

CIGA Test Parameters 2023

Category	Test Item	Specimen Type	Specimen Volume	Loading Volume	Reaction Time	Measuring Range	Clinical Reference	Clinical Application	Qualification
Vitamin	Vitamin D	Serum/Plasma	75 µL	75 µL	15 mins	5-100 ng/mL	30-100 ng/mL	1. Indicator of vitamin D body stores. 2. Monitoring therapy to prevent or treat osteoporosis. 3. Screening tool for Children and adults with suspected rickets and osteomalacia, respectively.	CE NMPA
Diabetic & Renal Injury Markers	HbA1c	WB/Capillary Blood	10 µL	75 µL	5 mins	4.0-14.5%	4-6.5%	1. Diabetes monitoring "golden standard" regulated by IDF. 2. Guide the control of blood glucose. 3. Associate to differentiate diagnosis of diabetes, Stress hyperglycemia and gestational diabetes.	CE NMPA
	One Step MAU	Urine	75 µL		3 mins	5-300 mg/L	0-20 mg/L	1. Sensitive indicators for early or minor kidney injury. 2. Early diagnosis and management of diabetic nephropathy. 3. Indicators of cardiovascular injury in hypertension patients. 4. Evaluate the safety of clinical medication [renal toxicity].	CE NMPA
	Cys C	WB/Serum/Plasma	10 µL		5 mins	0.2-10 mg/L	0.5-1.1 mg/L	1. Monitoring renal insufficiency. 2. Endogenous marker meets the requirements of ideal endogenous GFR markers. 3. Evaluation indicator of renal insufficiency with good sensitivity and high specificity. 4. Reflects the level of glomerular filtration function.	CE NMPA
	NGAL	Urine	75 µL		15 mins	10-1500 ng/mL	≤131.7 ng/mL	1. An early marker for diagnosis of kidney disease. 2. Values of this product are linked to the Abbott ARCHITECT Urine NGAL kit based on the respective instrument calibration traceability. 3. When kidney damage occurs in 2 hours, NGAL will rise rapidly in a very short time and is released into the urine and plasma.	CE NMPA
	β2-MG	WB/Serum/Plasma	10 µL		10 mins	0.3-20 mg/L	1.0-2.7 mg/L	1. An auxiliary marker for diagnosis of renal disease. 2. Increased in inflammatory diseases, some viral infections, renal dysfunction and autoimmune diseases.	CE NMPA
Thyroid Function	T3	WB/Serum/Plasma	75 µL	75 µL	15 mins	0.61-9.22 nmol/L	1.23-3.07 nmol/L	1. Screening for thyroid disease. 2. Treatment monitoring of hypothyroidism or hyperthyroidism.	CE NMPA
	T4	WB/Serum/Plasma	75 µL		15 mins	12.87-300 nmol/L	66-181 nmol/L	1. Diagnosing of hyperthyroidism, primary and secondary hypothyroidism. 2. monitoring of TSH suppression therapy.	CE NMPA
	TSH	WB/Serum/Plasma	75 µL		15 mins	0.1-100 mIU/L	0.3-4.2 mIU/L	1. Screening for thyroid disease. 2. Diagnosis of subclinical thyroid disease. 3. Treatment monitoring of hypothyroidism or hyperthyroidism.	CE NMPA
	FT3	WB/Serum/Plasma	75 µL		15 mins	0.40-50.00 pmol/L or 0.26-32.55 pg/mL	2.8-7.1 pmol/L (1.82-4.61 pg/mL)	The determination of free T3 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins.	CE
	FT4	WB/Serum/Plasma	75 µL		15 mins	1.00-100 pmol/L or 0.078-7.77 ng/dL	12-22 pmol/L (0.94-1.72 ng/dL)	1. The determination of FT4 is also suitable for monitoring thyrosuppressive therapy. 2. The determination of FT4 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins; additional determination of a binding parameter (T-uptake, TBG) is therefore unnecessary.	CE
