

Clinical Pathology Laboratories

Roche Immunoassay Reference Ranges

Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.

Effective November 14, 2016, Clinical Pathology Laboratories (CPL) will change the current immunochemistry instrumentation and reagents to Roche COBAS® Electrochemiluminescent (eCLIA) methodology. As a result of this change, all related reference ranges are reviewed. Ranges for certain analytes are modified in the validation process, and additional interpretive notes or information are added for selected assays. Gender and age stratification is applied as appropriate. The chart below summarizes all analytes to be performed on Roche COBAS® eCLIA. Laboratory reports will be appended with a notice. As always, please review your laboratory results in the context of the provided reference interval and flagging.

Please contact your Account Executive should you have any questions regarding this change.

Unit Code	Test Name	Gender	Age	Stage/Clinical Status	Reference Range	Units
4827	CA 15-3				≤ 25	U/mL
4976	CA 19-9				<35	U/mL
2645	CEA				0.0-3.8	ng/mL
				Otherwise healthy smokers	0.0-5.5	ng/mL
2070	CKMB	Male			≤ 7.7	ng/mL
		Female			≤ 4.3	ng/mL
		Not given			≤ 4.3	ng/mL
2655	Cortisol				4.8-19.5	µg/dL
4267	Cortisol, AM			AM (6-10 am)	4.8-19.5	µg/dL
4269	Cortisol, PM			PM (4-8 pm)	2.5-11.9	µg/dL
3034	Digoxin				0.6-2.0	ng/mL
2675	Estradiol	Male	≥18 yrs.		25.8-60.7	pg/mL
		Female	≥18 yrs.	Follicular	12.4-233.0	pg/mL
		Female		Ovulation	41.0-398.0	pg/mL
		Female		Luteal	22.3-341.0	pg/mL
		Female		Post-menopausal	< 138.0	pg/mL
		Female		1 st Trimester	154-3,243	pg/mL
		Female		2 nd Trimester	1,561-21,280	pg/mL
		Female		3 rd Trimester	8,525- >30,000	pg/mL
		Male	7-9 yrs.		≤ 17.0	pg/mL
		Male	10-12 yrs.		≤ 18.0	pg/mL
		Male	13-15 yrs.		≤ 51.0	pg/mL
		Male	16-17 yrs.		≤ 48.0	pg/mL
		Male		Tanner I	≤ 17.0	pg/mL

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Unit Code	Test Name	Gender	Age	Stage/Clinical Status	Reference Range	Units
		Male		Tanner II	≤ 17.0	pg/mL
		Male		Tanner III	≤ 49.0	pg/mL
		Male		Tanner IV/V	≤ 49.0	pg/mL
		Female	7-9 yrs.		≤ 51.0	pg/mL
		Female	10-12 yrs.		≤ 116.0	pg/mL
		Female	13-15 yrs.		≤ 324.0	pg/mL
		Female	16-17 yrs.		≤ 346.0	pg/mL
		Female		Tanner I	≤ 76.0.0	pg/mL
		Female		Tanner II	≤ 175.0	pg/mL
		Female		Tanner III	20.0-360.0	pg/mL
		Female		Tanner IV/V	≤ 337.0	pg/mL
2090	Ferritin	Male	0-1 month		25-200	ng/mL
		Male	2-5 months		50-200	ng/mL
		Male	6 mos. – 15 yrs.		7-140	ng/mL
		Male	16-150 yrs.		30-400	ng/mL
		Female	0-1 month		25-200	ng/mL
		Female	2-5 mos.		50-200	ng/mL
		Female	6 mos. – 15 yrs.		7-140	ng/mL
		Female	16 – 150 yrs.		13-200	ng/mL
2695	Folic Acid	Female			≥ 6.0	µg/L
2700	FSH	Male	≥ 18 yrs.		1.5-12.4	IU/L
		Female	≥ 18 yrs.	Follicular	3.5-12.5	IU/L
		Female		Mid-Cycle	4.7-21.5	IU/L
		Female		Luteal	1.7-7.7	IU/L
		Female		Post-Menopausal	25.8-134.8	IU/L
		Male	4 wks. – 5 mos.		0.2-4.1	IU/L
		Male	6 mos. – 2 yrs.		0.3-2.2	IU/L
		Male	3-4 yrs.		0.3-2.3	IU/L
		Male	5-6 yrs.		0.3-2.0	IU/L
		Male	7-9 yrs.		0.3-2.6	IU/L
		Male	10-12 yrs.		0.5-4.9	IU/L
		Male	13-15 yrs.		1.1-7.4	IU/L
		Male	16-17 yrs.		0.9-7.8	IU/L
		Male		Tanner I	0.3-2.9	IU/L
		Male		Tanner II	0.4-4.8	IU/L
		Male		Tanner III	1.0-6.6	IU/L
		Male		Tanner IV/V	1.0-8.2	IU/L
		Female	4 wks. – 5 mos.		0.2-14.2	IU/L
		Female	6 mos. – 2 yrs.		1.4-8.0	IU/L
		Female	3-4 yrs.		0.6-5.0	IU/L
		Female	5-6 yrs.		0.5-3.2	IU/L
		Female	7-9 yrs.		0.4-4.4	IU/L

