



Accurate POC

# Hipro Introduction

**01 Profile**  
History; Layout ; Plant ; GMP

**02 Qualification**  
Patent ; Certificates

**03 Product**  
Instrument; Reagent; Calibration

**04 Market**  
International market

**05 Hipro Update**

**Hipro Think Different**





## Company Profile:

History; Layout; Plant; GMP



## Founder, Chairman, CEO of Hipro technology Co.Ltd

*China association of medical equipment*

(Executive member of the Council)

*China association of medical equipment POCT branch*

(Vice president)

*Hebei biomedical engineering academy-----*(Vice president)

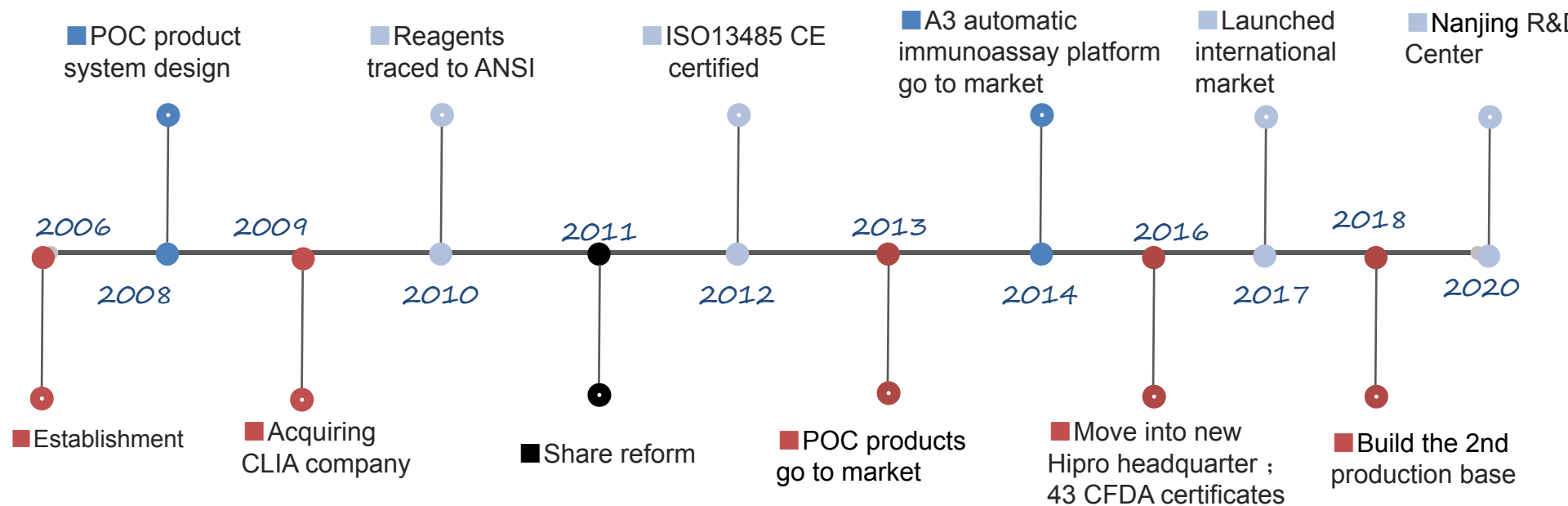
*Hebei patent protection association-----*(Vice president)

