



上海伯豪生物技术有限公司  
SHANGHAI BIOTECHNOLOGY CORPORATION

# Multiple Solutions for Genomics and Pharmacogenomics

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# SBC, one of the most systematic high-throughput -omics service providers in China



## **Shanghai Biochip Co., Ltd. / National Engineering Center for Biochip at Shanghai :**

- Established in 2001 with \$45 million seed fund, a leading biotech company located in the heart area of Zhangjiang Bio/Pharma valley; With 10 acres land, 300+ full time employee, 7 buildings with 220K SQF (20k m<sup>2</sup>) lab space with GMP, GCP and GLP compliance facilities.

## **Shanghai Biotechnology Corporation :**

- Established in 2008, formerly known as “ShanghaiBio Corporation (SBC) in China”. Effective July 1, 2011, its name was officially changed to be “Shanghai Biotechnology Corporation (SBC)”.
- As a CRO subsidiary of Shanghai Biochip Co., Ltd. /National Engineering Center for Biochip at Shanghai, Shanghai Biotechnology Corporation provides lab services with cutting-edge -omics technologies, partnering in genomics/ pharmacogenomics, and discovering biomarker for preclinical to clinical with leading global pharmaceuticals and biotech.
- The clinic testing laboratory at SBC is a certified clinical PCR testing lab and provides services for molecular diagnostics, target therapy, predictive medicine and companion diagnostics.



# Company Background



## Shanghai Biochip Co. Ltd



### Shareholders:

- Shanghai Venture Capital Co. Ltd.
- Shanghai Institutes of Biological Sciences (SIBS), Chinese Academics of Sciences (CAS)
- National Human Genomics Center at Shanghai
- Fudan University
- Jiaotong University
- Institute of Microsystems and Information Technology, CAS
- Rujin Hospital
- East Hepatobiliary Surgery Hospital
- BioStar Biochip Co., Ltd.
- Zhangjiang High-Tech Park Co., Ltd.



# Our Vision



*Deliver the highest quality, cost effective R&D solutions and clinical lab testing services to accelerate drug discovery efforts of global pharmaceutical, biotech and CRO companies with integrity and excellence.*



# SBC Facilities





- **Microarray Platforms** : SBC, Affymetrix, Agilent and Illumina
- **Next Generation Sequencing Platforms:** Illumina HiSeq 2000/2500 and GAIIx, ABI Ion Torrent, Ion Proton, PacBio, SOLiD4 and 5500, and Roche 454
- **Biomarkers Testing and Validation Platforms:** RT-qPCR, bDNA, sanger sequencing, luminex, protein microarray and ELISA etc.
- **Molecular Pathology Platforms:** FISH, IHC, tissue microarray
- **Sample Quality Control Platforms:** Agilent bioanalyzer, gel imaging and nanodrop
- **Bioinformatics/Biostatistics Platforms:** SBC Analysis System (SAS) and commercial software



# SBC Services and Capability



- **Microarray Analysis**
- **Next Generation Sequencing**
- **Biomarker Testing and Validation**
- **Molecular Pathology and Clinical Lab Testing**
- **Bioinformatics/ Biostatistics Analysis**

**Integrated Genomics and Pharmacogenomics Capabilities for  
Biomarker Discovery and Translational Medicine**



# Microarray Analysis Capability



- **Whole Genome SNP Genotyping**
  - Illumina Omni Whole-Genome Arrays
  - Affymetrix Genome-Wide Human SNP 6.0 Array
  - Affymetrix OncoScan™ FFPE Assay
- **Whole Genome Expression Array**
  - Affymetrix Human genome U133 Plus 2.0 array
  - Affymetrix Human Transcriptome Array (HTA) 2.0
  - Affymetrix GeneChip PrimeView Human Gene Expression Array
  - Affymetrix Human Gene 2.0 ST Array
  - Agilent Whole Human Genome Oligo Microarray
  - Agilent SurePrint G3 Human Gene Expression Microarray 8x60K
  - Illumina Whole-Genome DASL Ht-12 Assay-FFPE
- **miRNA Detection/Expression Microarray**
  - Agilent miRNA Microarray (human, mouse, rat), V19.0
  - Affymetrix miRNA 4.0 Array (human, mouse, rat)
- **ADME/DMET Array**
  - Affymetrix DMET™ Plus Premier Pack
  - Illumina VeraCode ADME Core Panel