Unit Code	Test Name	Gender	Age	Stage/Clinical Status	Reference Range	Units
		Female	10-12 yrs.		0.7-8.3	IU/L
		Female	13-15 yrs.		1.0-9.1	IU/L
		Female	16-17 yrs.		0.4-9.9	IU/L
		Female		Tanner I	0.4-6.5	IU/L
		Female		Tanner II	1.0-8.4	IU/L
		Female		Tanner III	1.0-9.5	IU/L
		Female		Tanner IV/V	0.6-9.4	IU/L
2713	HCG	Male			0-5	mIU/mL
		Female		Non-pregnant	0-5	mIU/mL
		Female		Post-menopausal	≤ 7	mIU/mL
		Female		GA 3 weeks	6-71	mIU/mL
		Female		GA 4 weeks	10-750	mIU/mL
		Female		GA 5 weeks	217-7,138	mIU/mL
		Female		GA 6 weeks	158-31,795	mIU/mL
		Female		GA 7 weeks	3,697-163,563	mIU/mL
		Female		GA 8 weeks	32,065-149,571	mIU/mL
		Female		GA 9 weeks	63,803-151,410	mIU/mL
		Female		GA 10 weeks	46,509-186,977	mIU/mL
		Female		GA 12 weeks	27,832-210,612	mIU/mL
		Female		GA 14 weeks	13,950-62,530	mIU/mL
		Female		GA 15 weeks	12,039-70,971	mIU/mL
		Female		GA 16 weeks	9,040-56,451	mIU/mL
		Female		GA 17 weeks	8,175-55,868	mIU/mL
		Female		GA18 weeks	8,099-58,176	mIU/mL
2776	LH	Male	≥18 yrs.		1.2-8.6	IU/L
		Female	≥18 yrs.	Follicular	2.4-12.6	IU/L
		Female		Mid-Cycle	14.0-95.6	IU/L
		Female		Luteal	1.0-11.4	IU/L
		Female		Post-Menopausal	7.7-58.5	IU/L
		Male	7-9 yrs.		0.0-0.7	IU/L
		Male	10-12 yrs.		0.0-3.4	IU/L
		Male	13-15 yrs.		0.3-5.6	IU/L