Fertility	β-HCG	WB/Serum/Plasma	20 µL	75 µL	15 mins	2-200,000 mIU/mL	negative: <5 mIU/mL positive: >25 mIU/mL	1. Auxiliary diagnosis of pregnancy in women of child-bearing age 2. Monitor the physiological changes of pregnant women during the pregnancy cycle, evaluation of fetal development. 3. Auxiliary diagnosis of trophoblastic cell disease.	CE NMPA
	LH	WB/Serum/Plasma	75 µL		15 mins	1-100 mIU/mL	Male: 1.81-8.16 mIU/mL Female: Follicular phase: 2.95-13.65 mIU/mL Ovulation period: 13.65-95.75 mIU/mL Luteal phase: 1.25-11.00 mIU/mL Menopause: 8.74-55.00 mIU/mL	1. An adjunct in the evaluation of menstrual irregularities. 2. Evaluating patients with suspected hypogonadism. 3. Predicting ovulation. 4. Evaluating infertility. 5. Diagnosing pituitary disorders.	CE NMPA
	FSH	WB/Serum/Plasma	75 µL		15 mins	1-100 mIU/mL	Male: 1.50-12.40 mIU/mL Female: Follicular phase: 4.46-12.43 mIU/mL Ovulation phase: 4.88-20.96 mIU/mL Luteal phase: 1.95-9.04 mIU/mL Menopause phase: 20.00-98.62 mIU/mL	1. Ascertaining whether ovulation occurred in a menstrual cycle. 2. Assessment of infertility. 3. Evaluation of abnormal uterine bleeding. 4. Evaluation of placental health in high-risk pregnancy. 5. Determining the effectiveness of progesterone injections when administered to women to help support early pregnancy. 6. Workup of some patients with adrenal disorders.	CE NMPA
	Prog	WB/Serum/Plasma	75 µL		15 mins	1.4-60 ng/mL	Male: <1.5 ng/mL Female: Follicular phase: <1.9 ng/mL Ovulation phase: <12.0 ng/mL Luteal phase: 1.7-28.7 ng/mL Postmenopausal: <1.4 ng/mL Pregnancy (<12 Weeks): 11.0-53.0 ng/mL Pregnancy (12-24th Weeks): 21.5-60.0 ng/mL	1. Screening tool of hyperprolactinemia. 2. Monitoring of tumor treatment for patient with prolactinoma. 3. Associate to screen for fertility problems or irregular periods etc.	CE NMPA
	PRL	WB/Serum/Plasma	75 µL		15 mins	1-200 ng/mL	Female (non-pregnant): 4.60-25.07 ng/mL Male: 3.45-17.42 ng/mL	1. Evaluation of hypogonadism and oligo-amenorrhea in females. 2. Assessing ovarian status, including follicle development, for assisted reproduction protocols. 3. As part of the diagnosis and workup of suspected disorders of sex steroid metabolism. 4. Monitoring low-dose female hormone replacement therapy in postmenopausal women. 5. Monitoring antiestrogen therapy.	CE NMPA
	E2	WB/Serum/Plasma	75 µL		15 mins	9-3000 pg/mL	Male: <85 pg/mL Female: Follicular Phase: 12-262 pg/mL Ovulation: 40-396 pg/mL Luteal Phase: 21-381 pg/mL Menopause: <190 pg/mL First trimester: 145-2698 pg/mL Second trimester: >1502 pg/mL	1. Assessment of infertility. 2. Evaluation of boys with delayed or precocious puberty. 3. Monitoring testosterone replacement and antiandrogen therapy. 4. Evaluation of women with hirsutism, virilization, oligo-amenorrhea and symptoms or signs of possible testosterone deficiency. 5. Evaluation of infants with ambiguous genitalia or virilization. 6. Diagnosis of androgen-secreting tumors.	CE NMPA
	Testosterone	WB/Serum/Plasma	75 µL		15 mins	0.2-15 ng/mL	Male: 20-49 years old: 1.91-8.41 ng/mL ≥50 years old: 1.61-8.01 ng/mL Female: 20-49 years old, ≤0.80 ng/mL ≥50 years old, <0.71 ng/mL	The AMH test is clinically used to assess ovarian reserve to reflect the number of preantral follicle and to predict the response to controlled ovulation.	CE NMPA
	AMH	WB/Serum/Plasma	75 µL		15 mins	0.1-16 ng/mL	Male: 0.92-13.89 ng/mL Female: 20-29 years old, 0.88-10.35 ng/mL 30-39 years old, 0.31-7.86 ng/mL 40-50 years old, ≤5.07 ng/mL		CE NMPA

