

# IVD Material

# Antibody and Antigen

Proven material for quality results

Human IL-6 Protein and Antibody  
Human CRP Protein and Antibody  
Human SAA Protein and Antibody  
Human Ferritin Protein and Antibody

# Who is BioBench?

BioBench – A one-stop-shop research service and product provider that specializes in the development of functional antibody biologists in 2013, Bio Bench has organized research teams which are equipped with leading instruments as well as solid Our passion: accelerate life science research for a healthier future!

## BioBench Service Modules and Blocks

### Small Scale Protein Expression and Purification

- Multiple expression hosts: E.coli, B.Subtilis, Yeast, Insect cell, Mammalian cell.
- Bioinformatic tool to optimize the codon usage.
- Cell/Bacteria culture volume from mL to XL.
- Protein expression at mini scale – µg to XXmg for preliminary study.
- Combination of purification methods: affinity purification, ion exchange, size exclusive, hydrophobic, etc.. Protein polishing up to 99.9% purity.

### Research Stable Cell Line / Cell Pool Establishment

- Mammalian cell line for protein over expression.
- Mammalian cell line and cell pool for cell function, signaling pathway study and/or antibody drug discovery.
- Membrane protein cell line.
- Cell line tested by different methods: flow cytometry, whole cell ELISA, WB, fluorescent microscopy, HCS, etc.
- Tandem protein purification methods to enhance the protein purity.

### Antibody Discovery

- Multiple choices for monoclonal antibody hosts: Llama, Mouse, Human, Rabbit and Chicken.
- Multiple choices for polyclonal antibody hosts: Llama, Mouse, Goat, Rabbit and Chicken.
- Multiple immunization methods: peptide, protein and/or gene.
- Monoclonal antibody through hybridoma method and/or phage display based antibody library.
- Antibody production from µg to XXg.
- mAb sequencing and cell line establishment.

### BioBench Service has helped researchers:

- > More than 3000 antibody projects delivered.
- > More than 10 000 lots of purified protein delivered.
- > More than 200 drug antibody discovery projects delivered.
- > More than 200 in vivo study for antibody drug candidates were finalized.

and biologically active protein for drug discovery, IVD kit and life sciences research. Founded by a group of innovation-driven know-how.

### Antibody Drug Discovery, in Vitro and in Vivo Study

- Qualified antibody library for drug discovery: 100-billion human antibody library, 10-billion human antibody library, 100-billion alpaca nanobody library and mouse antibody library.
- pM to sub nM extreme high affinity binders.
- Antibody engineering to improve drug candidate performance.
- Antibody physico-chemical characterization, in vitro analysis, in vivo animal model.
- Drug candidate cell line establishment according to FDA requirement.

### Midi Scale Protein Production

- Large volume fermentation for E.coli, insect cell and Mammalian expression hosts.
- Protein expression at midi scale – XXXmg to XXXg for pilot study and/or production.
- Midi scale purification process: affinity purification, ion exchange, size exclusive, hydrophobic. Protein polishing up to 99.9% purity.
- Protein physico-chemical characterization.
- Protein bioactivity characterization.

### Protein Production Bacteria Strain / Cell Line Establishment

- E.coli, Yeast and Mammalian high production strain/cell line establishment.
- Pre-CDMO development for antibody drug development (licensed cell lines).
- PCB/WCB establishment and test.
- Mammalian cell line for high production protein.
- Multiple methods for cell line characterization.
- USP (Up-Stream Process development) for antibody drug projects.



## Protein/Antibody Biological Activity Test Platform

- Immunology method based assays, including: PAGE and Western Blotting, ELISA, Immuno-Fluorescence assay, Flow Cytometry, High Content Screening assay, Immunohistochemistry, etc..
- Antibody affinity test, epitope mapping, or other binding/blocking assay by Biacore or ForteBio.
- Image based assays, like cell proliferation assay, scratch-wound assay.

## Protein/Antibody Physicochemical Test Platform

- UV, HPLC, LC-MS and MS instruments and methods to test protein concentration, purity, sequence, bonding and residues.
- CEX and iCIEF instruments and methods to test protein charge and isoelectric point.
- UPLC-FLD and MS instruments and methods to test Oligosaccharide and sialic acid.
- DSF instruments and method to test thermostability of the protein.
- HCP analysis by qrt-PCR.

## Antibody Engineering

- Bioinformatics software, data analysis to analyze your antibody sequence in 3D.
- Antibody drug proven engineering strategy to ensure the maximum efficacy.
- Plenty of applications support optimization, affinity maturation, pH sensitivity, etc..
- Biacore and/or ForteBio instruments to validate the result.



# BioBench



## In Vivo Test Platform

- Mouse model from credited provider and raised in certified lab, SPF or higher.
- Well trained person to operate animal.
- Method from credited source and adjusted by our biopharma industry experience.
- Data analysis by senior scientists team with rich biopharma knowledge.

## Cell Line Establishment and Validation Platform

- Flow cytometry cell sorter, single cell imaging instruments and methods.
- ELISA, immuno-fluorescent imaging or function assay to confirm the cell line.
- Cell bank establishment and test.
- 1L – 3L fermenter for medium scale cell culture and upstream process development.

## Engineering Platform

...e, database and method to  
...equence in both 2D and

...engineering and screening  
...maximum output.

