Chinese regulations on IVDs and traceability requirements

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CMD/NRCCRM
NIM China

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Outline

1. IVD In China
2. China’s Efforts on IVD traceability
3. Future Demands and Tendency
1. IVD Regulations In China

IVD Management in China

- SFDA: Quality Management
- NHFPC: Clinical Laboratory Management
- CNAS: Clinical Laboratory Accreditation
- SAC: Technique Standards
- NIM: Traceability Assurance
- AQSIO: Application In Clinical Laboratory

IVD products

Production

Registration

Application In Clinical Laboratory

Quality Management

Registration Management

Clinical Laboratory Management

Clinical Laboratory Accreditation

Technique Standards

Traceability Assurance

AQSIQ
1. IVD Regulations In China

**IVD Management in China - SFDA**

**Regulations** on the supervision and administration of medical devices (the State Council Order No. 650th)

- The Orders of the State Food & Drug Administration

- Quality Management
  - Quality supervision and administration of medical devices (Order No. 18th)
  - Medical device classification rules (Order No. 15th)
  - Administration of operating management of medical devices (Order No. 8th)
  - Administration of production management of medical devices (Order No. 7th)
  - Administration of medical device specification and labels (Order No. 6th)
  - Administration of registration of in vitro diagnostic reagents (Order No. 5th)
  - Administration of registration of medical devices (Order No. 4th)

- Production & operating Management
  - Administration of operating management of medical devices (Order No. 8th)
  - Administration of production management of medical devices (Order No. 7th)

- Registration Management
  - Administration of medical device specification and labels (Order No. 6th)
  - Administration of registration of in vitro diagnostic reagents (Order No. 5th)
  - Administration of registration of medical devices (Order No. 4th)
1. IVD Regulations In China

IVD Management in China - NHFPC

National Health and Family Planning Commission of the PRC (NHPFC)

Department of Medical Affairs Administration

Clinical Laboratory Management

Technical Specification and Guidelines

Basic Standards for Medical Laboratory

Category of laboratory medicine

Technical specification for clinical examination of blood lead

Guidelines for the detection of drug metabolism enzymes and drug target genes

Guidelines for individual treatment of tumor detection

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1. IVD Regulations In China

IVD Management in China - CNAS

General Laboratory Accreditation

General Accreditation of Medical Reference Measurement Laboratories

Specific Accreditation of Medical Reference Measurement Laboratories

- CNAS-CL25 Application of Laboratory Accreditation Criteria in the Field of Calibration
- CNAS-CL31 Requirements for In-house Calibration
- CNAS-CL32 Specific Accreditation Requirements for Reference Measurement Laboratories in Laboratory Medicine
- CNAS—AL11 Scopes for the Accreditation of Medical Reference Measurement Laboratories
- CNAS-CLxxxx Guidance on the Application of Testing and Calibration Laboratories Competence Accreditation Criteria in the Field of Reference Measurements of Metabolites and Non-peptide Hormone
1. IVD Regulations In China

IVD Management in China – SAC

General Standards of Clinical Laboratory and IVD

- Standards of the Quality of Medical Equipment and Clinical Laboratory
- Specific Standards of the Medical Equipment
- Criteria Categories

Standards of the Measurement Reference System

- Standards of Reference Materials
- Standards of Reference Methods
- Standards of Reference Laboratory

Standards of the IVD products

Common Criteria Categories

- Blood and body fluids
- Clinical Biochemistry
- Immunology
- Microorganism
- Molecular Biology

Specific Standards of Reference Materials

Specific Standards of Reference Methods

Specific Standards of Reference Laboratory

Product Standards

Method Standards

SAC/TC136 National medical clinical laboratory and in vitro diagnostic system

Total 157 document standards by the end of 2014

141 standards

16 standards

National standards

Industry standards
1. IVD Regulations in China

IVD Management in China – NIM

Traceability

JJGs “Verification Scheme of Measurement Instruments” and “Value traceability chart”

