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體外診斷醫療器材查驗登記須知中英文版

中文	英文翻譯
體外診斷醫療器材查驗登記須知	**Guidelines** for Registration of In Vitro Diagnostic Medical Device
壹、前言	Chapter I. Introduction
體外診斷醫療器材查驗登記應依醫療器材查驗登記審查準則及相關規定辦理。本須知所稱體外診斷醫療器材（In Vitro Diagnostic Device, IVD）係指蒐集、準備及檢查取自於人體之檢體，作爲診斷疾病或其他狀況（含健康狀態之決定）而使用之診斷試劑、儀器或系統等醫療器材。體外診斷試劑係指前述之任何試劑、校正物質或對照物質。	The Registration of In Vitro Diagnostic Medical Device (IVD) shall be done according to **Guidelines for Registration of Medical Devices** and relevant regulations. In the present guidance, In vitro diagnostic medical device (IVD) are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. While “In Vitro Diagnostic Reagents” are referring to reagent, calibrator or control material for the above described purpose.
爲了加強對於體外診斷醫療器材之管理，確保體外診斷醫療器材之安全性及功效性，特制定本須知，作爲第二等級及第三等級體外診斷醫療器材查驗登記審查之補充規定。第二等級及第三等級體外診斷醫療器材須依『醫療器材查驗登記審查準則』第十五條及第十七條要求檢附以下資料，以證明器材之安全性與功效性：	To facilitate an effective regulatory control of IVD, ensuring the safety and effectiveness of such products, the present guidance by Department of Health, Executive Yuan (DOH) aims to provide supplementary information on registration of class II and class III IVD. The following documents shall be submitted to demonstrate the safety and effectiveness of the device, when applying for the registration and market approval of class II and class III IVD, as according to Article 15 and 17 of **Guidelines for Registration of Medical Devices**:

一、黏貼或裝釘於標籤黏貼表上之中文仿單目錄、使用說明書、包裝及標籤。 二、臨床前測試及原廠品質管制之檢驗規格與方法、原始檢驗紀錄及檢驗成績書。 三、產品之結構、材料、規格、性能、用途、圖樣等有關資料。但申請查驗登記之醫療器材如係儀器類產品者，得以涵蓋本款資料之操作手冊及維修手冊替代之。 四、學術理論依據與有關研究報告及資料。 五、臨床試驗報告。 六、發生游離輻射線器材之輻射線防護安全資料。	1. Chinese translation of instructions, manual, packaging, and labels shall be affixed or stapled to the label attachment form. 2. The pre-clinical testing and original manufacturer quality control test specifications and methods, original test records, and test report. 3. Information on product construction, materials, specifications, performance, uses, and drawings etc. However, in the case of instruments, operating manuals and service handbooks covering the items in this subparagraph may be submitted instead. 4. Theoretical basis and relevant research reports and data. 5. Clinical trial reports. 6. Radiation safety information for equipment emitting ionizing radiation.
貳、適用範圍	Chapter II. Scope
本須知適用於列屬本署『醫療器材管理辦法』附件一 A 臨床化學及臨床毒理學、B 血液學及病理學、C 免疫學及微生物學，及其他相關規定之體外診斷醫療器材。	The scope of the present document is confined to devices described in Annex I of the Regulations Governing Management of Medical Devices, as indicated below: A. CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES; B. HEMATOLOGY AND PATHOLOGY DEVICES, and; C. IMMUNOLOGY AND MICROBIOLOGY DEVICES.
叁、第二等級體外診斷醫療器材查驗登記申請資料（不含行政資料）	Chapter III. Application Information for Registration of Class II In Vitro Diagnostic Medical Device (administrative information not included)
第一條 中文仿單目錄、使用說明書、包裝及標籤應提供下列資料：	Article 1: Chinese translation of instructions, manual, packaging, and labels shall contain the following information:

一、提供體外診斷醫療器材之實體相片或任何可說明實體之目錄。 二、中文仿單或外文仿單及其中文譯稿。所有體外診斷醫療器材均須考慮使用者所具備的訓練與知識而提供適當的仿單，並將其附著或黏貼於銷售的包裝上。 三、儘可能以符合國際標準（如 EN 980、ISO 15223）或本署公告之符號及顏色標示相關資訊。若無相關標準時，製造業者須提供符號與顏色的說明。 四、具危險性之體外診斷醫療器材要根據其成分與形式的特性，遵循相關公告之規定標示。假如體外診斷醫療器材無足夠空間可供黏貼，警示須置於標示或仿單上。 五、標籤或包裝應載明之資訊請參考附錄一。 六、仿單應載明之資訊請參考附錄二。	1. Photographs or product brochure describing the device. 2. Package Inserts in Chinese or package inserts in foreign language with a corresponding Chinese translation. Each device shall be accompanied by the appropriate information, taking account of the training and knowledge of the potential users, by attaching or affixing the information onto the sales packaging. 3. Where appropriate, symbol and identification color used shall conform to the international harmonized standards (e.g. EN980, ISO15223) or the relevant announcement made by Department of Health, Executive Yuan (DOH). If no relevant standards exist, the manufacturer shall provide a clear description and explanation about the symbols and color used with the product. 4. In the case of IVD which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, labeling requirements according to relevant announcement made by DOH shall be followed. If there is insufficient space to put all the information on the device itself or on its label, the relevant warning symbols shall be put on the label or instructions for use. 5. The labeling and packaging shall contain relevant information with reference to Appendix I 6. The product instruction and manual shall contain information as described in Appendix II
第二條 臨床前測試及原廠品質管制之檢驗規格與方法、原始檢驗紀錄及檢驗成績書應依據體外診斷醫療器材之特徵提供下列資料： 一、前項資訊通常包括但不限於以下項目：	Article 2: Information on the pre-clinical testing and original manufacturer quality control test specifications and methods, original test records, and test results report, taking into account the nature and properties of the IVD, shall contain the following: 1. Basic information shall in general include, but not limited to the following:

（一）靈敏度（Sensitivity）。 （二）特異性（Specificity）。 （三）干擾性研究（Interference study）。 （四）準確性（Accuracy）。 （五）精密度/再現性（Precision/Reproducibility）。 （六）閾值確認（Cut-off Value）。 （七）安定性（Stability）。 （八）追溯性（Traceability）。 （九）其他爲了證明符合相關安全性與功效性要求所需之化學、物理、電力、機械、生物性、電性安全、電磁相容性、軟體驗證、無菌或微生物限量等內容的說明資料。 （十）須檢附一份製造過程之流程圖及其描述。 （十一）須檢附一份主成份（Main Active Ingredient）及最終成品之檢驗成績書。	a. Sensitivity; b. Specificity; c. Interference study; d. Accuracy; e. Precision/Reproducibility; f. Validation of cut-off value; g. Stability; h. Traceability; i. Other chemical, physical, electrical, mechanical, biological, electrical safety, electromagnetic compatibility, software validation, sterility or microbiological control information relevant for demonstrating compliance to the safety and effectiveness requirement j. A representation and description of the manufacturing process flow. k. Testing results of main active ingredient(s) and final product.
二、臨床前測試應擇一符合下列基本要求，並建議於器材設計時採用本署公告之採認標準或其他國際標準。若因正當理由無法符合時，必須提供相當之替代方案。 （一）得與國內已核准上市或美國、日本、加拿大、瑞士、澳洲及歐盟中至少一國核准上市之同類產品進行比對測試。 （二）符合 GHTF Summary Technical Documentation (STED) for IVD、GHTF Essential Principle for IVD。	2. Selection of pre-clinical testing shall comply with one of the following requirement. It is recommended the design of the device should use standard recognized by DOH or other international harmonized standard. If compliance cannot be demonstrated through sound scientific rationale, an alternative but comparable method shall be used. a. Pre-clinical performance evaluation may be carried out in direct comparison with a device, which is currently marketed in Taiwan or one of the following countries or areas: United States, Japan, Canada, Switzerland, Australia, or European Union. b. Comply with GHTF Essential Principle with the use of Summary Technical Documentation (STED) for IVD.

