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IMMULITE 2000 XPi Assays Overview

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IMMULITE 2000® XPi Assays Overview

Disease State	Assay	Specimen Types	Sample Volume	Assay Range	Time to First Result	On Board Stability	Tests per Kit	SMN	Part Number	Calibration Interval	Calibrator Name	Accessories	IFU Reference
Allergy	AlaTOP Allergy Screen*	S	50 µL	Qualitative reactive/non reactive results only	65 min	90 days	200	10380878	L2KAT2	28 days	AlaTOP	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KAT-18, 2008-08-13
Allergy	3gAllergy Specific IgE Universal Kit	S	50 µL	0.10–100 kU/L	65 min	90 days	600	10380875	L2KUN6	14 days	3gAllergy Specific IgE	3gAllergy Specific IgE Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KUN-25, 2014-01-21
Allergy	Allergen Specific IgG*	S, P (EDTA, Heparinized)	5 µL	2–200 mg/L	65 mins	90 days	200	10380877	L2KGG2	14 days	Allergen Specific IgG	IgG/IgM Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KGG-16, 2009-10-06
							600	10380880	L2KGG6				
Allergy	Allergen Specific IgG ₄ *	S, P (EDTA, Heparinized)	5 µL	200–50,000 µg/L	65 mins	90 days	600	10380879	L2KG46	14 days	Allergen Specific IgG ₄	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KG4-9, 2009-03-23
Allergy	ECP*	S	5 µL	0.2–200 ng/mL	35 mins	90 days	200	10380874	L2KEO2	14 days	ECP	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KEO-17, 2012-03-01
Allergy	Total IgE	S	5 µL	1.0–2000 IU/mL	35 min	90 days	200	10380873	L2KIE2	14 days	Total IgE	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KIE-22, 2012-12-17
							600	10380872	L2KIE6				
Anemia	EPO*	S, P (Heparinized)	100 µL	1.0–750 mIU/mL	35 min	90 days	200	10487628	L2KEPN2	14 days	EPO	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KEPN-3, 2012-02-02
							600	10487629	L2KEPN6				

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Anemia	Ferritin	S	10 µL	0.4–1,500 ng/mL	35 min	90 days	200	10380908	L2KFE2	28 days	Ferritin	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PILKFE-14, 2008-07-29
							600	10380906	L2KFE6				
Anemia	Folic Acid	S, P (Heparinized), WB (absorbic acid-treated)	50 µL	1–24 ng/mL (2.3–54 nmol/L)	125 min	90 days	200	10380911	L2KFO2	28 days	Folic Acid	Vitamin B12/Folic Acid Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KFO-24, 2014-01-20
							600	10380912	L2KFO6				
Anemia	Vitamin B12	S, P (Heparinized)	75 µL	150–1000 pg/mL (111–738 pmol/L)	95 min	90 days	200	10380914	L2KVB2	14 days	Vitamin B12	Vitamin B12/Folic Acid Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KVB-28, 2013-07-15
							600	10380913	L2KVB6				
Autoimmune	Anti-CCP	S, P (EDTA, Lithium Heparin)	5 µL	1.50–200 U/mL	65 min	90 days	200	10368607	L2KPI2	14 days	Anti-CCP IgG	Autoantibody Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPI-7, 2013-03-14
Bone	Osteocalcin*	S, P (Heparinized)	10 µL	2–100 ng/mL	35 min	90 days	200	10381477	L2KON2	28 days	Osteocalcin	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KON-17, 2014-08-06
Bone	Pyrilinks-D	U	75 µL	7–300 nM	35 min	90 days	200	10381461	L2KPD2	28 days	Pyrilinks-D	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPD-15, 2010-09-09
Cardiac	CK-MB*	S, P (Heparinized)	50 µL	0.6–500 ng/mL	35 min	90 days	200	10381033	L2KMB2	14 days	CK-MB	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KMB-17, 2013-02-08

