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# ABOUT AIVD

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## Company Profile

Shenzhen Aivd Biotechnology Co., LTD., ISO 13485 and ISO 9001 certified, is a China high-tech enterprise specialized in supplying one-stop service such as raw material development, reagent development, system establishment, auxiliary registration, production team building for medical institutions, ICL and IVD companies.

AIVD owns a professional R&D team, quality system and registration team, as well as a well-equipped diagnostic raw material R&D center, diagnostic reagent R&D center, production center and quality center, can provide one-stop professional service for our customers, help our customers to quickly produce products, shorten the product launch cycle, and rapidly obtain the investment return.



## Laboratory Overview

01

Laboratory Overview

02

In Vitro Diagnostic Raw Materials Production Workshop

03

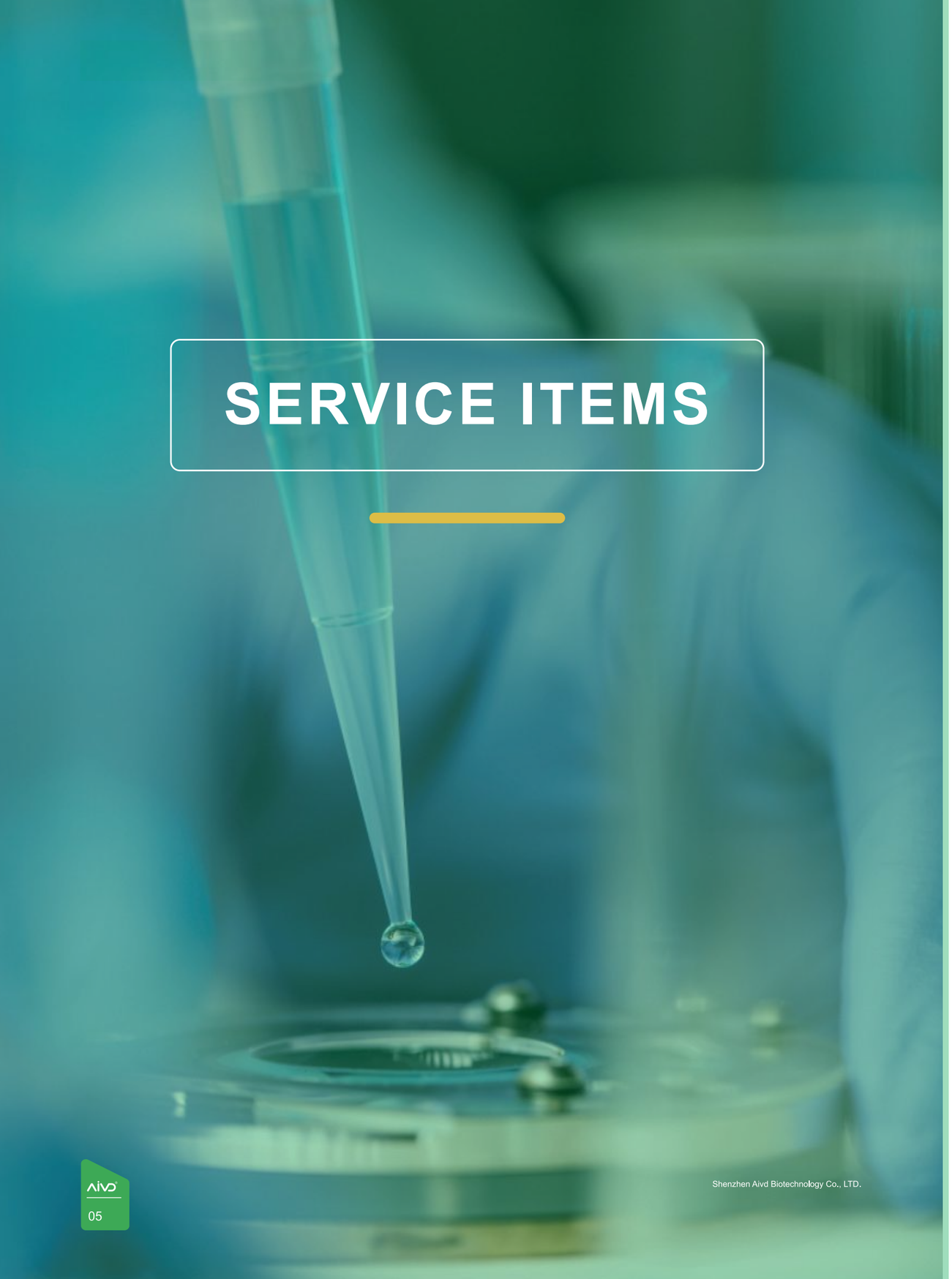
In Vitro Diagnostic Test Kits R&D Lab

04

In Vitro Diagnostic Test Kits GMP Workshop

## Company Advantages

- 2000 m² Standard GMP Workshop
- 3000 m² R&D lab, complete biochemical and immuno-molecular diagnostic product lines
- Professional R&D Team Led by 5 PhDs Senior Industry Experts
- Professional Registration Team Years of Experience in Registration Inspection
- ISO 9001 ISO 13485 Perfect Quality Management System ISO 9001 ISO 13485
- Class II, Class III In Vitro Diagnostic Reagents Production License