Traceability and Quality Assurance

Reference Measurement Procedure

JJF xxx The values of enzymatic activity concentrations assigned for the clinical enzymatic reference materials and the expression of measurement uncertainty

JJF xxx Reference Measurement Procedure of Hemoglobin A1c in Whole Blood (HPLC/CE)

JJF xxx Reference Measurement Procedure of Bilirubin

JJF xxx Reference Measurement Procedure of Total Serum Protein

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1. IVD Regulations In China

IVD Management in China – NIM

Traceability and Quality Assurance - cont.

- JJG 714-2012 Verification of blood cell analyzer
- JJG 861-2007 Verification of ELISA analytical instruments
- JJG 1051-2009 Verification of Electrolyte Analyzer
- JJG 464-2011 Verification of Semiantomatic clinical chemistry analyzer
- JJG xxx Verification of Automatic clinical chemistry analyzer
- JJF 1383-2012 Calibration Specification for Portable Blood Glucose Meters
- JJF 1129-2005 Calibration Specification for Urine Analyzer
- JJF xxx Calibration Specification for Immunoanalyzer
- ......

Verification

Calibration Specification
1. IVD Regulations In China

IVD Management in China – NIM

Traceability and Quality Assurance - cont.

- JJF 1005-2005 Terms and Definitions Used in Reference Materials
- JJG 1006-1994 Technical Norm of Primary Reference Material
- JJF 1186-2007 The Rules for Drafting of Contents for Certificates and Labels of Certified Reference Materials
- JJF 1507-2015 The Selection and Use of Reference Materials
- JJF 1343-2012 General and Statistical Principles for Characterization of Reference Materials
- JJF 1218-2009 The Rule for Drafting in Report of Reference Materials

Certified Reference Materials
1. IVD Regulations In China

IVD Management in China – NIM

NIM CHEMISTRY DEPARTMENT
Coordination of International Chemical Standard Activities

CCQM OAWG
- Organic purity
- CRMs

CJCTLM
Founded in 2007
- CCQM Comparison in Laboratory Medicine
- Reference Measurement Systems
- Proficiency Test
1. IVD Regulations In China

IVD Management in China – NIM

Mission of the Committee

- Drafting metrology technical specification in clinical medicine
- Evaluating reference materials, reference methods and reference laboratories
- Organizing intercomparisons for reference laboratories
- Providing support for Clinical Laboratory and Reference Laboratories preparing for accreditation
- Participating in the activities of JCTLM
- Organizing proficiency testing for clinical laboratories
- Transporting knowledge in metrology and training

CJCTLM developed to help IVD industry meet metrological traceability requirements of the CHINA IVD Directive

Contains:
- 31 members
- 2 Consultants

CJCTLM Chair: Wu Fangdi (NIM), Vice Chair: Li Hongmei (NIM)

CJCTLM Executive Secretary: Xu Bei (NIM)
1. IVD Regulations In China

## IVD Management in China – NIM

Reference Measurement Procedures Coordinated by CJCTLM

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>JJF 1383-2012</td>
<td>Calibration Specification for Portable Blood Glucose Meters</td>
</tr>
<tr>
<td>JJG1051-2009</td>
<td>Calibration Specification for Electrolytes Analyzers</td>
</tr>
<tr>
<td>JJG714</td>
<td>Verification Regulation of Blood CELL analyzer</td>
</tr>
<tr>
<td>JJF 1353-2012</td>
<td>Calibration Specification for Hemodialysis Equipment</td>
</tr>
</tbody>
</table>

**Finished in 2015**

- Reference method for total bilirubin in serum
- Reference method for total biliprotein in serum
- Reference method for glucose in serum (UV Spectrometer)
- Reference method for Catalytic activity of alkaline phosphatase in serum