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Cardiac	D-Dimer*	P (Citrate, Heparinized)	10 µL	100–15,000 ng FEU/mL	35 min	90 days	200	10381041	L2KDD2	28 days	D-Dimer	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KDD-14, 2010-01-27
Cardiac	High Sensitivity CRP	S, P (EDTA, Heparinized)	5 µL	0.2–100 mg/L	35 min	90 days	200	10381043	L2KCRP2	14 days	CRP	CRP Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KCRP-6, 2009-10-06
Cardiac	Myoglobin	S, P (Heparinized)	10 µL	0.5–1000 ng/mL	35 min	90 days	200	10381031	L2KMY2	14 days	Myoglobin	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KMY-15, 2014-09-09
Cardiac	NT-proBNP*	P (Heparinized)	50 µL	20–35,000 pg/mL (2.4–4,130 pmol/L)	35 min	90 days	200	10381036	L2KNT2	14 days	NT-proBNP	NT-proBNP Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KNT-14, 2008-08-13
Cardiac	Troponin I	S, P (EDTA, Heparinized)	100 µL	0.2–180 ng/mL	35 min	90 days	200	10381034	L2KTI2	14 days	Troponin I	Multi-Diluent 1, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTI-22, 2012-10-10
Diabetes	Albumin	U	25 µL	2.5–60 µg/mL	35 min	90 days	200	10381453	L2KHA2	14 days	Albumin	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KHA-12, 2008-07-29
Diabetes	C-Peptide	S, P (Heparinized), U	25 µL	0.1–20 ng/mL (0.03–6.6 nmol/L; 33–6,620 pmol/L)	35 min	90 days	200	10381450	L2KPEP2	14 days	C-Peptide	C-Peptide Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPEP-7, 2008-07-29

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Diabetes	Insulin	S, P (Heparanized)	100 µL	2–300 µIU/mL	65 min	90 days	200	10381455	L2KIN2	28 days	Insulin	Insulin Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KIN-29, 2009-10-06
							600	10381456	L2KIN6				
Growth	hGH	S	25 µL	0.05–40 ng/mL (0.15–120 mIU/L)	35 min	90 days	200	10381451	L2KGRH2	14 days	GH	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KGRH-9, 2013-10-08
Growth	IGF-I	S, P (Heparanized)	20 µL	20–1,600 ng/mL	65 min	90 days	200	10381448	L2KGF2	14 days	IGF-I	IGF-1 Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KGF-19, 2013-09-03
Growth	IGFBP-3	S, P (Heparanized)	5 µL	0.1–16 µg/mL	35 min	90 days	200	10381447	L2KGB2	14 days	IGFBP-3	IGFBP-3 Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KGB-14, 2012-06-18
Hepatitis	Anti-HBc IgM	S, P (Citrate, EDTA, Heparanized)	10 µL	Reactive: ≥10 U/mL Nonreactive: <10 U/mL	65 min	90 days	200	10381321	L2KMC2	28 days	Anti-HBc IgM	Anti-HBc IgM Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KMC-32CE, 2008-08-13
Hepatitis	Anti-HBc	S, P (Citrate, EDTA, Heparanized)	50 µL	Reactive: ratio of ≥1.15 Nonreactive: ratio of <0.85 Indeterminate: ratio between 0.85 and <1.15	65 min	90 days	200	10381311	L2KHC2	28 days	Anti-HBc	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KHC-31CE, 2008-08-13
Hepatitis	Anti-HBs	S, P (EDTA, Heparanized)	50 µL	Reactive: ≥10 mIU/mL Nonreactive: <10 mIU/mL	65 min	90 days	200	10381318	L2KAH2	28 days	Anti-HBs	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KAH-30CE, 2008-08-13

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Hepatitis	HBsAg	S, P (Citrate, EDTA, Heparanized)	100 µL	Reactive: ratio of ≥1.0 Nonreactive: ratio of <1.0	65 min	90 days	200	10381306	L2KHB2	28 days	HBsAg	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KHB-35CE, 2010-06-22
Hepatitis	HBsAg Conf	S, P (Citrate, EDTA, Heparanized)	410 µL	Reactive: if signal "blocked" is ≥50% less than signal "unblocked"	65 min	90 days	100	10381312	L2KCH1	28 days	HBsAg	HBsAg Confirmatory Assay Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KCH-2CE, 2012-03-27
Inflammation	IL-2R*	S	15 µL	50–7,500 U/mL	35 min	90 days	200	10381457	L2KIP2	28 days	IL2R	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KIP-9, 2008-07-29
Inflammation	IL-6*	S, P (EDTA, Heparinized)	100 µL	2–1,000 pg/mL	65 min	90 days	200	10381452	L2K6P2	14 days	IL-6	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2K6P-12, 2008-07-29
Inflammation	LBP*	S, P	5 µL	1.2–170 µg/mL	35 min	90 days	200	10381474	L2KLB2	14 days	LBP	LBP Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KLB-17, 2010-09-30
Metabolic	ACTH	P (EDTA)	75 µL	5–1,250 pg/mL	65 min	90 days	200	10381468	L2KAC2	28 days	ACTH	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KAC-15, 2008-07-29
Metabolic	Cortisol	S	10 µL	1–50 µg/dL (28–1380 nmol/L)	35 min	90 days	200	10381476	L2KCO2	28 days	Cortisol	Multi-Diluent 1, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KCO-23, 2013-06-07
							600	10381480	L2KCO6				