...supported: antibody human-  
...ion, functionality diversity,

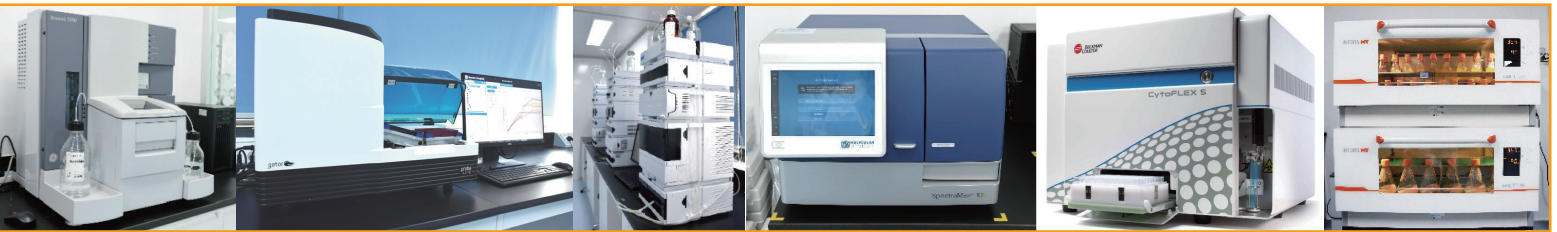
...o instruments and method

## Phage Display Antibody Discovery Platform

- Pre-established 100-billion and 10-billion human antibody library, qualified for antibody drug project.
- Pre-established 100-billion and 10-billion Alpaca antibody library, qualified for antibody drug project.
- Customizable antibody library for client's specific project: Alpaca, mouse, rabbit and chicken.
- Advanced antibody screening method to ensure maximum output.

## In Vitro Test Platform

- ADCC, ATCC, CDC assay.
- Protein/Cell binding, blocking assay.
- Luciferase assay.
- Scratch wound healing assay.
- Cell proliferation assay.
- Cell line purchased from credited source with traceable record.
- Flow cytometer, ELISA, cell imaging and HCS instruments and the methods.



# Research Platforms



## Elementary Molecular Biology Platform

- Plasmid construction, subcloning and extraction.
- DNA electrophoresis, imaging, quantity test and recovery.
- Protein electrophoresis, quantity test and gel recovery.
- Sample preparation for down-stream assays.
- Plasmid transformation and transfection instruments and reagents.

## Protein Production Purification and Modification Platform

- Small to mini scale incubator for culture volume from mL to XL.
- Scale up fermentation volume, 500L for bacteria, 200L for mammalian cell.
- AKTA purification instruments with multiple column selections, from affinity purification, ion exchange purification, size exclusive purification and hydrophobic purification.
- Essential protein operations such as tag removal, protein conjugation, endotoxin removal, etc..
- Essential protein modification like FITC.

## Content

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# Human IL-6 Protein and Antibody

## Related Products

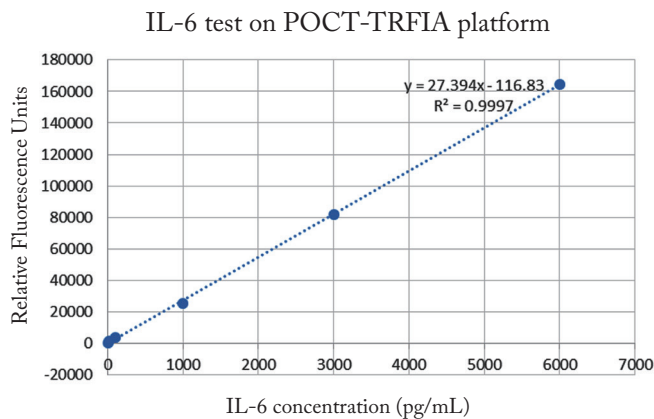
Product type	Product name	Catalog No.	Host	Antibody type	Clone number	Antibody pairing* / Protein usage	Advised IVD platform**
Protein/Antigen	Human IL-6 protein	CP0041	293T stable cell line expressed	\	N/A	Positive control, protein standard, reference substance	All
Monoclonal antibody	Anti Human IL-6, Mouse mAb, 01	MAB0310	Mouse hybridoma	Monoclonal antibody, IgG1	01	Capture Ab: clone 01 Detection Ab: clone 02	POCT
Monoclonal antibody	Anti Human IL-6, Mouse mAb, 02	MAB0311	Mouse hybridoma	Monoclonal antibody, IgG2a	02	Capture Ab: clone 01 Detection Ab: clone 02	
Monoclonal antibody	Anti Human IL-6, Mouse mAb, 31	MAB0312	Mouse hybridoma	Monoclonal antibody, IgG1	31	Capture Ab: clone 31 Detection Ab: clone 32	CLIA
Monoclonal antibody	Anti Human IL-6, Mouse mAb, 32	MAB0313	Mouse hybridoma	Monoclonal antibody, IgG1	32	Capture Ab: clone 31, clone 33, clone 34 Detection Ab: clone 32	
Monoclonal antibody	Anti Human IL-6, Mouse mAb, 33	MAB0314	Mouse hybridoma	Monoclonal antibody, IgG1	33	Capture Ab: clone 33 Detection Ab: clone 32, clone 34	
Monoclonal antibody	Anti Human IL-6, Mouse mAb, 34	MAB0315	Mouse hybridoma	Monoclonal antibody, IgG1	34	Capture Ab: clone 34 - Detection Ab: clone 32 Capture Ab: clone 33 - Detection Ab: clone 34	

Note:

\* Please test the usage of antibody pairs according to your own assay/method/platform/reagent. The listed data were tested in-house by BioBench and only shown as advice.

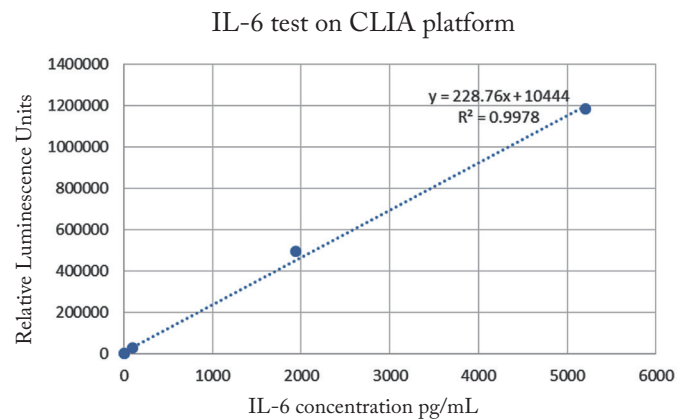
\*\* Adapted platforms were tested in-house by Bio Bench and only shown as advise. Different assay/method/platform/reagent may lead to different performance of the antibody and protein.

