



Human Product List

Item	Product	CE	Type	Tests/Kit	Specimen	Page
COVID-19	COVID-19 Ag	○	Device	20T	NP Swab	6
	SARS-CoV-2 抗原快速檢測(專業版鼻咽用)	○	Device	20T	Nasal Swab	7
	COVID-19 Ag Test Nasal	○	Device	20T	Nasal Swab	7
	SARS-CoV-2 抗原快速檢測(專業版鼻腔用)	○	Device	1T/2T/5T /10T/20T	Nasal Swab	8, 9
	COVID-19 Ag Home Test Nasal	○	Device	1T/2T/5T /10T/20T	Nasal Swab	8, 9
	SARS-CoV-2 抗原快速檢測(家用版鼻腔用)	○	Device	25T	S/P/WB	10
	COVID-19 IgG/IgM Combo	○	Device	25T	S/P/WB	10
Respiratory Diseases	SARS-CoV-2 IgG 及 IgM 抗體快速檢測	○	Device	20T	NP Swab	11
	CoviFlu Aq Duo	○	Device	20T	NP Swab	11
	SARS-CoV-2 及流感 A 和 B 抗原組合快速檢測(鼻咽用)	○	Device	20T	NP Swab	12
	Influenza A&B Quick Flu 3	○	Device	20T	NP Swab	12
Hepatitis Diseases	A 型和 B 型流感抗原檢測(鼻咽用)	○	Device	10T	NP Swab	12
	Quick Band Flu	○	Device	10T	NP Swab	12
	RSV Ag	○	Strip	25T	NP Swab	13
Hepatitis Diseases	呼吸道融合病毒抗原檢測(鼻咽用)	○	Device	25T	NP Swab	13
	HAV IgG	○	Device	10T/25T	S/P/WB	14
	A 型肝炎病毒抗體檢測	○	Device	25T/100T	Serum	15
	HBs Ag	○	Device	25T/100T	Serum	15
	B 型肝炎表面抗原檢測	○	Device	25T/100T	Serum	16
	Anti-HBs	○	Device	25T/100T	Serum	16
Enteric Diseases	B 型肝炎抗體檢測	○	Device	25T/100T	S/P/WB	17
	HCV Ab	○	Device	25T/100T	S/P/WB	17
	C 型肝炎病毒抗體檢測	○	Device	25T/100T	Serum	18
	H.pylori Ab	○	Device	25T/100T	Serum	18
	幽門螺旋桿菌抗體檢測	○	Device	20T	Stool	19
Malaria	H.pylori Ag	○	Device	20T	Stool	19
	幽門螺旋桿菌抗原檢測	○	Device	20T	Stool	20
	Rota Ag	○	Device	20T	Stool	20
	輪狀病毒抗原測試	○	Device	25T	WB	21
	Malaria Aq Pf (HRPII)	○	Device	25T	WB	22
	瘧疾抗原 Pf (HRPII) 檢測	○	Device	25T	WB	22
	Malaria Aq Pan (pLDH)	○	Device	25T	WB	23
	瘧疾抗原 Pan (pLDH) 檢測	○	Device	25T	WB	23
	Malaria Aq Pf/Pan (HRPII/pLDH)	○	Device	25T	WB	24
	瘧疾抗原 Pf/Pan (HRPII/pLDH) 檢測	○	Device	25T	WB	24
	Malaria Aq Pf/Pv (HRPII/pLDH)	○	Device	25T	WB	25
	瘧疾抗原 Pf/Pv (HRPII/pLDH) 檢測	○	Device	25T	WB	25
Malaria Ag Pf/Pv (pLDH/pLDH)**	○	Device	25T	WB	26	
瘧疾抗原 Pf/Pv (pLDH/pLDH) 檢測	○	Device	25T	WB	26	
Malaria Aq Pf (pLDH/HRPII)**	○	Device	25T	WB	27	
瘧疾抗原 Pf (pLDH/HRPII) 檢測	○	Device	25T	WB	27	
Malaria Aq Pf (pLDH)**	○	Device	25T	WB	27	
瘧疾抗原 Pf (pLDH) 檢測	○	Device	25T	S/P/WB	28	
Malaria Pf/Pv Ab	○	Device	25T	S/P/WB	28	
瘧疾 Pf / Pv 抗體檢測	○	Device	25T	S/P/WB	28	

Item	Product	CE	Type	Tests/Kit	Specimen	Page
Vector borne Diseases	Denque NS1 Aq 登革熱 NS1 抗原檢測	○	Device	10T/25T	S/P/WB	29
	Denque IgG/IgM 登革熱 IgG/IgM 檢測	○	Device	10T/25T	S/P/WB	30
	Denque NS1 Aq+Ab Duo 登革熱 NS1 抗原及抗體組合同步檢測	○	Device	10T/25T	S/P/WB	31
	Chikungunya IgM 基孔肯雅熱(屈公病) IgM 檢測	○	Device	10T/25T	S/P/WB	32
	Syphilis Ab 梅毒抗體檢測	○	Device	25T/100T	S/P	33
STD (Sexually Transmitted Diseases)	HIV 1/2 Ab 愛滋病 1 / 2 型抗體檢測		Device	25T	S/P/WB	34
	hCG 人類絨毛膜促性腺激素檢測		Device	25T	Urine	35
Fertility Hormones			Midstream	1T		
	LH 黃體生成激素檢測		Device	25T	Urine	36
			Strip	20T		
Tumor Marker	AFP alpha-胎兒蛋白抗原檢測		Device	25T/100T	S/P	37
	CEA 癌胚抗原檢測		Device	25T/100T	S/P	38
	PSA 前列腺特异性抗原檢測		Device	25T/100T	S/P	39
	FOB 糞便潛血檢測		Device	50T	Stool	40
	Etc.	Nicotine 尼古丁(可替寧)檢測		Device	1T/25T	Urine/Saliva

**Applied WHO PQ for 3 ERPD approved Malaria RDTs

S: Serum, P: Plasma, WB: Whole Blood, NP swab: Nasopharygeal swab