**To be finished in 2016**

- Reference method for Glycosylated hemoglobin concentration in whole blood
- Reference method for uric acid in serum
- Terminology for clinical medical metrology
2. China’s Efforts on IVD traceability

Hierarchy of Laboratories

- National Metrology Institutes
- Accredited Reference Laboratories
- Routine (Testing) Laboratories
2. China’s Efforts on IVD traceability

Reference Measurement Systems

REFERENCE METHODS

REFERENCE MATERIALS

REFERENCE LABORATORIES

A technical process to reach conformity of measurement procedures by applying highest scientific standards
2. China’s Efforts on IVD traceability

295 CRMs in JCTLM Database by NMIs & DIs

Related CRMs in JCTLM Database

- NMIs
- Others

JCTLM Database entries for available certified materials as of February 2015

- Vitamins and Micronutrients: 9
- Proteins: 7
- Nucleic Acids: 9
- Non-Peptide Hormones: 12
- Non-Electrolyte Metals: 58
- Metabolites and Substrates: 53
- Enzymes: 6
- Electrolytes: 15
- Drugs: 12
- Coagulation Factors: 2
- Blood Groupings: 3

Number of entries for materials

0 10 20 30 40 50 60 70

High-Purity Materials
Matrix Materials
2. China’s Efforts on IVD traceability

Related CRMs in JCTLM Database by NIM CHINA

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Matrix/Material</th>
<th>Name of the reference material</th>
<th>Producer</th>
<th>Quantity</th>
<th>Range of certified values in reference material</th>
<th>Range of expanded uncertainties for certified value</th>
<th>Listed in</th>
</tr>
</thead>
</table>
| cholesterol | cholesterol crystalline material | GBW09203b, cholesterol | NIM (National Institute of Metrology), China  
Phone: +86 10 6422 1811  
Fax: +86 10 6421 3149  
crm.service@nim.ac.cn | Mass fraction | 99.7 %  
0.1 %  
Level of confidence 95 % | | List I |
| uric acid      | uric acid crystalline material | GBW09202, uric acid | NIM (National Institute of Metrology), China  
Phone: +86 10 6422 1811  
Fax: +86 10 6421 3149  
crm.service@nim.ac.cn  
NIM (National Institute of Metrology), China  
Phone: +86 10 6422 1811  
Fax: +86 10 6421 3149  
crm.service@nim.ac.cn | Mass fraction | 99.8 %  
0.3 %  
Level of confidence 95 % | | List I |
| urea         | urea crystalline material  | GBW09201, urea | NIM (National Institute of Metrology), China  
Phone: +86 10 6422 1811  
Fax: +86 10 6421 3149  
crm.service@nim.ac.cn  
NIM (National Institute of Metrology), China  
Phone: +86 10 6422 1811  
Fax: +86 10 6421 3149  
crm.service@nim.ac.cn | Mass fraction | 99.9 %  
0.2 %  
Level of confidence 95 % | | List I |
## 2. China’s Efforts on IVD traceability

**73 CRMs** related to in China (not listed in JCTLM Database)

<table>
<thead>
<tr>
<th>Analyte category</th>
<th>No.</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Cell counting</td>
<td>3</td>
<td>CRMs for cell counting in whole blood</td>
</tr>
<tr>
<td>Electrolytes</td>
<td>11</td>
<td>Inorganic spices in urine, serum or hair matrix</td>
</tr>
<tr>
<td>Metabolites and substrate</td>
<td>18</td>
<td>UA, CK, UR, GLU, etc. high purity or serum matrix</td>
</tr>
<tr>
<td>Non-peptide hormones</td>
<td>10</td>
<td>Anabolic-androgenic steroids (AAS)</td>
</tr>
<tr>
<td>Proteins</td>
<td>16</td>
<td>C Peptide, BSA, Glycated Hemoglobin, etc.</td>
</tr>
<tr>
<td>Vitamins</td>
<td>8</td>
<td>Emodin, Rg1, Rb1, etc.</td>
</tr>
<tr>
<td>others</td>
<td>7</td>
<td>Viscosity CRMs</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td></td>
</tr>
</tbody>
</table>
2. China’s Efforts on IVD traceability