三、臨床前測試之表述方式包含： （一）實驗設計描述，至少包括：材料、方法、允收基準。 （二）資料分析方法。 （三）實驗報告（得以圖表表示）。 （四）實驗結論。 （五）本署審查時，原則得以含上述四項內容之文件作爲審查依據，惟必要時得要求檢附原始測試紀錄（Raw data）。	3. Information on pre-clinical testing shall include: a. the description of study design, including but not limited to e.g. materials used, method, acceptance criteria etc. b. the method of data analysis. c. the study report (can be graphically presented). d. the study conclusion. e. Review of the registration will be based on submitted documents containing the above described information, and when necessary, raw data of tests shall be submitted upon request.
四、若爲供使用者自我測試之家用體外診斷醫療器材，應檢附非專業使用者自我測試之評估報告。	4. User performance evaluation/usability study for home-use IVD device, if appropriate, shall be conducted to determine the device's performance when used by lay users, unassisted, following instructions provided in the labeling.
五、若爲無菌製品，須檢附滅菌確效資料。	5. Documentation on sterilization process validation shall be submitted for sterile product.
六、若爲具輻射性的體外診斷醫療器材，須提供詳細的資訊，說明輻射的性質、防護措施、防止誤用、及防止裝設時產生危害的方法。	6. The operating instructions for devices emitting radiation giving detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.
七、無同類產品可供比對測試及新檢驗項目、新方法、新原理之體外診斷醫療器材，則以新體外診斷醫療器材管理。除上述資料外，應一併檢附學術理論依據與有關研究報告及資料，並檢附臨床評估報告，臨床評估得參考第肆章第十三條規定辦理。	7. IVD that employs new method, new principle or no comparable product exists shall be deemed as new IVD for regulatory purpose. For new IVD, other theoretical theory and related relevant research report and information, in addition to the information above, shall be submitted together with clinical evaluation reports as prepared according to Chapter 4, Article 13 of the present document.
第三條 產品之結構、材料、規格、性能、用途、圖	Article 3: Submission of product construction, materials, specifications, performance,

樣應提供下列資料：（申請查驗登記之醫療器材如係儀器類者，得以涵蓋本款資料之操作手冊及維修手冊替代之。）	uses, and drawings information. In the case of instruments, operating manuals and service handbooks covering the items in this Subparagraph may be submitted instead.
一、預期用途，其內容得包含： （一）器材的檢測標的。 （二）器材是否爲自動化。 （三）器材的預期用途。 （四）器材爲定性、半定量或定量。 （五）用於特定疾病、狀況或風險因子的檢測、定義或判別。 （六）檢體的種類（例如：血清、血漿、全血、組織切片、尿液）。 （七）受檢族群。	1. The intended use. This may include: a. what is being detected by the assay; b. whether the assay is automated; c. what the device is intended for; d. whether the test is qualitative, quantitative or semi-quantitative; e. for a specific disorder, condition or risk factor of interest that the test is intended to detect, define or differentiate; f. the type of specimen(s) required (eg. serum, plasma, whole blood, tissue biopsy, urine); g. testing population.
二、體外診斷醫療器材的功能敘述（篩檢、監控、診斷或協助診斷、疾病的分期）。 三、檢測方法或儀器操作原理之敘述。 四、預期的使用者（專業或非專業使用者）。 五、器材所有組成之敘述，如：抗原、抗體、受質、核酸引子、緩衝液、建議搭配使用的品管材料與校正品等。 六、檢體採集及其運送材料之敘述。	2. A clear statement of the function of the IVD medical device (screening, monitoring, diagnostic or aid to diagnosis, staging or aid to staging of disease); 3. A general description of the principle of the assay method or instrument principles of operation; 4. The intended user (lay person or professional); 5. A description of all components of the assay, including but not limited to antibodies, antigens, nucleic acid primers, buffers, assay controls and calibrators used with the IVD medical device; 6. A description of the specimen collection and transport materials provided with the IVD medical device;
七、自動化分析儀器的分析特徵及其預定使用試驗之	7. A description of the appropriate assay characteristics or dedicated assays for

敘述。（如適用） 八、自動化試驗所使用的儀器及其特徵之敘述。（如適用） 九、所使用軟體之敘述。（如適用） 十、體外診斷醫療器材各種組合或包裝的敘述或完整清單。（如適用） 十一、配件及其他配合使用之相關產品敘述。（如適用）	instruments of automated assays; 8. A description of the appropriate instrumentation characteristics or dedicated instrumentation for automated assays; 9. If applicable, a description of any software to be used with the IVD medical device; 10. If applicable, a description or complete list of the various configurations/variants of the IVD medical device that will be made available; 11. If applicable, a description of the accessories, other IVD medical device and other products which are not IVD medical device, and are intended to be used in combination with the IVD medical device.
肆、第三等級體外診斷醫療器材查驗登記之特殊要求	Chapter IV. Special Requirements for Class III In Vitro Diagnostic Medical Device
第四條 第三等級體外診斷醫療器材除前章所述資料外，尚應提供下列補充資料： 一、主成分（Main Active Ingredient）與半製（成）品之規格與分析方法。（如適用） 二、成品之規格與技術性資料。 三、成品製造及純化過程。（如適用） 四、製程管制或批次製造紀錄。 五、安定性資料。（如適用） 六、分析方法確效。 七、臨床評估報告。	Article 4: For Class III IVD, in addition to the information mentioned in Chapter III, the following supplementary information shall be submitted: 1. Specification and analytical methods of main active ingredient and semi-finished product. (if appropriate) 2. Specification and technical information of final product. 3. The manufacturing and purification process of final product. (if appropriate) 4. Process Control or Batch Production Records 5. Stability information (if appropriate) 6. Analytical Method Validation documents 7. Clinical Evaluation Reports
第五條 主成分與半製（成）品之規格與分析方法：	Article 5: Specification and analytical methods of main active ingredient and semi-finished product:
一、主成分與半製（成）品須檢附原廠規格：	1. Original manufacturer’s specification of main active ingredient and semi-finished