## Range of Linerity



**Fig.1-1 Range of Linerity, POCT platform**

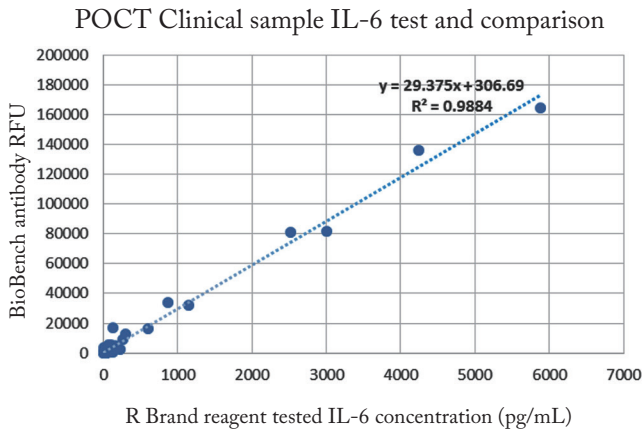
IL-6 antibody pair was used for TRFIA assay (Time Resolved Fluoroimmunoassay). Result show good linerity range 7 – 6,000 pg/mL.



**Fig.1-2 Range of Linerity, CLIA platform**

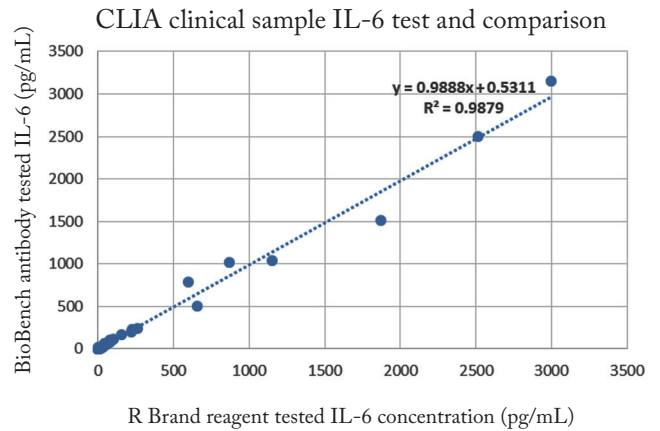
IL-6 antibody pair was used for the CLIA test (ChemiLuminescent Immune Assay). Result show good linerity range 2 – 5,000 pg/mL.

### Clinical Sample Test and Result Comparison



**Fig.1-3 Clinical sample test on POCT platform and result comparison with R Brand reagent**

Patient samples (n=103) were tested by BioBench antibody and R Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with R Brand reagent.



**Fig.1-4 Clinical sample test on CLIA platform and result comparison with R Brand reagent**

Patient samples (n=149) were tested by BioBench antibody and R Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with R Brand reagent.

### IL-6 Antibody and Protein Technical Specifications

Antibody pair suggestion, performance and application suggestion

Tested Platform / Method	Coating Antibody	Detection Antibody	BioBench Comment on Test Result	LOD / Sensitivity	Antigen Linearity Range
POCT	Clone 01	Clone 02	**** Good result	≤ 5 pg/mL	7 – 6,000 pg/mL
CLIA	Clone 31	Clone 32	*** Good sensitivity	≤ 1.5 pg/mL	2 – 5,000 pg/mL
	Clone 33	Clone 34	*** Good sensitivity		
	Clone 33	Clone 32	**** Good specificity		
	Clone 34	Clone 32	**** Low background		

These results were tested in-house by BioBench with limited selection of assay/platform/method/instrument/reagents. Please test the performance in your lab to confirm the performance.

### Cross reactivity

Substance	HBsAb	HAV Ab	HCV Ab	HIV Ab	TP Ab	EB Ab	RF	ANA	CMV Ab	RV Ab	TOXO Ab	HSV Ab	HCG
Reaction	No	No	No	No	No	No	No	No	No	No	No	No	No



Interfering substance

<b>Interfering substance</b>	Bilirubin	Hemoglobin	Triglyceride
<b>Concentration</b>	200 µg/mL	10 mg/mL	20 mg/mL