Unit Code	Test Name	Gender	Age	Stage/Clinical Status	Reference Range	Units
		Male	16-17 yrs.		1.1-9.0	IU/L
		Male		Tanner I	0.0-1.0	IU/L
		Male		Tanner II	0.0-3.6	IU/L
		Male		Tanner III	0.2-6.4	IU/L
		Male		Tanner IV/V	1.1-8.5	IU/L
		Female	7-9 yrs.		0.0-0.7	IU/L
		Female	10-12 yrs.		0.0-6.8	IU/L
		Female	13-15 yrs.		0.0-23.0	IU/L
		Female	16-17 yrs.		0.0-26.4	IU/L
		Female		Tanner I	0.0-2.8	IU/L
		Female		Tanner II	0.0-7.9	IU/L
		Female		Tanner III	0.0-23.0	IU/L
		Female		Tanner IV/V	0.0-25.3	IU/L
2790	Progesterone	Male			< 0.15	ng/mL
		Female		Follicular	0.06-0.89	ng/mL
		Female		Ovulation	0.12-12.00	ng/mL
		Female		Luteal	1.83-23.90	ng/mL
		Female		Post-Menopausal	< 0.13	ng/mL
		Female		1 st Trimester	11.00-44.30	ng/mL
		Female		2 nd Trimester	25.40-83.30	ng/mL
		Female		3 rd Trimester	58.70-214.0	ng/mL
2800	Prolactin	Male			4.0-15.2	ng/mL
		Female		Non-pregnant	4.8-23.3	ng/mL
2690	RBC Folate				499-1504	ng/mL
4600	Rubella IgG			Reactive	≥ 10	IU/mL
2991	SHBG	Male	1-7 days		12.3-46.2	nmol/L
		Male	8-15 days		16.2-60.7	nmol/L
		Male	16 days – 3 yrs.		21.1-97.5	nmol/L
		Male	4-6 yrs.		32.9-119.1	nmol/L
		Male	7-8 yrs.		39.8-102.3	nmol/L
		Male	9-10 yrs.		29.6-141.6	nmol/L
		Male	11 yrs.		43.0-129.1	nmol/L
		Male	12 yrs.		30.0-145.3	nmol/L
		Male	13 yrs.		23.6-133.5	nmol/L
		Male	14 yrs.		16.9-86.4	nmol/L
		Male	15 yrs.		19.5-120.3	nmol/L
		Male	16 yrs.		19.6-96.5	nmol/L
		Male	17 yrs.		21.0-67.6	nmol/L
		Male	18-20 yrs.		14.5-56.2	nmol/L
		Male	21-49 yrs.		16.5-55.9	nmol/L
		Male	≥ 50 yrs.		19.3-76.4	nmol/L
		Female	1-7 days		11.1-33.3	nmol/L

Unit Code	Test Name	Gender	Age	Stage/Clinical Status	Reference Range	Units
		Female	8-15 days		13.3-46.6	nmol/L
		Female	16 days – 3 yrs.		15.6-83.2	nmol/L
		Female	4-6 yrs.		39.4-110.7	nmol/L
		Female	7-8 yrs.		38.9-125.7	nmol/L
		Female	9-10 yrs.		29.7-148.9	nmol/L
		Female	11 yrs.		33.3-132.7	nmol/L
		Female	12 yrs.		29.8-121.5	nmol/L
		Female	13 yrs.		25.5-134.3	nmol/L
		Female	14 yrs.		16.0-113.6	nmol/L
		Female	15 yrs.		25.4-130.1	nmol/L
		Female	16 yrs.		27.7-137.8	nmol/L
		Female	17 yrs.		24.4-109.4	nmol/L
		Female	18-20 yrs.		23.5-124.9	nmol/L
		Female	21-49 yrs.		24.6-122.0	nmol/L
		Female	≥ 50 yrs.		17.3-125.0	nmol/L
4017	Troponin T				<0.010	µg/L
2830	Testosterone	Male	10-11 yrs.		≤ 150	ng/dL
		Male	12-13 yrs.		≤ 561	ng/dL
		Male	14-15 yrs.		28-664	ng/dL
		Male	16-17 yrs.		143-749	ng/dL
		Male		Tanner I	≤ 14	ng/dL
		Male		Tanner II	≤ 275	ng/dL
		Male		Tanner III	≤ 771	ng/dL
		Male		Tanner IV/V	147-768	ng/dL
		Male	18-39 yrs.		300-1080	ng/dL
		Male	40-59 yrs.		300-890	ng/dL
		Male	≥60 yrs.		300-720	ng/dL
		Female	10-11 yrs.		≤ 29	ng/dL
		Female	12-13 yrs.		≤ 45	ng/dL
		Female	14-15 yrs.		≤ 47	ng/dL
		Female	16-17 yrs.		≤ 53	ng/dL
		Female		Tanner I	≤ 15	ng/dL
		Female		Tanner II	≤ 36	ng/dL
		Female		Tanner III	≤ 57	ng/dL
		Female		Tanner IV/V	≤ 56	ng/dL
		Female	18-59 yrs.		< 50	ng/dL
		Female	≥ 60 yrs.		< 29	ng/dL
N/A	Testosterone, Free	Male	10-11 yrs.		≤ 0.6	ng/dL
		Male	12-13 yrs.		≤ 10.3	ng/dL
		Male	14-15 yrs.		0.2-14.5	ng/dL
		Male	16-17 yrs.		3.9-18.2	ng/dL
		Male		Tanner I	≤ 0.3	ng/dL