- **Genome sequencing:**
  - Whole genome sequencing
  - Whole exome sequencing
  - Target gene capture sequencing
  - Disease panel gene sequencing
- **Transcriptome sequencing:**
  - RNA sequencing (with or without reference genome)
  - miRNA sequencing
- **Epigenome sequencing:**
  - ChIP sequencing
  - MeDIP sequencing

# Biomarkers Testing and Validation Capability



- RT-qPCR and genotyping using ABI 7900, ABI 7500, ABI 3730 xl and Roche COBAS
- Multiplex gene expression (bDNA ) assays using Panomics technology
- Sanger Sequencing on ABI 3730 xl
- FISH using Abbott ThermoBrite
- Protein biomarker assays using Luminex and ELISA
- Protein Microarray
- SiRNA screening for biomarker pathway validations



# Clinical Molecular Testing Capability



- Early diagnostics
- Molecular tests for target disease therapy
- Companion diagnostics
- Biomarker discovery and validation including but not limited to:  
ALK, BCR/ABL1, BRAF, BRCA1, CYP2D6, CYP2C9,  
CYP2C19, del (5q), DPYD, EGFR, ERBB2, ESR1, PGR, ESR1,  
FIP1L1/PDGFR, Her2, HLA-B, IFNL3, KIT, KRAS, Ph  
Chromosome, PI3K-AKT, PML/RARA, PTEN, TPMT,  
SERPINC1, UGT1A1, NAT1-2, VKORC1



# Bioinformatics Analysis Capability

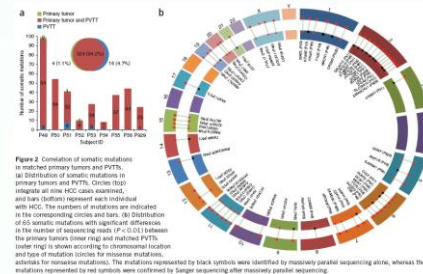
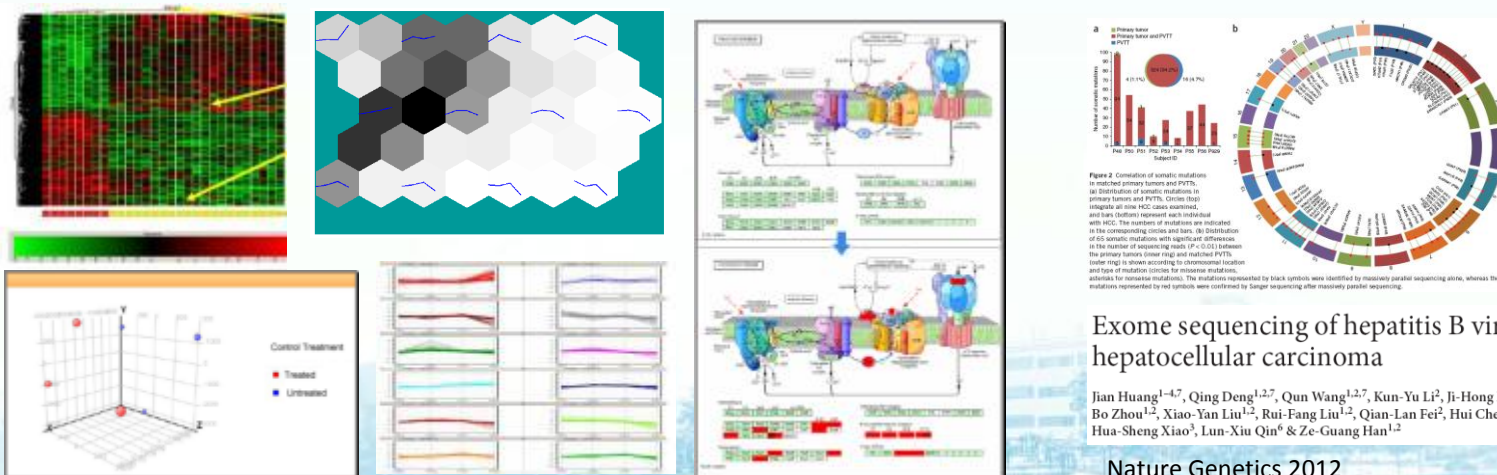


## Microarray data analysis

- Online SBC Analysis System (SAS)
- Gene expression microarray data analysis
- miRNA microarray data analysis
- lncRNA microarray data analysis
- Methylation microarray data analysis
- SNP microarray data analysis
- aCGH microarray data analysis

## NGS data analysis

- Whole exome seq data analysis
- RNAseq data analysis with reference genome
- RNAseq data analysis without reference genome
- miRNA seq data analysis
- Methylation seq data analysis