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Metabolic	Homocysteine	S, P	15 µL	2–50 µmol/L	65 min	90 days	200	10381040	L2KHO2	28 days	Homocysteine	Homocysteine Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KHO-21, 2013-02-28
Oncology	AFP	S, AF	10 µL	0.2–300 IU/mL	65 min	90 days	200	10381187	L2KAP2	28 days	AFP	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KAP-21, 2014-02-26
							600	10381184	L2KAP6				
Oncology	BR-MA	S	5 µL	1–300 U/mL	65 min	90 days	200	10380983	L2KBR2	14 days	BR-MA	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KBR-18, 2014-08-22
Oncology	Calcitonin	S, P (Heparinized)	75 µL	2–2000 pg/mL (0.6–585 pmol/L)	65 min	90 days	200	10381446	L2KCL2	28 days	Calcitonin	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PILKCL-17, 2013-04-26
Oncology	CEA	S	15 µL	0.15–550 ng/mL	65 min	90 days	200	10380994	L2KCE2	14 days	CEA	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KCE-12, 2014-03-07
							600	10380995	L2KCE6				
Oncology	Free PSA	S	25 µL	0.07–25.0 ng/mL	65 min	90 days	200	10380984	L2KPF2	14 days	Free PSA	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPF-24, 2014-01-13
Oncology	GI-MA*	S	50 µL	1.0–1000 U/mL	65 min	90 days	200	10380988	L2KGI2	14 days	GI-MA	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KGI-20, 2014-03-12

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Oncology	OM-MA	S	50 µL	1–500 U/mL	65 min	90 days	200	10380972	L2KOP2	28 days	OM-MA	OM-MA Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KOP-14, 2014-03-19
Oncology	PAP	S	50 µL	0.02–100 ng/mL	35 min	90 days	200	10380975	L2KPA2	14 days	PAP	Multi-Diluent 1, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPA-14, 2008-07-29
Oncology	PSA	S	10 µL	0.04–150 ng/mL	35 min	90 days	200	10380986	L2KPS2	28 days	PSA	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPS-19, 2014-12-02
							600	10380996	L2KPS6				
Reproductive Endocrinology	Androstenedione	S	25 µL	0.3–10 ng/mL (1.04 to 35 nmol/L)	65 min	90 days	200	10381188	L2KAO2	14 days	Androstenedione	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KAO-19, 2012-10-25
Reproductive Endocrinology	DHEA-SO ₄	S	5 µL	15–1000 µg/dL (0.41–27 µmol/L)	35 min	90 days	200	10381193	L2KDS2	28 days	DHEA-SO ₄	Multi-Diluent 1, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KDS-19, 2013-06-11
Reproductive Endocrinology	Estradiol	S	25 µL	20–2000 pg/mL (73–7342 pmol/L)	65 min	90 days	200	10381178	L2KE22	14 days	Estradiol	Estradiol Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KE2-25, 2013-07-15
Reproductive Endocrinology	Free Beta hCG*	S	5 µL	2–200 ng/mL	65 min	90 days	200	10381175	L2KBF2	14 days	Free Beta HCG	HCG Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KFB-20, 2009-09-24

