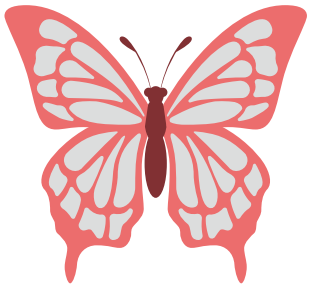
FlowAI®

ANAs

FlowAI Fully Automated Flexible High-throughput Quantitative Detection

Autoantibody Spectrum (16 Analytes)
Antinuclear Antibody Plus (ANAs Plus)

Multiplexed Bead ImmunoAssay Methodology



Autoantibody Spectrum (16 Analytes)	
ANAs	dsDNA, Nucleosome, Histone, Jo-1, Scl-70, PM/Scl, Ribosomal P, SS-B, SS-A 52, SS-A 60, RNP, Sm, AMA (M2-3E), CENPB, PCNA
Plus	C1q

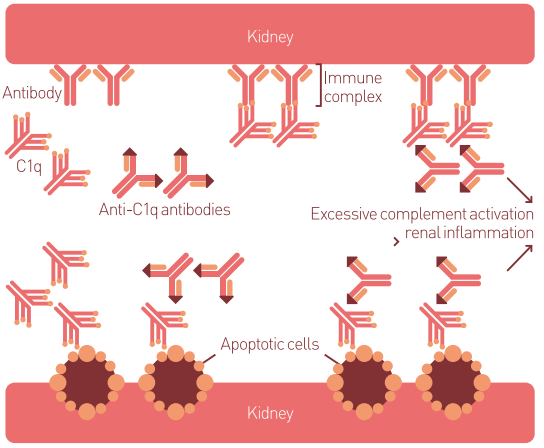
Autoantibody	Clinical Significance
Anti-dsDNA Antibody	Very high specificity for systemic lupus erythematosus (SLE) (positivity rate 40-90%), Related to disease activity and can be used for disease monitoring
Anti-C1q Antibody	Closely related to lupus nephritis (LN), can be used as an important marker for LN activity. Positivity rate 20-40% in systemic lupus erythematosus (SLE) patients
Nucleosome Antibody	Also known as anti-chromatin antibody, a specific marker for systemic lupus erythematosus (SLE) (positvity rate 50-95%). Increase detection rate of SLE when combined with anti-dsDNA antibody
Histone Antibody	Commonly seen in drug-induced lupus (positivity rate 95%). Seen in 30-70% of systemic lupus erythematosus (SLE) patients; and 15-50% of rheumatoid arthritis (RA) patients
Anti-RNP Antibody	Also known as anti U1-RNP antibody, positivity rate 30-40% for systemic lupus erythematosus (SLE). High-titer anti RNP antibody is specific for mixed connective tissue disease (MCTD) diagnosis (positivity rate 95-100%)
Anti-Sm Antibody	Anti-Sm antibody and anti-dsDNA antibody are both markers for systemic lupus erythematosus (SLE), positivity rate 5-10%. Commonly seen with anti-RNP antibody.
Ribosomal P Antibody	Marker for systemic lupus erythematosus (SLE), positivity rate 5-15%. Related to SLE's neuropsychiatric symptoms and kidney/liver wear out, its titer is related to SLE activity
Anti SS-A60 Antibody	Related to many autoimmune diseases. Commonly seen in sjogren's syndrome (SS) (40-80%) and systemic lupus erythematosus (SLE) (30-40%). It can cause neonatal cardiac transmission block in newborn lupus erythematosus
Anti SS-A52 Antibody	Also known as Ro52 antibody, appears in a number of autoimmune diseases. If appear along with other antibodies (such as anti SS-A60 antibody), then might be an indication of related diseases.
Anti SS-B Antibody	Almost only seen in sjogren's syndrome (SS) (30-60%) and systemic lupus erythematosus (SLE) (20-30%) patients, commonly seen with anti SS-A antibody
Anti Scl-70 Antibody	Specific antibody for systemic sclerosis (diffuse SSc), positivity rate 25-75%
Anti CENP B Antibody	Closely resembles CREST syndrome, positivity rate 70-90%. Antibody also detected in primary biliary cholangitis (PBC), positivity rate 10-30%
Anti Jo-1 Antibody	Markers for polymyositis (PM) and dermatomyositis (DM). Positivity rate for PM is 25-30%, commonly related with pulmonary interstitial fibrosis
Anti PM/Scl Antibody	Commonly seen in overlapping polymyositis (PM) and sclerosis syndrome. Positivity rate of around 50%, also seen in PM and systemic sclerosis.
Anti PCNA Antibody	Specific antibody for systemic lupus erythematosus (SLE). Positivity rate of 1-5% only, related to rash, raynaud phenomenon, neuropsychiatric symptoms and kidney tiredness
Anti M2-3E Antibody	Antibodies against M2-3E are markers for primary biliary cholangitis (PBC) with a positivity rate of 92% and specificity of 95%, making it one of the important diagnostic markers