## Exome sequencing of hepatitis B virus-associated hepatocellular carcinoma

Jian Huang<sup>1-4,7</sup>, Qing Deng<sup>1,2,7</sup>, Qun Wang<sup>1,2,7</sup>, Kun-Yu Li<sup>2</sup>, Ji-Hong Dai<sup>2</sup>, Niu Li<sup>1,2</sup>, Zhi-Dong Zhu<sup>3</sup>, Bo Zhou<sup>1,2</sup>, Xiao-Yan Liu<sup>1,2</sup>, Rui-Fang Liu<sup>1,2</sup>, Qian-Lan Fei<sup>2</sup>, Hui Chen<sup>2</sup>, Bing Cai<sup>2</sup>, Boping Zhou<sup>4</sup>, Hua-Sheng Xiao<sup>5</sup>, Lun-Xiu Qin<sup>6</sup> & Ze-Guang Han<sup>1,2</sup>

Nature Genetics 2012

# Distinguishing features of the biotechnical services at SBC



## Integrated and high-throughput: Genomics-Transcriptomics-Epigenomics-Proteomics

**Flexibility:** multiple platforms, species, formats and forms

**Multiple platforms :** Affymetrix, Agilent, Illumina, Life Technologies, Roche, SBC .....

**A variety of Technologies :** NGS, Microarray, qPCR, FISH, IHC.....

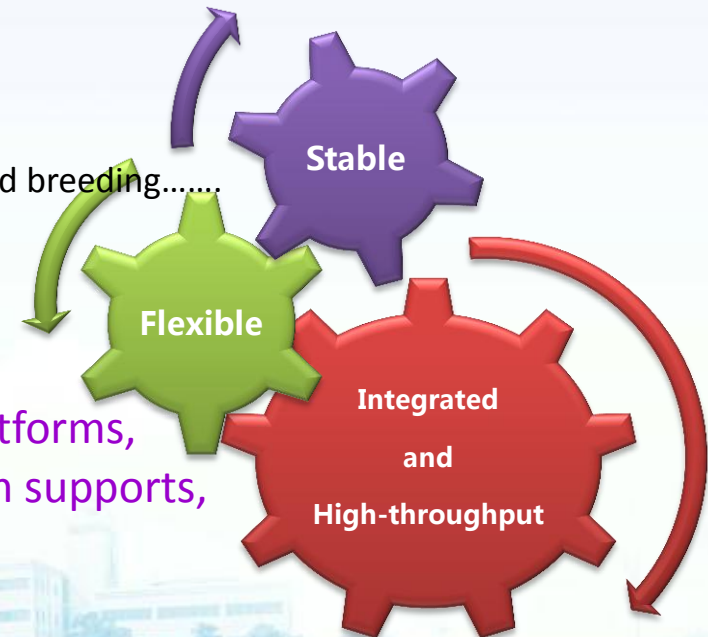
**A variety of species :** Animals, plants , Microorganisms.....

**A variety of applications:** Human diseases , animal and plant diseases and breeding.....

**A variety of formats :** 1× , 2× , 4× , 8× , 12× .....

**A variety of forms :** Commercial products + custom products

**Stability:** More than 10 years established technology platforms, engaged technical services with well trained staff, custom supports, marketing/sales network and QA systems.



Since 2004, SBC and its clients have published >500 papers with total impact factor >2000

# IT Support



**Hardware - high performance computing system + high speed network + efficient data storage**

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- Data mining, storage, backup, and transfer under secured controls
- Part 11 like compliance



**IT Center** in SBC



**Data Backup Facility**

China Telecom in WuXi, (Jiangsu)







- Origin of samples – inside and outside China
- Sample import, green channel permit logistics
- Samples are shipped at customer specified temperatures
- All outside China sample shipments – World Courier
- Anonymization or de-identification of samples
- Well established sample handling protocols in the laboratories
- Specific freezer operation and maintenance
- Documentation of storage and withdrawal
- Sample destruction logistics

# Quality Assurance System in SBC



- ❖ **Strict quality standards:** we monitor sample management, project processes and lab tests strictly following 128 SOPs.
- ❖ **Complete experimental records:** ensure all the records available for backtracking.
- ❖ **Multiple quality controls (3-step QC):** QC on lab test, data analysis and project management, to ensure high quality data.

