Hangzhou CIRS Co., Limited (CIRS China)
11F,1# Building Dongguan High Tech Zone, 288# Qiuyi Road,
Binjiang District, Hangzhou, Zhejiang, China
Tel: 0086 571 87206541 Fax: 0086 571 87206533
Email: Edwin.wen@cirs-group.com

Guiding Principle for the Instructions of In Vitro Diagnostic Reagents

The instruction of In vitro diagnostic reagents includes intended use, inspection methods, and explanation for inspection consequence, cautions, and other important information. The instruction is important technical document to guide operators to use properly and doctors to understand correctly and apply reasonably.

The guide principle explains the write format and various contents of instruction of In vitro diagnostic reagents in detail in according with relevant requirements of 《Administrative Rules for the Instructions and Labels of Medical Devices》 issued by CFDA. The purpose of the guide principle is providing principled guidance for instruction of In vitro diagnostic reagents, as well as providing technical reference for instruction review for registration administrative department.

The instruction of In vitro diagnostic reagents is not the same because of wide specialty span, multiple methodology, and different intended use. Applicant compiles instruction should in according with product feature and intended use to help followers to get accurate information.

Article 1

Format of instruction in vitro diagnostic reagents

××××（Common Name）Instruction

【Product Name】

【Packing Specification】

【Intended Use】

【Inspection Mechanism】

【Main Composition】

【Storage Condition and Validity Term】

【Applied Instrument】

【Specimen Requirement】

Address: 11/F., Building 1, Dongguan Hi-Tech Park, 288 Qiuyi Road, Binjiang District, Hangzhou 310052, China
Tel: +86 571 8720 6555 | Fax: +86 571 8720 6533 | Email: Edwin@cirs-reach.com

【Inspection Method】

【Positive Estimate Value or Reference Interval】

【Explanation for Inspection Consequence】

【Limitation of Inspection Method】

【Performance Index】

【Cautions】

【Explanation for Marks】

【Reference】

【Basic Information】

【Registration Serial Number/Record Number/Technical Requirement】

【Instruction Manual Approval and Revision Date】

Some of above requirements can be absent if it is not applicable for the product.

Article 2

Introductions of various contents

The contents of instruction should be all expressed in Chinese in principle. If including international abbreviations or abbreviations widely accepted in industry, the abbreviations can be marked in parenthesis behind Chinese. If there is no proper Chinese term for the expression of product, it can use corresponding English or abbreviations.

【Product Name】

1. Common Name

   Common name should be named in according with the nomenclature of 《Administrative Measures for the Registration of In Vitro Diagnostic Reagents》, and refer corresponding “Classified Catalogue” and/or GB and YY standards.

   Except for the products with special use can note the sample type in common name, the rest products cannot note the sample type, qualitative/quantitative, and other contents.

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2. English Name

【Packing Specification】

Noting the number of samples those are able to be used for testing or packing volumes. For example: ××sample number/Case, ××mL. Except for measuring unit used internationally, other contents should be expressed in Chinese. If the product contains different components, it can specify name of the components. If the product has Art.No., it can add Art.No.information.

【Intended Use】

The first paragraph should detail the intended use (such as qualitative/quantitative determination self testing validation, etc.), sample type, analyte, and so on. The specific expressional forms can make appropriate adjustments in according with product feature. The sample source should be noted if the samples come from special subjects such as pregnant woman, newborn, and so on.

The second paragraph should detail the clinical applicability and background which are related to intended use, and explain relevant clinical diagnostic methods or laboratory diagnostic methods, and so on.

【Inspection Mechanism】

Specify the inspection mechanism and methods through texts or diagrams if necessary.

【Main Composition】

1 Reagent component which is included in the product:
  1.1 Specify name, quantity and proportion or concentration of reaction system. It should provide biological source, activity and other feature if they are important for correct operation.
  1.2 Specify whether each component of reagent kit with different batch number can be interchange or not.
  1.3 Specify the information of consumable such as name, quantity, and so on if the kit includes consumable. The consumable are plastic dropper, microplate sealer, valve bag, and so on.
2 For reagent component which is not included in the product and necessary for the test, it should detail the name, purity, dilution method or mixed method, and other relevant information.
3 Calibrator and quality control
  3.1 Specify main composition and biological source.
  3.2 Note the constant value of calibrator and traceability.
  3.3 Note the target value range of quality control. If the range of each batch product

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is different, it should note the specificity of each batch, and attach the individual target value list.

【Storage Condition and Validity Term】

1 Specify the storage condition, such as 2 ~ 8℃, below -18℃, avoid/forbid freezing. Other conditions which can affect stability should be detailed, such as: light, humidity, etc. If the stability of the products or components will change after opening, the storage condition of opened product should be specified.
2 Validity term: specify the validity term in the storage condition. If the stability of the products or components will change after opening, the validity term of opened product should be specified.
3 If the stability of each component is different, the storage condition and validity term of each component should be specified respectively.

【Applied Instrument】

Specify the applied instrument and model and provide relevant information to help user to use correctly.

【Specimen Requirement】

Specify the following:

1 Applied specimen type
2 Special remarks in the process of specimen collection
3 The necessary anticoagulation and protective agent, etc. which can ensure the stability of each specimen component
4 Known chaff interferent
5 The storage, disposable and transportation which can ensure the stability of specimen

【Inspection Method】

In order to ensure the test can be made properly, it should specify the every step as following:

1 Reagent preparation: dilution, mixture and other necessary procedure of each component.
2 Test condition must be met: PH value, temperature, time and wavelength of each step, stability of final reaction product. Matter that needs attention in test process.
3 Calibration procedure (if necessary): calibrator preparation and usage, drawing method of calibration curve.
4 Quality control procedure: quality control usage and method.
5 Test result calculation or read, include explanation of every coefficient and every

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calculation steps. If possible, it should illustrate.

【Positive Estimate Value or Reference Interval】

Specify the positive estimate value or reference interval, and brief describe the determination method of positive estimate value or reference interval.

【Explanation for Inspection Consequence】

Specify the factors which may affect the test results and what circumstances the validation test need be made.

【Limitation of Inspection Method】

Specify the limitation of inspection method.

【Performance Index】

Specify the performance index of product.

【Cautions】

Specify the necessary cautions, such as only used for in vitro diagnosis.

If the product includes human-derived substance and animal-origin substance, it should give the warning of potential infection.

【Explanation for Marks】

If there is graph or symbol in the instruction, it should explain the significance of the product.

【Reference】

Note the references

【Basic Information】

1 In vitro diagnostic reagents within China

1.1 Registrant (Recorder) and manufacturer should belong to the same industry. It should label the basic information as following:

Registrant (Record)/ Manufacturer Name

Address

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Contact information

After-sales service organization Name

Contact information

Address of manufacturing site

Production license number or Production record number

1.2 For commissioning manufacture, it should label the basic information as following:

Registrant (Record)/ Manufacturer Name

Address

Contact information

After-sales service organization Name

Contact information

Commissioned manufacturer Name

Address

Address of manufacturing site

Production license number or Production record number

2 Imported in vitro diagnostic reagent

It should label the basic information as following:

Registrant (Record)/ Manufacturer Name

Address

Address of manufacturing site

Contact information

After-sales service organization Name

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Contact information

Agent Name

Address

Contact information

【Registration Serial Number/Record Number/Technical Requirement】

Note the registration serial number or record number.

【Instruction Manual Approval and Revision Date】

Note the date of approval. If the instruction has applied changes, it should note the data changed of the instruction.

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