

# **CENTRAL DRUGS STANDARD CONTROL ORGANISATION**

## **(Medical Devices and Diagnostic Division)**

### **In - Vitro Diagnostic (IVD) Devices**

### ***Frequently Asked Questions***

**Doc No.: CDSCO/MD/FAQ/IVD/01/00**

**Date :**

**CENTRAL DRUGS STANDARD CONTROL ORGANIZATION  
DIRECTORATE GENERAL OF HEALTH SERVICES  
MINISTRY OF HEALTH & FAMILY WELFARE  
GOVT. OF INDIA**

**CDSCO**

**Notice:**

*The replies to the FAQs are aimed only for creating public awareness about In-Vitro Diagnostic Devices Regulation by CDSCO and are not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act & Rules and respective Guidelines / Clarifications issued by CDSCO time to time for all their professional needs.*

## Frequently Asked Questions on In-Vitro Diagnostic Devices

**1. Whether In-Vitro Diagnostic kits/reagents are regulated in India?**

**Ans:**Yes, In Vitro Diagnostic kits/reagents are regulated in India under the provisions of the Drugs & Cosmetic Act 1940 & Rules 1945.

**2. Where can we get a copy of the Drugs & Cosmetic Act 1940 & Rules 1945?**

**Ans:**The copy of the Drugs & Cosmetic Act 1940 & Rules 1945 is available under Link: <http://cdsco.nic.in/Drugs&CosmeticAct.pdf>

**3. Which is the Regulatory Authority that governs the regulations of Import of IVD kits/reagents in India?**

**Ans: Drugs Controller General (India),**Central Drugs Standard Control Organization (CDSCO), *Directorate General of Health Services* , Ministry of Health and Family Welfare, Government of India , FDA Bhavan, ITO, Kotla Road, New Delhi -110002 Phone: 91-11-23236965 / 23236975, Fax: 91-11-23236973, E-mail:- [dcg@nb.nic.in](mailto:dcg@nb.nic.in)

**4. Which division of CDSCO(HQ) is responsible for review of IVD kits/reagents (Import)?**

**Ans:** Medical Devices& Diagnostics Division, Central Drugs Standard Control Organization (CDSCO), *Directorate General of Health Services*, Ministry of Health and Family Welfare, Government of India FDA Bhavan, ITO, Kotla Road, New Delhi -110002

**5. What is an In-Vitro Diagnostic Product (IVD)?**

**Ans:** In-Vitro Diagnostic Products are those substances that are intended to be used for or in the use in diagnosis of disease or disorders in human being or animals. IVDs are considered as “Drugs” as defined under sub-clause (i) of clause (b) of Section 3 of Drugs and Cosmetic Act 1940.

**6. How are IVDs classified?**

**Ans:**The diagnostic kits and reagents have been classified as ‘Notified’ and ‘Non-Notified’.

**7. Which class of IVD kits/reagents falls under the category of Notified IVD products?**

**Ans:** Following IVD kits/reagents are Notified as “Drugs” under Drugs and Cosmetic Act 1940.

- a) In-Vitro Diagnostic Devices for HIV
- b) In-Vitro Diagnostic Devices for HBV
- c) In-Vitro Diagnostic Devices for HCV
- d) In-Vitro Blood grouping sera.

**8. Which class of IVD kits/reagents would be covered under the category of Non- Notified IVD products?**

**Ans:** All In-Vitro Diagnostic kits and Reagents excluding those listed under Notified category would be covered under the category of Non-Notified IVD products.

**9. What are the requirements for import of Notified IVD kits and reagents in India?**

**Ans:** For the import of Notified IVD kits/reagents in India, Registration Certificate in Form 41 and Import License in Form 10 are required as per provisions of the Drugs & Cosmetic Act & Rules. For import of Notified IVD kits/reagents, the manufacturing site and products (IVD kits/reagents) are required to be registered with Indian Drug Regulatory Authority (i.e. Central Drugs Standards Control Organization).

**10. What are the requirements for import of Non-Notified IVD kits and reagents in India?**

**Ans:** For the import of Non- Notified IVD kits/reagents in India, only Import License in Form 10 is required as per provisions of the Drugs & Cosmetic Act & Rules.

**11. Who can import IVD kits and reagents into India?**

**Ans:** Any person/firm/enterprise etc. holding a valid wholesale license and/or manufacturing license issued under Drugs and Cosmetics Act, 1940 and Rules 1945 can be an applicant for Registration and Import of IVD kits and reagents into India.

