Liquid, 13 Week open stability	RE	0-14000 pmol/L 0-3814 pg/mL (pg/mL = pmol/L x 0.2724)	A	Competitive	(central 95%) Normal Follicular Phase 97.5-592 pmol/L 26.6-161 pg/mL Normal Pre-ovulatory 685-1404 pmol/L 187-382 pg/mL Normal Luteal Phase 120-738 pmol/L 32.7-201 pg/mL Post Menopause 19.7-141 pmol/L 5.37-38.4 pg/mL Normal Males 19.7-242 pmol/L 5.37-65.9 pg/mL	40	10 pmol/L 2.72 pg/mL	25	8 weeks
Ferritin Ferr	S, P _H	3 Levels, Lyophilized, 13 Week reconstituted stability	Anemia	0-1000 ng/mL	B	Immunometric	(central 95%) Females: <50 yrs 6.24-137 ng/mL ≥50 yrs 11.1-264 ng/mL Males 17.9-464 ng/mL	42	< 1 ng/mL	15	8 weeks
Folate Fol	S, P _H , WB _H , WB _E ‡	3 Levels, Liquid (Frozen), Open stability: 3 Day at 2-8 °C 4 Week at -18 °C or below	Suitable Controls	0-20 ng/mL 0-45.3 nmol/L (nmol/L = ng/mL x 2.265)		Competitive	(central 95%) Serum/Plasma- Normal Adults 2.76- >20 ng/mL 6.25- >45.3 nmol/L Serum/Plasma- Folate Deficient Patients 1.04-2.79 ng/mL 2.36-6.32 nmol/L Whole Blood- Normal adults 141-1018 ng/mL 319-2306 nmol/L Whole Blood- Folate Deficient Patients 31.2-146 ng/mL 70.7-331 nmol/L	73	<0.20 ng/mL <0.45 nmol/L	S, P _H 53, WB _H and WB _E 25	8 weeks
Free β-hCG FβhCG	S	2 Levels, Lyophilized, 6 Week reconstituted stability	Free βhCG	0-400 mIU/mL (ng/ mL) (ng/mL = mIU/mL)		Immunometric	Normal Adults < 0.20 mIU/mL (ng/mL)	42	0.20 mIU/mL 0.20 ng/mL	20	8 weeks
Free T3 FT3	S, P _E , P _H	3 Levels, Lyophilized, 4 Week reconstituted stability	Free Thyroid	0-35 pmol/L 0-22.8 pg/mL (pg/mL = pmol/L x 0.651)	Do not dilute	Competitive	Euthyroid Reference Interval (central 95%) 4.26-8.10 pmol/L 2.77-5.27 pg/mL	24	0.60 pmol/L 0.39 pg/mL	25	8 weeks
Free T4 FT4	S	3 Levels, Lyophilized, 4 Week reconstituted stability	Free Thyroid	0-90 pmol/L 0-6.99 ng/dL (ng/dL = pmol/L x 0.0777)	Do not dilute	Competitive	Euthyroid Reference Interval (central 98%) 10.0-28.2 pmol/L 0.78-2.19 ng/dL	24	0.40 pmol/L 0.03 ng/dL	25	8 weeks
FSH	S, P _E , P _H	2 Levels, Liquid, 13 Week open stability	RE	0-200 mIU/mL (IU/L) (IU/L = mIU/mL)		Immunometric	(central 95%) Normal female follicular phase 1.98-11.6 mIU/mL (IU/L) Normal female mid-cycle peak (observed range) 5.14-23.4 mIU/mL (IU/L) Normal female luteal phase 1.38-9.58 mIU/mL (IU/L) Postmenopausal females 21.5-131 mIU/mL (IU/L) Normal males 1.55-9.74 mIU/mL (IU/L)	24	0.50 mIU/mL 0.50 IU/L	40	8 weeks
HBeAg# HBeAg	S	1 Level, Lyophilized, Reconstituted stability: 5 Week at 2-8 °C 13 Week at -20 °C	HBe	Qualitative		Immunometric	Reactive ≥ 1.20 Non-reactive < 0.80 Borderline ≥ 0.80 and < 1.20	37	Refer to Instructions for Use	80	8 weeks

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† Open reagent packs can be stored onboard the VITROS ECI/ECIQ System or at 2°-8°C in a sealed reagent pack storage box containing dry desiccant.

‡ 2nd morning void.

§ 24-hour urine.

¶ Whole Blood samples must be treated with VITROS Red Cell Folate reagent pack.