（一）特性描述：用以製造體外診斷試劑最終成品的主成分與半製（成）品均須有明確之敘述，如化學結構、一級和次單元結構（primary and subunit structure）、分子量、分子式、名稱、抗體種類/亞型（antibody class / subclass），及針對其特性進行鑑別、效價、特異性、純度、安定性、一致性等分析測試結果。	product shall be submitted: a. Characterization and Description: A clear description of each main active ingredient and semi-finished product shall be provided. These descriptions may include, but are not limited to, any of the following: chemical structure, primary and subunit structure, molecular weight, molecular formula, name, antibody class/subclass, etc., as appropriate. Results of all characterization analytical testing shall be submitted, including information on identity, potency, specificity, purity, stability, consistency, etc.
（二）物理化學試驗：依實際需要選擇適當項目分析之，例如： 1、(1)胺基酸分析(2)氮端與碳端之胺基酸序列(3)完整胺基酸序列(4)核酸序列(5)胜肽圖譜/酵素水解圖譜(6)雙硫鍵鍵結的測定(7)SDS-PAGE（Sodium Dodecyl Sulfate-Polyacrylamide Gel Electrophoresis，包括還原及非還原條件）(8)等電點聚焦電泳(9)傳統與高效液相層析，如逆相（reverse-phase）、分子篩（size exclusion）、離子交換（ion -exchange）等(10)質譜儀圖譜(11)測定蛋白質之去胺基（deaminated）、被氧化（oxidized）、斷裂（clipped）和聚集（aggregated）形式或其他變異物，如胺基酸置換（substitutions）、併接（adducts）/衍生物(12)測定非專一性宿主蛋白、DNA 與試劑之殘餘量(13)免疫化學分析(14)負荷菌與內毒素之定量(15)抗體中和反應(16)凝血反應(17)抑制凝血反應試驗(18)蛋白質之氮含量。	b. Physicochemical Characterization: the following list of analysis should be performed as necessary: • amino acid analysis • amino- and carboxyl-terminal sequencing • full amino acid sequencing • nucleic acid sequencing • peptide mapping/enzymatic mapping • determination of disulfide linkage • Sodium Dodecyl Sulfate-Polyacrylamide Gel Electrophoresis (SDS-PAGE) (reduced and non-reduced) • isoelectric focusing • Conventional and High Pressure Liquid Chromatography (HPLC), e.g., reverse-phase, size exclusion, ion-exchange, etc. • mass spectroscopy • assays to detect substance-related proteins including deaminated, oxidized, clipped, and aggregated forms and other variants, e.g., amino acid substitutions, adducts/derivatives

	• assays to detect residual non-specific host proteins, DNA, reagents • immunochemical analyses • assays to quantitate bioburden and endotoxin • antibody neutralization • hemagglutination • hemagglutination inhibition • protein nitrogen level
2、於修飾作用（modification），如醣化作用，以及與其他物質如蛋白質、酵素、放射性核種或化學藥品等形成衍生物質，其物理化學特性也須予以敘述，包括衍生或結合之程度、未修飾原料之含量、游離物質（例如酵素、蛋白質、放射性核種等）之去除、以及經修飾原料之安定性。	(b) Additional physicochemical characterization may be necessary for substances undergoing post-translational modifications, e.g., glycosylation, and for substances derivatized with other agents, including other proteins, enzymes, radionuclides, or chemicals. The information submitted shall include the degree of derivatization or conjugation, the amount of unmodified substance, removal of free materials (e.g., enzymes, proteins radionuclides, etc.), and the stability of the modified substance as a result of the manufacturing process.
3、所有的測試方法須有完整的敘述以及結果，包括色層分析圖、電泳的原始照片、光譜及質譜等之資料。	(c) All test methods shall be fully described, and the results provided. The application shall also include the actual data such as chromatograms, photographs of SDS-PAGE or agarose gel, spectra, etc.
4、前述資料得以允收標準、測試步驟及測試結果輔助審查。	(d) Information of the above shall be submitted with acceptance criteria, testing procedures and testing results to facilitate submission review.
（三）規格與分析方法： 1、主成分與半製（成）品之規格及測試： 須詳述放行測試（release testing）之規格及分析方法、有效期限之制定、運送條件及主成分與半製（成）品	c. SPECIFICATIONS/ANALYTICAL METHODS (a) Specifications and Tests for main active ingredients and semi-finished products: Specifications and analytical methods used for release testing, shelf life determination and distribution conditions shall be described in

之鑑別、純度、強度及/或效價、特異性、批次間一致性等規格與檢驗方法。若爲非學術理論公認之檢驗方法，須予確效以證實其合適性。	detail, in addition to the specifications and tests for their identity, purity, strength and/or potency, specificity, and batch to batch consistency. The analytical systems shall be validated and the data shall be provided for non-compendial methods to demonstrate the system suitability.
2、不純物： 必要時須提供不純物包括主成分與半製（成）品蛋白質是否變異（如斷裂、聚集、去胺與氧化）與其他不純物(如製程中試劑和細胞培養成分等)之分析資料。	(b) Impurities Profile If appropriate, analytical information of variants of the protein main active ingredient and semi-finished product (e.g., clipped, aggregated, deaminated, and oxidized forms), as well as non-product related impurities (e.g., process reagents and cell culture components), shall be included.
二、對照標準品/血清組： （一）對照標準品：如使用國際對照標準品，須檢附該標準品之規格與分析成績書。若無對照標準品，可自行建立廠內一級對照標準品（in-house, primary reference standards），但須檢附該標準品之特性、規格與分析成績書。	2. REFERENCE STANDARDS/PANELS a. Reference Standard: If an International Reference Standard is used, the citation for the standard and a certificate of analysis shall be submitted. If no reference standard exists and the applicant establishes in-house, primary reference standards, a description of the characterization, specifications and test report of the standards shall be provided.
（二）廠內工作標準品：廠內工作對照標準品（working reference standards）須檢附其製備、特性、規格、測試、更新與分析成績書。	b. In-house Reference Standard: In-house working reference standards shall be used and the descriptions of the preparation, characterization, specifications, testing, substitutions, and results shall be provided.
第六條 成品之規格資料： 除前章第二條所述之資料外，原廠品質管制之檢驗規格與方法、原始檢驗紀錄及檢驗成績書，尚須敘述所有用於成品製造之組成說明，包括數量、比率或配方	Article 6: The Specification of the finished product In addition to the information mentioned in Article 2, the original manufacturer quality control test specifications and methods, original test records, and test results report, a description of the finished product including the composition, such as quantity, ratio or