Reference Laboratories

JCTLM Database entries for reference measurement services provided by reference laboratories worldwide as of February 2015

- Distribution of the services by country of origin of service providers
- Distribution of the services listed by category of analytes
2. China’s Efforts on IVD traceability

CCQM Key Comparisons, http://kcdb.bipm.org/

Participation in key comparisons

Laboratories not participating in the CIPM MRA are not shown.
Light yellow: number of key comparisons in which at least one laboratory of the country is a participant, without being the pilot laboratory.
Light green: number of key comparisons in which one laboratory of the country is the pilot laboratory.
The number on the y-axis is the number of comparisons.

NIMC

Member States of the BIPM, Associates of the CGPM (*), International Organizations (**).
## 2. China’s Efforts on IVD traceability

### CCQM Key Comparisons, [http://kcdb.bipm.org/](http://kcdb.bipm.org/)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Analyte category</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCQM-K6</td>
<td>Cholesterol in human serum , 2000</td>
<td>Metabolites and substrates</td>
</tr>
<tr>
<td>CCQM-K12.1</td>
<td>Creatinine in human serum , 2005</td>
<td>Metabolites and substrates</td>
</tr>
<tr>
<td>CCQM-K63a</td>
<td>Non-peptide hormones in serum: Cortisol , 2007</td>
<td>Non-electrolyte metals</td>
</tr>
<tr>
<td>CCQM-K63b</td>
<td>Non-peptide hormones in serum: Progesterone,2007</td>
<td>Non-electrolyte metals</td>
</tr>
<tr>
<td>CCQM-K80</td>
<td>Creatinine in human serum ,2010</td>
<td>Metabolites and substrates</td>
</tr>
<tr>
<td>ACRM</td>
<td>co-validation of uric acid and creatinine in human serum</td>
<td>Metabolites and substrates</td>
</tr>
</tbody>
</table>
2. China’s Efforts on IVD traceability

CCQM Key Comparisons, http://kcdb.bipm.org/

Co-validation of Uric Acid CRM
2. China’s Efforts on IVD traceability

CCQM Key Comparisons, http://kcdb.bipm.org/

Co-validation of Creatinine CRM
## 2. China’s Efforts on IVD traceability

Participation in 5 Key Comparisons (IAWG & BAWG), http://kcdb.bipm.org/

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Analyte category</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCQM-K14</td>
<td>Calcium in human serum, 2003</td>
<td>Electrolytes</td>
</tr>
<tr>
<td>CCQM-K49</td>
<td>Toxic and essential elements in bovine liver, 2006</td>
<td>Electrolytes</td>
</tr>
<tr>
<td>CCQM-K89</td>
<td>Trace and essential elements in Herba Ecliptae, 2011</td>
<td>Electrolytes</td>
</tr>
<tr>
<td>CCQM-K107</td>
<td>Elements and Se speciation in human serum, 2013</td>
<td>Electrolytes</td>
</tr>
<tr>
<td>CCQM-K115</td>
<td>Peptide purity determination - synthetic human C peptide (HCP), 2014</td>
<td>Proteins</td>
</tr>
</tbody>
</table>
2. China’s Efforts on IVD traceability