Methodoloy Comparison with Luminex Shows 0.919-0.996 Overall Compliance Rate

- Kappa 83.3%~96.9% (Kappa>0.75 shows same height)

Quantitative Anti-C1q Antibody

- This marker can be used to monitor LN activity
- For SLE patients with secondary nephropathy, sensitivity is 86% and specificity is 95%
- Combining C1q and dsDNA autoantibody detection, sensitivity and specificity can reach 91% and 90% respectively



Pathogenic mechanism of anti-C1q antibody

Quantitative Anti-dsDNA Antibody

- Quantitative calibrator trace back to World Health Organization (WHO - Wo/80)
- The linear correlation index r is ⩾0.990 within the linear range 3IU/mL~300IU/mL
- Comparable specificity with Lucilia brachyhymena indirect immunofluorescence method (96.5% and 97.1% respectively)

Methodology Comparison

Sensitivity and Specificity Comparison of 3 Different Methodologies for Autoimmune Diseases

Methodology	Sensitivity(%)	Specificity(%)
Western Blot	79.6[a]	86.4[b]
Multiplexed Bead ImmunoAssay	70.3	98.3
Indirect Immunofluorescence	92.8[a]	76.3[a]

Indirect immunofluorescence method has the highest sensitivity;
Multiplexed bead immunoassay has the highest specificity;
When combined, these two methods has the highest Youden's Index of 0.706

Note: Compared with MBFFI, $^{a}P<0.01$, $^{b}P<0.05$;
compared with IB, $^{c}P<0.01$

Operating Procedure

Blood Collection

Automated Multiplexed Bead ImmunoAssay analyzer TESMI F4000

Quantitative Test Report Supports LIS Connection

Product Specification

Sample Type	Packing Specification	Compatible Machine
Blood Serum	100 tests/kit (including calibrator and QC) 100 tests/kit (including QC)	Automated Multiplexed Bead ImmunoAssay analyzer TESMI F4000

FlowAI

FlowAI Fully Automated Flexible High-throughput Quantitative Detection

Anti-Cyclic Citrullinated Peptide (CCP) Antibody Testing Kit

Multiplexed Bead ImmunoAssay Methodology

CCP

Recommendation from Authorities

Authorities such as American College of Rheumatology (ACR), European League Against Rheumatism (EULAR), Chinese Medical Association recommend to use anti-CCP2 antibody as diagnostic standard for rheumatoid arthritis (RA). In the ACR/EULAR 2010 Rheumatoid Arthritis Classification Criteria, this marker represents 3 points (only ⩾6 points are needed to diagnose RA)

Product Advantages

Stable Performance

CV⩽5%, good reproducibility, accurate

Quantitative Results

Quantitative traceability, analyze concentration with numbers

Quality Assurance

Second generation of original European CCP antigen (CCP2) with high specificity and superior quality

Easy Operation

Compatible with TESMI analyzing system, the one-step solution to autoimmune assays with automated, high-throughput, flexible detection

Disease Characteristics

Clinical manifestations include synovitis, pannus formation, cartilage and bone damage, eventually leading to joint deformity and loss of function. Complications like cardiovascular diseases can occur. Early discovery and timely treatment can effectively stop or slow down disease progression, thereby decreasing disability rate and improving the quality of life

Clinical Significance

Anti-CCP2 antibody is the most specific marker for RA in serology and can be used for disease prediction and diagnosis, it can accurately differentiate seropositive and seronegative RA, making sure patients are safe from serious complications and permanant damage. Positivity rate can reach 70-80%. Studies show that anti-CCP2 antibody has the most value in RA disease prediction and this antibody can be detected 4.5 years on average before clinical symptoms occur

Intended Use

Quantitative detection of anti-cyclic citrullinated peptide (CCP2) IgG antibody concentration in human serum