Hepatitis and HIV assays are "Co-Developed with CHIRON". Chiron Corporation, Emeryville, CA, USA

Derived Tests			
Test	Calculation	Test	Calculation
FT3I Free T3 Index	(TT3 / T3 uptake units) (TT3 x T3 uptake%) / 100 (TT3 x T3 uptake %)	L/F LH / FSH Ratio	(LH / FSH)
FT4I Free T4 Index	(TT4 / T3 uptake units) (TT4 x T3 uptake %) / 100 (TT4 x T3 uptake %)	T3/T4 TT3/TT4 Ratio	(TT3 / TT4)

Abbreviations			
Specimen Type			
A	Amniotic Fluid	S	Serum
P_C	Citrate Plasma	U	Urine
P_E	EDTA Plasma	WB_E	EDTA Whole Blood
P_H	Heparin Plasma	WB_H	Heparin Whole Blood

Assay Summary

Assay Name/ Abbreviation*	Specimens	Calibrator**	Control	Reportable (Dynamic) Range	Recommended High Sample Diluent	Methodology	Suggested Reference Interval or Cutoff	Time to First Result (Minutes)	Sensitivity (Analytical)	Sample Volume (µL)	Open Reagent Pack Stability†
HBsAg† HBsAg	S, P _C , P _E , P _H	1 Level, Liquid, 12 Week open stability	HBsAg (CAT 680 0598)	Qualitative		Immunometric	Reactive ≥ 1.00 Non-reactive < 0.90 Borderline ≥ 0.90 and < 1.00	37	Refer to instructions for Use	80	8 weeks
LH LH	S, P _E , P _H	2 Levels, Liquid, 13 Week open stability	RE	0-200 mIU/mL (IU/L) (IU/L= mIU/mL)		Immunometric	(central 95% - exception of the mid-peak cycle) Normal female follicular phase 2.58-12.1 mIU/mL (IU/L) Normal female mid-cycle peak (observed range) 27.3-96.9 mIU/mL (IU/L) Normal female luteal phase 0.833-15.5 mIU/mL (IU/L) Postmenopausal females 13.1-86.5 mIU/mL (IU/L)	24	0.5 mIU/mL 0.5 IU/L	50	8 weeks
Myoglobin MYOG	S, P _E , P _H	3 Levels, Lyophilized, 24 Hour reconstituted stability at 2-8°C only	Suitable Controls	0-2000 ng/mL 0-2000 µg/L (ng/mL=µg/L)	B	Immunometric	(upper 97.5 percentile) All Individuals 101 ng/mL (µg/L) Male 121 ng/mL (µg/L) Female 61.5 ng/mL (µg/L)	16	< 2.0 ng/mL (µg/L)	10	12 weeks
N-Telopeptide NTx	U	3 Levels, Liquid, 13 Week open stability	NTx	0-3000 nM BCE (Bone collagen equiv- alents)	A	Competitive	(central 95 percentile) Postmenopausal 26-124 nM BCE/mM creatinine Premenopausal 17-94 nM BCE/mM creatinine Males 21-83 nM BCE/mM creatinine	38	<10 nM BCE	25	8 weeks
Progesterone Prog - Lot 750 or greater	S, P _E , P _H	3 Levels, Lyophilized 13 Week reconstituted stability	RE	0-178 nmol/L 0-56.0 ng/mL (ng/mL= nmol/L x 0.3145)	A	Competitive	(central 95%) Follicular Phase 0.44-6.47 nmol/L 0.14-2.03 ng/mL Periovulatory 1.27-14.2 nmol/L 0.40-4.47 ng/mL Mid luteal Phase 16.6-72.2 nmol/L 5.22-22.7 ng/mL Luteal Phase 4.53-52.9 nmol/L 1.42-16.6 ng/mL	24	< 0.25 nmol/L < 0.08 ng/mL	25	12 weeks
Prolactin Prol	S, P _E , P _H	2 Levels, Lyophilized, Reconstituted stability: 5 Week at 2-8°C 10 Week at -20°C	RE	0-7000 mIU/L 0-329 ng/mL (ng/mL= mIU/L x 0.047)	A	Immunometric	(central 95%) Normal Non-pregnant 64-395 mIU/L 3.0-18.6 ng/mL Males 78-380 mIU/L 3.7-17.9 ng/mL	24	30.0 mIU/L 1.4 ng/mL	35	8 weeks
PSA PSA	S, P _E , P _H	3 levels, Liquid 12 Week open stability	Oncology	0-100 ng/mL	B	Immunometric	Normal Males ≤ 40 years 200-198 > 40 years 167-166 Subjects < 4ng/mL ≥ 4 ng/mL 200 198 2 167 166 1 Refer to Instructions for Use for Non-Malignant Conditions and Malignant Disease	37	0.03 ng/mL	15	8 weeks