CCQM K89: Lead measurement results and uncertainties

http://kcdb.bipm.org
2. China’s Efforts on IVD traceability

CCQM K89: Zinc measurement results and uncertainties

http://kcdb.bipm.org
## 2. China’s Efforts on IVD traceability

### Participation in Pilot Studies

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Analyte category</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCQM-P54</td>
<td>DNA primary quantification</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P54.1</td>
<td>DNA quantification (repeat)</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P55</td>
<td>Peptide / protein quantification</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P55.1</td>
<td>Peptide / protein quantification (repeat)</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P55.2</td>
<td>Peptide purity determination - synthetic human C peptide (HCP)</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P58</td>
<td>Fluorescence in ELISA</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P58.1</td>
<td>Fluorescence in ELISA (Stage 2)</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P59</td>
<td>Protein structural measurements by CD</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P59.1</td>
<td>Protein structural measurements by CD (repeat)</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P94</td>
<td>Quantification of DNA methylation</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P94.1</td>
<td>Quantification of DNA methylation</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P94.2</td>
<td>Quantification of DNA methylation</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P102</td>
<td>Quantification of cells with specific phenotypic characteristics</td>
<td>Proteins</td>
</tr>
</tbody>
</table>
## 2. China’s Efforts on IVD traceability

### Participation in Pilot Studies

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Analyte category</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCQM-P103</td>
<td>Measurement of multiplexed biomarker panel of RNA transcripts</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P103.1</td>
<td>Measurement of multiplexed biomarker panel of RNA transcripts</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P123</td>
<td>Cell quantification on solid substrate</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P137</td>
<td>Clinical amylase measurement</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P154</td>
<td>Absolute quantification of DNA</td>
<td>Proteins</td>
</tr>
<tr>
<td>CCQM-P155</td>
<td>Multiple cancer cell biomarker measurement</td>
<td>Proteins</td>
</tr>
<tr>
<td>ACRM</td>
<td>Co-validation of Porcine Insulin CRM</td>
<td>Proteins</td>
</tr>
<tr>
<td>ACRM</td>
<td>Co-validation of C Reactive Protein</td>
<td>Proteins</td>
</tr>
<tr>
<td>ACRM</td>
<td>Co-validation of hGH</td>
<td>Proteins</td>
</tr>
<tr>
<td>ACRM</td>
<td>Co-validation of HbA1c</td>
<td>Proteins</td>
</tr>
</tbody>
</table>
2. China’s Efforts on IVD traceability

Participants

CCQM P58.1 Measurement of cTnI in solution by ELISA
2. China’s Efforts on IVD traceability

GB-T 22576-2008/ISO 15189

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Process Control
- Information Management
- Documents & Records
- Occurrence Management
- Assessment
- Process Improvement
- Customer Service
- Facilities & Safety
2. China’s Efforts on IVD traceability

Primary reference measurement procedure:
- MBA (Mass Balance Approach)
- QNMR (Quantitative NMR)

Higher Order Reference Procedure:
- CCQM-K11.1 (GC-IDMS)
- CCQM-K11.2 (LC-IDMS)

NIM certification of Glucose Purity CRM (GBW10062)

Serum Glucose CRM GBW(E)090432-090436

Definition of the measurand

Reference Procedure traceable to higher order reference procedure (WST350-2011 Reference Procedure of Measurement of glucose in Serum) “Hexokinase”

Traceability

Uncertainty
2. China’s Efforts on IVD traceability

Organization of Serum Glucose PT

- Define/review Protocol
  - Specify/review quality criteria
  - Prepare/validate test materials
  - Score/analyse participant results
  - Review outcome/modify scheme

- Define analytical procedures
  - Analyse test materials
  - Report results
  - Review procedures
2. China’s Efforts on IVD traceability

- **Proficiency Test for Reference Laboratory**

- **2014-2015**: Proficiency testing programs to improve reference laboratories traceability in serum glucose assay

- **Participates**: 11 reference labs
- **Measurand**: Serum Glucose
2. China’s Efforts on IVD traceability

Proficiency Test for Reference Laboratory

**Z-score**

\[ z = \frac{x - \mu}{\sigma_p} \]

- \( x \) is the participant’s reported results.
- \( \mu \) is the assigned value.
- \( \sigma_p \) is the standard deviation for proficiency assessment

- \(|z| \leq 2\): “Satisfactory” (“S”) performance.
- \(2 < |z| < 3\): “Questionable” (“Q”) performance.
- \(|z| \geq 3\): “Unsatisfactory” (“U”) performance.