Suitable in

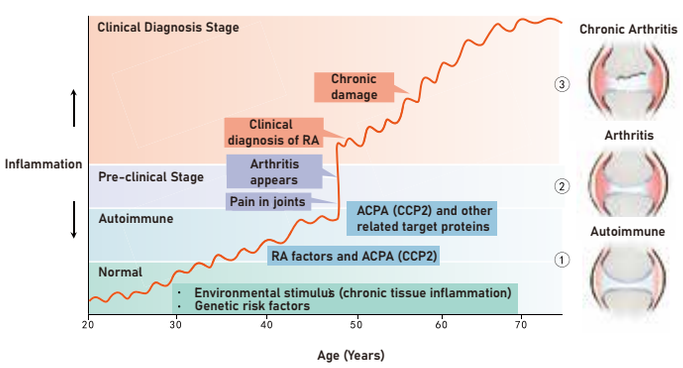
Rheumatology, orthopedics, geriatrics, pediatrics, medical and physical departments, physical examinations, specialist hospitals and so on

Suitable for

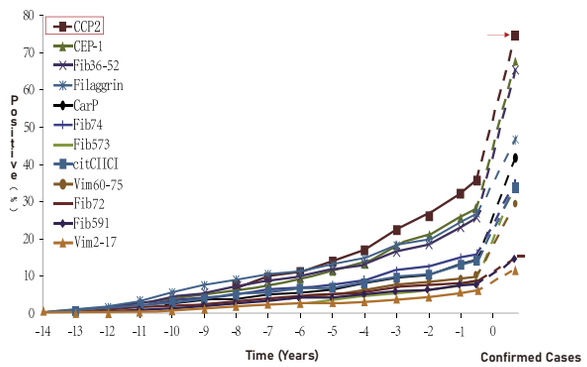
Health check-ups, people with high risk of RA, people suspected of RA, RA patient prognosis, RA patient treatment monitoring

Disease Progression

Anti-CCP2 Antibody Detected in Rheumatoid Arthritis (RA) before Clinical Symptoms



Anti-CCP2 Antibody has Highest Prediction Value in Rheumatoid Arthritis (RA)



FlowAI

FlowAI Fully Automated Flexible High-throughput Quantitative Detection

Antiphospholipid Syndrome (APS) Antibody Testing Kit

Multiplexed Bead ImmunoAssay Methodology

Recommendation from Authorities

Authorities such as International Society on Thrombosis and Haemostasis (ISTH), Global Antiphospholipid Syndrome Score (GAPSS), and Chinese Medical Association recommend anticardiolipin antibody (aCL IgM/IgG) and anti-β2-glycoprotein1 (aβ2GP1 IgM/IgG) as the diagnostic standard for antiphospholipid syndrome (APS)

APS Diagnostic Standard Recommended by Chinese Medical Association and ISTH:

◆ Clinical Manifestations

1. Thrombus formation
2. Recurrent pregnancy loss

◆ Laboratory Standards

1. Lupus anticoagulant (LAC) positive
2. Anticardiolipin antibody (aCL IgM/IgG) positive
3. Anti-β2-glycoprotein1 (aβ2GP1 IgM/IgG) positive

(At least x2 positive lab standards, each ⩾12 weeks apart)

APS Diagnostic Standard – at least 1 clinical manifestation + 1 laboratory standard

Product Advantages

- ◆ **Accurate** Quantitative standard traces back to international standards (GPL/MPL), making reports accurate and reliable
- ◆ **Fast** Say goodbye to long wait-time with initial report in half an hour; flexible testing with tube-reaction
- ◆ **2 in 1** Good value for money with 2 analytes in 1 assay
- ◆ **Easy** Suitable for TESMI system, the one-stop solution for autoimmune assays with automated, high-throughput, flexible testing

Disease Characteristics

Antiphospholipid syndrome (APS) an autoimmune disease defined by clinical manifestations such as vascular thrombosis, pregnancy morbidity, thrombocytopenia, and the presence of antiphospholipid antibody (aPL) in serology. APS display a series of clinical symptoms which might affect multiple organs in the body. Therefore, early discovery, early diagnosis, and timely treatment in patients is significantly important for disease monitoring and prognosis

Clinical Significance

Anticardiolipin antibody (aCL IgM/IgG) is related to thrombus formation and is one of the most widely used aPLs clinically with high sensitivity (positivity rate 80-90%)
Anti-β2-glycoprotein1 (aβ2GP1 IgM/IgG) has high specificity and is related to thrombus formation and pregnancy morbidity (positivity rate 60-90%)
Studies show that aCL and aβ2GP1 has great value to predicting thrombus formation and pregnancy morbidity

Intended Use

Quantitative determination of anticardiolipin antibody (aCL IgM/IgG) and anti-β2-glycoprotein1 (aβ2GP1 IgM/IgG) in human serum (in 2 separate kits)

Suitable in

Rheumatology, cardiology, neurology, gynecology, hematology, dermatology, physical examination department, etc.