## SBC Quality Assurance System and Certificates



# Certificates and Accreditations (selected)



- Certificate of ISO 9001:2008
- Business License
- Clinical lab License
- Certified Clinical PCR Testing Lab
- Trade License
- Custom Import and Export Business Certificate
- Custom Clearance Certificate
- Certificate of High-tech Enterprises
- Certificated Key Service Outsourcing Enterprises in Shanghai
- Certificate of Shanghai Pathogenic Microbiology Laboratory
- Certificate of Pilot Company in the Inspection and Quarantine Reform Program
- Certificate of Affymetrix DMIT Array Accuracy Training
- Applied Biosystems SOLiD Demo lab
- Certificated GeneChip Services Provider by Agilent
- Certificated GeneChip Services Provider by Affymetrix
- Certified Service Provider (CSPPro) by Illuminas
- Supplier Award by Novartis 2012
- Award of Excellence/Agilent Best Certified Service Provider in Genomics
- Award of Affymetrix Service Provider of Excellence
- Award of Excellence/Agilent Best Distributor for Certified Service Products



# Quality Control on Experiment



## Strict quality standards:

Perform lab tests strictly following 128 Chinese-English bilingual SOPs.

- ▶ SOP (ADM)
- ▶ SOP (LAB)
- ▶ SOP (IT)
- ▶ Record of Documentation Development/Revision
- ▶ Record of Document Review
- ▶ Record of Deviation Report
- ▶ Record of Laboratory Incident Report
- ▶ Records of ADM Document
- ▶ Record of Equipment Calibration
- ▶ SOP Reading Training Record
- ▶ SOP Distribution and Return Record
- ▶ Internal Audit Document
- ▶ QA Audit Report
- ▶ Corrective Action Plan
- ▶ Customer Complaints Form



## Selected Administration SOPs

- S0001 Quality Objective
- S0002 Quality Assurance
- S0003 Document Control
- S0004 Format and Guidelines for Standard Operating Procedures
- S0005 Document Control Numbering
- S0006 QA Auditing Procedures
- S0007 Security Assurance
- S0008 Staff Training Management
- S0009 QA Management Archival Process and Security
- S0010 Records Management
- S0011 Deviation Management
- S0012 Laboratory Incidents Reports
- S0013 Preparation for Quality Assurance Audits and Responding to Audit Reports
- S0014 Supplier Assessment and Management
- S0015 Management of Customer Complaints
- S0016 Proficiency Testing
- S1017 Business Continuity/Recovery Plan
- S0018 Outsourcing Project Management
- S0019 Handling of Fraud
- S0021 Customer Satisfaction Survey
- S0024 Quality Assurance and Performance Improvement
- S1044 Procedures for Sample Receiving, Storage, Delivery and Destroy

## Complete experimental records:

Ensure all the records available for backtracking.

## Multiple quality controls (3-step QC):

QC on lab test, data analysis and project management, to ensure high quality data deliverable to clients

# Data Management and Report



- Data backup in our secured servers
- Data management following Part11 guidelines
- Data upload through our secured FTP or sponsors secured FTP
- External hard disks/DVDs/CDs locked with pass code
- Email for small size data files with pass code
- Our IT system strictly protect data and ensure analysis, storage, backup and transportation safety