# 02

## Human CRP Protein and Antibody

### Related Products

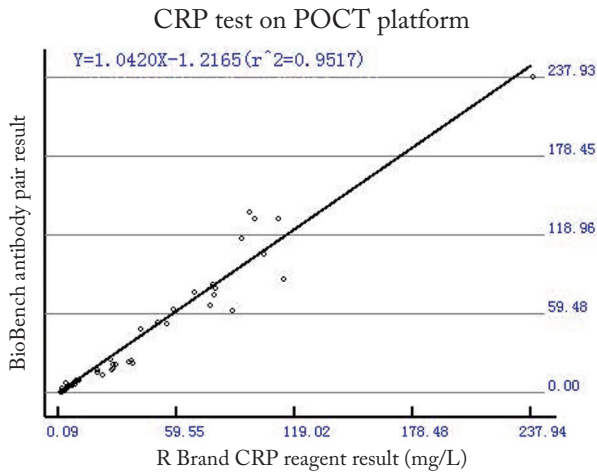
Product type	Product name	Catalog No.	Host	Antibody type	Clone number	Antibody pairing* / Protein usage	Advised IVD platform**
Protein/Antigen	Human CRP	CP0042	293T stable cell line expressed	\	N/A	Positive control, protein standard, reference substance	All
Monoclonal antibody	Anti Human CRP, Mouse mAb, 01	MAB0316	Mouse hybridoma	Monoclonal antibody, IgG1	01	Capture Ab: clone 01 Detection Ab: clone 02	POCT
Monoclonal antibody	Anti Human CRP, Mouse mAb, 02	MAB0317	Mouse hybridoma	Monoclonal antibody, IgG1	02	Capture Ab: clone 01 Detection Ab: clone 02	
Monoclonal antibody	Anti Human CRP, Mouse mAb, 03	MAB0318	Mouse hybridoma	Monoclonal antibody, IgG1	03	Capture Ab: clone 03 Detection Ab: clone 02	
Monoclonal antibody	Anti Human CRP, Mouse mAb, 05	MAB0319	Mouse hybridoma	Monoclonal antibody, IgG1	05	Capture Ab: clone 05 Detection Ab: clone 06	
Monoclonal antibody	Anti Human CRP, Mouse mAb, 06	MAB0320	Mouse hybridoma	Monoclonal antibody, IgG1	06	Capture Ab: clone 06 Detection Ab: clone 05	
Monoclonal antibody	Anti Human CRP, Mouse mAb, 31	MAB0321	Mouse hybridoma	Monoclonal antibody, IgG1	31	Capture Ab: clone 31 Detection Ab: clone 32	CLIA
Monoclonal antibody	Anti Human CRP, Mouse mAb, 32	MAB0322	Mouse hybridoma	Monoclonal antibody, IgG1	32	Capture Ab: clone 31 Detection Ab: clone 32	
Monoclonal antibody	Anti Human CRP, Mouse mAb, 33	MAB0323	Mouse hybridoma	Monoclonal antibody, IgG1	33	Capture Ab: clone 33 Detection Ab: clone 32	
Monoclonal antibody	Anti Human CRP, Mouse mAb, 81	MAB0324	Mouse hybridoma	Monoclonal antibody, IgG1	81	Not necessary for LETIA.	LETIA
Monoclonal antibody	Anti Human CRP, Mouse mAb, 82	MAB0325	Mouse hybridoma	Monoclonal antibody, IgG1	82	Not necessary for LETIA.	

Note:

\* Please test the usage of antibody pairs according to your own assay/method/platform/reagent. The listed data were tested in-house by BioBench and only shown as advice.

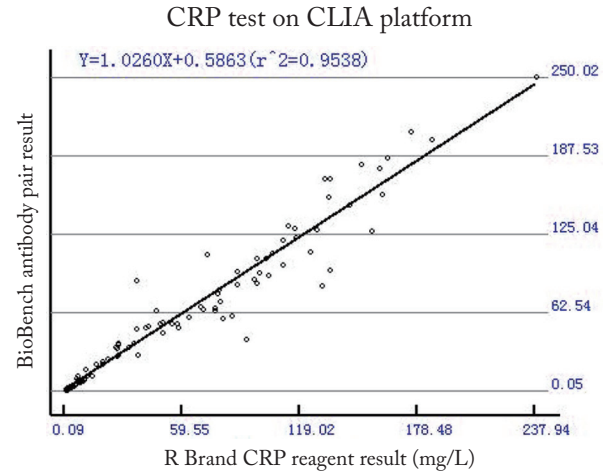
\*\* Adapted platforms were tested in-house by Bio Bench and only shown as advice. Different assay/method/platform/reagent may lead to different performance of the antibody and protein.

Clinical Sample Test and Result Comparison



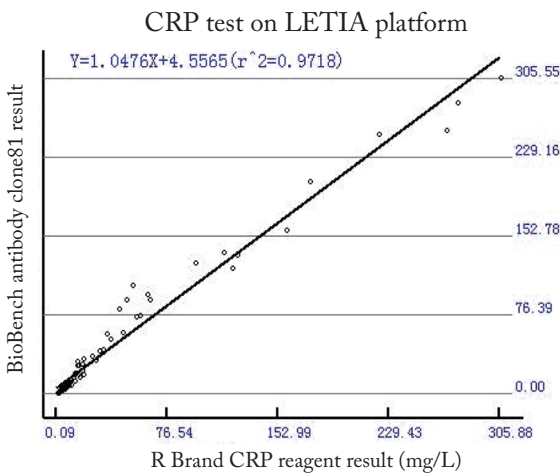
**Fig.2-1 Clinical sample test on POCT platform and result comparison with R Brand reagent**

Patient samples (n=64) were tested by BioBench antibody pair and R Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with R Brand reagent. BioBench antibody pair is clone 01-clone 02, we confirm that other antibody pairs show similar result.



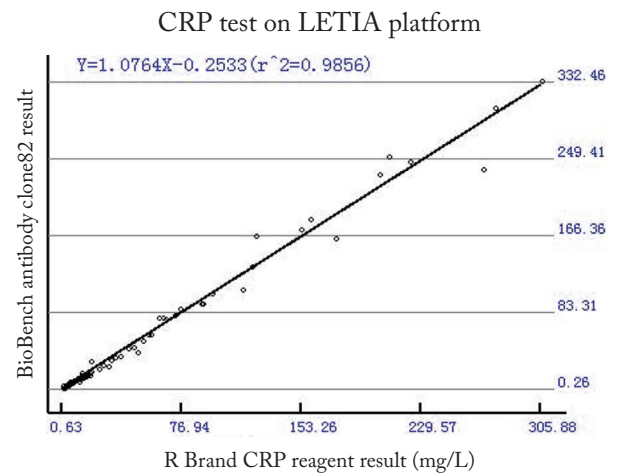
**Fig.2-2 Clinical sample test on CLIA platform and result comparison with R Brand reagent**

Patient sample (n=159) were tested by BioBench antibody pair and R Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with R Brand reagent. BioBench antibody pair is clone 31-clone 32, we confirm that other antibody pairs show similar result.