Technology leader of Shijiazhuang city

Medical talents of China Medical city

Special allowance expert in Shijiazhuang

# 1 Profile History

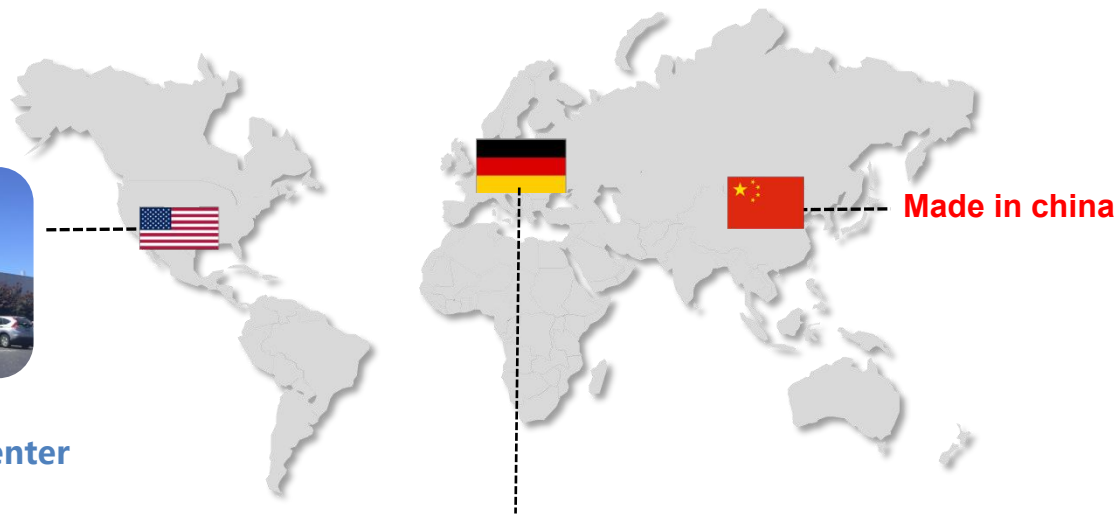


# 1 Profile

Layout in the world



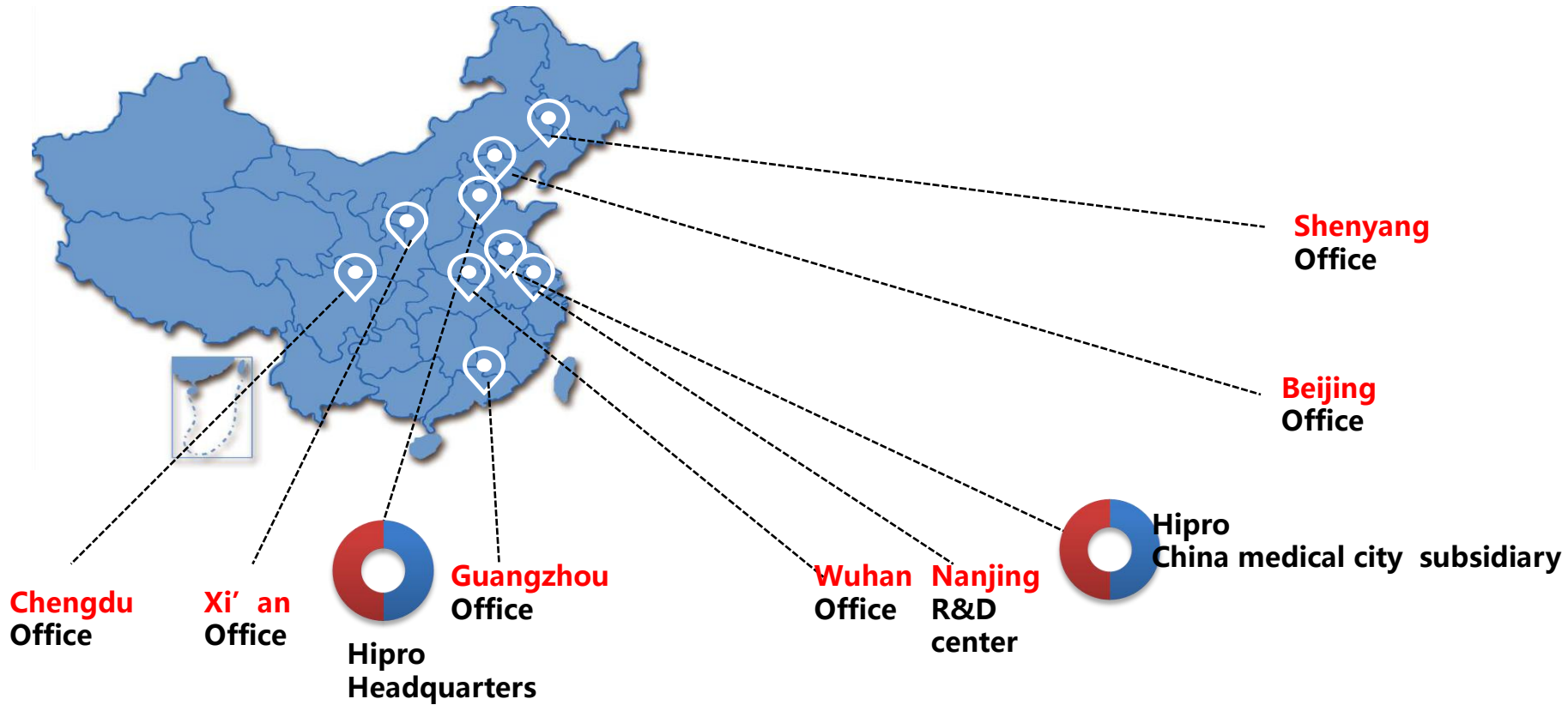
Hipro USA R&D Center



Hipro Freiburg R&D center

# 1 Profile

## Layout in China



# 1 Profile Plant



**Plant area : 86000 squ.ft**

**Staff : 300 employees**



**Academic Hall**



**Patents Wall**



**Laboratory**

# 1 Profile GMP



**Production capacity : 150,000 TESTs/day**



**100 , 000 class GMP Reagent  
production**



**10 , 000 class Antibody  
Preparation**



# 1

## Profile

Hipro China Medical City



First Prize for “Innovation competition  
in China Medical City”  
40 thousand sq.m;



50,000 sq.m GMP for POC reagents  
and microfluidic products

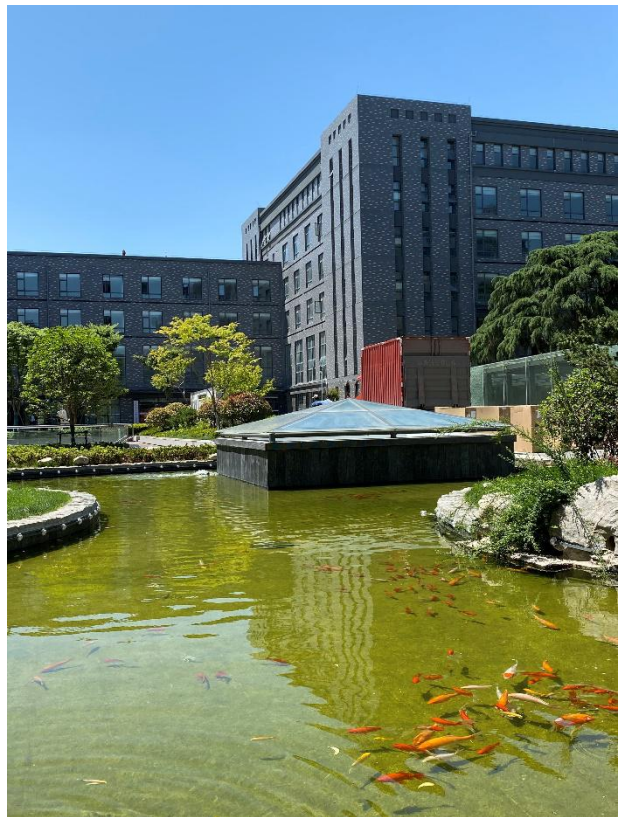
Sampler: 500,000 Tests/day  
Disk: 250 , 000 pieces/day

1

# Profile

## Hipro Nanjing Research Center

**Hipro** | 禾柏生物技术股份有限公司  
HIPRO BIOTECHNOLOGY CO.,LTD





## Qualification:

Patent; Certificates

## 2 Qualification Patents



**21 patents SimplyREAD**

**01**

2 patents for invention  
11 patents for utility model  
8 patents for design



**42 patents A3 Automatic  
Immunoassay system**

**02**

18 patents for invention  
31 patents for utility model  
3 patents for design



# 2

## Qualification Patents



禾柏生物技术股份有限公司  
HIPRO BIOTECHNOLOGY CO.,LTD

**90** patents under application —  
Microfluidic products

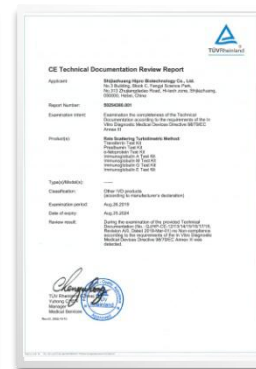
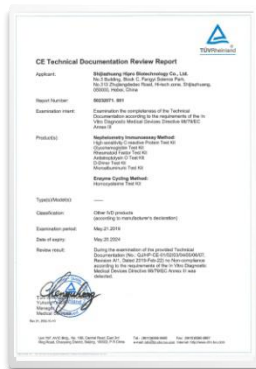