等。檢驗成績書包括以下事項： 一、須註明批號、檢驗日期、檢驗人員及負責人簽名。 二、須包括所有主成分、半製（成）品及成品之檢驗成績書。 三、須依規格逐項檢驗。 四、主成分檢驗成績書須爲所附成品批次使用之主成分檢驗成績書。 五、檢驗結果爲數值者須以數據表示，檢驗方法爲比對標準品者可以「Pass」表示。	formulation etc shall be submitted. The test report shall include: 1. The lot/batch number, test date, signatures of the tester and the responsible person. 2. Test reports of main active ingredient used, semi-finished product and finished product. 3. Test results against each and all specification. 4. Test reports for the main active ingredient of the batch that is being used to manufacture the specified finished product. 5. Test data for quantitative test result, and “Pass” or “Fail” for presenting result of comparison test against standard reference materials.
第七條 基本技術規格：	Article7: COMMON TECHNICAL SPECIFICATIONS (CTS)
用於檢測、確認、定量HIV-1、HIV-2、HTLV- I、HTLV-II及肝炎病毒（HAV、HBV、HCV、HDV、HEV）之體外診斷醫療器材之基本技術規格如下： 一、用於檢測病毒之體外診斷醫療器材，無論用於篩檢或診斷之測試，都須符合相當之靈敏度與特異性要求。	CTS for IVD in the detection, confirmation and quantification of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis (HAV, HBV, HCV, HDV, HEV) should include the following: 1. Devices which detect virus infections placed on the market for use as either screening or diagnostic tests, shall meet the same requirements for sensitivity and specificity.
二、用以測試非血清或非血漿之體液（例如：尿液或唾液等）之試劑，須符合對血清或血漿之靈敏度與特異性要求。臨床性能評估須自相同個體取得測試檢體進行測試，且分別進行血清或血漿測試。	2. Devices intended for testing body fluids other than serum or plasma, e.g. urine, saliva, etc. shall meet the same CTS requirements for sensitivity and specificity as serum or plasma tests. The clinical performance evaluation shall test samples from the same individuals in both the tests to be approved and in a respective serum or plasma assay.
三、用以自我測試之試劑，須符合專業用試劑對靈敏度與特異性之相同要求，並由適當消費者執行（或重複）性能評估，以確保使用者可正確操作並判讀結果。	3. Devices intended for self-test, shall meet the same CTS requirements for sensitivity and specificity as respective devices for professional use. Relevant parts of the performance evaluation or usability study shall be carried out (or

	repeated) by appropriate lay users to validate the operation of the device and interpretation of test result.
四、在早期感染階段（血清轉換）之測試靈敏度必須以陽轉血清組（sero-conversion panels）進行評估。	4. Devices intended for early stage infection (seroconversion), the sensitivity shall be evaluated with sero-conversion panels.
五、用於臨床評估之陰性檢體，須能反映測試標的之族群，例如：血液捐贈者、醫院病患、孕婦等。	5. Negative specimens intended for used in a clinical performance evaluation shall be able to reflect the target population for which the test is intended, for example blood donors, hospitalized patients, pregnant women etc.
六、用於捐血者篩檢用之體外診斷試劑之性能評估，須於測試進行前，至少在二個捐血中心執行血液捐贈族群之調查。	6. Devices intended for screening of blood donor, the donor population profile of at least two blood donation centers shall be studies before performing the performance evaluations.
七、用於捐血者篩檢用之體外診斷試劑須具備至少99.5%之特異性，若無法符合時，須提供合理說明。	7. Devices intended to screen for blood donors shall have a specificity of at least 99.5%, justification shall be provided for any discrepancy.
八、用於可同時檢測血清及血漿之試劑，須證明於血清或血漿其性能評估均相同，且須至少驗證50 組檢體。	8. Devices intended to be used with serum and plasma, the performance evaluation shall demonstrate serum to plasma equivalency. This shall be demonstrated for at least 50 sets of specimen.
九、適用於血漿之試劑，須至少驗證 50 組檢體，查證說明使用於該試劑之抗凝血劑對該試劑之性能評估。	9. Devices intended for use with plasma, the performance evaluation shall verify the performance of the device using all anticoagulants which the manufacturer indicates for use with the device. This shall be demonstrated for at least 50 sets of specimen.
十、爲分析風險，須進行弱陽性檢體之重複試驗，以進行整體系統失效率（whole system failure rate）導致僞陰性結果之風險評估。	10. Devices should be subject to risk analysis and the whole system failure rate leading to false-negative results shall be determined in repeat assays on low-positive specimens.
十一、輸入之 HIV 體外診斷試劑須檢附十大先進國中一國之核准上市證明，並須包括與另一經十大先進	11. IVD imported for HIV diagnosis shall accompany proof of pre-market clearance from one of the following countries or areas: United States, Japan, Canada, United

國中至少一國核准使用之上市產品比對之試驗結果，且須包含HIV-1 subtype O 六例以上之檢體測試結果。國內開發之HIV 體外診斷試劑，因國內後天免疫缺乏症候群（AIDS）病例有限，本署將視試劑發展過程及靈敏度測定之方法予以個案審定，必要時得要求廠商於國外進行比對試驗，若爲用於捐血者篩檢用之體外診斷試劑，仍須包含HIV-1 subtype O 六例以上之檢體測試結果，或須加入subtype O 抗原於試劑製程設計中。	Kingdom, Belgium, Germany, Switzerland, France, Australia, or Sweden, a comparison test report against another product with market clearance from one of the above listed countries, and test report for test against at least 6 samples of HIV-1 subtype O. With limited domestic cases of AIDS, IVD for HIV diagnosis developed domestically, DOH shall review the submission on a case by case basis depending on the development process and method for measuring the sensitivity. The manufacturers can be requested to perform comparison testing overseas, and for IVD that screen against blood donors, test report against at least 6 samples of HIV-1 subtype O or to include subtype O antigen in the IVD design.
十二、無論何種原理與方法，B 型肝炎表面抗原（HBsAg）體外診斷試劑之檢驗靈敏度（analytical sensitivity），以能測出每毫升（mL）血清含若干國際單位（IU）之Second International Standard for HBsAg, subtype adw2, genotype A, NIBSC code: 00/588 爲標準，須「小於或等於0.130 IU/mL」。	12. For device intended for assay against HBsAg, independent of the testing principle and method, the analytical sensitivity shall be expressed in terms of the Second International Standard for HBsAG, subtype adw2, genotype A, NIBSC code:00/588 and should be less than or equal to 0.130 IU/mL of serum.
十三、B 型肝炎e 抗原不得以逆向被動血球凝集法（RPHA）測試。	13. For HBeAg device, it shall not be tested by reverse passive hemagglutination method (RPHA).
十四、HIV-1 抗原體外診斷試劑之檢驗靈敏度（analytical sensitivity），以能測出每毫升（mL）血清含若干國際單位（IU）之HIV-1 p24 Antigen, 1st International Reference Reagent, NIBSC code: 90/636 爲標準，須「小於或等於2 IU/mL」。	14. For device intended for assay against HIV-1 antigen, the analytical sensitivity shall be expressed in terms of the concentration of HIV-1 p24 Antigen, 1st International Reference Reagent, NIBSC code: 90/636, and shall be less than or equal to 2 IU/mL.
十五、Anti-HBs 體外診斷試劑之檢驗靈敏度（analytical sensitivity），以能測出每毫升（mL）血	15. For device intended for assay against Anti-HBs, the analytical sensitivity shall be expressed in terms of the concentration of WHO 1st International Reference