Suitable for

APS-suspected patients, woman with habitual abortions, smokers, people at high-risk of autoimmune diseases, stroke patients, people with hypertension, hyperglycaemia, and hyperlipidaemia, etc.

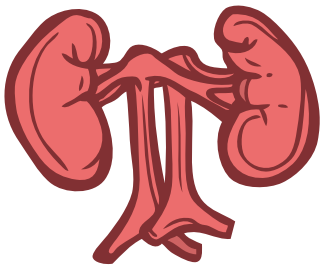
APS

FlowAI™

Vasculitis

FlowAI Fully Automated Flexible High-throughput Quantitative Detection

Anti-MPO, Anti-PR3, Anti-GBM Testing Kit



Multiplexed Bead ImmunoAssay Methodology

Product Advantages

- **Quantitative** Traceable quantitative standard, numeric interpretation of antibody concentration
- **Stable** Good repeatability with intrabatch CV≤5%, interbatch CV≤10%
- **Multiplex** Good value for money with 3 analytes in 1 assay
- **Easy** Suitable for TESMI system, the one-stop solution for autoimmune assays with automated, high-throughput, flexible testing

Recommendation from Authorities

- Among the different detection methods for specific autoantibody testing, such as ELISA/LIA/MFIA/CLIA/FEIA, multiplexed fluorometric immunoassay (MFIA) offers easy automation, high-throughput, flexible testing with high sensitivity and specificity

Taken from the Chinese Journal of Laboratory Medicine

Expert Consensus on the Clinical Application of Anti-neutrophil Cytoplasmic Antibody Detection, 2018

- High-quality immunoassays are the preferred methods for diagnostic evaluation of AAV patients, without the categorical need for indirect immunofluorescence (IIF), particularly for granulomatosis with polyangiitis (Wegener's, GPA) and microscopic polyangiitis (MPA).

Taken from Nature Reviews Rheumatology

Revised 2017 International Consensus on Testing of ANCAs in Granulomatosis with Polyangiitis and Microscopic Polyangiitis, 2017

Clinical Significance

MPA patients are usually myeloperoxidase (MPO) antibody positive (positivity rate 60-80%). GPA patients are usually protease 3 (PR3) antibody positive (positivity rate 66-90%). Patients with lung-involved anti-glomerular basement membrane disease, including pulmonary-renal syndrome are usually GBM antibody positive (positivity rate 80-90%).

Suitable in

Nephrology, rheumatology, pulmonology, endocrinology, hematology, medical department, physical examination, etc.

Suitable for

Patients suspected of AAV, screening for high-risk AAV population, AAV patient prognosis, AAV patient treatment monitoring, non-AAV autoimmune disease patients and so on.

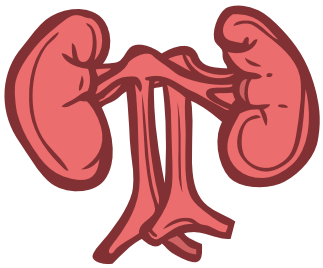
FlowAI™

PLA2R

FlowAI Fully Automated Flexible High-throughput Quantitative Detection

Anti-Phospholipase A2 Receptor Antibody Testing Kit

Multiplexed Bead ImmunoAssay Methodology



Product Advantages

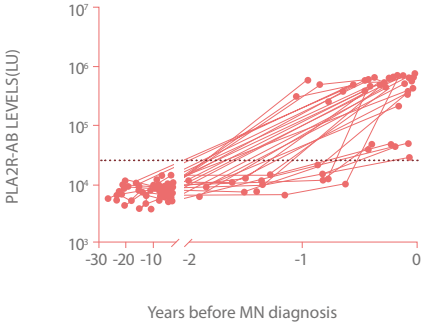
- **Quantitative** Traceable quantitative standard, numeric interpretation of antibody concentration
- **Easy** Suitable for TESMI system, the one-stop solution for autoimmune assays with automated, high-throughput, flexible testing