Unit Code	Test Name	Gender	Age	Stage/Clinical Status	Reference Range	Units
		Male		Tanner II	≤ 2.1	ng/dL
		Male		Tanner III	≤ 10.3	ng/dL
		Male		Tanner IV	3.6-17.8	ng/dL
		Male		Tanner V	4.2-25.2	ng/dL
		Male	≥ 18 yrs.		4.8-25.7	ng/dL
		Female	10-11 yrs.		≤ 0.3	ng/dL
		Female	12-13 yrs.		≤ 0.6	ng/dL
		Female	14-15 yrs.		≤ 0.7	ng/dL
		Female	16-17 yrs.		≤ 1.0	ng/dL
		Female		Tanner I	≤ 0.1	ng/dL
		Female		Tanner II	≤ 0.4	ng/dL
		Female		Tanner III	0.1-0.7	ng/dL
		Female		Tanner IV	≤ 1.6	ng/dL
		Female		Tanner V	≤ 0.9	ng/dL
		Female	18-30 yrs.		≤ 0.7	ng/dL
		Female	31-40 yrs.		≤ 0.9	ng/dL
		Female	41-51 yrs.		≤ 0.5	ng/dL
		Female	≥ 52 yrs.		≤ 0.3	ng/dL
2606	Total PSA	Male			≤ 4.00	ng/mL
2613	Total PSA, Age-Adjusted	Male	≤ 30 yrs.		1.30	ng/mL
		Male	31-32 yrs.		< 1.40	ng/mL
		Male	33-34 yrs.		< 1.60	ng/mL
		Male	35-36 yrs.		< 1.70	ng/mL
		Male	37-38 yrs.		< 1.80	ng/mL
		Male	39-40 yrs.		< 1.90	ng/mL
		Male	41 yrs.		< 2.00	ng/mL
		Male	42-43 yrs.		< 2.20	ng/mL
		Male	44 yrs.		< 2.30	ng/mL
		Male	45-46 yrs.		< 2.40	ng/mL
		Male	47 yrs.		< 2.50	ng/mL
		Male	48 yrs.		< 2.60	ng/mL
		Male	49-50 yrs.		< 2.80	ng/mL
		Male	51 yrs.		< 2.90	ng/mL
		Male	52 yrs.		< 3.00	ng/mL
		Male	53 yrs.		< 3.10	ng/mL
		Male	54 yrs.		< 3.30	ng/mL
		Male	55 yrs.		< 3.40	ng/mL
		Male	56 yrs.		< 3.50	ng/mL
		Male	57 yrs.		< 3.60	ng/mL
		Male	58 yrs.		< 3.70	ng/mL
		Male	≥ 59 yrs.		< 4.00	ng/mL
2840	Vitamin B-12				200-950	pg/mL

Note: Several analytes are accompanied by additional interpretive information or methodology statements. Those are as given below. With migration to Roche Cobas electrochemiluminescent immunoassay (ECLIA), methodology, specific tumor marker specimens will be maintained for 30 days for comparative testing for re-base lining with the prior method. Those are:

- CA15-3
- CA19-9
- CEA
- Prolactin

PSA specimens will be maintained for 7 days for re-base lining upon request. Please review laboratory results in the context of the provided reference interval. Please contact Client Services to arrange parallel testing.