清含若干毫國際單位（mIU）之WHO 1st International Reference Preparation 1977; NIBSC, United Kingdom 爲標準，須「小於10 mIU/mL」。	Preparation 1977; NIBSC, United Kingdom and shall be less than 10 mIU/mL.
第八條 核酸擴增技術（Nucleic acid Amplification Techniques, NAT）之額外要求： 一、藉由標的序列的放大分析方法，每個測試檢體宜有內部對照組（internal control），以反映其分析狀態。	Article 8: Additional requirements for nucleic acid amplification techniques (NAT): 1. For target sequence amplification assays, there should be an internal control for each specimen tested to reflect the status of analysis.
二、基因型檢測須提供適當設計之引子（primer）或探針（probe）設計確認資料，並須由已知基因型檢體進行確效（validation）。	2. Genotype detection shall be demonstrated by appropriate primer or probe design validation and shall also be validated by testing characterized genotyped samples. These information shall be submitted as necessary.
三、定量之NAT結果須追溯國際標準品或經校正之對照標準品，並儘可能以國際單位（IU）表示其數值。	3. Quantitative NAT assays shall have results traceable to international standards or calibrated reference materials, if available, and be expressed in international units (IU) utilized in the specific field of application.
四、因免疫複合體中之病毒與游離病毒之作用機轉可能不同，於再現性試驗中須包含前陽轉血清組檢體（pre-sero-conversion samples）。	4. In the reproducibility study, pre-sero-conversion samples shall be included, as viruses within immune-complexes may behave differently in comparison to free viruses.
五、爲了研究檢體間之交互污染，於再現性試驗時須交互操作強陽性與陰性檢體至少五次以上。強陽性檢體須爲自然感染且具高效價之病毒。	5. For investigation of potential carry-over, at least five runs with alternating high-positive and negative specimens shall be performed during robustness studies. The high positive samples shall comprise of samples with naturally occurring high virus titers.
六、應測試弱陽性檢體以評估造成僞陰性結果之整體系統失效率。弱陽性檢體應相當於偵測極限三倍之病毒濃度。	6. The whole system failure rate leading to false-negative results shall be determined by testing low-positive specimens. Low positive specimens shall contain a virus concentration equivalent to three times the detection limit of the virus concentration.

七、必要時，需證實能偵測突變株或各種基因多型性。	7. The ability to detect mutants and different geno-diversity shall be demonstrated, where necessary.
第九條 成品製造及純化過程：	Article 9: The manufacturing and purification process of final product
對於第三等級體外診斷試劑製程中之管制須有完整之敘述，並檢附書面作業程序。 一、製造流程圖：應有一份完整製造過程之流程圖及其描述。	For class III IVD, a complete and detailed description of the control of the manufacturing process shall be submitted accompanying the relevant SOP. 1. Flow Charts: A complete representation and description of the manufacturing process flow shall be submitted.
二、原料： （一）須表列所有使用於製造過程中之原料與半製（成）品成份之名稱、測試方法與規格，或其參考文獻。對於購買之原料，須有供應商之分析證明或廠內檢測結果。	2. Raw Materials and Substances a. A list of all components used in the manufacturing process, their qualifying tests and specifications, or reference to official compendia, shall be submitted. For purchased raw materials, representative certificates of analysis from the supplier(s) and in-house acceptance testing results shall be submitted.
（二）須表列所有使用於製造原料與半製品之特殊試劑與材料，如培養基、稀釋液、染劑、試劑、緩衝液、血清、抗生素、單株抗體、保藏劑之測試方法、測試結果與其相關之規格。某些情況下（如使用胜肽或單株抗體爲製造原料與半製（成）品時）則須詳述其製備過程及特性。	b. A list of qualifying tests, test results and acceptance criteria for all special reagents and materials used in the manufacturing process, e.g., culture media, diluents, dyes, reagents, buffers, sera, antibiotics, monoclonal antibodies, preservatives shall be submitted. In some cases (e.g., if peptide or monoclonal antibody is used as raw material or semi-finished product), a detailed description of preparation and characterization shall be provided.
（三）動物性原料、試劑及成分的管制：若於製造過程中有使用由動物來源取得之原料時，需證明其不含外來物質，如牛海綿狀腦病變（Bovine Spongiform Encephalopathy, BSE）物質，或其他動物病毒。	c. Control of raw materials, reagents and components of animal origin: Information or certification supporting the freedom of substances from harmful agents, e.g., Bovine Spongiform Encephalophathy agent (BSE) or virus of animal origin, shall be included in the submission, if raw material of animal origin is used in the production process.

三、製造過程：依其原料來源之不同，須有其安全性相關之資料，例如：	3. Manufacturing process: Safety related information as according to the origin of the raw materials shall be provided:
（一）動物來源：對於在製造過程中所使用的動物，如用來製造腹水的老鼠、產生血清抗體的兔子、或是基因轉殖動物，須依實際需要載明： 1、所使用之動物來源和種類（若爲基因轉殖動物，則須包含其製備原理及基因安定性）。 2、外來物質的篩選與檢疫步驟。 3、對於牛製品須註明其來源地區及地點。 4、所使用免疫原之（1）免疫原性（2）特異性（3）純度（4）無菌性（5）安定性（6）免疫接種方式、劑量及時程（7）佐劑。 5、所收集原料之重要物質的敘述：（1）收集方法、體積、容器與時程（2）製程步驟與組成之敘述（3）試驗項目之力價（titer）/效價（potency）、親和性、特異性、靈敏度、負荷菌、安定性（4）貯藏條件（5）其他對於原料、製程或用途之特別敘述。	a. Animal Sources Information submitted concerning animals used in manufacturing, such as mice used for ascites production, rabbits used for serum-antibody production, or transgenic animals, shall include detailed information on the following: (a) source and type of animals used (if transgenic, include the method of creation and the genetic stability) (b) harmful agents screening and the quarantine procedures used used (c) specify geographic source and location of herd(s) for bovine products (d) immunogens used • immunogenicity • specificity • purity • sterility • stability • immunization type, dose and schedule • adjuvant if any (e) Description of substance of interest harvested from the raw material • collection method, volume, receptacle, and schedule • description of processing steps and components • testing performed (titer/potency, affinity, specificity, sensitivity, bioburden, stability) • storage conditions • other characteristics unique to the raw material, process or intended

	use.
（二）人來源：對於在製造過程中所使用材料爲人來源時，須依實際需要載明： 1、供應者之合適性/接受允收標準。 2、收集方法、體積和容器。 3、使用之抗凝血劑。 4、重要組成之敘述。 5、成分之處理。 6、測試項目：（1）感染性疾病標記試驗（2）力價（效價）（3）親和性（4）特異性（5）靈敏度（6）負荷菌（7）安定性。 7、純化與去活化步驟。 8、貯藏條件。 9、病毒去活化步驟。 10、免疫注射劑量與時程。 11、其他對於原料、製程或用途之特別敘述。	b. Human Sources The information submitted concerning the use of source material of human origin shall include, but is not limited to, the following: (a) donor suitability/acceptance criteria (b) collection method, volume, and receptacle (c) anticoagulants used (d) description of component of interest (e) component processing (f) testing performed • infectious disease marker tests • titer (potency) • affinity • specificity • sensitivity • bioburden • stability (g) purification and inactivation procedures (h) storage conditions (i) viral inactivation procedures (j) immunization dose and schedule (k) other characteristics unique to the raw material, process or intended use.
（三）細胞來源：對於所使用材料爲細胞來源如單株抗體或重組DNA技術時，須依實際需要載明：	c. Cellular Sources The information submitted concerning the use of source material of cellular