# SERVICE ITEMS





## SERVICE ITEMS

### 1.Services List

#### (1) Project Review

**Patent Review**

- Patent Review
- Clinical Review
- Technical Review
- Regulatory Review
- Market Review

#### (2) Custom Development of Proteins - Multiple active protein development platforms and technologies to meet the needs of different diagnostic reagents for core raw materials

**Recombinant Antigen R&D Platform**

- a. E.coli Expression Platform
- b. Pichia Pastoris/Saccharomyces Cerevisiae Expression
- c. Insect Baculovirus Expression
- d. Mammalian Cell Expression

**Antibody R&D and Preparation Platform**

- a. Conventional Antibody Production
- b. Nanobody Production
- c. Phage & Yeast Display Technology
- d. Antibody Affinity Maturation

#### (3) Custom Development of Test Kits - 8 Reagent Development Platforms

**Custom Developable Test Kits Platforms**

- a. Colloidal gold chromatography platform
- b. Fluorescence chromatography platform
- c. Chemiluminescence platform
- d. Enzyme immunoassay platform
- e. Specific protein platform
- f. Biochemical platform
- g. qPCR platform
- h. Thermostatic amplification platform

**Technical Training**

- a. Production training
- b. Process training
- c. Management system training
- d. Workshop design consultation

## (4) Production Verification

### Production Verification

- a. Sample, small batch production
- b. Performance testing and validation
- c. Intermediate test
- d. Stability assessment
- e. Process optimization

## (5) Global Quality Management System

### Global Quality Management System

- GMP YY/T0287
- QSR820
- ISO13485
- MDSAP
- CAPA

### Service content

- a. Relevant laws and regulations collection and application counseling services
- b. Quality management system establishment training services
- c. Infrastructure, working environment and equipment configuration coaching services
- d. Personnel requirements training services
- e. Quality management system document preparation coaching services
- f. Quality management system operation diagnosis and counseling services
- g. Registered quality management system verification simulation and rectification counseling services, etc.

## (6) Global Registration

### Global Registration

- NMPA
- FDA
- CE
- MHLW

### Service content

- a. Classification definition application
- b. Innovative product application
- c. Registration scheme design
- d. Technical requirements preparation
- e. Product testing agent
- f. Research data preparation
- g. Format document arrangement
- h. Technical review communication



## (7) Clinical Trials

### Clinical Trials

- a. Clinical protocol design
- b. Ethical data preparation
- c. Experimental data management
- d. Medical report preparation
- e. Clinical evaluation/monitoring

## (8) Supply Chain Management and Mass Production

### Supply Chain Management and Mass Production

- a. Global sourcing
- b. Supplier recommendation
- c. Diagnostic raw materials production
- d. Diagnostic test kits production
- e. OEM production
- f. Scale up production
- g. Warehouse management
- h. Cold chain distribution

## (9) Circulation Sales

### Circulation Sales

- a. Global sales
- b. Matching distributor resources
- c. Auxiliary marketing
- d. After-sales technical support