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Cardiac Markers	NT-proBNP	WB/Serum/Plasma	75 µL	75 µL	15 mins	18-35000 pg/mL	<75 years old, 0-300 pg/mL ≥75 years old, 0-450 pg/mL	1. Preferred marker for auxiliary diagnosis of heart failure. 2. Differential diagnosis of cardiac dyspnea and non-cardiac dyspnea. 3. Judge severity of heart failure, guide and monitor treatment of heart failure, assess the prognosis of heart failure. 4. Assess the prognosis of ACS.	CE NMPA
	BNP	WB/Plasma	75 µL		15 mins	5-5000 pg/mL	0-100 pg/mL		
	cTn I	WB/Serum/Plasma	75 µL		15 mins	0.1-150 ng/mL	0-0.3 ng/mL	1. Preferred marker for the diagnosis of acute coronary syndrome, available for risk stratification and prognosis assessment. 2. Diagnose acute myocardial infarction, assess myocardial infarct size. 3. 3-6 hours after the onset of significant increase, differential diagnosis of chest pain / dyspnea. 4. Thrombolysis treatment evaluation.	CE NMPA
	Myo	WB/Serum/Plasma	75 µL		15 mins	2.0-400 ng/mL	0-58 ng/mL	1. Early diagnostic biomarkers of AMI and ACS. 2. A significant increase 1-3 hours after onset. 3. High sensitivity, Continuous negative can exclude AMI and ACS. 4. Diagnosis of reinfarction or complications of infarction, effect evaluation of myocardial reperfusion.	CE NMPA
	CK-MB	WB/Serum/Plasma	75 µL		15 mins	0.3-100 ng/mL	0-5 ng/mL	1. Assisted diagnosis of acute coronary syndrome, acute myocardial infarction. 2. Markedly elevated within 3-6 hours of onset. 3. Diagnose reinfarction or infarction complications. 4. Diagnosis of perioperative or perinatal myocardial injury.	CE NMPA
	H-FABP	WB/Serum/Plasma	75 µL		15 mins	1-120 ng/mL	0-7 ng/mL	1. Early diagnosis markers for acute myocardial infarction. 2. Myocardial infarct area assessment. 3. Early diagnosis of acute coronary syndrome.	CE NMPA
	cTn I/CK-MB/Myo	WB/Serum/Plasma	75 µL		15 mins	Same with single items	Same with single items	1. Improve diagnostic accuracy of acute coronary syndrome, acute myocardial infarction. 2. Assisted diagnosis of skeletal muscle injury and chronic renal failure patients with myocardial injury. 3. Combined detection of myocardial injury markers can help clinicians make better diagnoses.	CE NMPA
	cTn I/NT-proBNP	WB/Serum/Plasma	75 µL		15 mins	Same with single items	Same with single items	1. Prefer marker for the diagnosis of myocardial infarction and suspected congestive heart failure. 2. Assess the prognosis of acute coronary syndrome.	CE NMPA
	hsCRP	WB/Serum/Plasma	10 µL		3 mins	0.1-10 mg/L	≤1.0 mg/L	1. A sensitive index to distinguish the low level inflammation. 2. An auxiliary assessment of diagnose the atherosclerosis (AS) and acute cerebral infarction (ACI). 3. Early warning indicator for the recurrence of coronary artery disease or acute coronary syndrome.	CE NMPA
	Lp-PLA2	WB/Serum/Plasma	75 µL		15 mins	10-1000 ng/mL	225 ng/mL	1. Aid to the assessment of the coronary heart disease (CHD) and ischemic stroke. 2. Independent risk marker for cardiovascular disease(CVD), including CHD and ischemic stroke.	NMPA
One Step cTnT	WB/Serum/Plasma	100 µL for whole blood 75 µL for plasma/serum	15 mins	0.03-10 ng/mL	0-0.1 ng/mL	cTnT is better than cTnI in terms of predictions of death 30 days after AMI.	CE NMPA		