**Fig.2-3 Clinical sample test on LETIA platform and result comparison with R Brand reagent**

Patient sample (n=89) were tested by BioBench antibody pair and R Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with R Brand reagent. BioBench antibody is clone 81, we confirm that other antibodies show similar result.



**Fig.2-3 Clinical sample test on LETIA platform and result comparison with R Brand reagent**

Patient sample (n=89) were tested by BioBench antibody pair and R Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with R Brand reagent. BioBench antibody is clone 82, we confirm that other antibodies show similar result.

**CRP Antibody and Protein Technical Specifications**

Antibody pair suggestion, performance and application suggestion

Tested Platform / Method	Coating Antibody	Detection Antibody	BioBench Comment on Test Result	LOD / Sensitivity	Antigen Linearity Range
POCT	Clone 01	Clone 02	****	≤ 0.3 mg/L	0.5 – 200 mg/L
	Clone 03	Clone 02	***	≤ 0.3 mg/L	0.5 – 200 mg/L
	Clone 05	Clone 06	****	≤ 0.5 mg/L	0.7 – 200 mg/L
CLIA	Clone 31	Clone 32	****	≤ 0.05 mg/L	0.1 – 200 mg/L
	Clone 33	Clone 32	***		
LETIA	Clone 81		****	≤ 0.3 mg/L	0.5 – 300 mg/L
	Clone 82		****	≤ 0.5 mg/L	0.7 – 300 mg/L

These results were tested in-house by BioBench with limited selection of assay/platform/method/instrument/reagents.  
Please test the performance in your lab to confirm the performance.

## Cross reactivity

Substance	HBsAb	HAV Ab	HCV Ab	HIV Ab	TP Ab	EB Ab	RF	ANA	CMV Ab	RV Ab	TOXO Ab	HSV Ab	HCG	SAA	PCT	IL-6
Reaction	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

## Interfering substance

Interfering substance	Bilirubin	Hemoglobin	Triglyceride
Concentration	200 µg/mL	10 mg/mL	20 mg/mL

## Human SAA Protein and Antibody

### Related Products

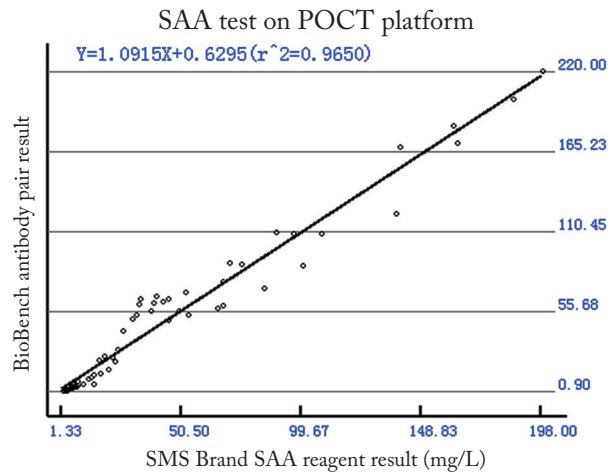
Product type	Product name	Catalog No.	Host	Antibody type	Clone number	Antibody pairing* / Protein usage	Advised IVD platform**
Protein/Antigen	Human SAA	CP0043	293T stable cell line expressed	\	01	Positive control, protein standard, reference substance	All
Protein/Antigen	Human SAA	CP0044	293T stable cell line expressed	\	02	Positive control, protein standard, reference substance	All
Monoclonal antibody	Anti Human SAA, Mouse mAb, 01	MAB0326	Mouse hybridoma	Monoclonal antibody, IgG1	01	Capture Ab: clone 01 - Detection Ab: clone 02 Capture Ab: clone 01 - Detection Ab: clone 06 Capture Ab: clone 01 - Detection Ab: clone 08 Capture Ab: clone 02 - Detection Ab: clone 01	POCT
Monoclonal antibody	Anti Human SAA, Mouse mAb, 02	MAB0327	Mouse hybridoma	Monoclonal antibody, IgG1	02	Capture Ab: clone 01 - Detection Ab: clone 02 Capture Ab: clone 02 - Detection Ab: clone 01	
Monoclonal antibody	Anti Human SAA, Mouse mAb, 06	MAB0328	Mouse hybridoma	Monoclonal antibody, Ig2a	06	Capture Ab: clone 01 Detection Ab: clone 06	
Monoclonal antibody	Anti Human SAA, Mouse mAb, 08	MAB0329	Mouse hybridoma	Monoclonal antibody, IgG1	08	Capture Ab: clone 01 Detection Ab: clone 08	
Monoclonal antibody	Anti Human SAA, Mouse mAb, 31	MAB0330	Mouse hybridoma	Monoclonal antibody, IgG1	31	Capture Ab: clone 33 - Detection Ab: clone 31 Capture Ab: clone 32 - Detection Ab: clone 31 Capture Ab: clone 31 - Detection Ab: clone 32	CLIA
Monoclonal antibody	Anti Human SAA, Mouse mAb, 32	MAB0331	Mouse hybridoma	Monoclonal antibody, IgG1	32	Capture Ab: clone 32 - Detection Ab: clone 31 Capture Ab: clone 31 - Detection Ab: clone 32	
Monoclonal antibody	Anti Human SAA, Mouse mAb, 33	MAB0332	Mouse hybridoma	Monoclonal antibody, IgG1	33	Capture Ab: clone 33 - Detection Ab: clone 31	
Monoclonal antibody	Anti Human SAA, Mouse mAb, 81	MAB0333	Mouse hybridoma	Monoclonal antibody, IgG1	81	Coating Ab: Clone 81 - Pairing Ab: Clone 82 Coating Ab: Clone 81 - Pairing Ab: Clone 83	LETIA
Monoclonal antibody	Anti Human SAA, Mouse mAb, 82	MAB0334	Mouse hybridoma	Monoclonal antibody, IgG1	82	Coating Ab: Clone 82 - Pairing Ab: Clone 81	
Monoclonal antibody	Anti Human SAA, Mouse mAb, 83	MAB0335	Mouse hybridoma	Monoclonal antibody, IgG1	83	Coating Ab: Clone 83 - Pairing Ab: Clone 81	

**Note:**

\* Please test the usage of antibody pairs according to your own assay/method/platform/reagent. The listed data were tested in-house by BioBench and only shown as advice.