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Reproductive Endocrinology	FSH	S	50 µL	0.1–170 mIU/mL	35 min	90 days	200	10381201	L2KFS2	28 days	FSH	FSH Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KFS-15, 2013-07-25
							600	10381180	L2KFS6				
Reproductive Endocrinology	HCG	S, U	5 µL	0.4–5000 mIU/mL	35 min	90 days	200	10381206	L2KCG2	28 days	HCG	HCG Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KCG-32, 2014-06-18
							600	10381194	L2KCG6				
Reproductive Endocrinology	LH	S	75 µL	0.05–200 mIU/mL	35 min	90 days	200	10381211	L2KLH2	28 days	LH	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KLH-20, 2013-07-16
							600	10381212	L2KLH6				
Reproductive Endocrinology	PAPP-A*	S, P (Heparinized)	10 µL	0.025–10 mIU/mL	35 min	90 days	200	10381213	L2KPC2	28 days	PAPP-A	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPC-27, 2009-09-24
Reproductive Endocrinology	Progesterone	S	25 µL	0.2–40 ng/mL (0.6–127 nmol/L)	35 min	90 days	200	10381181	L2KPW2	14 days	Progesterone	Multi-Diluent 1, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPW-21, 2013-12-17
							600	10381170	L2KPW6				
Reproductive Endocrinology	Prolactin	S	25 µL	0.5–150 ng/mL (10.6–3180 mIU/L)	35 min	90 days	200	10381200	L2KPR2	28 days	Prolactin	Prolactin Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPR-20, 2013-08-13
							600	10381199	L2KPR6				
Reproductive Endocrinology	SHBG	S	10 µL	0.02–180 nmol/L	35 min	90 days	200	10381198	L2KSH2	14 days	SHBG	SHBG Sample Diluent, SHBG Sample Diluent Module, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KSH-18, 2010-05-27

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Reproductive Endocrinology	Total Testosterone	S, P (Heparinized)	20 µL	20–1600 ng/dL (0.7–55 nmol/L)	65 min	90 days	200	10381190	L2KTW2	7 days	Total Testosterone	Multi-Diluent 1, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTW-15, 2013-04-16
							600	10381191	L2KTW6				
Reproductive Endocrinology	Unconjugated Estradiol	S	40 µL	0.07–12 ng/mL (0.24–42 nmol/L)	35 min	90 days	200	10381192	L2KUE32	14 days	Unconjugated Estriol	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KUE3-4, 2010-07-29
							600	10381171	L2KUE36				
Special ID	EBV-EBNA IgG*	S, P (EDTA, Heparinized)	10 µL	Reactive: ratio of ≥ 1.1 Nonreactive: ratio of < 0.9 Indeterminate: ratio between 0.9 and < 1.1	65 min	90 days	200	10381307	L2KEB2	14 days	EBV-EBNA IgG	IgG/IgM Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KEB-5, 2009-10-06
Special ID	EBV-VCA IgG*	S, P (EDTA, Heparinized)	10 µL	Reactive: ratio of ≥ 1.1 Nonreactive: ratio of < 0.9 Indeterminate: ratio between 0.9 and < 1.1	65 min	90 days	200	10381330	L2KVG2	14 days	EBV-VCA IgG	IgG/IgM Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KVG-7, 2009-10-06
Special ID	EBV-VCA IgM*	S, P (EDTA, Heparinized)	10 µL	Reactive: ratio of ≥ 1.1 Nonreactive: ratio of < 0.9 Indeterminate: ratio between 0.9 and < 1.1	65 min	90 days	200	10488005	L2KEM2	14 days	EBV-VCA IgM	IgG/IgM Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KEM-5, 2009-10-06
Special ID	H. pylori	S	10 µL	0.4–8.0 U/mL	65 min	90 days	200	10381336	L2KHPG2	7 days	H. pylori IgG	H. pylori IgG Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KHPG-22, 2009-10-06
							600	10381335	L2KHPG6				

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Special ID	Syphilis	S, P (Heparinized)	100 µL	Reactive: ratio of ≥1.1 Nonreactive: ratio of <0.9 Indeterminate: ratio between ≥0.9 and <1.1	35 min	90 days	200	10489085	L2KSY2	14 days	Syphilis Screen	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KSY-13, 2010-11-01
							600	10488319	L2KSY6				
Special Proteins	Beta-2 Microglobulin	S, U	5 µL	4.0–500 ng/mL	35 min	90 days	200	10380992	L2KBM2	28 days	Beta-2 Microglobulin	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KBM-19, 2012-11-05
TDMs	Carbamazepine	S, P (Heparinized)	20 µL	1.25–20 µg/mL (5.29–85 µmol/L)	35 min	90 days	200	10381550	L2KCB2	14 days	Carbamazepine	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KCB-11, 2008-07-29
TDMs	Digitoxin	S	10 µL	5–60 µg/mL (6.5–78 nmol/L)	35 min	90 days	200	10381538	L2KDG2	14 days	Digitoxin	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KDG-6, 2008-07-29
TDMs	Digoxin	S, P (Heparinized)	50 µL	0.5–8 ng/mL (0.6–10 nmol/L)	35 min	90 days	200	10381529	L2KDI2	14 days	Digoxin	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KDI-12, 2008-07-29
TDMs	Phenobarbital	S, P (Heparinized)	20 µL	5–80 µg/mL (22–347 µmol/L)	35 min	90 days	200	10381542	L2KPB2	14 days	Phenobarbital	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPB-12, 2008-08-13
TDMs	Phenytoin	S, P (Heparinized)	10 µL	2.5–40 µg/mL (9.9–158 µmol/L)	35 min	90 days	200	10381548	L2KPN2	14 days	Phenytoin	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPN-15, 2008-08-13
TDMs	Theophylline	S	50 µL	1–60 µg/mL	35 min	90 days	200	10381539	L2KTN2	14 days	Theophylline	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTN-9, 2008-07-29