Coagulation	D-Dimer	WB/Plasma	15 µL for whole blood 10 µL for plasma	75 µL	5 mins	0.1-10 mg/L	0-0.5 mg/L	1. Key indicator of PE, DVT and DIC. 2. Early diagnostic screening of fibrinolytic system disease (DIC, various thrombus), diseases related with fibrinolytic system (tumor, pregnancy syndrome). 3. Monitoring of thrombolytic therapy and relapse after thrombolysis.	CE NMPA
	One Step D-Dimer	WB/Plasma	100 µL for whole blood 75 µL for plasma	15 mins	0.1-10 mg/L	0-0.5 mg/L	CE NMPA		
Inflammation Markers	PCT	WB/Serum/Plasma	75 µL for whole blood 50 µL for plasma/serum	75 µL	15 mins	0.1-100 ng/mL	0-0.5 ng/mL	1. In terms of disease surveillance, PCT has a natural advantage. 2. PCT will appear later and have half-life onset. It is a definite indicator of (bacterial infection) sepsis.	CE NMPA
	CRP	WB/Serum/Plasma/ Capillary Blood	8.5 µL for whole blood 5 µL for plasma/serum		3 mins	0.5-200 mg/L	CRP:0-10 mg/L hsCRP:0-1 mg/L	1. Infection type identification. 2. Treatment process monitoring. 3. Antibiotic efficacy observation. 4. Assessment of cardiovascular disease risk.	CE NMPA
	CRP/PCT	WB/Serum/Plasma	75 µL		15 mins	CRP:0.5-150 mg/L PCT:0.1-100 ng/mL	CRP:<10 mg/L PCT:<0.5 ng/mL	1. Prefer marker for specifically differentiating bacterial infection and other causes of inflammatory reactions. 2. Determine disease progress or the effectiveness of treatment.	CE NMPA
	SAA	WB/Serum/Plasma	8.5 µL for whole blood 5 µL for plasma/serum		3 mins	1.0-500mg/L	0-10 mg/L	1. Early diagnosis of infectious diseases. 2. Combined with CRP to identify bacterial infections. 3. Clinically widely used, SAA is increased in cardiovascular diseases, malignant tumors, transplant rejection, amyloidosis and other diseases. 4. Guide treatment, dynamic observation of treatment effect.	CE NMPA
	IL-6	WB/Serum/Plasma	75 µL		15 mins	3~4000 pg/mL	≤10 pg/mL	1. Monitor the immune status and inflammatory response of the body. 2. A key component of the inflammatory mediator network and plays an important role in the inflammatory response. 3. Produced earlier than CRP and PCT, induces CRP and PCT; IL-6 is proportional to the severity of inflammation and sepsis.	CE NMPA
Tumor Markers	AFP	WB/Serum/Plasma	75 µL	75 µL	15 mins	5-400 ng/mL	0-20 ng/mL	1. Screening of primary hepatoma. 2. Use to classify germ cell tumors of the testes and ovary associated with HCG. 3. Screening tool for neural tube defects, down syndrome etc.	CE NMPA
	PSA	WB/Serum/Plasma	75 µL		15 mins	2-100 ng/mL	0-4 ng/mL	1. Screening for prostate cancer. 2. Screening of benign prostatic hypertrophy or inflammatory conditions of other adjacent genitourinary tissues. 3. Treatment monitoring of tumor resection, recurrent disease or persist with residual disease.	CE NMPA
	CEA	WB/Serum/Plasma	75 µL		15 mins	1-500 ng/mL	0-5 ng/mL	1. Screening of colorectal carcinoma. 2. Monitoring of before and after removing cancerous tissues. 3. Screening tool for other malignancies including medullary thyroid carcinoma and breast, gastrointestinal tract, liver, lung, ovarian, pancreatic, and prostatic cancers.	CE NMPA
	fPSA	WB/Serum/Plasma	75 µL		15 mins	0.2-30 ng/mL	< 1 ng/mL	1. Screening for early prostate cancer. 2. Associate to differentiate prostate cancer from benign prostatic hyperplasia. 3. Treatment monitoring of tumor resection, recurrent disease or persist with residual disease.	CE NMPA