## 2

# Qualification Certificates



48CE  
marks





## Products:

Instrument; Reagent; Calibration

# 2

## Product Instrument Portfolio

**Hipro** | 禾柏生物技术股份有限公司  
HIPRO BIOTECHNOLOGY CO.,LTD



**A1**  
Model: HP-AFS/1



**A3**  
Model: HP-AFS/3



**A1-pro**  
Model: HP-AFS/1-pro

# 2

## Product

### A3/A1—Automatic Immunoassay Analyzer

#### Automated Platform



#### Methodologies

Nephelometry

Biochemistry

Turbidimetry

Immunofluorescence

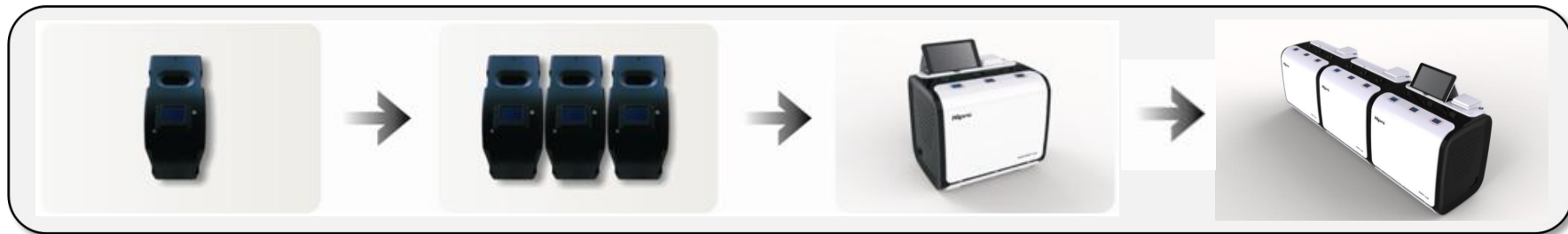
3

Product

A3/A1--AutomaticImmunoassay Analyzer

Hipro

## Single Module Full functions



All functions



1 modules



48 modules

3

Product

— A3/A1--Automatic Immunoassay Analyzer

Hipro

## Simple operation



Collect sample

1



Insert into Cuvette

2



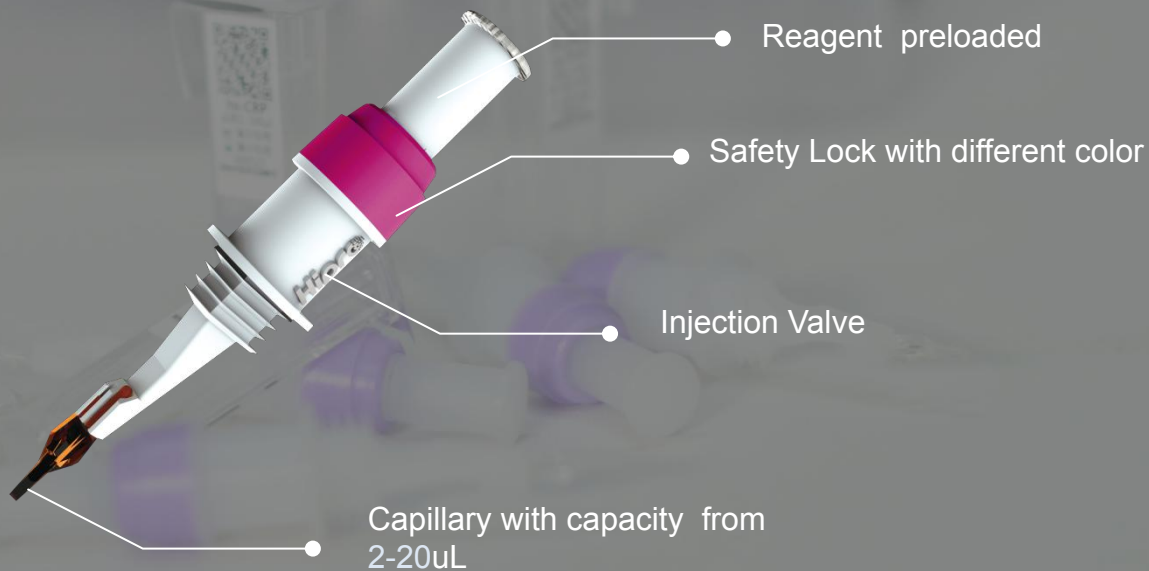
Insert into channel

3

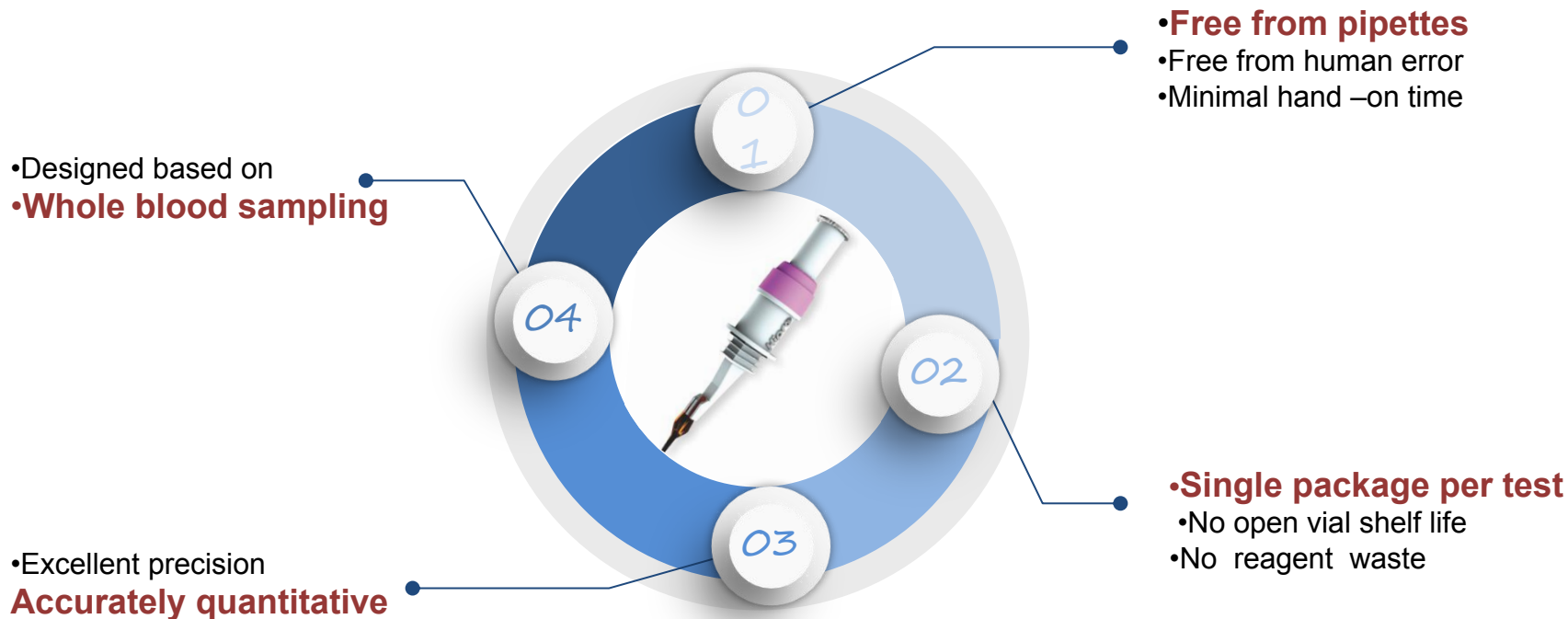
# 3 Product Reagent Portfolio



Integrated  
sampling  
and testing device



# 3 Product Reagent Portfolio

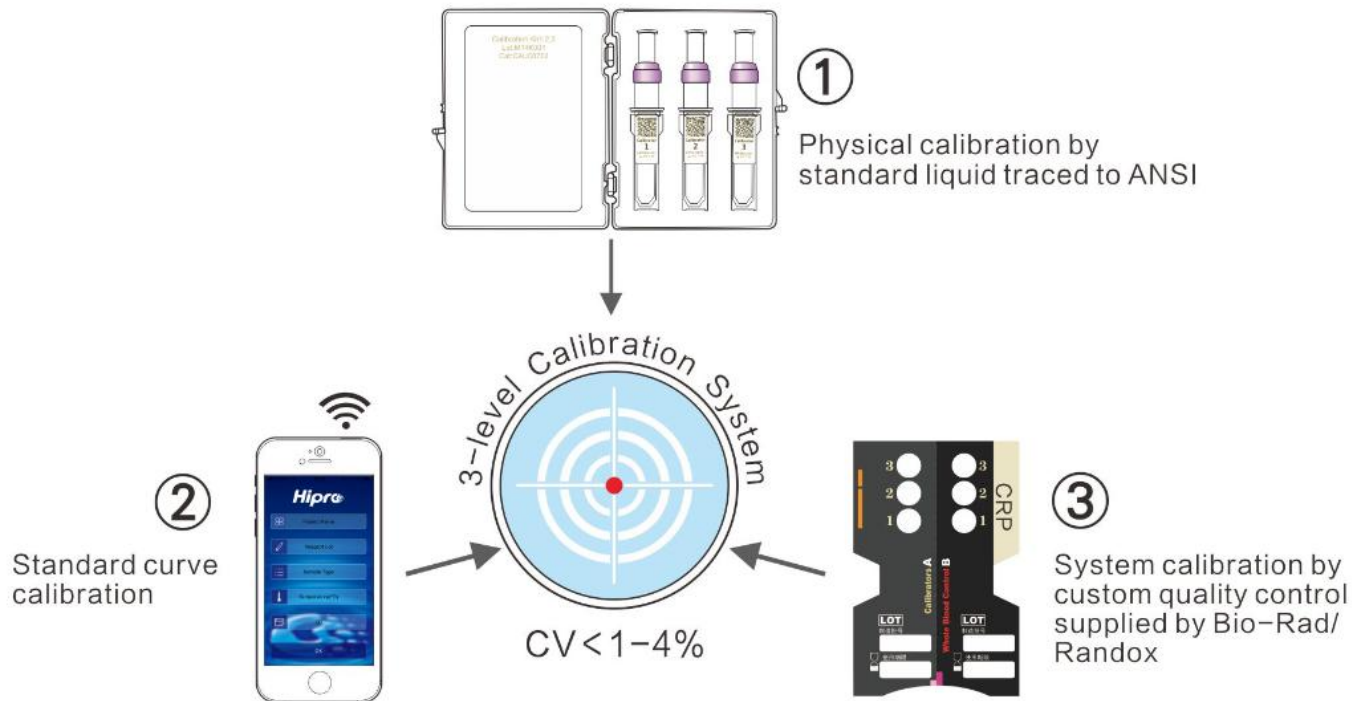


## Most comprehensive test menu in China POC market

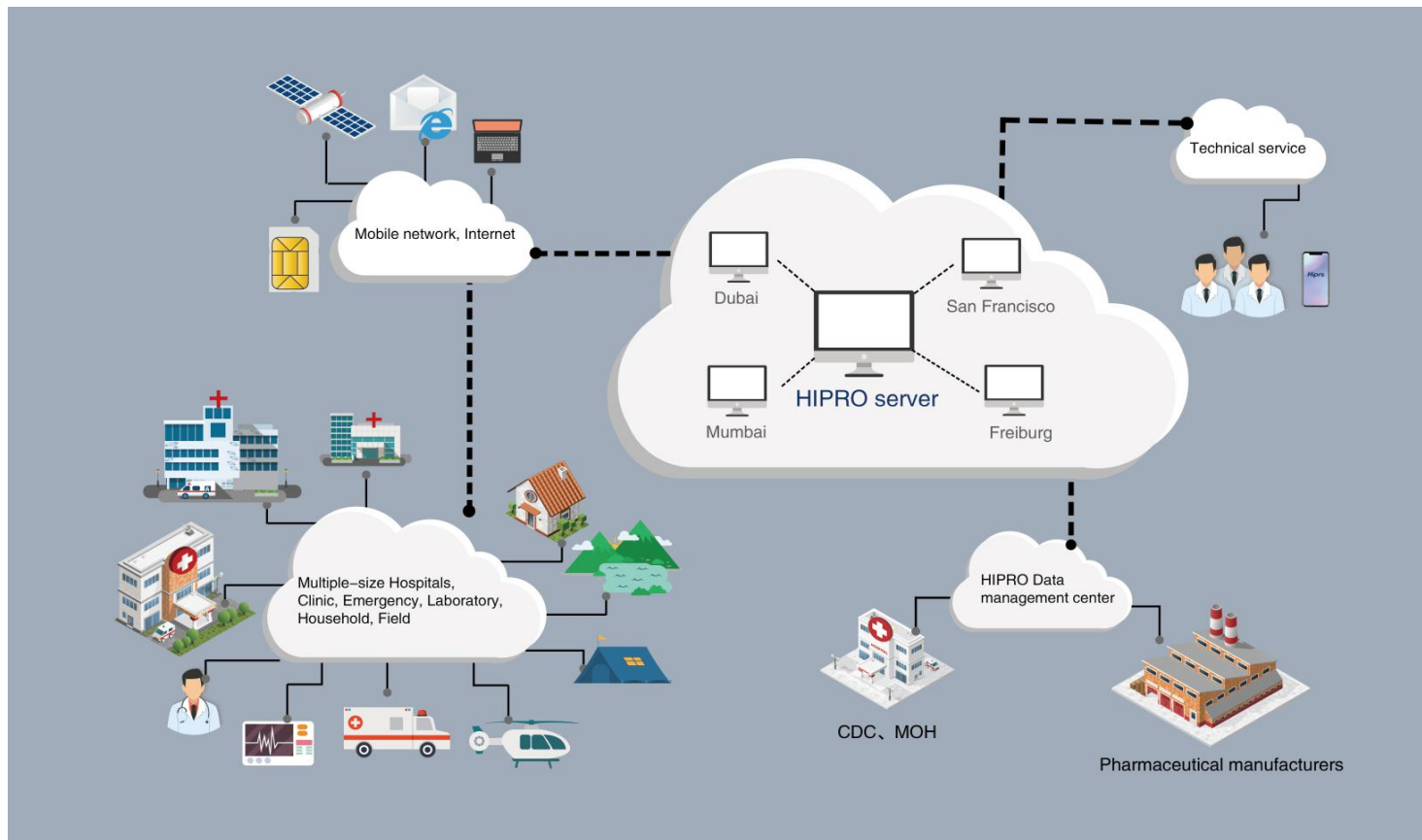
|                              |                       |                         |                       |                     |
|------------------------------|-----------------------|-------------------------|-----------------------|---------------------|
| <b>SAS-Cov-2</b>             | D-Dimer               | HbA1c                   | PGII                  | <b>Tumor marker</b> |
| 2019-nCoV IgM / IgG Antibody | HDL-C                 | Crea                    | HP                    | AFP                 |
| SAS-Cov-2-Antigen            | TG                    | mALB                    | G17                   | CEA                 |
| <b>Infection</b>             | BNP                   | Cys-C                   | <b>Liver function</b> | <b>Microelement</b> |
| CRP                          | NT-ProBNP             | $\alpha$ 1-MG           | PA                    | 25'-VD              |
| hs-CRP                       | TCHO                  | $\beta$ 2-MG            | TRF                   | Ferritin            |
| PCT                          | FER                   | NGAL                    | ADA                   | BAP                 |
| SAA                          | HCY                   | RBP                     | <b>Autoimmunity</b>   | GH                  |
| HBP                          | cTn I                 | <b>Rheumatism</b>       | IgA                   | BGP                 |
| <b>Cardiovascular</b>        | MYO                   | ASO                     | IgM                   | 25-OH-VD            |
| H-FABP                       | LDL-C                 | RF                      | IgE                   |                     |
| CK-MB                        | MPO                   | Anti-CCP                | IgG                   |                     |
| LP (a)                       | cTnT                  | <b>Gastric Function</b> | <b>Hormone</b>        |                     |
| Lp-PLA2                      | <b>Renal function</b> | PGI                     | HCG                   |                     |