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TDMs	Valproic Acid	S, P (Heparinized)	10 µL	10–200 µg/mL (69–1,386 µmol/L)	35 min	90 days	200	10381544	L2KVA2	14 days	Valproic Acid	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KVA-11, 2008-08-13
Thyroid	Anti-TG	S, P (EDTA, Heparinized)	5 µL	20–3,000 IU/mL	65 min	90 days	200	10381659	L2KTG2	14 days	Anti-TG Ab	Thyroid Autoantibody Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTG-19, 2010-07-15
							600	10381655	L2KTG6				
Thyroid	Anti-TPO	S, P (EDTA)	5 µL	5.0–1,000 IU/mL	65 min	90 days	200	10381650	L2KTO2	14 days	Anti-TPO Ab	Thyroid Autoantibody Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTO-21, 2009-06-24
							600	10381649	L2KTO6				
Thyroid	FT3	S	100 µL	1.0–40 pg/mL (1.5–61 pmol/L)	65 min	90 days	200	10381675	L2KF32	14 days	Free T3	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KF3-21, 2013-08-15
							600	10381682	L2KF36				
Thyroid	FT4	S, P (Heparinized)	10 µL	0.3–6 ng/dL (3.9–77.2 pmol/L)	35 min	90 days	200	10381678	L2KFT42	14 days	Free T4	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KFT4-8, 2013-10-01
							600	10381677	L2KFT46				
Thyroid	iPTH	S, P (EDTA)	50 µL	3–2,500 pg/mL	65 min	90 days	200	10381441	L2KPP2	28 days	Intact PTH	Intact PTH Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KPP-19, 2008-08-13
							600	10381442	L2KPP6				
Thyroid	Rapid TSH	S	75 µL	0.01–75 µIU/mL	35 min	90 days	200	10381651	L2KRT2	28 days	Rapid TSH	TSH Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KRT-15, 2014-06-24

Disease State	Assay	Specimen Types	Sample Volume	Assay Range	Time to First Result	On Board Stability	Tests per Kit	SMN	Part Number	Calibration Interval	Calibrator Name	Accessories	IFU Reference
Thyroid	Third Generation TSH	S	75 µL	0.004–75 µIU/mL	65 min	90 days	200	10381665	L2KTS2	28 days	TSH	TSH Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTS-18, 2014-06-24
							600	10381667	L2KTS6				
Thyroid	Thyroid Uptake	S	20 µL	10–70%TU	35 min	90 days	200	10381669	L2KTU2	28 days	Thyroid Uptake	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTU-15, 2013-08-22
Thyroid	TBG	S	20 µL	3.5–80 µg/mL (65–1,480 nmol/L)	35 min	90 days	200	10381660	L2KTB2	7 days	TBG	TBG Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTB-18, 2010-07-07
Thyroid	Thyroglobulin	S, P (Heparinized)	50 µL	0.2–300 ng/mL	65 min	90 days	200	10381648	L2KTY2	14 days	Thyroglobulin	Thyroglobulin Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTY-17, 2008-07-29
Thyroid	Total T3	S	25 µL	40–600 ng/dL (0.61–9.2 nmol/L)	35 min	90 days	200	10381654	L2KT32	14 days	Total T3	Multi-Diluent 1, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KT3-19, 2013-09-19
							600	10381657	L2KT36				
Thyroid	Total T4	S	15 µL	1.0–24 µg/dL (13–309 nmol/L)	35 min	90 days	200	10381685	L2KT42	14 days	Total T4	Multi-Diluent 1, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KT4-23, 2013-04-22
							600	10381664	L2KT46				
TORCH	CMV IgG	S	10 µL	Reactive: ratio of ≥1.1 Nonreactive: ratio of <0.9 Indeterminate: ratio between 0.9 and <1.1	65 min	90 days	200	10381309	L2KCVG2	28 days	CMV IgG	IgG/IgM Sample Diluent, IgG/IgM Sample Diluent Module, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KCVG-15, 2009-10-06