1、細胞來源與種類。 2、細胞之基因型與表現型。 3、母細胞株之特性。 4、單株選殖步驟。 5、不朽化（immortalization）之步驟。 6、監控與測試步驟。 7、基因構築之特性。 8、載體之特性。 9、細胞庫之建立、特性、維持、與安定性。 10、細胞培養步驟。 11、收集步驟。 12、純化與去活化步驟。 13、下游製程步驟。 14、其他對於原料、製程或用途之特別敘述。	origin, e.g., in monoclonal antibody or recombinant DNA technology, shall include, as appropriate, but is not limited to, the following: (a) . source and type of cells (b) phenotype and genotype of cells (c) characterization of the parent cell line (d) cloning procedures (e) immortilization procedures (f) . testing and monitoring procedures (g) characterization of gene construct (h) characterization of vector (i) establishment, characterization, maintenance, and stability of cell banks (j) cell culture procedures (k) harvesting procedures (l) . purification and inactivation procedures (m) downstream processing procedures (n) other characteristics unique to the raw material process or intended use.
（四）合成來源：對於所使用的材料爲合成來源如人工合成胜肽、核苷酸等，須依實際需要載明： 1、名稱。 2、分子式。 3、化學結構。 4、序列。 5、純化步驟。 6、純度。 7、安定性。	d. Synthetic Sources Information shall be submitted concerning the use of materials from synthetic sources, e.g., synthetic peptides. The information submitted shall include, but is not limited to, the following: (a) Name (b) Molecular formula (c) Chemical structure (d) Sequence (e) Purification procedures

8、特異性。 9、其他對於原料、製程或用途之特別敘述。	(f) Purity (g) Stability (h) Specificity (i) Any other special description of raw materials, manufacturing process, or the intended uses.
第十條 製程管制或批次製造紀錄： 須有製程管制標準書或與成品同批之完整批次製造與測試之完整紀錄。	Article 10: Process Control or Batch Production Records Process control procedures and complete batch production record/device history record of the entire process of manufacturing and testing shall be submitted.
一、製程中之管制： 爲確保最終成品符合效能規格（functional requirement）須有製程中管制之監控與測試等，例如固相被覆（solid-phase coating）之完整性、標示於抗體/抗原結合物上酵素之純度與效價。	1. In-process Controls A description of the methods used for in-process controls, i.e., monitoring, testing, etc., used to assure that the functional requirement of the final product is met, e.g., integrity of solid-phase coatings, purity of enzyme labeled antibody/antigen conjugates, and potency, shall be submitted.
二、製程確效： 須有製程確效之研究與其結果。如製程變更或生產規模放大以及製造步驟中有所改變，則須重新評估其製程。爲確保例行之製造，須於製程中指出關鍵性參數，作爲其管制點。	2. Process Validation A description and the results of the process validation studies shall be submitted. If the manufacturing process was changed or scaled-up for commercial production and involved changes in the manufacturing steps, the re-evaluation of the process shall be described, and the data and results provided. The description shall include studies for the following processes which identify critical parameters to be used as in-process controls to ensure the success of routine production.
三、須進行確效研究之製程，例如： （一）細胞生長與收集過程。 （二）純化過程。	3. Validation studies shall be submitted for the following: a. cell growth and harvesting processes b. purification processes

（三）去活化或去除感染性病原之製程。 （四）對於標示須無菌或使用保藏劑之原料，須證明在其易受微生物污染的製程具有適當之管制措施。 （五）固相被覆過程。 （六）結合（conjugation）或衍生（derive）過程。 （七）效價之調整。 （八）其他。	c. inactivating or removing any infectious pathogens from materials used in the manufacturing process d. to demonstrate microbiologic control over those processes susceptible to microbiological contamination for substances labeled as sterile or where preservatives are used. e. . solid-phase coating processes f. conjugation or derivation processes g. . potency adjustments h. . others as appropriate
第十一條 安定性資料：	Article 11: Stability
一、檢附三批成品及半成品之安定性試驗結果。應提供即時（Real Time）安定性試驗資料，並得以加速性安定性試驗之相關文獻與試驗報告補充安定性試驗資料之審查。安定性試驗計畫建議參考本署公告之藥品安定性試驗基準進行之。	1. Stability test report for 3 batches of finished products and semi-finished product shall be submitted. Real time stability test information shall be provided, and can be supplemented with relevant reference report and testing report of accelerated stability study for review. DOH has issued a public announcement on Stability Testing for Pharmaceutical, and is recommended for planning of the stability study implementation.
二、須提供安定性試驗計畫書及安定性試驗結果，以訂定其儲存條件與有效期限。如需經稀釋或再配製後使用之組成，尚須檢附稀釋或再配製後，在特定儲存或運送 條件下之安定性試驗資料。	2. A description of stability study protocol and results shall be provided for supporting the proposed storage conditions and shelf-life. This shall include information on the stability of intermediate fluids, labeled dilutions or formulated bulk under specified holding or shipping conditions, as appropriate.
四、須提供相關之資料，以確保試劑之設計、製造與包裝，在儲存與運送之溫度、溼度等情形下，其用途之特徵與性能不會受到不良影響。	3. The devices shall be designed, manufactured and packed in such a way that the characteristics and performances during their intended use will not be adversely affected under storage and transport conditions (temperature, humidity, etc.)

	taking account of the instructions and information provided by the manufacturer.
五、須列出該產品適當的保存程序以保持其安定性，如：溫度、光線、潮濕度和其他相關的因素。	4. Storage instruction for maintaining the stability shall include temperature, light and humidity or other conditions.
六、適用時，須使用對成品具合適性之容器與封蓋，並提供合適性和生物測試資料，以及容器與封蓋於成品有效期限內完整性之證明。	5. A description of the container and closure systems, and their compatibility and biological tests with the final product should be provided. Evidence of container and closure integrity shall be provided for the duration of the proposed expiry period.
第十二條 分析方法確效：提供必要之方法確效與數據分析，通常係指臨床前（Pre-Clinical）性能評估測試報告。	Article 12: Analytical Method Validation Information on methods validation and data analysis shall be submitted. This can be the pre-clinical performance testing
第十三條 臨床評估（clinical evaluation）：	Article 13: Clinical Evaluation
一、須檢附有關產品臨床評估資料，如再現性（reproducibility）、靈敏度（sensitivity）、特異性（specificity）、交互反應（cross reaction）等臨床評估資料以利審查。	1. Information on the product clinical evaluation, e.g. reproducibility, sensitivity, specificity, cross reactivity shall be submitted for review.
二、臨床評估得與國內已核准上市或本署認定之十大先進國（美國、日本、加拿大、英國、比利時、德國、瑞士、法國、澳洲、瑞典）中至少一國核准使用之同類產 品進行比對測試。	2. Clinical evaluation can be carried out in direct comparison with device, which is currently marketed in Taiwan or in one of the following countries or areas: United States, Japan, Canada, United Kingdom, Belgium, Germany, Switzerland, France, Australia, or Sweden.
三、若臨床評估發現部分測試結果有差異，須以下列方法再確認測試結果，例如： （一）以另一測試系統評估此不一致之檢體。 （二）使用其他替代方法或標的物。	3. If discrepant test results are identified as part of an evaluation, these results shall be resolved as far as possible, for example: a. by evaluation of the discrepant sample in further test systems, b. by use of an alternative method or marker,