Clinical Significance

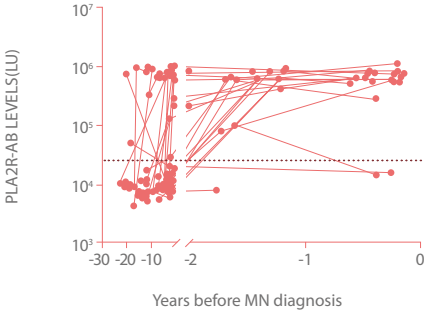
- **Early-screening**

  83% of membranous nephropathy (MN) patients are positive for PLA2R antibody a year within diagnosis and 29% of patients continues to stay positive for PLA2R antibody.

A Less than 1 year before(n=33/59)



B More than 1 year before(n=26/59)



- **Differential diagnosis**

  Anti-PLA2R antibody has a sensitivity of 70%~80% and a specificity of 100% in patients with primary membranous nephropathy.

- **Disease progression and treatment monitoring**

  Monitor anti-PLA2R antibody level to evaluate treatment effects for guiding future therapy.

- **Draft treatment plan and risk assessment**

  Evaluate the risk of kidney damage according to anti-PLA2R antibody levels and provide a treatment plan.

- **Prognosis and kidney transplant relapse monitoring**

  The higher the level of anti-PLA2R antibody, the worse the prognosis, and the higher the chance of disease recurrance after kidney transplant.

References:
KDIGO CLINICAL PRACTICE GUIDELINE ON GLOMERULAR DISEASES. KDIGO 2020 June, PUBLIC REVIEW DRAFT.

Suitable in

Nephrology department

Suitable for

Patients suspected of primary membranous nephropathy (pMN) , pMN treatment plan evaluation, pMN therapy monitoring, pMN prognosis, risk assessment in pMN patients with kidney transplant and so on.

Tellgen

Product Parameters

Testing Speed	120-4000 T/H (According to the targets per assay/joint assay, testing speed is calculated by 120 samples x joint assay number)
	First Report Time: 38 mins
Testing Principle	Multiplexed Bead Flow Fluorescence Technology
Processing Method	Automatic Processing Method Supports A&E Testing with Cut-the-queue Priority Slots
Reaction Area	76 Reaction Cup Slots
	Temperature Accuracy: ＜0.5℃
	Temperature Fluctuation: ＜1℃
Sample Area	125 Regular Sample Slots, 15 A&E Testing Slots Both Supporting Different Types of Blood Containers
	Supports BarCode Reading
	Supports Automatic Dilution

Reagent Area	25 Reagent Slots
	Comes with Refrigeration Function (4-10℃)
	Supports BarCode Reading
Consumables Area	Single-use Pipette Tips to Prevent Cross-contamination
	600 Pipette Tips Slots
	600 Reaction Cup Slots
Calibration Method	Calibration Type: Batch Calibration
	Calibration Mode: 2 or 6 Spot Calibration
Size	1030 mm (W) x 1320 mm (L) x 1260mm (H)
	Weight: 400KG
Software System	Machine Operation and Analysis in One Software
	Everyday Maintenance such as Start-up, Washing, and Shut-down
	Supports Automatic Calibratoin and Quality Control
	Automated Calculation of All Analyzed Assays
Others	Supports LIS/HIS Connection
	Supports Formation of Assembly Line

Tellgen Corporation, founded in 2003, is an in vitro diagnostics company located in the the 'global research centre' Zhangjiang Hi-Technology Park in Shanghai, P.R. China. We are a listed company focusing on research and producing high-end IVD products.

With our company's slogan "Deeper Understanding of Life", we aim to explore the scientific field of research and bring our research results to help aid in auxillary diagnosis. We focus on early-stage tumor screening to provide diagnostic help, determination of personalized medicine, and the prediction of drug use.

Tellgen Corporation is the first to release the TESMI system, based on the high-throughput flow fluorescence mutiplexed bead technology, leading a role in the IVD industry. Until now, we have different detection platforms covering immunology, molecular biology, boichemistry, mass spectrometry and more that uses technologies such as multiplexed bead flow fluorescence, chemiluminescence, multiplex-PCR, liquid chromatography tandem mass spectrometry and others. Our products range from full-course tumor monitoring, reproductive health detection, autoimmunity detection, infectious diseases detection, cardiovascular disease detection, and DNA methylation detection. We have innovative products such as tumor marker joint assay (first in China to release), the first CFDA-approved Y chromosomal microdeletion detection kit, and the first CFDA-approved SHOX2+RASSF1A DNA methylation detection kit for lung cancer screening.