Disease State	Assay	Specimen Types	Sample Volume	Assay Range	Time to First Result	On Board Stability	Tests per Kit	SMN	Part Number	Calibration Interval	Calibrator Name	Accessories	IFU Reference
TORCH	CMV IgM	S, P (EDTA, Heparinized)	10 µL	Reactive: ratio of ≥ 1.1 Nonreactive: ratio of < 0.9 Indeterminate: ratio between 0.9 and < 1.1	95 min	90 days	200	10381320	L2KCM2	14 days	CMV IgM	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KCM-14, 2014-09-30
TORCH	Herpes I & II IgG	S	10 µL	Reactive: ratio of ≥ 1.1 Nonreactive: ratio of < 0.9 Indeterminate: ratio between 0.9 and < 1.1	65 min	90 days	600	10381333	L2KHVG6	28 days	Herpes I & II IgG	IgG/IgM Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KHVG-17, 2009-10-06
TORCH	Rubella IgG	S	10 µL	Reactive: ≥ 10 IU/mL Nonreactive: < 5 IU/mL Indeterminate: ≥ 5 – 10 IU/mL	65 min	90 days	200	10381338	L2KRUB2	14 days	Rubella Quantitative IgG	IgG/IgM Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KRUB-18, 2011-12-06
							600	10381305	L2KRUB6				
TORCH	Rubella IgM	S, P (EDTA, Heparinized)	10 µL	Reactive: ratio of ≥ 1.1 Nonreactive: ratio of < 0.9 Indeterminate: ratio between 0.9 and < 1.1	65 min	90 days	200	10381327	L2KRM2	14 days	Rubella IgM	IgG/IgM Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KRM-30, 2009-10-06
TORCH	Toxoplasma IgM* (µ Capture)	S, P (EDTA, Heparinized)	10 µL	Reactive: ratio of ≥ 1.1 Nonreactive: ratio of < 0.9 Indeterminate: ratio between 0.9 and < 1.1	65 min	90 days	200	10381298	L2KTZ2	14 days	Toxoplasma IgM (µ-Capture)	IgG/IgM Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTZ-15, 2009-10-06
TORCH	Toxoplasma IgG	S	10 µL	Reactive: ≥ 8 IU/mL Nonreactive: < 6.5 IU/mL Indeterminate: ≥ 6.5 – < 8 IU/mL	65 min	90 days	200	10381323	L2KTXP2	28 days	Toxoplasma Quantitative IgG	IgG/IgM Sample Diluent, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KTXP-22, 2009-10-06

Disease State	Assay	Specimen Types	Sample Volume	Assay Range	Time to First Result	On Board Stability	Tests per Kit	SMN	Part Number	Calibration Interval	Calibrator Name	Accessories	IFU Reference
Veterinary	Veterinary Free T4	S	10 µL	0.3–6 ng/dL (3.9–77.2 pmol/L)	35 min	90 days	200	10484863	L2KVF42	14 days	Veterinary Free T4	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KVF4-3, 2010-08-24
Veterinary	Canine TLI	S	20 µL	0.3–50 ng/mL	35 min	90 days	200	10380534	L2KLI2	14 days	Canine TLI	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KLI-8, 2008-09-25
Veterinary	Canine Total T4	S	20 µL	0.5–15 µg/dL (6.4–193 nmol/L)	35 min	90 days	200	10380531	L2KCT2	14 days	Canine Total T4	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KCT-13, 2008-09-25
							600	10380528	L2KCT6				
Veterinary	Canine TSH	S	25 µL	0.03–12 ng/mL	65 min	90 days	600	10380533	L2KKT6	14 days	Canine TSH	Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KKT-13, 2010-04-12
Other	Gastrin	S	50 µL	5–1,000 pg/mL	65 min	90 days	200	10380979	L2KGA2	14 days	Gastrin	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KGA-15, 2008-11-14
Other	Nicotine Metabolite*	S, U	20 µL	10–500 ng/mL	35 min	90 days	200	10381536	L2KNM2	14 days	Nicotine Metabolite	Multi-Diluent 2, Chemiluminescent Substrate, Probe Wash Module, Probe Cleaning Kit	PIL2KNM-17, 2014-08-18

* Not available for sale in the United States

AF: Amniotic Fluid
P: Plasma
S: Serum
U: Urine

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