# 3 Product

## 3-Level Calibration System

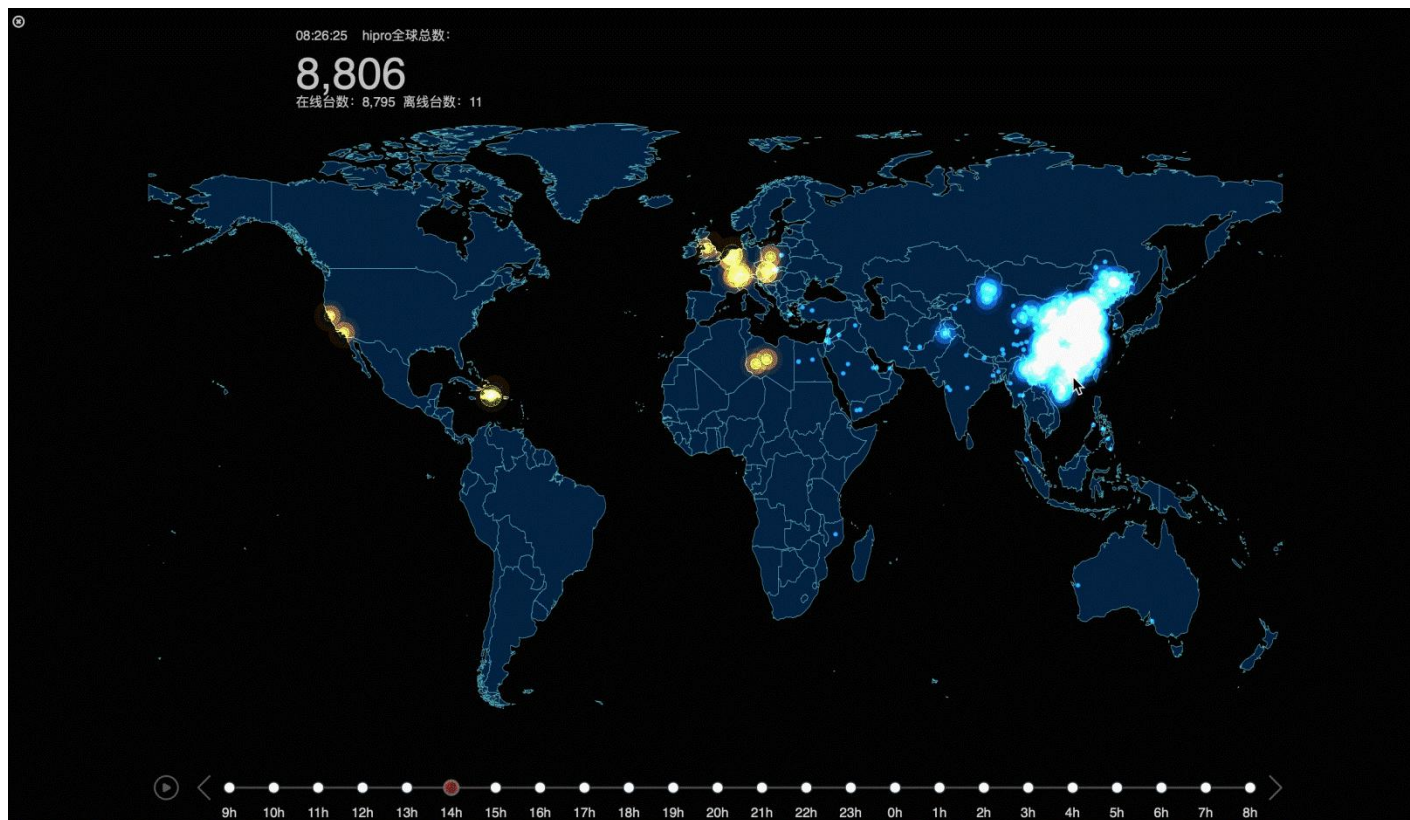


# 3 Product IT system



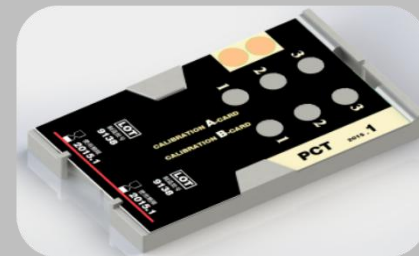
# 3 Product IT system

Hipro



# 3 Product Whole platform

**Hipro**



## Reagent Platform

SimplyRead™

-----World initiative

## Instrument series

**A1、A3**

**A1-Pro**(Throughput: 50T/h )

----- World initiative

## Control

3 level calibration system

---World initiative

## Easy

Patented integrated sampler  
One step operation  
Ready to use kits

## Rapid

From sample to result , within **5**  
min . Simple operation, quick  
reaction, quick analysis.

## Comprehensive

4 methodologies,  
International reagent platform

## Accurate

Classical liquid phase  
methodology.  
3 level calibration system assures  
the accurate and reliable results



## Appointed Products by MOH of China for Stroke Screening



**228** Tier-III Hospitals

### 3 Uniqueness

- **Accurate**  
Third party calibration
- **Real-time** data upload  
2000GHz Server /IT center
- **One instrument** all assays
- Multi-methodologies

**HbA1c + HCY**

#### 国家卫生健康委脑卒中防治工程委员会

##### 关于在 2018 年度脑卒中高危人群筛查和干预项目中统一检测检验耗材型号的函

各项目参与单位：

2017 年度脑卒中高危人群筛查和干预项目（以下简称“项目”），在全国各级卫生计生行政部门、疾控机构、项目基地医院和基层医疗卫生单位的共同努力下，超额完成任务。特别在全国统一耗材型号同质化的基础上，项目工作质量得到有效保证，数据实现实时上传，避免了错误、漏项现象的发生，得到了专家和项目相关单位的充分认可。

基于 2017 年度项目工作质控经验，2018 年度项目将继续对全人群开展血脂、血糖、同型半胱氨酸、糖化血红蛋白检测，并采用统一快速检测检验耗材。为更好开展工作，我办经过材料会相关单位公开邀请，并组织临床、医学检验和公共卫生等专家对快速检测实验室检测设备进行竞争性磋商，专家组综合评价结果认为：“Hipro（希柏）”同型半胱氨酸检测试剂盒（酶法）和“Hipro（希柏）”糖化血红蛋白试剂盒（免疫散射比浊法），质量可靠，价格合理，符合项目工作要求。请项目参与单位积极使用，以保证全国项目工作质量稳步提升。

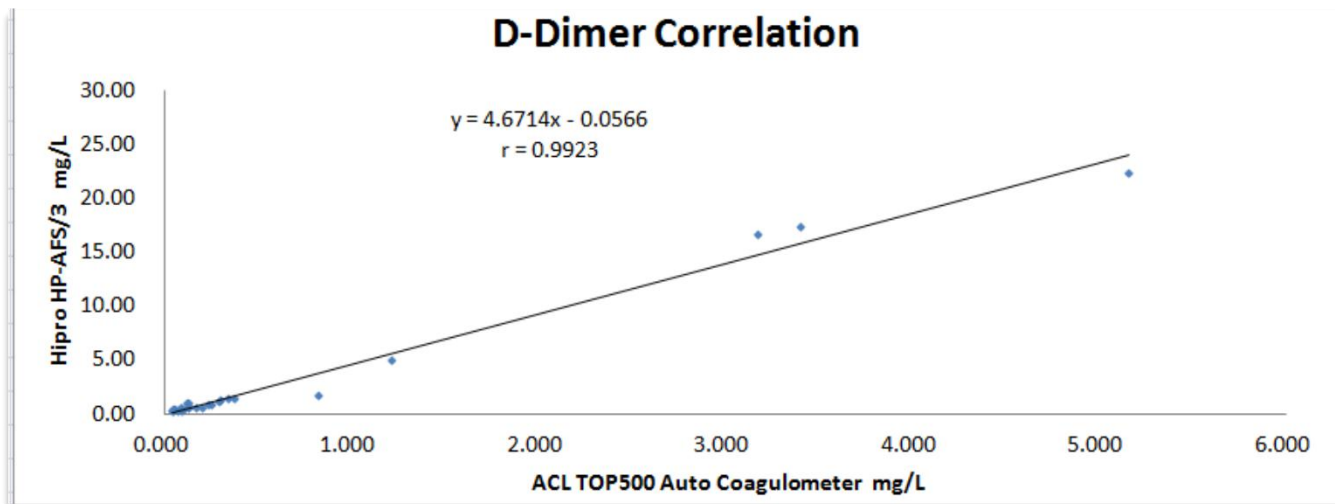
让我们携手为降低我国脑卒中发病率、死亡率，同时为政府和社会提供科学有效的心脑血管病筛查和干预数据做出应有的贡献。

