FIC-Q10 Testing procedure

Testing Procedure/ Standard Test (Single Test)

① Add sample ② Insert test cassette ③ Click "Standard Test" ④ Result printed automatically

Testing Procedure/ Quick Test (Batch Test)

① Add sample and countdown ② Insert test cassette after countdown complete ③ Click "Quick Test" ④ Result printed automatically

>100 Test per hour

3-18 min rapid detection

Multiple Markers
HBP, CRP, PCT, SAA, IL-6 ...

Treatment Plan
Provides data to set up a treatment plan

FIC-M6 Testing procedure

Testing Procedure/ Standard Test (Single Test)

① Add sample ② Insert test cassette ③ Click "Standard Test" ④ Result printed automatically

Testing Procedure/ Quick Test (Batch Test)

① Add sample and countdown ② Insert test cassette after countdown complete ③ Click "Quick Test" ④ Result printed automatically

HBP meets the 4 key criteria to be an ideal biomarker of sepsis[1,2]

① Biological plausibility

- Stored in neutrophils.
- Prefabricated (i.e. not produced after stimulation like PCT and IL-6).Secreted into the environment from secretory vesicles that are the first to undergo exocytosis.
- Inductor of vascular leakage and modulator of inflammatory responses of many cell types.
- Release induced by bacterial structures.
- UNLIKE PCT and IL-6, HBP is present at the site of infection.

② High sensitivity, specificity and positive and negative predictive values

- Sensitivity 87.1%
- Specificity 95.1%
- Positive predictive value 88.4%
- Negative predictive value 94.5%

HBP is superior to PCT, CRP, WBC, IL-6 and lactate.

③ Broad reproducibility outside the institution of development

HBP as a biomarker of sepsis and organ dysfunction has been validated by several independent research groups.

④ Validated in independent patient cohort(s)

In an international multicentre study from Sweden, the USA and Canada, HBP was the best marker in diagnosing and predicting organ dysfunction compared to PCT, CRP, WBC and lactate in diagnosing and predicting organ dysfunction compared to PCT, CRP, WBC and lactate.

HBP is a biomarker that is highly biologically plausible to be elevated early in response to infections and predictive of organ failure. During sepsis, HBP levels increase significantly and correlate with the development of hypotension and organ dysfunction. Early detection of HBP could be valuable for the diagnosis of severe sepsis, and modulating HBP could be a useful therapeutic target for bacterial infections[1].

Interpretation of Results

HBP level	Clinical significance	Recommendation
<11.4 ng/ml	The likelihood of the presence of a bacterial infection is extremely low, or in the early stages of a viral infection or a mild viral infection.	If clinical symptoms are present, it is recommended to recheck every 6-24 hours.
11.4-28.1 ng/ml	Suggests a possible bacterial infection and a low likelihood of organ dysfunction in the next 72 hours.	It is recommended to review every 6-24 hours.
28.1-103.5 ng/ml	Suggests the presence of bacterial infection and a high probability of hypotension, organ dysfunction, and sepsis in the next 72 hours. The *AUC for diagnosing sepsis was 0.893 when the cut-off value of HBP was > 28.1 ng/ml.*[3]	It is recommended to review every 6-24 hours. Calculation of 48-hour HBP clearance for prognostic assessment.
>103.5 ng/ml	Suggests severe infection with a high probability of organ dysfunction, sepsis, and septic shock. *The AUC for the diagnosis of septic shock is 0.760 when the cut-off value of HBP is > 103.5 ng/ml.*[3]	It is recommended to review every 6-24 hours. Calculation of 48-hour HBP clearance for prognostic assessment.