**12. To whom shall the application be submitted for Registration/Import License for IVD kits and reagents in India?**

**Ans.** Applications for Registration/ Import License of IVD kits and reagents shall be submitted to the Drugs Controller General (India), Central Drugs Standard Control Organization (CDSCO), FDA Bhawan, ITO, Kotla

Road, Delhi-110002. Phone: 91-11-23236965 / 23236975. Fax: 91-11-23236973.

**13. What is the procedure to apply for the "Registration certificate" in Form-41 for Notified IVD kits/reagents in India?**

**Ans: Following steps may be adopted for Registration application**

**STEP 1.** Pay the required Registration fee through TR-6 Challan (in triplicate) in Bank of Baroda, Kasturba Gandhi Marg, New Delhi.

A fee of one thousand and five hundred US dollars [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 as registration fee for the manufacturing premises meant for manufacturing of Notified IVD kits/reagents intended for import into and use in India.

A fee of one thousand US dollars [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 for the registration of a single Notified IVD kits/reagents meant for import into and use in India and an additional fee at the rate of one thousand US dollars for each additional Notified IVD kits/reagents:

**STEP 2.** Compilation of Registration dossier as per the guidance documents available at the link: [http://cdsco.nic.in/draft\\_guidance.htm](http://cdsco.nic.in/draft_guidance.htm)

**STEP 3.** Submit Product Registration application at CDSCO (HQ), New Delhi

**14. Whether Notified IVD kits/reagents manufacturing site required to be inspected before grant of Registration Certificate in Form 41? If yes, how much fees for the inspection or visit of the manufacturing premises of Notified IVD kits/reagents?**

**Ans:** No, however if required the applicant shall be liable for the payment of a fee of five thousand US dollars [or its equivalent in Indian rupees] for expenditure as may be required for inspection or visit of the manufacturing premises.

**15. How the fees shall be paid in India?**

**Ans:** The fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines":

Provided that in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account "0210-Medical and Public Health, 04- Public Health, 104-Fee and Fines", and the original receipt of the said transfer shall be

treated as an equivalent to the bank challan, subject to the approval by the Bank of Baroda that they have received the payment.

**16. Is there any system of prescreening of applications for issue of grant of Registration Certificate/ Import License at the time of submission at CDSCO (HQ) New Delhi?**

**Ans:** Yes, application will be prescreened as per checklist available under link: [http://cdsco.nic.in/prescreening\\_checklist.htm](http://cdsco.nic.in/prescreening_checklist.htm)

**17. What is the time period for Grant of Registration Certificate?**

**Ans:** If the application is complete in all respects and information specified in Schedules D-I and D-II are in order, the licensing authority shall, within nine months from the date of receipt of an application, issue such Registration Certificate in Form 41.

**18. What is the Duration/Validity of "Registration certificate" in Form-41 for Notified IVD kits/reagents in India?**

**Ans:** A Registration Certificate, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue

**19. How to register additional Notified IVD kit(s)/reagent(s) in the already approved/valid Registration Certificate?**

**Ans:** Importer has to apply for endorsement to the existing Registration Certificate along with the requisite documents, provided that the additional IVD(s) is being manufactured at the same manufacturing site as stated in the Registration Certificate, for each additional device 1000 USD is to be paid as a Registration fee. The requirements for endorsement of additional Device(s) to the valid Registration Certificate are remains same to the fresh Registration Certificate except Site Registration Fees (1500 USD) and Plant Master File.

**20. When should an application for Re-Registration of Notified IVD kits/reagents be submitted?**

**Ans:** Applications for Re-Registration should be submitted minimum Nine months ahead of the expiry of the registration certificate.

**21. What are the requirements for Re-Registration of Notified IVD kits/reagents?**

**Ans:** The requirements for Re-registration of Notified IVD kits/reagents are remains same as fresh Registration requirements except requirement of hard copy of Plant Master File (PMF) and Device Master File (DMF) provided there are no changes in the PMF and DMF, However soft copy of PMF and DMF in the form of compact disc shall be provided along with the application.

**22. Whether the applicant can make application for Import license along with the registration application for Notified diagnostic kits?**

**Ans:** Yes, an applicant can apply for both Registration Certificate (Form 41) and Import License (Form 10) together, provided Indian agent and importer remain same.