联系人：高泰鹏 曹雷

国家卫生健康委脑卒中防治工程委员会办公室



# Hipro VS Armed Police General Hospital, Beijing----April 12,2018



|        |       |       |
|--------|-------|-------|
| AVEDEV | 1.45  | 6.66  |
| STDEV  | 0.02  | 0.13  |
| CV     | 1.24% | 1.89% |

Precision Test---D-Dimer  
 Manufacturer: Hipro Biotechnology Co.  
 Instrument Model: HP-AFS/3  
 Reagent Lot NO.DA180401

## Symposium POC d-dimer test 17th Dec 2019



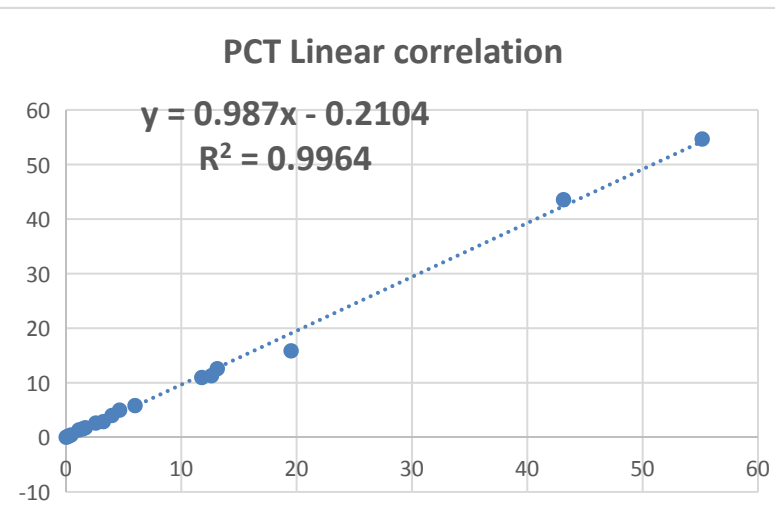
| Afkap 500 µg/L<br>Prev. 17%                                                        | Sensitiviteit                                                                       | Specificiteit                                                                       | Efficiency<br>% geen echo of<br>CT (100-FP)                                         | Failure rate<br>FN                                                                  |
|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| STA referentie                                                                     | 97                                                                                  | 61                                                                                  | 61                                                                                  | 0,6%                                                                                |
| Nanochecker                                                                        | +/-                                                                                 | +                                                                                   | ++                                                                                  | +/-                                                                                 |
| Afias 1                                                                            | +/-                                                                                 | +                                                                                   | ++                                                                                  | +/-                                                                                 |
| I Chroma II                                                                        | -                                                                                   | +                                                                                   | ++                                                                                  | -                                                                                   |
| Standard F200                                                                      | +                                                                                   | -                                                                                   | +/-                                                                                 | +                                                                                   |
| Hipro                                                                              | +/-                                                                                 | ++                                                                                  | ++                                                                                  | +/-                                                                                 |
|  |  |  |  |  |
| Nanochecker<br>Nano-ditech                                                         | Afias 1<br>Boditech                                                                 | i Chroma II<br>Boditech                                                             | Standard F200<br>SD Biosensor                                                       | HP-AFS/1<br>Hipro                                                                   |

# 4 Product Recognition



| Precision measurement of PCT--3days ( ng/ml) |       |       |       |       |       |        |        |        |        |
|----------------------------------------------|-------|-------|-------|-------|-------|--------|--------|--------|--------|
| Roche E411 reference                         | 0.25  | 0.44  | 1.68  | 3.24  | 5.99  | 11.78  | 19.52  | 43.14  | 55.16  |
| 10. 26, 2019                                 | 0. 26 | 0. 40 | 1. 72 | 2. 66 | 5. 62 | 10. 28 | 16. 00 | 45. 14 | 55. 45 |
|                                              | 0. 22 | 0. 40 | 1. 75 | 2. 72 | 5. 50 | 9. 77  | 16. 42 | 42. 58 | 53. 41 |
|                                              | 0. 27 | 0. 48 | 1. 71 | 2. 87 | 5. 64 | 10. 92 | 15. 00 | 45. 04 | 55. 41 |
|                                              | 0. 23 | 0. 45 | 1. 74 | 2. 89 | 5. 85 | 11. 25 | 15. 67 | 40. 33 | 51. 78 |
|                                              | 0. 23 | 0. 45 | 1. 71 | 2. 85 | 5. 85 | 9. 78  | 15. 27 | 43. 44 | 52. 27 |
| 10. 27, 2019                                 | 0. 24 | 0. 45 | 1. 74 | 2. 96 | 5. 82 | 10. 81 | 15. 58 | 42. 64 | 57. 95 |
|                                              | 0. 27 | 0. 45 | 1. 82 | 2. 86 | 5. 76 | 11. 20 | 16. 28 | 44. 75 | 55. 84 |
|                                              | 0. 24 | 0. 43 | 1. 78 | 2. 94 | 6. 03 | 11. 01 | 15. 68 | 42. 20 | 54. 58 |
|                                              | 0. 26 | 0. 40 | 1. 82 | 2. 93 | 5. 92 | 11. 62 | 15. 59 | 45. 85 | 58. 20 |
|                                              | 0. 27 | 0. 42 | 1. 84 | 2. 92 | 5. 97 | 10. 41 | 15. 59 | 44. 55 | 56. 73 |
| 10. 28, 2019                                 | 0. 24 | 0. 43 | 1. 74 | 2. 90 | 5. 63 | 11. 49 | 15. 49 | 43. 38 | 50. 01 |
|                                              | 0. 20 | 0. 39 | 1. 76 | 2. 93 | 6. 20 | 12. 07 | 14. 86 | 42. 64 | 52. 50 |
|                                              | 0. 24 | 0. 42 | 1. 76 | 2. 98 | 6. 00 | 11. 61 | 14. 76 | 43. 28 | 55. 13 |
|                                              | 0. 27 | 0. 43 | 1. 78 | 2. 90 | 5. 81 | 11. 46 | 19. 25 | 42. 30 | 55. 96 |
|                                              | 0. 27 | 0. 45 | 1. 78 | 2. 88 | 5. 74 | 10. 88 | 16. 15 | 45. 11 | 54. 89 |
| Mean                                         | 0. 25 | 0. 43 | 1. 76 | 2. 88 | 5. 82 | 10. 97 | 15. 84 | 43. 55 | 54. 67 |
| CV                                           | 8. 4% | 5. 9% | 2. 3% | 3. 0% | 3. 2% | 6. 1%  | 3. 3%  | 3. 4%  | 4. 2%  |

## Hipro A1pro VS Roche E411





# CN POC Project

Hipro product evaluation Result

**Linearity and Bias assessment and multisite imprecision estimation**

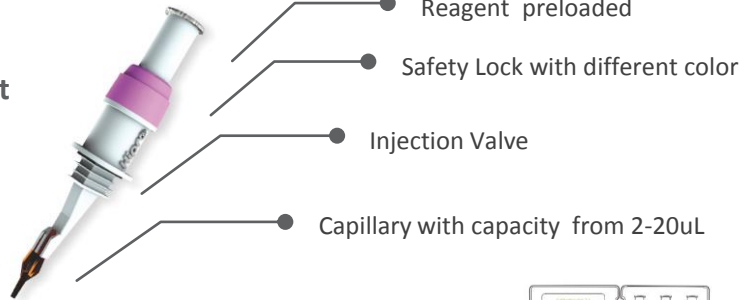
# Hipro product platform and PCT assay offering