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	iFOB	Feces	6 different parts of the feces	3 drops of sample dilution solution	5 mins	25-1000 ng/mL	<100 ng/mL	Clinically, it is mainly used as an aid for the gastrointestinal bleeding disorders	CE
COVID-19	2019-nCoV Antibody	WB/Serum/Plasma/Capillary Blood	10 µL	75 µL	10 mins	Qualitative	Negative	1. Used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by 2019-nCoV. 2. The test provides preliminary test results. Negative results don't preclude 2019-nCoV infection and they cannot be used as the sole basis for treatment or other management decision.	CE
	2019-nCoV IgM	WB/Serum/Plasma	10 µL		10 mins	Qualitative	Negative		CE
	2019-nCoV IgG	WB/Serum/Plasma	10 µL		10 mins	Qualitative	Negative		CE
	2019-nCoV IgM/IgG	WB/Serum/Plasma	10 µL		10 mins	Qualitative	Negative		CE
	2019-nCoV Antigen	nasopharyngeal swab or oropharyngeal swab	/	80µL (about 3-4 drops) processed specimen	15 mins	Qualitative	Negative	CE	
	2019-nCoV RBD Antibody	fingerstick whole blood, venipuncture whole blood, serum or plasma	20 µL	75 µL	15 mins	Qualitative	Negative (<1 AU/mL or <20 BAU/mL) Positive (≥1 AU/mL or ≥20 BAU/mL)	1. The 2019-nCoV RBD antibodies/2019-nCoV neutralizing antibodies are protective antibodies produced by the human body after inoculation with 2019-nCoV vaccine or infection with 2019-nCoV. 2. The test is intended as an aid to assess the adaptive humoral immune response to the 2019-nCoV RBD protein.	CE
CranioCerebral Injury Markers	S100β	WB/Serum/Plasma	75 µL	75 µL	15 mins	0.05-10 ng/mL	< 0.2 ng/mL	1. Aid to the assessment of the level of cerebral injury. 2. The concentration of S100β in blood significantly increase in the following cases, such as cerebral ischemia, cerebral hemorrhage and brain tissue injury caused by trauma.	NMPA
Hypertension	Cortisol	WB/Serum/Plasma	75 µL	75 µL	15 mins	50-1000 nmol/L	7:00~10:00a.m: 134~522nmol/L 4:00~8:00p.m: 77~317nmol/L	1. Screening of Cushing's disease and Addison's disease. 2. Diagnosis of hypopituitarism. 3. Screening of adrenal hyperplasia and cancer.	NMPA
Anemia	Ferritin	WB/Serum/Plasma	75 µL	75 µL	10 mins	5-1000 ng/mL	Male 30-400 ng/mL Female 13-150 ng/mL	1. Diagnose Iron-Deficiency Anemia 2. Diagnose Iron Overload 3. Predicting the severity of 2019-nCoV 4. Assistant diagnosis and prognostic various malignancies	CE NMPA
Rheumatoid Arthritis	ASO 	WB/Serum/Plasma	10 µL	75 µL	5 mins	20 ~1000 IU/mL	adult ≤200 IU/mL children ≤150 IU/mL	The test is used as an aid in the diagnosis of diseases related to streptococcal infections.	CE
	RF 	WB/Serum/Plasma	10 µL		5 mins	10 ~ 650 IU/mL	0~15.9 IU/mL	Help diagnosis Rheumatoid Arthritis.	
	Anti-CCP 	WB/Serum/Plasma	10 µL		10 mins	3.5-300 U/mL	<5 U/mL	Highly specific indicator for the early diagnosis of Rheumatoid Arthritis.	
Allergy	Total IgE	WB/Serum/Plasma	75 µL	75 µL	10 mins	1 ~ 1000 IU/mL	Age (years old) Reference interval (IU/mL) < 1 ≤ 15 1-5 ≤ 60 6-9 ≤ 90 10-15 ≤ 200 ≥16 ≤ 100	The test is used as an aid in diagnosis of allergic disease.	CE
Infection	Dengue NS1 Ag	WB/Serum/Plasma	75 µL	75 µL	12 mins	Qualitative	<0.9 Negative 0.9-1.1 Indeterminate ≥1.1 Positive	Early Screening of Dengue Virus Infection	CE
	H.pylori Ag 	Feces	6 different parts of the feces	3 drops of sample dilution solution	10 mins	qualitative	COI<1 Negative for H.pylori Ag; COT ≥1 Positive for H.pylori Ag	It is useful as an aid in the diagnosis of H. pylori infection .	