（三）檢視病人臨床狀態。 （四）後續檢體追蹤。	c. by a review of the clinical status and diagnosis of the patient, and d. by the testing of follow-up-samples.
四、臨床評估所使用之陽性檢體須廣泛選擇，以反映疾病之不同階段、不同抗體型、不同基因型、不同亞型（subtype）等。	4. Positive specimens used in the performance evaluation shall be selected to reflect different stages of the respective disease(s), different antibody patterns, different genotypes, different subtypes, etc.
五、臨床評估須評估潛在干擾物質之影響。潛在干擾物質須被視爲體外診斷醫療器材基本要求中，風險分析之一部份，例如： （一）其他相關感染疾病之檢體。 （二）取自產婦之檢體，例如：多產婦或是類風濕性因子陽性病患之檢體。 （三）基因重組抗原系統產生之不純物質，例如：抗大腸桿菌或抗酵母菌的抗體。	5. Devices shall be evaluated to establish the effect of potential interfering substances, as part of the performance evaluation. Potential interfering substances shall be identified as part of the risk analysis required by the essential requirements for each new device but may include, for example: a. specimens representing “related” infections, b. specimens from multipara, i.e. women who have had more than one pregnancy, or rheumatoid factor positive patients, c. for recombinant antigens, human antibodies to components of the expression system, for example anti-E.coli, or anti-yeast,
六、國內臨床評估： 體外診斷醫療器材之臨床評估非屬醫療法第8條所稱之人體試驗，符合本署『醫療機構人體試驗委員會得快速審查之案件範圍』。體外診斷醫療器材之國內臨床評估，應符合本署『醫療器材優良臨床試驗基準』、『研究用人體檢體採集與使用注意事項』、『醫療器材臨床試驗相關規定』及下列基本要求：	6. Clinical evaluation performed domestically: Clinical evaluation of IVD does not fall within the scope of clinical trial as defined in Article 8 of Medical Care Act, and is eligible for simplified review process of IRB. The conducting of clinical evaluation for IVD domestically shall comply with Good Clinical Practice for Medical Devices, Guidelines on Collection and Use of Specimen from Human for Research Purpose, relevant regulation on medical device clinical trial announced by DOH, and the following requirements:
（一）HBV、HCV及新體外診斷試劑用於捐血者篩檢之用者，除須檢附性能評估資料外，需另依下列原則執行國內臨床評估：	a. Beside the submission of performance evaluation information, tests for HBV, HCV and new IVD that is used in screening of blood donors, the clinical evaluation conduct domestically shall adhere to the following requirements:

1、應與國內已核准上市之同類產品比對，若國內尚無已核准上市之同類產品時，得與本署認定之十大先進國中至少一國已核准上市之同類產品進行比對。 2、比對結果若發生歧異時，應以Western blot、臨床診斷或其他試驗來加以證實。 3、臨床評估之設計與結果須能顯示或證明器材之實質相等性。 4、得執行國內臨床評估之單位，以台灣血液基金會台北捐血中心、高雄捐血中心及教學醫院，由上列單位擇三單位進行，每單位至少各測試二百份以上之檢體，且須包含陽性及陰性檢體。若陽性或陰性檢體於國內取得不易，得以國際檢體組（International panel）取代之。 5、無同類產品可供比對測試之試劑，則以新體外診斷醫療器材管理。除與公共衛生或血液安全相關之新體外診斷醫療器材，必要時本署得要求計畫書送署審查外，其餘計畫書毋須送署審查，惟臨床評估仍須經醫療機構人體試驗委員會核准後始得執行。 6、臨床評估之檢體，須依衛生署公告之「研究用人體檢體採集與使用注意事項」進行之。 7、執行臨床評估之場所，須考量操作之生物安全性，並進行適當之防護。 8、肝炎體外診斷試劑與同類產品比對之特異性誤差不得大於百分之二。	(a) There shall be comparison with other similar products which have been authorized and put on the market clearance in Taiwan, and if no such product exists, it should be compared with similar products that have market clearance in one of the aforementioned 10 advanced countries. (b) In the comparison, if there is any deviation, another verification test shall be used such as Western Blot or clinical diagnostic tests. (c) The design and results of clinical evaluations shall be able to show or prove the substantial equivalency of the products. (d) Clinical evaluation shall be conducted from any 3 of the following institutions, Taipei Blood Center of the Blood Services Foundation, Kaohsiung Blood Center of the Blood Services Foundation and teaching hospitals, and at least 200 samples are tested at each of the selected institutes, including both positive and negative specimens. In cases where positive or negative specimens are difficult to obtain, an International panel should be used instead, (e) In cases where no similar IVD product is available for comparison, the device shall be regulated as new IVD. With the exception of new IVD that related to public health or blood safety, whereby DOH could request the submission of protocol for review, otherwise clinical evaluation can be conducted after the approval of IRB of the evaluation institutions and do not have to first submit the proposal to DOH for review. (f) Collection of Specimen for the clinical evaluation shall be done according to the "Guidelines on Collection and Usage of Human

	Specimen" announced by the Department of Health. (g) When conducting clinical evaluation, consideration shall be given to the operational biosafety at the location, and shall carry out the appropriate safety measures. (h) For comparison of IVD for hepatitis against a similar product, the specificity should not be differ by more than 2%.
（二）除上述產品外，其他體外診斷醫療器材由廠商依據產品特性，利用各種統計工具及方法，規劃臨床評估所需樣本數，並提供樣本數計算方法及其參考依據。本署建議臨床評估樣本數應至少具有80%以上之檢定力（Power）宣稱的性能，或以其他方法訂定臨床評估樣本數。臨床評估報告之檢體組成及數量，須足以支持仿單宣稱之測試項目或性能。臨床評估報告經審議後，如具有人種差異性、地區特異性等體外診斷醫療器材，本署得要求另執行國內臨床評估。	b. For IVD other than above mentioned, the number of samples used for clinical evaluations shall be depending on the characteristics of the product and calculate using statistical tools and method. The calculation of sample number and relevant references should be provided by the manufacturer. DOH recommends that the number of clinical evaluation samples should have at least 80% of the statistical power to support the declaration of performance, or to use other method to establish the number of samples for clinical evaluation. The number and profile of specimens in the clinical evaluation report shall be adequate to support the declaration of test item and performance stated on the instruction. After reviewing the clinical evaluation report, DOH can request for clinical evaluation conducted domestically for IVD performance that can have racial or geographical variance.
（三）本署鼓勵醫療院所及臨床評估之實驗室、管理、品保及研究人員遵循本署推動及落實之「藥物非臨床試驗優良操作規範（GLP）」，並辦理「GLP 自願性查核」。	c. DOH encourages clinical institutions and clinical evaluation laboratories, management, quality control and research professionals to follow Good Laboratory Practice (GLP) of DOH and to apply for voluntary GLP audit.
附錄一、標籤或包裝須載明下列資訊：	Appendix I. Labeling and packaging information
一、製造業者的名稱與地址。輸入醫療器材應註明輸	1. Name and address of the manufacturer. For devices imported into Taiwan, it