## Specially designed user-friendly sampling system

**Simplyread™**

### Integrated sampling and test

- Free from pipettes
- Whole blood testing (for specific assays)
- Single package per test

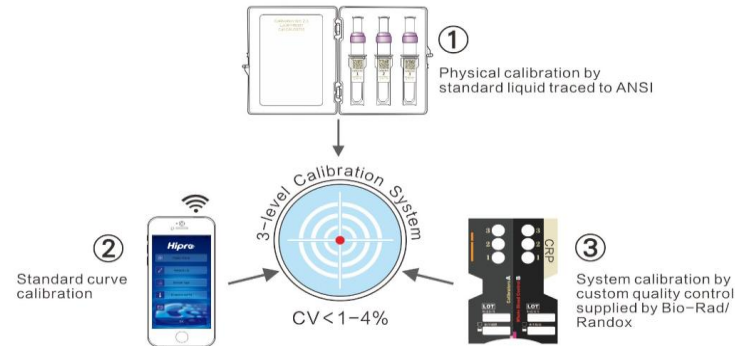


- One platform covers Nephelometry, Biochemistry, Turbidimetry, immunofluorescence methodologies
- A1pro fully automated
- Multi-A3 to be expandable

## Test equipment



## 3 level calibration



- Physical calibration by standard liquid traced to ANSI;
- Remote standard curve calibration;
- System calibration by custom quality control supplied by Bio-Rad.

## Friendly testing operation



## PCR assay offering

Principle: Immuno-turbidity / Fluorescence

Package: 25T/Kit, single package

Sample type: Serum/Plasma

Sample volume: 15ul

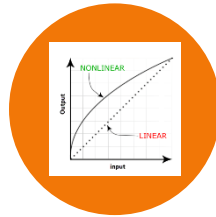
Linearity: 0.2-60ng/ml



\* For PCT test, serum or plasma (not whole blood) will be collected by sampler

For internal use only

# OUR PROTOCOLS



## Bias Estimation

1. 133 clinical samples covering (0.2-60ng/ml) prepared for analysis, 11 pooled samples included.
2. The study was performed over 4 days.
3. All samples were run in random sequence
4. One replicate tested on each sample
5. Calculated the matched sample-to-sample bias comparison

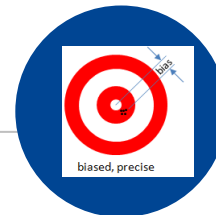
1

## Linearity

1. Pooled clinical samples prepared for analysis
2. Claimed linearity check (0.2-60ng/ml)
3. 11 levels prepared for analysis
4. 2 replicates each level
5. The linear range claims do not hold for the conc. chosen (0.2 – 60ng/ml), so:
  - 0.14 – 17.75ng/ml
  - 0.14 – 5ng/ml
  - 12.71 – 69.19ng/ml

| S = 11 samples |                |
|----------------|----------------|
| 1              | Low (L)        |
| 2              | 0.90L + 0.10H  |
| 3              | 0.80L + 0.20H  |
| 4              | 0.70L + 0.3H   |
| 5              | 0.60L + 0.40H  |
| 6              | 0.50L + 0.50H  |
| 7              | 0.40L + 0.60H  |
| 8              | 0.30L + 0.70H  |
| 9              | 0.20L + 0.80H  |
| 10             | 0.10 L + 0.90H |
| 11             | High (H)       |

2





## Between-laboratory Precision

1. 5×5×3 design – five days, one run per day, five replicates per run on three instruments with 3 lots of reagents -- yield a total of 25 results per sample per lot of reagent on each instrument
2. 20×2×2 design – 20days, two runs per day, two replicates per run on one instruments with 3 lots of reagents – yield a total of 80 results per sample per lot of reagent
3. Pooled samples: 0.25ng/ml, 0.5ng/ml, 2ng/ml and 10ng/ml

3

## Within-laboratory Precision

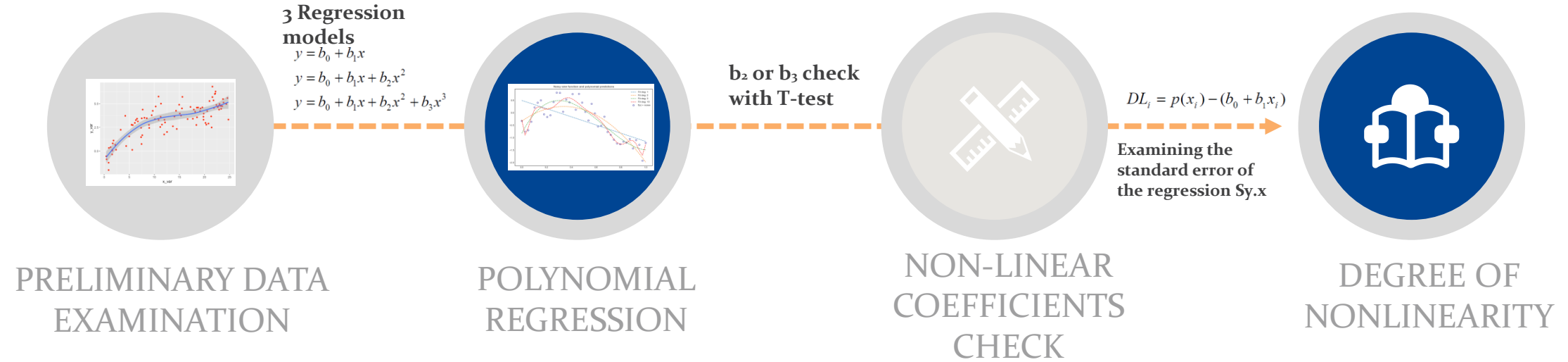
1. 5×5 design -- five days, one run per day, five replicates per run on one instrument with one lot of reagent – yield a total of 25 results per sample
2. Pooled samples : 0.25ng/ml, 0.5ng/ml, 2ng/ml and 10ng/ml

4



# Evaluation of the Linearity of Quantitative Measurement Procedure

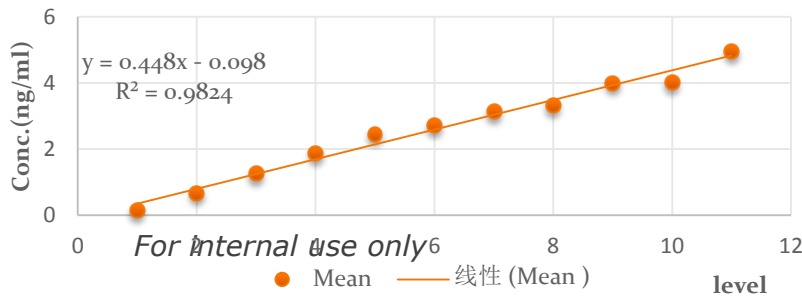
## Statistical data analysis steps and its logic behind



Determine whether the nonlinearity is at either end of the range of concentration or in the middle of the range. One option is to remove the point where  $DL_i$  is too large, and re-run the statistical analysis.