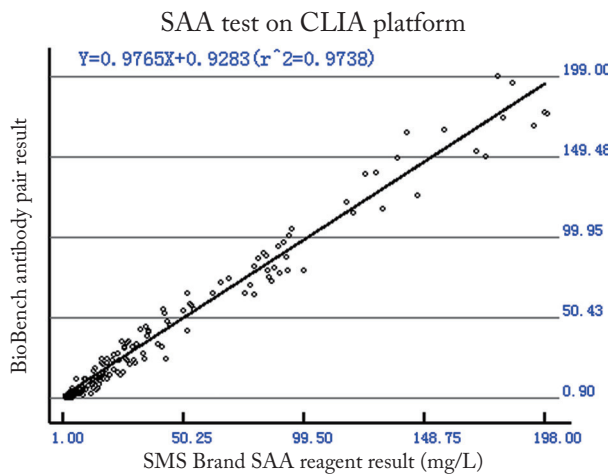
\*\* Adapted platforms were tested in-house by Bio Bench and only shown as advice. Different assay/method/platform/reagent may lead to different performance of the antibody and protein.

Clinical Sample Test and Result Comparison



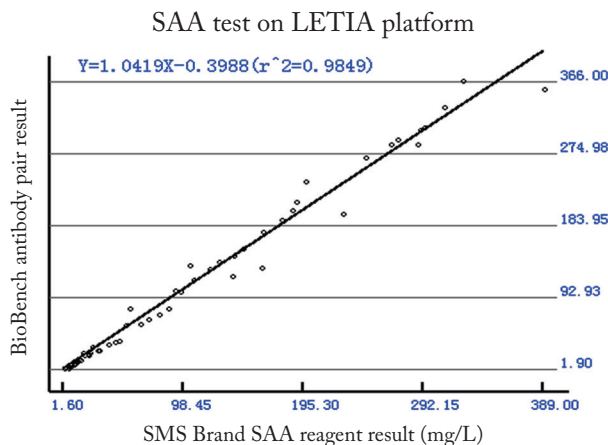
**Fig.3-1 Clinical sample test on POCT platform and result comparison with SMS Brand reagent**

Patient sample (n=61) were tested by BioBench antibody pair and SMS Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with SMS Brand reagent. BioBench antibody pair is clone 01-clone 08, we confirm that other antibody pairs show similar result.



**Fig.3-2 Clinical sample test on CLIA platform and result comparison with SMS Brand reagent**

Patient sample (n=129) were tested by BioBench antibody pair and SMS Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with SMS Brand reagent. BioBench antibody pair is clone 33-clone 31, we confirm that other antibody pairs show similar result.



**Fig.3-3 Clinical sample test on LETIA platform and result comparison with SMS Brand reagent**

Patient sample (n=68) were tested by BioBench antibody pair and SMS Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with SMS Brand reagent. BioBench antibody pair is clone 81-clone 82, we confirm that other antibody pairs show similar result.

**SAA Antibody and Protein Technical Specifications**

Antibody pair suggestion, performance and application suggestion

Tested Platform / Method	Coating Antibody	Detection Antibody	BioBench Comment on Test Result	LOD / Sensitivity	Antigen Linearity Range
POCT	Clone 01	Clone 08	***** Firstly recommended.	≤ 2 mg/L	2 – 200 mg/L
	Clone 08	Clone 01	**** Secondly recommended.	≤ 2 mg/L	2 – 200 mg/L
	Clone 01	Clone 02	**** Thirdly recommended.	≤ 2 mg/L	2 – 200 mg/L
	Clone 01	Clone 06	**** Fourthly recommended.	≤ 2 mg/L	2 – 200 mg/L
	Clone 02	Clone 01	*** Fifthly recommended.	≤ 2 mg/L	2 – 200 mg/L
CLIA	Clone 31	Clone 32	****	≤ 0.3 mg/L	1 – 200 mg/L
	Clone 32	Clone 31	*****	≤ 0.5 mg/L	1 – 300 mg/L
	Clone 33	Clone 31	*****	≤ 0.5 mg/L	1 – 400 mg/L
LETIA	Coating Ab: Clone 81 – Pairing Ab: Clone 82		****	≤ 1 mg/L	2 – 400 mg/L
	Coating Ab: Clone 81 – Pairing Ab: Clone 83		****	≤ 0.5 mg/L	1 – 300 mg/L
These results were tested in-house by BioBench with limited selection of assay/platform/method/instrument/reagents. Please test the performance in your lab to confirm the performance.					