入藥商與製造廠之名稱與地址。 二、供使用者鑑別該體外診斷醫療器材以及包裝內容之詳細資訊。 三、若爲無菌產品，須標示「無菌」字樣。 四、批號或產品系列編號。 五、試劑須標示最終成品之製造日期及有效期間或保存期限、保存方法，並須儘可能標示器材或配件的安全及性能完整性的使用期限。期限須儘可能以年份/月份/日期的順序表達。 六、「供體外診斷使用 For In Vitro Diagnostic Use」等字樣。 七、特別的儲存及處理條件。 八、特別的操作指示。 九、適當的警告及注意事項。 十、明確載明是否爲供使用者自我測試之家用體外診斷醫療器材。	should clearly labeled with the name and address of the importer and the original manufacturer; 2. Details necessary for the user to uniquely identify the device and the contents of the packaging; 3. Labeling with the word 'STERILE', where appropriate; 4. Batch code, preceded by the word 'LOT', or the serial number; 5. Date of manufacture and expiration period or the storage period and storage condition should be labeled on the product. If appropriate, an indication of the date by which the device or part of it shall be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order; 6. The statement "For In Vitro Diagnostic Use" indicating the in vitro use of the device; 7. Storage and/or handling conditions; 8. Operating instructions; 9. Warnings and/or precautions to take; 10. Indication for self-testing, if appropriate.
附錄二、仿單須明確說明其效能及用途，並儘可能包括以下事項：	Appendix II. The content of the instruction shall clearly state the performance and use, and, where possible, contains the following:
一、除了無須載明批號及使用期限外，仿單須依前述標籤須載明之內容刊載相關資訊。 二、試劑之成分，包括性質、主成分的量或濃度或套組的敘述。若該試劑含其他可能影響量測結果之成分，亦須加以說明。	1. Details referred to in Appendix I with the exception of the batch number and expiration date; 2. Composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the

三、拆封後之儲存條件與有效期限，並附有試劑的儲存條件與安定性資訊。 四、所需的特殊設備以及確保該設備正常運作的資訊。 五、所使用檢體的形式，蒐集檢體的特殊要求，採檢前的準備。必要時，須包括儲存條件及病患準備的說明。	measurement; 3. Storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working reagents; 4. Indication of any special equipment required including information necessary for the identification of that special equipment for proper use; 5. The type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;
六、須詳細說明試劑方法原理及須遵循的操作程序，包括使用前的必要處理程序，如配製、反應時間、稀釋、儀器檢查等。 七、須包括特定的分析性能特徵，例如靈敏度、特異性、準確度、精密度、重複性、再現性、偵測之限制、量測範圍、以及使用者可使用的參考量測程序與參考物質。 八、計算分析結果所使用的數學方法。 九、須提供校正液的量測追溯性。 十、當器材分析效能改變時須採取之措施。	6. Detailed description of the principle of the method and procedure to be followed in using the device, and details of any further procedure or handling needed before the device can be used, for example, reconstitution, incubation, dilution, instrument checks, etc; 7. Specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, and information about the use of available reference measurement procedures and materials by the user,- the principle of the method; 8. Mathematical approach upon which the calculation of the analytical result is made; 9. Traceability of the calibrator; 10. Measures to be taken in the event of changes in the analytical performance of the device;
十一、所判定的量的參考區間（reference intervals），包括適當的參考群體之敘述。 十二、若須與其他器材或設備合併、組裝或連接，須提供詳細的鑑別資料來辨識正確的器材或設備，以便	11. Reference intervals for the quantities being determined, including a description of the appropriate reference population; 12. If the device shall be used in combination with or installed with or connected to

安全與正確的組裝。 十三、須提供正確組裝以及確保正確而安全地操作所需的資訊。並包含品管、校正規定的詳細內容，以確保正確及安全的操作及安全棄置的資訊。 十四、使用前的加工或處理程序，如滅菌與最終組裝等。 十五、保護包裝損壞時的必要指示及重新滅菌或去污染措施。	other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination; 13. All the information needed to verify whether the device is properly installed and can operate correctly and safely, details of quality control and calibration needed to ensure that the device operates properly and safely; information about safe waste disposal; 14. Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.); 15. The necessary instructions in the event of damage to the protective packaging and details of appropriate methods of resterilization or decontamination;
十六、可重複使用的器材，須說明重複使用次數及再處裡的程序，包括清潔、消毒、包裝、重新滅菌或淨化，以及重複使用的限制。 十七、關於可能暴露於環境中的磁場、外部電氣干擾、靜電、壓力或壓力之變化、加速度、熱燃源等的注意事項。 十八、關於體外診斷醫療器材之使用或棄置之特別、不正常風險（Unusual risk）的注意事項，包括特別保護措施及使用或儲存環境中之不良影響，如熱源等。當器材包括來自人類或動物原料時，須特別注意其潛在傳染性。 十九、用於自我測試之家用體外診斷醫療器材，另須遵守以下各項： （一） 測試結果須清楚表示使非專業人士易於了	16. Information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and resterilization or decontamination, and any restriction on the number of reuses, if the device is reusable; 17. Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc. 18. Precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures, the use or storage at an unfavorable conditions e.g. heat source; where the device includes substances of human or animal origin, attention shall be drawn to their potential infectious nature; 19. Specifications for home-use devices: a. the results need to be expressed and presented in a way that is readily

解，必須提供使用者須採取的措施（如在陽性、陰性、或中間值的情形）的資訊，以及產生僞陰性或僞陽性結果的可能性。 （二）若製造業者所提供之相關資訊足以讓使用者了解試劑操作方法與試劑所產出的結果，某些特定事項得省略之。 （三）須清楚地告知使用者，不應在諮詢醫師前，採取任何醫療措施。 （四）若使用於監控已知疾病時，須說明病患須經過適當訓練，方可以進行治療程序。 二十、仿單的發行日期或最新修正版。 二十一、指明使用者是否需經特殊的訓練。	understood by a lay user; information needs to be provided to the user on action to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result, b. specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device, c. the information provided shall include a statement clearly directing that the user shall not take any decision of medical relevance without first consulting his or her medical practitioner, d. the information shall also specify that when the device for self-testing is used for the monitoring of an existing disease, the patient shall only adapt the treatment if he has received the appropriate training to do so; 20. Date of issue or latest revision of the instructions for use; 21. Indication of any particular training requirement

英文參考文件：

1、US FDA 21 CFR 809.3

2、DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 October 1998 on in vitro diagnostic medical devices, ANNEX I ESSENTIAL REQUIREMENTS.

3、Guidance for Industry：Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product，FDA / CBER, Mar. 1999.

4、GHTF/SG1(PD)/NO63 Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices, March 26, 2009.

5、Commission decision 2009/108/EC of 3 February 2009 amending Decision 2002/364/EC on common technical specifications for in vitro-diagnostic medical devices, European communities.

6、Guideline for the Manufacture of In Vitro Diagnostic Products，FDA / CDRH，Jan. 1994。

7、法規名稱英譯統一標準表 (行政院九十二年七月三日院臺規字第○九二○○八六四七一號函核定)
http://law.moj.gov.tw/Service/standard_en.aspx