**Project summary report (hard copy)**



**Test report ( e-copy )**

**Data and test report**



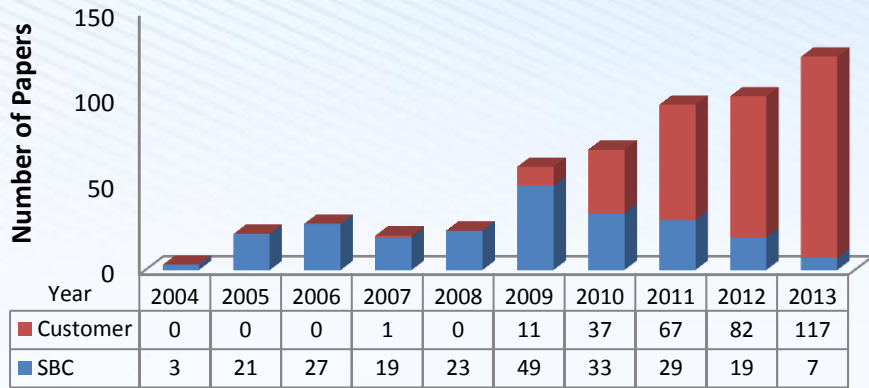
**upload to secured FTP**

following SOPs to ensure account and data safety

# Publications

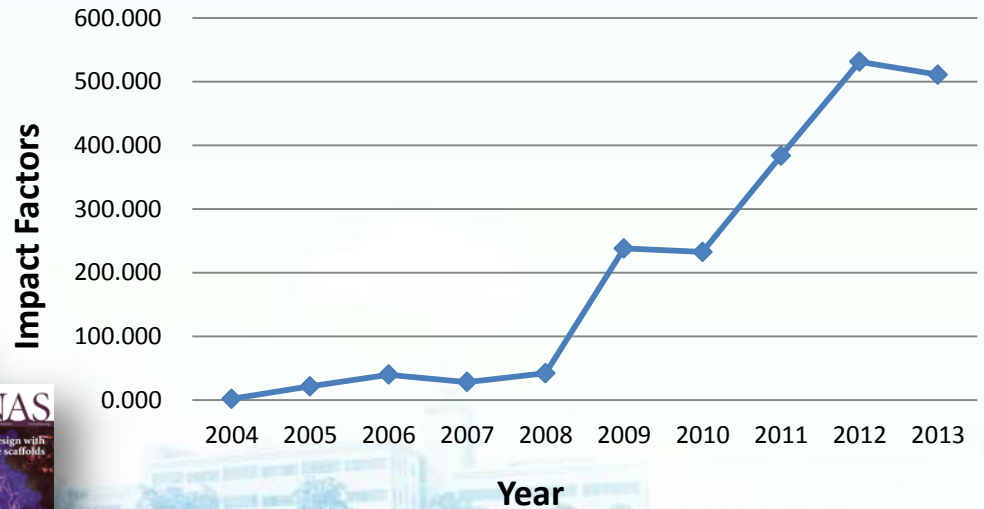


Number of Papers (2004-2013)



Since 2004, SBC and its clients have published more than 500 papers with total impact factor >2000

Impact Factors of Papers (2004-2013)





# Case Study (1)



- **Consortium Project Collaborating with ACRG (Asian Cancer Research Group) members (Pfizer, Merck and Lilly)**
  - **SBC's responsibilities:**
    - Inviting and coordinating three pharmas to plan the ACRG project since 2008
    - Writing SOPs for sample collections, clinical info and follow-up data collections, and all analysis platforms
    - Microarray analysis using Affymetrix U133 plus 2.0, SNP 6.0 for 2000 samples from lung and gastric Asian cancer patients with full clinical info and follow-up data
    - TMA constructions and biomarker assays (IHC, etc) for selected target genes



# Case Study (2)



- **Integrated sample collections, Omics , and biomarker analysis for top large pharmas' biomarker discovery projects**
  - **SBC's responsibilities:**
    - Custom sample collections from hospitals or search matched samples from our tissue bank
    - Generate Omics data using combined array platforms of gene expression, SNP, microRNA, DNA methylation, etc
    - Generate Next-Gen sequencing and data analysis
    - qPCR/genotyping/mutation sequencing for selected target genes
    - Protein biomarker analysis using Luminex for selected Cytokine analytes
    - Make TMAs and IHC/FISH for selected biomarkers
    - Submit raw data and QC report to sponsors
    - Advanced data analysis for sponsors if needed

# Case Study (3)



- **Real-time clinical biomarker service, screen patients for global Phase III clinical trial in China**

- **SBC's responsibilities:**

- Collect FFPE samples from multi-centers of hospitals in China
- Train pathologists in multi-centers to prepare blocks and FFPEs following the SOPs
- Conduct validation project, results are consistent with other global testing centers
- Receive FFPE blocks or slides from multi-centers in China and log into LIMS (Day 1)
- Macrodissection tumor samples from FFPE slides (Day 1-2)
- RNA extractions for samples from FFPE and QC/QA (Day 3)
- RT-PCR (Day 4)
- RT-PCR data report to sponsor's database for Sponsor to make therapy decision (Day 5)





# Why SBC?



- Well-known CRO service provider in China and great facility in the heart area of Zhangjiang Pharma Valley in Shanghai
- More than 10 years experience in preclinical and clinical testing for domestic and global customers
- Integrated Microarray/PGx/NGS/Biomarker analysis platforms
- GLP/GCP Central lab capability for clinical sample testing, biobanking and clinical trial sample storage
- Comprehensive quality assurance system and QC procedures
- Data management following Part11 guidelines
- Green channel for sample import logistics
- high quality output, low service cost and short turnaround time
- Strong support from shareholders of top academic institutes and hospitals in China for extended capabilities



# Client Locations



The services and data quality from SBC's technical platforms have been widely recognized by domestic researchers and international Pharmaceutical companies.



# Contact SBC



## Shanghai Biotechnology Corporation (SBC)

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**Thanks for your support!**



**We are looking forward to a successful  
collaboration with you.**