Unit Code	Test Name	Interpretive Notes
4825	CA 15-3	NOTE: NEW METHODOLOGY IS ROCHE COBAS ELECTROCHEMILUMINESCENT IMMUNOASSAY (ECLIA) ASSOCIATED WITH REFERENCE INTERVAL CHANGE. SPECIMEN IS RETAINED IN LABORATORY FOR 30 DAYS. IF INDICATED FOR COMPARATIVE TESTING, PLEASE CONTACT LABORATORY TO REASSESS WITH PRIOR METHOD.
4976	CA 19-9	NOTE: NEW METHODOLOGY IS ROCHE COBAS ELECTROCHEMILUMINESCENT IMMUNOASSAY (ECLIA). SPECIMEN IS RETAINED IN LABORATORY FOR 30 DAYS. IF INDICATED FOR COMPARATIVE TESTING, PLEASE CONTACT LABORATORY TO REASSESS WITH PRIOR METHOD.
2645	CEA	NOTE 1: In otherwise healthy smokers, 95% of patients fall in the range of 0.0-5.5 ng/mL. NOTE 2: NEW METHODOLOGY IS ROCHE COBAS ELECTROCHEMILUMINESCENT IMMUNOASSAY (ECLIA) ASSOCIATED WITH REFERENCE INTERVAL CHANGE. SPECIMEN IS RETAINED IN LABORATORY FOR 30 DAYS. IF INDICATED FOR COMPARATIVE TESTING, PLEASE CONTACT LABORATORY TO REASSESS WITH PRIOR METHOD.
3034	Digoxin	NOTE: CONCENTRATIONS ABOVE 2.0 NG/ML ARE GENERALLY CONSIDERED TOXIC. THE RECOMMENDED THERAPEUTIC RANGE FOR DIGOXIN IS 0.6-1.2 NG/ML (ESC GUIDELINES, 2008).
2695	Folic Acid	NOTE: ***** INTERPRETIVE RANGES ***** DEFICIENCY UG/L <4.0 POSSIBLE DEFICIENCY. UG/L 4.0-5.9 SUFFICIENT UG/L >=6.0
2800	Prolactin	NOTE: NEW METHODOLOGY IS ROCHE COBAS ELECTROCHEMILUMINESCENT IMMUNOASSAY (ECLIA) ASSOCIATED WITH REFERENCE INTERVAL CHANGE. SPECIMEN IS RETAINED IN LABORATORY FOR 7 DAYS. IF INDICATED FOR COMPARATIVE TESTING, PLEASE CONTACT LABORATORY TO REASSESS WITH PRIOR METHOD.

2690	RBC Folate	<p>NOTE:</p> <p>***** INTERPRETIVE RANGES *****</p> <p>DEFICIENCY NG/ML <=150</p> <p>POSSIBLE DEFICIENCY NG/ML 151-498</p> <p>SUFFICIENT NG/ML 499-1504</p> <p>EXCESS NG/ML >1504</p>
4017	Troponin T	<p>NOTE:</p> <p>NEGATIVE: <0.010 UG/L</p> <p>CARDIAC TROPONIN T (cTnT) IN THIS RANGE IS BELOW THE 99TH PERCENTILE OF APPARENTLY HEALTHY ADULT PATIENTS.</p> <p>LOW POSITIVE: 0.010-0.099 UG/L</p> <p>cTnT VALUES IN THIS RANGE ARE ABOVE THE 99TH PERCENTILE BUT BELOW THE WORLD HEALTH ORGANIZATION (WHO) AND RECEIVER OPERATOR CURVE (ROC) CUTOFFS. VALUES IN THIS RANGE MAY REPRESENT MYOCARDIAL NECROSIS BUT OTHER CAUSES SUCH AS ANGINA, CONGESTIVE HEART FAILURE, RENAL FAILURE AND PULMONARY EMBOLISM CANNOT BE EXCLUDED.</p> <p>HIGH POSITIVE: >=0.100 UG/L</p> <p>cTnT VALUES IN THIS RANGE ARE ABOVE WHO CUTOFF.</p>
2606	Total PSA	<p>NOTE:</p> <p>NEW METHODOLOGY IS ROCHE COBAS ELECTROCHEMILUMINESCENT IMMUNOASSAY (ECLIA). SPECIMEN IS RETAINED IN LABORATORY FOR 7 DAYS. IF INDICATED FOR COMPARATIVE TESTING, PLEASE CONTACT LABORATORY TO REASSESS WITH PRIOR METHOD.</p>

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