Multiple Solutions for Genomics and Pharmacogenomics

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Shanghai Biotechnology Corporation (SBC)

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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 m²) 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 Platforms

• 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
• 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
Next Generation Sequencing Analysis Capability

• **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/PDGFRα, 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
- IncRNA 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 Huang1,2, Qiong Dong1,2, Qun Wang1,2, Keen-Yu Li2, Ji-Hong Dai2, Niu Li1,2, Zhi-Dong Zhao3, Bo Zhou4, Xiao-Yan Liu1,2, Rui-Fang Liu1,2, Qun-Lan Fei5, Rui Chen1, Bing Cai2, Boping Zhou2, Hua-Sheng Xiao6, Lin-Xia Qin6 & Ze-Guang Han1,2
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

- 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)
Sample Logistics

• 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.
Certificates and Accreditations
(selected)

- 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 (CSPro) 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
Strict quality standards:
Perform lab tests strictly following 128 Chinese-English bilingual SOPs.

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

Data and test report upload to secured FTP following SOPs to ensure account and data safety
Since 2004, SBC and its clients have published more than 500 papers with total impact factor >2000.
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
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)
    • Macrodisection 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
The services and data quality from SBC’s technical platforms have been widely recognized by domestic researchers and international Pharmaceutical companies.
Contact SBC

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Thanks for your support!

We are looking forward to a successful collaboration with you.