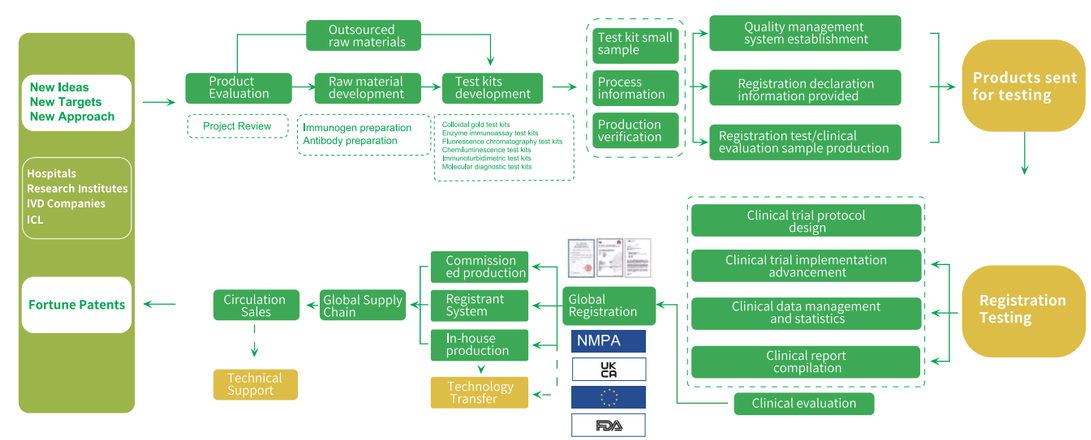
## (10) Registrant System

**Raw material development→test kit development→technology transfer→registration declaration→commissioned production**

- Time to obtain registration certificate reduced > 1 year
- Cost investment reduced by 50%
- Technical support by professional staff
- Antigen development cycle 1-2 months
- Antibody development cycle 4-6 months
- IVD test kit development cycle 3-4 months

## 2. CDMO Service Process

### CDMO Service Flow Chart



## 3. Core Business

Custom development of proteins → Custom development of test kits → Medical device registration → Registrant system

### Custom development of proteins

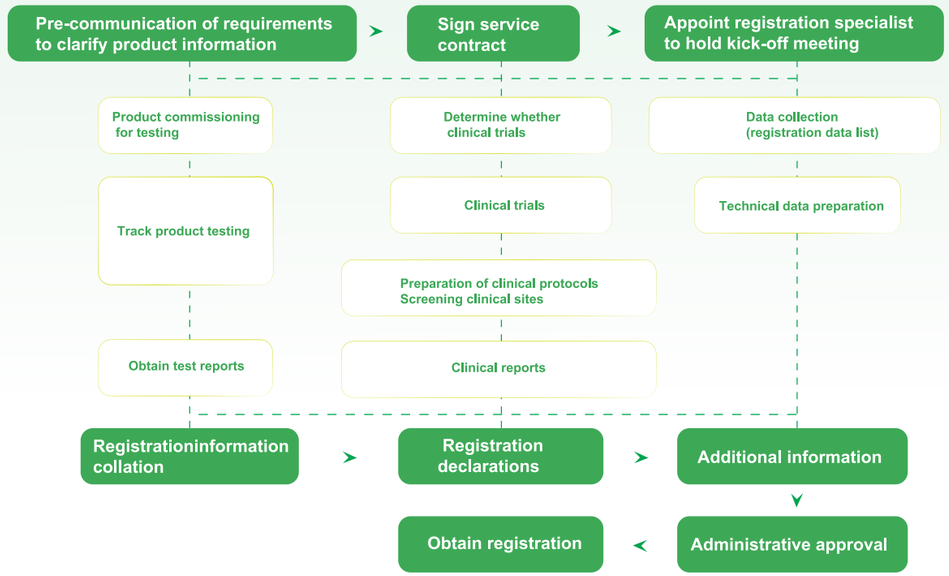
| Development Process | Experiment Schedule | Cycle Time | Experiment Content |
|---|---|---|---|
| 1.Immunogen preparation | Preparation of immunogens | 4-5 weeks | Gene synthesis and expression purification |
| 2.Antibody preparation | Phase I: Immunization | 6-8 weeks | Protein immunity or DNA immunity, cellular immunity |
| | Phase Ⅱ: Cell fusion and screening | 3-4 weeks | Electrofusion, ELISA screening and retesting |
| | Phase Ⅲ: Subclonal screening and performance validation | 6-8 weeks | Subclone screening, performance verification |
| | Phase Ⅳ: Delivery of recombinant antibodies | 3-4 weeks | Hybridoma sequencing, paired antibody preparation, 3-5 mg each |