ORDERING INFORMATION:

PRODUCT	N° Tests	Code
Heparin Binding Protein Detection Kit	25	JS-FFHBP500C
Heparin Binding Protein Control Kit	Level 1: 1 x 1 ml	JS-FZHBP100AC
	Level 2: 1 x 1 ml	JS-FZHBP100BC
	Level 3: 1 x 1 ml	JS-FZHBP100CC
	Collective packing: Level 1: 1 x 1 ml Level 2: 1 x 1 ml Level 3: 1 x 1 ml	JS-FZHBP100DC

1. Fisher J, Linder A. ***Heparin-binding protein: a key player in the pathophysiology of organ dysfunction in sepsis.*** J Intern Med. 2017 Jun;281(6):562-574.
2. Wasson JH, Sox HC, Neff RK, Goldman L. ***Clinical prediction rules. Applications and methodological standards.*** N Engl J Med 1985; 313: 793-9.
3. Zhou Y, Liu z, Huang J, et al. ***Usefulness of the heparin-binding protein level to diagnose sepsis and septic shock according to Sepsis-3 compared with procalcitonin and C reactive protein: a prospective cohort study in China.*** BMJ Open,2079,9(4):e026527

CE IVD

AB ANALITICA ADVANCED BIOMEDICINE **AB ANALITICA srl** Via Svizzera, 16 - 35127 Padova ITALY | P.IVA 02375470289
Tel. +39 049 761689 | Fax. +39 049 8709510 | **www.abanalitica.com** | **customersupport@abanalitica.it**

HBP_Brochure_e20240322

HBP

Heparin Binding Protein

A NEW BIOMARKER FOR SEPSIS MANAGEMENT

Heparin Binding Protein, also known as CAP37 or azurocidin, is synthesized in neutrophils. Once released from activated neutrophils, it induces a rearrangement of the endothelial cell cytoskeleton, resulting in increased permeability of the endothelium. At the site of infection, HBP is responsible for the recruitment and activation of monocytes and other inflammatory mediators. It is also internalized by monocytes to prolong survival and enhance cytokine production. HBP therefore directly contributes to the maintenance and progression of inflammation[1].
The level of HBP in healthy people is extremely low, and once the body is infected, the pathogen rapidly stimulates neutrophils to release HBP with a half-life of only 1 hour.
The released HBP has three major effects: bactericidal, chemotactic, and vascular leakage inducing effects.