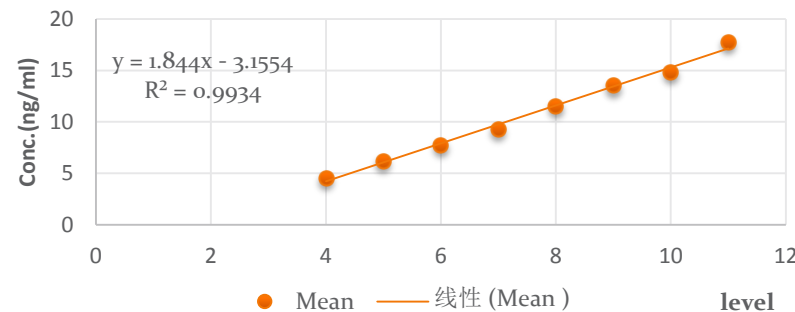
### Linear range from 0.14 to 4.95

Prepared from 0.14 to 4.95



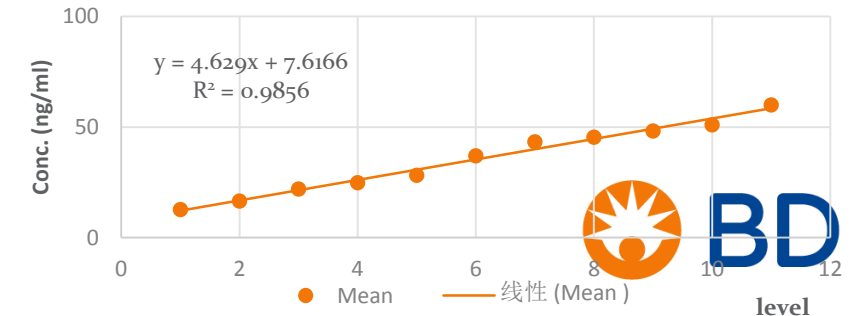
### Linear range from 4.56 to 17.75

prepared from 0.1 to 17.75



### Linear range from 12.71 to 69.19

Prepared from 12.71 to 69.19



# Measurement procedure comparison and bias estimation per its different linear ranges

## Conclusion

Linear rang from 0.14 to 4.95, both methods (Hipro and Roche cobass e411) are **identical**.

| Claimed Citeria 10% |      |      |       |                |
|---------------------|------|------|-------|----------------|
| Clinical cut-off    | y    | diff | diff% | Range          |
| 0.25                | 0.27 | 0.02 | 9%    | ( 0.22, 0.28 ) |
| 0.5                 | 0.52 | 0.02 | 4%    | ( 0.45, 0.55 ) |
| 2                   | 2.08 | 0.08 | 4%    | ( 1.87, 2.13 ) |

## Conclusion

Linear rang from 4.56 to 17.75, both methods (Hipro and Roche cobass e411) are **identical**.

| Claimed Citeria 10% |      |      |       |                 |
|---------------------|------|------|-------|-----------------|
| Clinical cut-off    | y    | diff | diff% | Range           |
| 10                  | 9.74 | -0.3 | -3%   | ( 9.74, 10.26 ) |

## Conclusion

Linear rang from 12.71 to 69.19, both methods are identical through passing-bablok regression, the linear regression error tells us how wrong the regression model is on average, smaller error indicates that the observations are closer to the fitted line.

| Linear range  | Std Error<br>Regression (S <sub>y, x</sub> ) |
|---------------|----------------------------------------------|
| 12. 71-69. 91 | 0. 74                                        |
| 4. 56-17. 75  | 0. 3                                         |
| 0. 14-4. 95   | 0. 21                                        |

# Multisite Imprecision Estimation

| Conc.(ng/ml) | Instrument | %CV <sub>RPT</sub> | %CV <sub>RPO</sub> |
|--------------|------------|--------------------|--------------------|
| 0.25         | A1 at CRDC | 6%                 | 7%                 |
| 0.5          | A1 at CRDC | 5%                 | 6%                 |
| 2            | A1 at CRDC | 2%                 | 5%                 |
| 10           | A1 at CRDC | 2%                 | 4%                 |
| 0.25         | A2 at CRDC | 6%                 | 8%                 |
| 0.5          | A2 at CRDC | 6%                 | 7%                 |
| 2            | A2 at CRDC | 1%                 | 4%                 |
| 10           | A2 at CRDC | 2%                 | 5%                 |
| 0.25         | A3 at CRDC | 5%                 | 8%                 |
| 0.5          | A3 at CRDC | 5%                 | 7%                 |
| 2            | A3 at CRDC | 2%                 | 5%                 |
| 10           | A3 at CRDC | 2%                 | 4%                 |

\*\*\*Overall conclusion: The performance ( Linearity ,Bias assessment and multisite imprecision ) of Hipro PCT (immunofluorescence method ) is in concordance with the specifications stated in the instrument user manual and reagent package inserts.

**Linearity** : R>0.990 in different con.

**Bias** <10% in different con,

**Multisite imprecision** <10% in Hipro and BD Lab





## Hipro Market:

International Market



**Overseas market: 62 countries**

## 4 Hipro market Strategic Partners



Biyotest Health Services Ltd as  
Hipro' s strategic distributor , are  
committed to providing premium  
products and excellent after-sales  
service in Turkey.



17 March 2020

Hipro Biotechnology Co., Ltd

**Subject: Appreciation for donation of medical supplies to Wuhan through the UN in China**

I am writing to extend my heart-felt gratitude towards your Company for donating and facilitating the transportation of medical supplies to Hubei Provincial Disease Prevention and Control Center. This is part of the coordinated emergency response from the United Nations in China, in response to the outbreak of the COVID-19 and shows our strong and firm support for the people in Wuhan.

As our emergency response has gradually come to an end, the UN in China is gearing up our efforts to provide medium and longer-term support for China's development, to mitigate the economic and social impact of the COVID-19 and cope with cross-cutting challenges on the health system, education and poverty reduction, etc. Equally important, we must also work with China to share its best practices and lessons learnt so as to support other countries in need to control the outbreak.

I look forward to working with you and your colleagues to promote sustainable development both in China and in other countries, including on joining up our efforts in the recovery work in China and providing assistance to other countries in need.

Yours sincerely,

Nicholas Rosellini  
UN Resident Coordinator





# Complete Covid-19 Diagnosis Solution



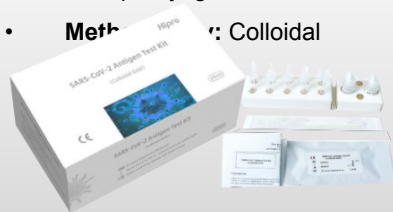
## IgM/IgG Antibody Test Kit

- **Clinical Significance:**  
Indicators of acute, previous or late infection
- **Specimen:** whole blood, serum or plasma
- **Methodology:** Colloidal Gold



## Antigen Test Kit

- **Clinical Significance:**  
Quickly detect SARS-CoV-2 antigen in nasopharyngeal and provide auxiliary diagnosis for Covid-19 infections
- **Specimen:** Saliva  
Nasopharyngeal swab
- **Methodology:** Colloidal



## Neutralizing Antibody Test Kit

- **Clinical Significance:**  
An important marker for assessing the effectiveness of the new coronavirus vaccines
- **Specimen:** Whole blood, serum or plasma
- **Methodology:** Colloidal



## Total Antibody & Neutralizing Antibody Test Kit

- **Clinical Significance:**  
Quickly detect acute, previous or late infection, and assess the effectiveness of the new coronavirus vaccines
- **Specimen:** Whole blood, serum or plasma
- **Methodology:** Colloidal Gold





THANKS

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