We have a stable cooperation with Hitachi and collaborated to release the Hitachi-Tellgen compatible assembly line which offers high-throughput sample pre-treatment and biochemical analyzing system. With the addition of TESMI F4000 to this assembly line, we can achieve high-throughput target detection.

Tellgen insists to adhere to research and actively collaborates with companies from around the world to produce new innovative products and contribute to human health.

Tellgen Corporation

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Official Website

WeChat Programme

Automated Multiplexed Bead Flow Fluorescence Immunoanalyzer

TESMI F4000

Tellgen

Tellgen

TESMI F4000

Tellgen's Automated Multiplexed Bead Flow Fluorescence Immunoanalyzer

Tellgen's Automated Multiplexed Bead Flow Fluorescence Immunoanalyzer is developed and designed by Tellgen Corporation based on flow fluorescence multiplexed bead technology. This detection system gathers advantages of both flow fluorescence and multiplexed bead array assay, realizing high-throughput detection with multiple markers with high sensitivity and excellent repeatability. Tellgen perfectly combines flow fluorescence technology and immune sample pre-treatment, enabling this detection platform to have better temperature control and easier maintenance.

Technological Advantages

✓ High-throughput with joint detection assays, reaching up to 4000 T/H

This system is able to detect 120 samples per hour with up to 35 targets per sample. This realizes a total of 120-4000 targets per hour with 120 samples, making this system more than 10 times more efficient than traditional chemiluminescence analyzers.

✓ Multiple reagent slots for detection of up to a hundred targets in one run on a single machine

There are 25 reagent slots with 4 targets per channel, making this machine able to detect 100 targets in a single machine. Detection target number depends on the corresponding kit. This greatly reduces the number of machines needed and eliminates the need to separate samples onto different machines.

✓ Integrated design for better temperature control and maintenance

The detection module and sample pre-treatment modules are integrated in this machine, making temperature control and daily maintenance easier.

✓ Fully automated and can attached to assembly lines

Supports two-way communication, continuous sampling, emergency testing, and integration into the Hitachi-Tellgen assembly line.

Applicable Fields

- ✓ 21 Tumor Marker Assays
- ✓ 4 Liver Fibrosis Marker Assays
- ✓ FlowAI Series for Autoimmunity Assays
- ✓ 10 ToRCH Assays
- ✓ Quantitative fecal occult blood test (FOBT)

Compatible Assays

✓ 21 Tumor Marker Assays

• AFP • CEA • CA242 • CA125 • NSE • CYFRA21-1 • HE4 • t-PSA • ProGRP
• CA19-9 • CA15-3 • CA72-4 • G17 • SCCA • CA50 • AMH

Special Joint Detection Assays

• 2 frequently used tumor markers
CEA
AFP
* Mainly targets hepatic carcinoma and other digestive system tumors

• 2 prostate cancer markers
t-PSA
f-PSA
* Preffered markers for male prostate cancer

• 2 gastric cancer markers
PGI
PGII
* Helps identify high-risk gastric cancer groups by using serological biopsy of gastric mucosa

• 3 lung cancer tumor markers
CEA
CYFRA21-1
NSE
* Can be used on top of CA125 and SCCA Assays for a more thorough screening

• 7 selected tumor markers
AFP CA125
CEA CA242
NSE free-β-HCG
CYFRA21-1
* Covers more than 85% of commonly seen malignant tumors

• Other combinations
* On top of these joint assays, we can add any other assays to these joint combinations according to specific needs

✓ 10 ToRCH Assays

ToRCH IgM • Toxo IgM • Rubella IgM • CMV IgM • HSV-I IgM • HSV-II IgM
ToRCH IgG • Toxo IgG • Rubella IgG • CMV IgG • HSV-I IgG • HSV-II IgG

✓ Autoimmunity Assays (FlowAI Series)

• 16 Assays for Antinuclear Antibody
• Assay Type I Diabetes
• 3 Assays for Vasculitis Antibody
• 4 Assays for Antiphospholipid Antibody
• Autoimmune Liver Disease Antibody
• Assay for Myositis Antibody
• Assay for Anti-CCP Antibody
• Assay for Neuroimmunity Antibody

✓ Other Assays

Quantitative fecal occult blood test (FOBT), liver fibrosis assays, etc.