No outliers
2. China’s Efforts on IVD traceability

Proficiency Test for Reference Laboratory

- 2008-2009: Proficiency testing programs to improve reference laboratories traceability in Clinical Enzyme assay
- Participates: 12 reference labs
- Measurands: lactate dehydrogenase (LDH), creatine kinase (CK)
## 2. China’s Efforts on IVD traceability

<table>
<thead>
<tr>
<th>Analyte Category</th>
<th>Analyte</th>
<th>Location of Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzymes</td>
<td>Alanine aminotransferase</td>
<td>China</td>
</tr>
<tr>
<td></td>
<td>Alkaline phosphatase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alpha-amylase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Aspartate aminotransferase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Creatine kinase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gamma-glutamyltransferase</td>
<td>Spain</td>
</tr>
<tr>
<td></td>
<td>Lactate dehydrogenase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alkaline phosphatase</td>
<td></td>
</tr>
<tr>
<td>Metabolites &amp; Substrates</td>
<td>Glucose</td>
<td>Italy</td>
</tr>
<tr>
<td></td>
<td>Glucose</td>
<td>China</td>
</tr>
<tr>
<td></td>
<td>Urea</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total glycerol</td>
<td>Germany</td>
</tr>
<tr>
<td></td>
<td>Uric acid</td>
<td></td>
</tr>
<tr>
<td>Non Peptide Hormones</td>
<td>Thyroxine</td>
<td>Germany</td>
</tr>
<tr>
<td></td>
<td>Testosterone</td>
<td></td>
</tr>
<tr>
<td>Proteins</td>
<td>HbA1c</td>
<td>France</td>
</tr>
<tr>
<td></td>
<td>Total protein</td>
<td>China</td>
</tr>
</tbody>
</table>
Statistics from the Ministry of Health show that: China's medical devices industry has made rapid progress and the annual growing rate has reached 15% ~ 20% since 2001.

In 2008, the gross output value of medical devices reached 300 billion Yuan.

by 2020, China will become the world's second largest healthcare market.

http://mcevoyandfarmer.com/china.html
3. Future Demands and Tendency

**IVD document standards**

- **Priority**
  - Biochemical diagnosis
  - Immunodiagnosis
  - Molecular diagnosis

- ~20 items/year
- ~100-120 items (2016-2020)
- ~75% product standards
- ~25% management standards
3. Future Demands and Tendency

IVD Quality Assurance - CRMs

- Fundamental Research
  - Primary methods
  - Biosimilar
  - Commutability

- CRM production (including pure CRM and Serum matrix CRMs)
  - Critical disease biomarker CRMs, such as tumor, cardio-cerebrovascular disease and diabetes.
3. Future Demands and Tendency

**IVD Quality Assurance – Verification and Calibration**

- **Verifications**
  - Biochemical diagnosis devices, eg. Automatic biochemistry analyzer;

- **Calibration Specifications**
  - Immunodiagnosis devices, eg. Micro plate chemiluminescence analyzer;
  - Cytodiagnosis devices, eg. Urinary sediment analyzer.
## 3. Future Demands and Tendency

### IVD Quality Assurance – Standards & CRMs

<table>
<thead>
<tr>
<th></th>
<th>~600 Clinical inspection items by WS/T 102-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>~120 Products Standards By the end of 2014</td>
<td>~100-120 new Standards in the next 5 years</td>
</tr>
<tr>
<td>~50 Clinical CRMs By the end of 2014</td>
<td>~50 Clinical CRMs In the next 5 years</td>
</tr>
<tr>
<td></td>
<td>~100-120 New Gap of Clinical CRMs To support IVD standards!</td>
</tr>
</tbody>
</table>

Gap of document standards!

Gap of total clinical CRMs

A long way to go!
Thank you for your Attention!