Rubella IgG Rub G	S, P _C , P _E , P _H	3 Levels, Liquid, 13 Week open stability	Suitable Controls	0-350 IU/mL	B	Immunometric	Positive ≥15.0 IU/mL Negative ≤9.99 IU/mL Low Positive 10.0 to 14.9 IU/mL	35	Refer to instructions for Use	10	12 weeks
T3 Uptake T3U	S, P _E , P _H	2 Levels, Lyophilized, 2 Week reconstituted stability	Total Thyroid	17-65% uptake 2.21-0.515 uptake units		Competitive	Euthyroid Reference Interval T3 uptake (central 95%) FT4 { TT4 (nmol/L) x T3U (% uptake)/100 TT4 (µg/dL) x T3U (% uptake)/100 23.5-40.5% uptake 1.37-0.736 uptake units 21.2-49.8 nmol/L 1.65-3.89 µg/dL	24		10	8 weeks
Testosterone Testo	S, P _E , P _H	3 Levels, Liquid, 13 Week open stability	Testoster- one	0-75 nmol/L 0-2163 ng/dL (ng/dL= nmol/L x 28.84)		Competitive	(central 95%) Normal males 20-49 years 4.56-28.2 nmol/L 132-813 ng/dL Normal males > 50 years 2.49-21.6 nmol/L 71.8-623 ng/dL Females with normal menstrual cycles 0.198-2.67 nmol/L 5.71-77.0 ng/dL	40	< 0.03 nmol/L < 0.865 ng/dL	25	8 weeks
Toxoplasma IgG Tox G	S, P _C , P _E , P _H	2 Levels, Liquid, 13 Week open stability	Suitable Controls	0-500 IU/mL	B	Immunometric	Reactive ≥8.00 IU/mL Negative ≤3.99 IU/mL Borderline 4.00 to 7.99 IU/mL	35	Refer to instructions for Use	10	8 weeks
Total β-hCG β-hCG	S, P _E , P _H	2 Levels, Lyophilized, 13 Week reconstituted stability	RE or Oncology	0-1000 mIU/mL (IU/L) (IU/L= mIU/mL)	B	Immunometric	Normal Non-pregnant < 6.15 mIU/mL < 6.15 IU/L	24	0.50 mIU/mL 0.50 IU/L	25	8 weeks
Total T3 TT3	S, P _E , P _H	3 Levels, Liquid, 13 Week open stability	Total Thyroid	0-12 nmol/L 0-7.81 ng/mL (ng/mL= nmol/L x 0.651)		Competitive	Euthyroid Reference Interval (central 95%) 1.49-2.60 nmol/L 0.970-1.69 ng/mL	37	0.150 nmol/L 0.100 ng/mL	20	8 weeks
Total T4 TT4	S, P _E , P _H	3 Levels, Liquid, 13 Week open stability	Total Thyroid	0-320 nmol/L 0-24.9 µg/dL (µg/dL= nmol/L x 0.0777)		Competitive	Euthyroid Reference Interval (central 95%) 71.2-141 nmol/L 5.53-11.0 µg/dL	24	4.00 nmol/L 0.311 µg/dL	10	8 weeks
Troponin I TropI	P _H	2 Levels, Lyophilized, 1 Week reconstituted (in plastic tubes) stability	Suitable Controls	0-100 ng/mL 0-100 µg/L (µg/L= ng/mL)	B	Immunometric	Upper Reference Limit (99th percentile) AMI Cutoff (ROC curve analysis) Refer to Instructions for Use for additional information 0.08 ng/mL (µg/L) 0.4 ng/mL (µg/L)	16	< 0.038 ng/mL < 0.038 µg/L	75	12 weeks
TSH TSH	S, P _E , P _H	3 Levels, Liquid, 13 Week open stability	Free Thyroid or Total Thyroid	0-100 mIU/L 0-100 µIU/mL (µIU/mL= mIU/L)	A	Immunometric	Euthyroid Reference Interval (central 95%) 0.465-4.68 mIU/L 0.465-4.68 µIU/mL	37	0.003 mIU/L 0.003 µIU/mL (Functional: 0.015 mIU/L 0.015 µIU/mL)	80	8 weeks
TSH30 TSH30	S, P _E , P _H	3 Levels, Liquid, 13 Week open stability	Free Thyroid or Total Thyroid	0-65 mIU/L 0-65 µIU/mL (µIU/mL= mIU/L)	A	Immunometric	Euthyroid Reference Interval (central 95%) 0.302-3.05 mIU/L 0.302-3.05 µIU/mL	37	0.002 mIU/L 0.002 µIU/mL (Functional: 0.010 mIU/L 0.010 µIU/mL)	80	8 weeks
Vitamin B12 B12	S, P _E , P _H	2 Levels, Liquid 13 Week open stability	Anemia	0-1000 pg/mL 0-738 pmol/L (pmol/L=0.738 x pg/ mL)		Competitive	Normal Adults (central 95%) 239 - 931 pg/mL 176 - 687 pmol/L	57	< 90 pg/mL < 66.4 pmol/L	30	12 weeks 8 weeks (Pack 3)

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