AB ANALITICA ADVANCED BIOMEDICINE

Test item

Assay	Full name	Clinical utility	TAT	Range	Sample Type	Package
Infections						
HBP *ref.* JS-FFHBP500C *	Heparin Binding Protein Detection Kit	Prediction of sepsis, organ dysfunction and blood pressure. Early diagnosis of sepsis. Prognostic evaluation of sepsis. Differential diagnosis of bacterial and viral meningitis. As the pathogenic factor of sepsis can be the drug target in sepsis management.	18min	5.9-300 ng/mL	Plasma (sodium citrate)	25Test/box
PCT *ref.* JS-FFPCTJ500C *	Procalcitonin Detection kit	Early identification of bacterial infection. Improves the accuracy of clinical diagnosis of bacterial infections and sepsis. Antibiotic medication management.	12min	0.1-100 ng/mL	Serum/Plasma /whole blood (EDTA,sodium citrate)	25Test/box
hsCRP+CRP *ref.* JS-FFCRP1300C *	Whole Course C-Reactive Protein Detection Kit	Differential diagnosis of bacterial and viral infection. Risk assessment of cardiovascular disease.	3min	0.5-200 mg/L	Serum/Plasma/Whole Blood (EDTA)	25Test/box
SAA *ref.* JS-FFSAA400C *	Serum amyloid A Detection Kit	Differential diagnosis of viral infection and bacterial infection.	5min	5.0 mg/L-200.0 mg/L	Serum/Plasma/Whole Blood (EDTA,sodium citrate)	25Test/box
IL-6 *ref.* JS-FFIL6400C *	Interleukin-6 Detection Kit	IL-6 is an inflammatory marker. The level of IL-6 rise is closely related to the active period of the disease, the development of the tumor, the degree of rejection, and the therapeutic effect. Therefore, the detection of IL-6 level in the patient's body fluid can reflect the patient's condition.	18min	3pg/mL-5000pg/mL	Serum/Plasma/Whole Blood (EDTA,sodium citrate)	25Test/box
Thrombosis						
D-Dimer *ref.* JS-FFDDMJ400C *	D-Dimer Detection Kit	Exclusion diagnosis of VTE (venous thromboembolism), including DVT (deep vein thrombosis) and PE (pulmonary embolism). Diagnosis of DIC (disseminated intravascular coagulation). Evaluation indicator of thrombolytic therapy.	12min	50-10000 ng/mL	Plasma/Whole Blood (sodium citrate)	25Test/box
Cardiovascular						
NT-proBNP *ref.* JS-FFNTB400C *	N-terminal prohormone of Brain Natriuretic Peptide Detection Kit	Heart failure marker, early differential diagnosis of cardiogenic and pulmonary dyspnea. Diagnosis and prognostic evaluation of heart failure	18min	30-35000 pg/mL	Plasma/Whole Blood (EDTA)	25Test/box
BNP *ref.* JS-FFBNPJ400 *	Brain Natriuretic Peptide Detection Kit	Heart failure markers, early differential diagnosis of cardiogenic and pulmonary dyspnea. Diagnosis and prognostic evaluation of heart failure	18min	5pg/mL-5000pg/mL	Plasma/Whole Blood (EDTA)	25Test/box
cTnI *ref.* JS-FFTNI400C *	Troponin I Detection Kit	One of the three indicators of myocardial infarction, can be used to diagnose AMI and risk stratification.	15min	0.05ng/mL-30.0ng/mL	Serum/Plasma/Whole Blood (EDTA)	25Test/box
MYO *ref.* JS-FFMYO400C	Myoglobin Detection Kit	One of the three indicators of myocardial infarction, can be used to diagnose AMI and exclude AMI early	14min	2.4ng/mL-400.0ng/mL	Serum/Plasma/Whole Blood (EDTA)	25Test/box
CK-MB *ref.* JS-FFCKMJ400C	Creatine kinase MB isoenzyme Detection Kit	One of the three indicators of myocardial infarction, can be used to diagnose AMI	15min	1.0ng/mL-80.0ng/mL	Serum/Plasma/Whole Blood (EDTA)	25Test/box
H-FABP *ref.* JS-FFHFA400C *	Heart-type fatty acid binding protein detection Kit	A high-sensitivity early marker of myocardial ischemia, earliest indicator after AMI, can be used to diagnose AMI	15min	1.0 ng/mL-120.0 ng/mL	Serum/Plasma/Whole Blood (EDTA)	25Test/box
Lp-PLA2 *ref.* JS-FFLPP100C *	Lipoprotein associated phospholipase A2 Detection Kit	Specific vascular inflammatory marker, a highly accurate independent risk factor for atherosclerotic plaque inflammation and thrombotic events	18min	5ng/mL-800ng/mL	Serum/Plasma/Whole Blood (EDTA)	25Test/box
Reproductive Health						
AMH *ref.* JS-FFAMH400C *	Anti-Müllerian Hormone Detection kit	An objective and accurate indicator of ovarian reserve function, independent of the menstrual cycle and hormonal contraceptives	15min	0.050ng/mL-25.000ng/mL	Serum/Plasma/Whole Blood (EDTA)	25Test/box
β-HCG *ref.* JS-FFhCG800C *	β-Human Chorionic Gonadotropin Detection Kit	Auxiliary diagnosis of early pregnancy. Auxiliary diagnosis of ectopic pregnancy. Auxiliary diagnosis of genital System Tumors.	15min	5-50000 mIU/mL	Serum/Plasma/Whole Blood (EDTA)	25Test/box
PROG *ref.* JS-FFProg100 *	Progesterone Detection Kit	It is mainly used to determine ovulation, progesterone treatment monitoring and early pregnancy status evaluation, and is of particular importance in judging the functional status of the corpus luteum.	10min	0.37-40 ng/mL	Serum/Plasma/Whole Blood (EDTA)	25Test/box
Kidney disease						
NGAL *ref.* JS-FFNGAL800C*	Neutrophil gelatinase-associated lipocalin assay kit	Optimal marker for early diagnosis of AKI (acute kidney injury), CIN (contrast induced nephropathy) and DN (diabetic nephropathy). Independent risk indicator to evaluate the progression of CKD (chronic kidney disease).	15min	50-5000 ng/mL	Plasma/Whole Blood (EDTA)/ Urine	25Test/box
β2-MG *ref.* JS-FFB2M400C *	β2-Microglobulin Detection Kit	Sensitive indicator of glomerular and tubular lesions that can be used to monitor proximal tubular function and assess tubular damage.	10min	Plasma/serum: 0.40mg/L-20.00mg/L Urine: 0.15mg/L-8.00mg/L	Serum/Plasma(EDTA)/Urine	25Test/box
MAU *ref.* JS-FFMAU400C *	Microalbumin Detection Kit	A marker of kidney damage, as well as a marker of systemic vascular endothelial cell damage	10min	5mg/L-300mg/L	Urine	25Test/box
Gastrointestinal function						
PGI /PG II *ref.* JS-FFPGD200 *	Pepsinogen I / Pepsinogen II Detection Kit	It can be used for the auxiliary diagnosis of gastric function disease. Early screening for stomach cancer.	10min	PGI: 3.0ng/mL-200.0ng/mL PGII:1.5ng/mL-100.0ng/mL	Serum/Plasma/Whole Blood (EDTA)	25Test/box