### Custom development of test kits

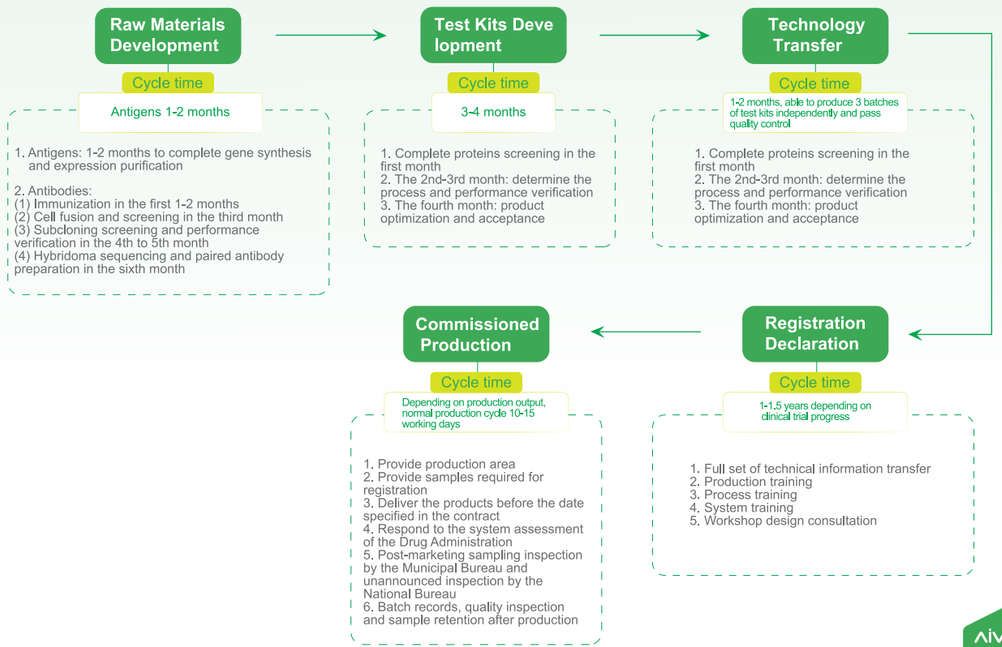
| Development Process | Cycle Time | Experiment Content |
|---|---|---|
| Primary sieving of raw materials | 1-2 weeks | Preliminary screening of raw materials |
| Process and reaction System optimization | 6-8 weeks | Determination of encapsulation concentration, determination of encapsulation system, optimization and determination of labeling conditions, and determination of treatment solution formulation, determination of reaction system (determination of dilution ratio, determination of reaction time, determination of screening and adaptation of consumables, etc. |
| Small sample validation | 1 week | Verification of the performance of small samples |
| Intermediate test Thermal stability assessment | 1 week | Produce 3 batches of intermediate tests and conduct thermal stability assessment |
| Sample acceptance and optimization | 3-4 weeks | Sending samples to customers, acceptance,reagent optimization according to customer feedback |



## Medical Devices Registration

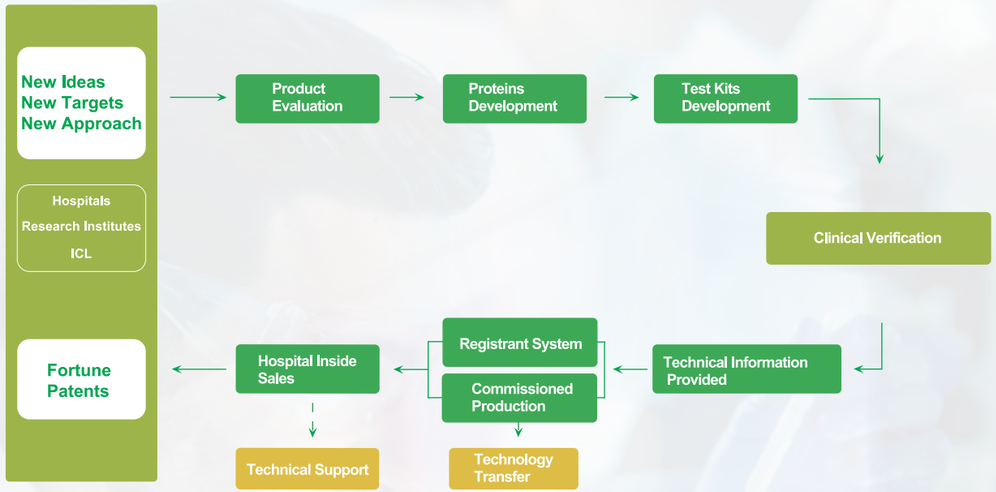



## Registrant System



## 4. Featured Services

### LDTs (Lab Development Tests) Service Flow Chart






# TEAM ADVANTAGES

## Team Advantages

- Ph.D. and Postdoctoral: 5 people
- Master's degree: 15 people
- R&D staff: 50 people
- Company staff: 100 people

### Company Technology Leaders

Professor, PhD Tutor

Senior Investigator at the National Institutes of Health

### Diagnostic Raw Materials R&D Director

Ph.D., senior expert with over 30 years of experience in recombinant protein and antibody development

### Diagnostic Test Kits R&D Director

Ph.D., graduated from University of Bayreuth, Germany, 12 years in diagnostic reagent R&D

### Registration Director

16 years in the industry, 6 years in medical device companies + 10 years in certification consulting.

Coaching on the preparation of technical documents for various products.

Cumulative service of more than 200 clients for mainstream system construction.

Covering most medical device categories.



# PARTNERS

# In Vitro Diagnostic Reagents CDMO Service Provider

Shenzhen Aivd Biotechnology Co., LTD.

In Vitro Diagnostic Reagents CDMO/CRO Service Provider

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