**23. How much fees for a duplicate copy of "Registration certificate" in Form-41 for Notified IVD kits/reagents in India?**

**Ans:** A fee of three hundred US dollars [or its equivalent in Indian rupees] shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

**24. What is the procedure to apply for the "Import License" in Form-10 for Notified IVD kits/reagents in India?**

**Ans:** The procedure to apply for the "Import License" is available on "Guidance Document on Common Submission Format for Import License of Notified diagnostics kits in India" available on the CDSCO website under Link: [http://cdsco.nic.in/draft\\_guidance.htm](http://cdsco.nic.in/draft_guidance.htm)

**25. What is the procedure to apply for the "Import License" in Form-10 for Non- Notified IVD kits/reagents in India?**

**Ans:** The procedure to apply for the "Import License" is available on "Guidance Document on Common Submission Format for Import License of Non-Notified diagnostic kits in India" available on the CDSCO website under Link: [http://cdsco.nic.in/draft\\_guidance.htm](http://cdsco.nic.in/draft_guidance.htm)

**26. What is the time period for Grant of Import license?**

**Ans:** If the application is complete in all respects and information are in order, the licensing authority may within Three months from the date of receipt of an application, issue an import license in Form 10.

**27. What is the Duration of "Import License" in Form-10 for Notified & Non-Notified IVD kits/reagents in India?**

**Ans:** An "Import License" in Form-10, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue

**28. How much fees for the "Import License" in Form-10 for Notified & Non-Notified IVD kits/reagents in India?**

**Ans:** A fee of one thousand rupees for a single IVD and an additional fee at the rate of one hundred rupees for each additional IVD meant for import into and use in India.

**29. How much fees for a duplicate copy of "Import License" in Form-10 for Notified & Non- Notified IVD kits/reagents in India?**

**Ans:** A fee of two hundred and fifty rupees shall be paid for a duplicate copy of the license issued, if the original is defaced, damaged or lost.

**30. What are the requirements for grant Import License for Non Notified IVD kits/reagents in India?**

**Ans:** The requirements for grant of import license in Form 10 for Non-Notified Diagnostic Kits are available on the CDSCO website under Link: [http://cdsco.nic.in/prescreening\\_checklist.htm](http://cdsco.nic.in/prescreening_checklist.htm)

**31. If the importer has valid import license in Form-10 for the particular manufacturer (both legal / actual) further he want to import some more products from the same manufacturer, whether importer can take fresh import license in Form-10 for the products or he can take Endorsements to the existing import license?**

**Ans:** Importer has to apply for Endorsements to the existing import license along with the requisite documents including copy of the existing import license and Fees.

**32. Whether fees should be paid for different category like test strip, cassettes, midstream, etc?**

**Ans:** Yes, Applicant is required to submit separate fee for each categories like test strip, cassettes, midstream, etc which the firm intent to import/Register.

**33. When should an application for renewal of Import License be submitted?**

**Ans:** Applications for renewal should be submitted minimum Three months ahead of the expiry of the Import license.

**34. Whether IVD kits/reagents, having valid Import License, can be imported from any notified ports of India?**

**Ans:** Yes

**35. If the importer has valid import license in Form-10 for the particular area or state in the country whether importer has to take separate import license in Form-10 for other areas or states?**

**Ans:** Single license may be issued, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer to the Importer through which importer can import the products thorough any notified port under Drugs and Cosmetics Act and Rules.

**36. Whether devices imported under valid import license can stock in any other wholesale license premises other than stated in the Import License?**

**Ans:** Yes

**37. What are all the In-Vitro diagnostic Kits / Reagents need NOC from the other departments for import/ Manufacturing?**

**Ans:**

- a. NOC from department of Animal Husbandry, Dairying and Fisheries (DADF), Government of India, KrishiBhavan, New Delhi in respect of products intended for veterinary purpose
- b. Expert Opinion/ Technical Recommendation from DG, ICMR, New Delhi for the product intended for influenza

**38. Whether the applicant has to mention intended use of the proposed product in the product list during the submission of the applications?**

**Ans:** Yes; applicant has to mention the specific intended use of the proposed product in the product list matching with product insert / brochure, not more than 50 words.