Cross reactivity

Substance	HBsAb	HAV Ab	HCV Ab	HIV Ab	TP Ab	EB Ab	RF	ANA	CMV Ab	RV Ab	TOXO Ab	HSV Ab	HCG
Reaction	No	No	No	No	No	No	No	No	No	No	No	No	No

Interfering substance

Interfering substance	Bilirubin	Hemoglobin	Triglyceride
Concentration	200 µg/mL	10 mg/mL	20 mg/mL

# 04

## Human Ferritin Protein and Antibody

### Related Products

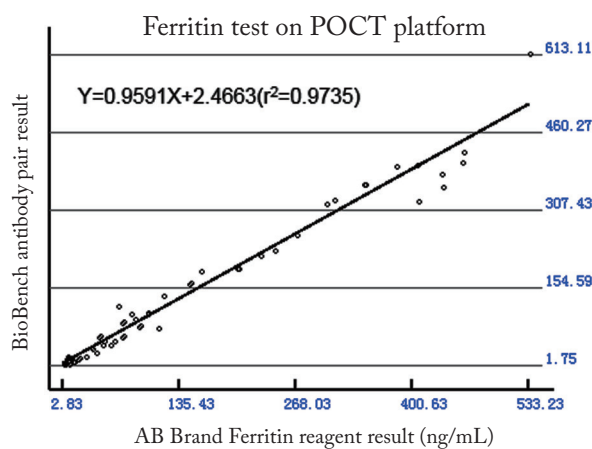
Product type	Product name	Catalog No.	Host	Antibody type	Clone number	Antibody pairing* / Protein usage	Advised IVD platform**
Protein/Antigen	Human Ferritin	CP0045	293T stable cell line expressed	\	N/A	Positive control, protein standard, reference substance	All
Monoclonal antibody	Anti Human Ferritin, Mouse mAb, 01	MAB0336	Mouse hybridoma	Monoclonal antibody, IgG1	01	Capture Ab: clone 01 - Detection Ab: clone 02 Capture Ab: clone 01 - Detection Ab: clone 04	POCT
Monoclonal antibody	Anti Human Ferritin, Mouse mAb, 02	MAB0337	Mouse hybridoma	Monoclonal antibody, Ig2a	02	Capture Ab: clone 01 Detection Ab: clone 02	
Monoclonal antibody	Anti Human Ferritin, Mouse mAb, 04	MAB0338	Mouse hybridoma	Monoclonal antibody, IgG1	04	Capture Ab: clone 01 Detection Ab: clone 04	
Monoclonal antibody	Anti Human Ferritin, Mouse mAb, 31	MAB0339	Mouse hybridoma	Monoclonal antibody, IgG1	31	Capture Ab: clone 31 Detection Ab: clone 32	CLIA
Monoclonal antibody	Anti Human Ferritin, Mouse mAb, 32	MAB0340	Mouse hybridoma	Monoclonal antibody, IgG1	32	Capture Ab: clone 31 Detection Ab: clone 32	

Note:

\* Please test the usage of antibody pairs according to your own assay/method/platform/reagent. The listed data were tested in-house by BioBench and only shown as advice.

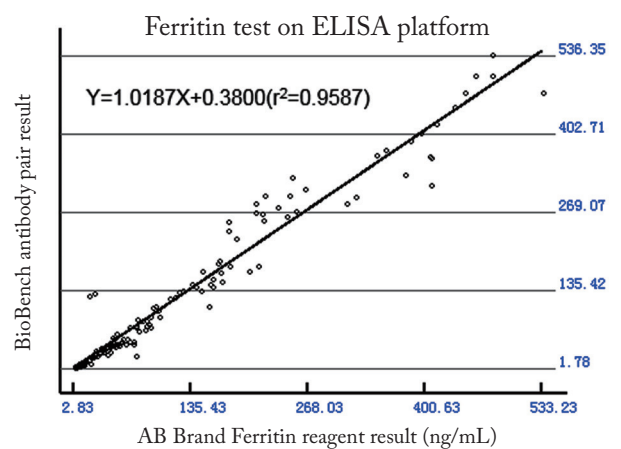
\*\* Adapted platforms were tested in-house by Bio Bench and only shown as advise. Different assay/method/platform/reagent may lead to different performance of the antibody and protein.

### Clinical Sample Test and Result Comparison



**Fig.4-1 Clinical sample test on POCT platform and result comparison with AB Brand reagent**

Patient sample (n=71) were tested by BioBench antibody pair and AB Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with AB Brand reagent. We confirm that all of the antibody pairs show similar result.



**Fig.4-2 Clinical sample test on ELISA platform and result comparison with AB Brand reagent**

Patient sample (n=144) were tested by BioBench antibody pair and AB Brand reagent. Data from both reagents were analyzed. Result reveals that BioBench antibody generate the same result compare with AB Brand reagent. We confirm that all of the antibody pairs show similar result.



## Ferritin Antibody and Protein Technical Specifications

Antibody pair suggestion, performance and application suggestion

Tested Platform / Method	Coating Antibody	Detection Antibody	BioBench Comment on Test Result	LOD / Sensitivity	Antigen Linearity Range
POCT	Clone 01	Clone 02	*****	≤ 2 ng/mL	5 – 500 ng/mL
	Clone 01	Clone 04	****	≤ 3 ng/L	5 – 500 ng/mL
CLIA	Clone 31	Clone 32	*****	≤ 0.2 ng/mL	1 – 1,000 ng/mL

These results were tested in-house by BioBench with limited selection of assay/platform/method/instrument/reagents. Please test the performance in your lab to confirm the performance.