* Control kit available

FIC-Q100

(Jet-iStar 800)

ref. 08-1030047

IVDR certified

Ideally suited to small to mid-sized medical institutions with results in as little as 3 minutes.

Single channel immunofluorescence analyzer

Features

1. **Multiple methodology**
   Classic immunofluorescence, fluorescence microparticles.
2. **Multiple product offerings including**
   infection markers, cardiac markers, women reproductive health markers, kidney disease markers, gastrointestinal markers .
3. **Multiple sample types**
   whole blood (venous blood and fingertip blood), serum, plasma, urine and cerebrospinal fluid.
4. **Simple testing procedure**
   Standard Testing mode or Quick Test mode with a read time of only ten seconds.
5. **Simple Calibration**
   Internal calibration curve read by scanning QR code of each test.
6. **Operation mode**
   7" LCD touchscreen, extensive on board data storage (as many as 50K test results) or transfer to external hard devices. Built-in thermal printer.
7. **Extensive field applications including**
   ER, outpatient settings, hospital laboratory, clinical departments, primary healthcare, clinics, pharmacies etc.
8. **Instrument size and weight**
   280 (L) x 245 (W) x 130 (H) mm - 2 Kg

FIC-M6

(Jet-iStar 800 Plus)

ref. 08-1030055

IVDR certified

Ideally suited to small to mid-sized medical institutions with results in as little as 3 minutes.

Multichannel immunofluorescence analyzer

Features

1. **Multiple methodology**
   Classic immunofluorescence, fluorescence microparticles.
2. **Multiple product offerings including**
   infection markers, cardiac markers, women reproductive health markers, kidney disease markers, gastrointestinal markers .
3. **Multiple sample types**
   whole blood (venous blood and fingertip blood), serum, plasma, urine and cerebrospinal fluid.
4. **Easy operation**
   6 samples tested at the same time, detection time < 20s, detection speed > 120 T/H
5. **Simple Calibration**
   Internal calibration curve read by scanning QR code of each test.
6. **Operation mode**
   7" LCD touchscreen, extensive on board data storage (as many as 50K test results) or transfer to external hard devices. Built-in thermal printer.
7. **Extensive field applications including**
   ER, outpatient settings, hospital laboratory, clinical departments, primary healthcare, clinics, pharmacies etc.
8. **Instrument size**
   320 (L) x 315 (W) x 300 (H) mm - < 7,5 Kg