**39. Whether the applicant is required to submit performance evaluation report for 3 lots of Notified IVD kits/reagents during the submission of application for registration certificate**

**Ans:** Yes: Evaluation shall be carried out at the National Institute of Biologicals, Noida

**40. Whether the Notified kits/reagents may be tested in Laboratories other than National Institute of Biologicals, Noida?**

**Ans:** No, only for cases where Closed System/Testing facilities are not available in NIB, Noida, CDSCO may consider approval of alternate laboratories like CMC Vellore, NIV Pune, AllMS, Nizam Institute of Medical Sciences (NIMS) or other Govt. institutes of national repute for testing purposes of Notified In Vitro Diagnostic Devices on case to case basis.

**41. Whether Non Notified diagnostics kits/reagents need Performance Evaluation Report during the submission of import application?**

**Ans:** No, however for the IVD Kits/reagents intended for Malaria, TB, Dengue, Chikunguniya, Typhoid, Syphilis and Cancer, Performance Evaluation reports for 3 batches from India need to be submitted during the submission of import license.



**42. Where the Rare Blood Grouping Reagents or Gel Card is tested for Performance Evaluation?**

**Ans:** National Institute of Biological(NIB), Noida has standardized and validated the various recommended procedures required for quality evaluation of following Rare Blood Grouping Reagents and also mentioning the volume required for the testing of these reagents.

S.No	Name of the Reagent	Volume required
1.	Anti-Fya Reagent	1ml x 6 vials 2 ml x 4 vials
2.	Anti-Fyb Reagent	-Do-
3.	Anti-Jka Reagent	-Do-
4.	Anti-Jkb Reagent	-Do-
5.	Gel card for Anti-A1 (Lectin)	100 cards
6.	Gel card for Direct Anti globulin test	100 cards
7.	Gel card for Anti-H (Lectin)	100 cards

**43. Where the IVD Kits/reagents intended for Malaria, TB, Dengue, Chikunguniya, Typhoid, Syphilis and Canceris tested for Performance Evaluation Report?**

**Ans:** Any Govt. institutes of National repute or any other NABL, CAP, NABH accredited Laboratory/Institute in India.

**44. Name some of the laboratories for conducting the performance evaluation of the Kits/reagents intended for TB, Malaria, Dengue, Chikunguniya, and Cancer?**

**Ans:** Following laboratories on the basis of Infrastructure, facilities, technical expertise/specialties etc., available for the testing and evaluation of the said kits:

**For TB Kits / Reagents:**

1. National Institute for Research in Tuberculosis,  
Mayor Sathiyamoorthy Road, Chetpet, Chennai - 600 031, INDIA  
e-mail : [icmrtrc@vsnl.com](mailto:icmrtrc@vsnl.com), Phone:91-44-2836 9500, Fax: 91-44-2836 2528
2. National Tuberculosis Institute 'AVALON' No.8, Bellary Road, Bangalore  
560 003, India Phone:+91 80 23441192, 23441193, 23447951  
e-mail: [nti@ntiindia.org.in](mailto:nti@ntiindia.org.in)
3. LRS Institute of TB and Respiratory Diseases  
Sri Aurobindo Marg, Near Qutub Minar  
New Delhi-110030  
Phone: 26963335 (Office)

Fax: 26568227

E-mail: [dirlrsi@bol.net.in](mailto:dirlrsi@bol.net.in)

4. NATIONAL JALMA INSTITUTE OF LEPROSY AND OTHER MYCOBACTERIAL DISEASES  
P.O BOX 101, Dr. M. Miyazaki Marg, Tajganj, Agra - 282001, INDIA, E-mail:- [jalma@sancharnet.in](mailto:jalma@sancharnet.in)  
Phone:-2331756, 2333595, 2232222  
Fax: - (91)-(562)-2331755

**For Malaria Kits / Reagents:**

1. National Institute of Malaria Research (ICMR)  
Sector 8, Dwarka  
Delhi-110077 (India)  
Phones: +91-11-253071103, 104, 105  
E-mail: [director@mrcindia.org](mailto:director@mrcindia.org)

**For Dengue Kits / Reagents:**

1. National Centre for Disease Control  
22, Sham Nath Marg, New Delhi-110 054, India  
Phone: +91-11-23913148, 23946893  
Fax: +91-11-23922677  
E-mail: [dirnicd@nic.in](mailto:dirnicd@nic.in), [dirnicd@gmail.com](mailto:dirnicd@gmail.com), [dirnicd@bol.net.in](mailto:dirnicd@bol.net.in), [dirnicd@del3.vsnl.net.in](mailto:dirnicd@del3.vsnl.net.in)
2. NATIONAL INSTITUTE OF VIROLOGY  
20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India  
Phones: 020-26127301  
Fax No. : 91-20-26122669