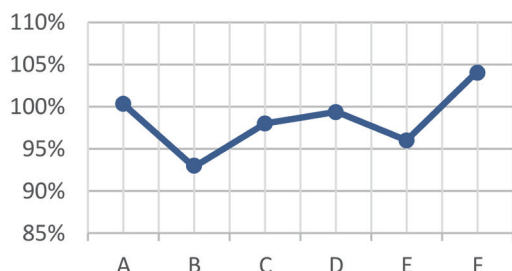
## Cross reactivity

Substance	HBsAb	HAV Ab	HCV Ab	HIV Ab	TP Ab	EB Ab	RF	ANA	CMV Ab	RV Ab	TOXO Ab	HSV Ab	HCG
Reaction	No	No	No	No	No	No	No	No	No	No	No	No	No

## Interfering substance

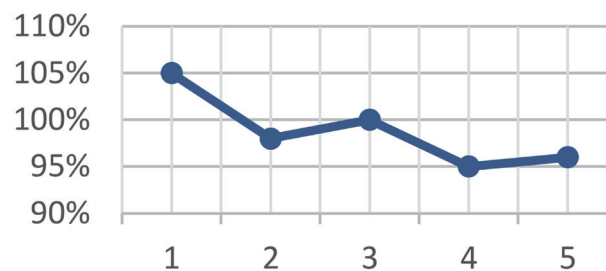
Interfering substance	Bilirubin	Hemoglobin	Triglyceride
Concentration	200 µg/mL	10 mg/mL	20 mg/mL

## Antibody thermal stability and freeze-thaw stability test



**Fig.4-3 Antibody thermo stability test 37°C**

6 different batches (A - F) of antibody were incubated in either 37°C or 4°C for 7 days then were tested their performance. The data of each sample from 4°C group was defined as 100%. Each data point is the activity of antibody from 37°C group, shown in percentage. Result shows that the antibody has good thermo stability.



**Fig.4-4 Antibody freeze-thaw stability test**

Antibody was either freeze-thawed for maximum 5 cycles or stayed at 4°C. The antibody performance was tested after each freeze-thaw cycle. The data of each sample from 4°C group was defined as 100%. Each data point is the activity of antibody from 37°C group, shown in percentage. Result shows that the antibody has good stability after even 5 times of freeze-thaw.

# 05

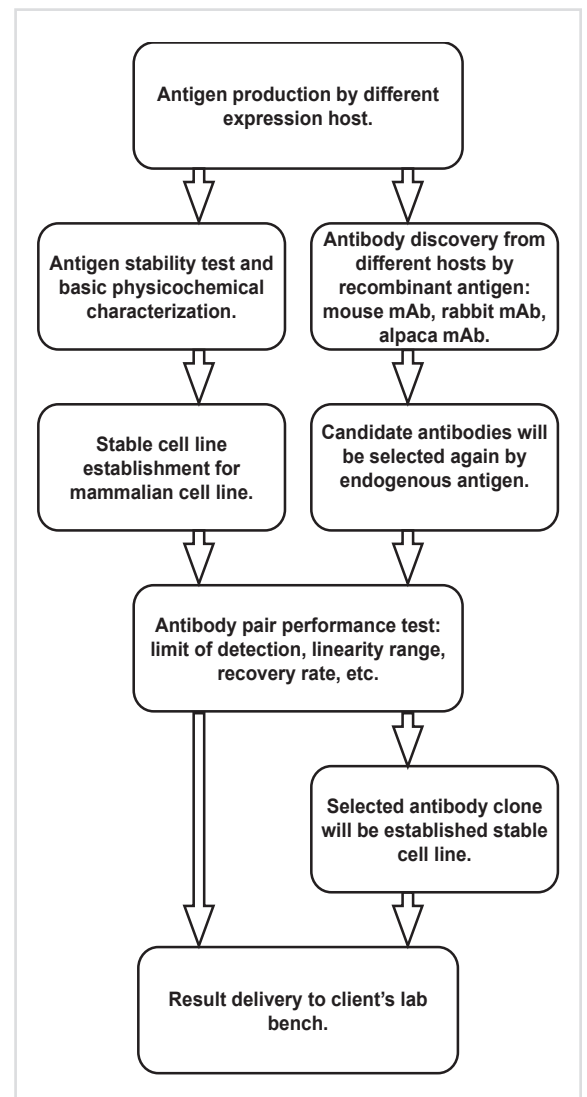
## IVD kit / Reagent Kit Material Development Service

Good antibodies or antibody pairs are playing the key role in the performance of immunological method-based IVD kits. Kits that use high quality antibody/antibody pair show better stability, better linearity, a wider detection range, and higher detection sensitivity. High quality proteins are used for animal immunization, clone selection, establishing the standard curve, as positive control in the kit and as QC standard.

The BioBench research team has rich experience in key material development. You only need to send us the antigen name and your expected application, and we will help you create the top antibody and protein.

We develop antibody/protein for the following IVD assays:

1. ELISA
2. Flow Cytometry
3. Latex particle-enhanced Turbidimetric Immunoassay (LETIA) as well as other types of POCT.
4. Lateral-Flow Immunochromatographic Assay (LFIA)
5. chemiluminescence immunoassay (CLIA)
5. Other types of immunological method based assay.



Typical work flow of IVD kit material development

## Service Content - IVD Kit Material Development

Service	Service Content	Client Provide	Deliverables	Lead Time
K142 IVD kit material development service	<ol style="list-style-type: none"> <li>1. Antigen expression by client selected cell line or bacteria strain.</li> <li>2. Antibody discovery through mouse hybridoma, rabbit monoclonal antibody (phage display technology), or screening from alpaca antibody library.</li> <li>3. Antibody pair analysis to find the best antibody pairs.</li> <li>4. Antibody pair performance test.</li> <li>5. Antibody and antigen stability test and basic physicochemical test.</li> </ol>	<ol style="list-style-type: none"> <li>1. Antigen sequence.</li> <li>2. Expected assay.</li> </ol>	<ol style="list-style-type: none"> <li>1. 5 – 30 positive clones, 100µg per clone.</li> <li>2. 1 – 5 antibody pairs, 100µg per clone.</li> <li>3. Purified antigen 1mg.</li> <li>4. Report.</li> </ol>	Start from 12 weeks, depends on exact operation.
<ol style="list-style-type: none"> <li>1. Please contact <a href="mailto:info@bio-bench.com">info@bio-bench.com</a> for your detailed requirements.</li> <li>2. Time line, exact service content and deliverables may vary due to different requirements.</li> </ol>				