**For Cancer Kits / Reagents**

1. Institute of Cytology and Preventive Oncology (ICPO)  
I-7, Sector - 39,  
Noida - 201301 Uttar Pradesh, INDIA  
Phone: 0120 -2579471  
Fax: 0120 -2579473  
Email: [directoricpo@icmr.org.in](mailto:directoricpo@icmr.org.in)

- 45. How much sample can be tested for performance evaluation of the IVD Kits/reagents intended for Malaria, TB, Dengue, Chikunguniya, Typhoid, Syphilis and Cancer?**

**Ans:** The sample size should be statistically significant to establish/demonstrate the clinical sensitivity & specificity of the proposed kits/reagents in Indian population.

**46. What is the criteria for evaluation of Rapid & ELISA (HIV, HBsAg, HCV) Diagnostic kit adopted by NIB, Noida**

**Ans:**

S.No	Type of infection	Type of Kit	Sensitivity(%)	Specificity(%)
1.	Anti-HIV	Rapid/ELISA	≥99.5	≥98
2.	HBsAg	Rapid/ELISA	≥99 & 0.5ng/ml	≥98
3.	HCV	Rapid/ELISA	≥99.5	≥98

**47. What are the Minimum criteria for evaluation of IVD Kits/reagents intended for Malaria, TB, Dengue, Chikunguniya, Typhoid, Syphilis and Cancer?**

**Ans:** Complies with the Clinical sensitivity, specificity, standards etc. as declared in the IFU/COA/Product insert issued by the manufacturer

**48. What are the minimum requirements in the Performance Evaluation Reports?**

**Ans:** Typically a Performance Evaluation Report should mention following details: Product name, lot / Batch number, manufacturer name, importer name, import / Test licenses number, number of samples tested, testing principle (ELISA/Rapid/NAAT,etc.), information about reference used, Testing procedure, Specificity, Sensitivity, Positive predictive value, Negative predictive value, Report number, Date of analysis, designation & Signature of analyst and authorized signatory of the laboratory etc.

**49. Whether any license is required for import of the small quantity of diagnostic kits/reagents for the purpose of examination, test or analysis in India**

**Ans:** Yes, for importing small quantity of diagnostic kits/reagents for the purpose of examination, test or analysis, a license in Form-11 (Test License) is required under the provision of Drugs & Cosmetic Rules 1945

**50. What is the Test license in Form 11?**

**Ans:** The Test License in Form 11 is to import small quantities of drugs / Medical Devices/ Diagnostic kits, for the purpose of examination, test or analysis provided that Imported IVDs under Form 11 should not be used for any commercial purpose.

**51. What are essential documents required for import of IVDs for examination, test and analysis in Form 11?**

**Ans:** Please refer to the "Checklist for Pre Screening of Applications for Grant of Test License available on the CDSCO website. Under Link: [http://cdsco.nic.in/prescreening\\_checklist.htm](http://cdsco.nic.in/prescreening_checklist.htm)

**52. How much fees for the "Test License" in Form-11 for IVD kits/reagents in India?**

**Ans:** Every application in Form 12 shall be accompanied by a fee of one hundred rupees for a single drug (In vitro diagnostics kits/reagents) and an additional fee of fifty rupees for each additional drug (In vitro diagnostics kits/reagents).

**53. What is the Duration of "Test License" in Form-11 for IVD kits/reagents in India?**

**Ans:** A Test License unless, it is sooner suspended or cancelled, shall be valid for a period of one year from the date of its issue

**54. Whether Kit intended for use in determining the presence of host cell protein contamination, in products manufactured by expression in the CHO cell line and other technology for Research and manufacturing use only and is not intended for diagnostic use in humans or animals are being regulated under the provision of Drug and Cosmetic Acts & Rules (through Form 10 or Form 11) during Import?**

**Ans:** No.

**55. Whether In – Vitro diagnostic kits / reagents used in determining the presence of histamine, drugs substances , Microbial detection in food & food products, animal feeds, liquor (wine, beer), environmental samples like water & Soil etc. are being regulated under the provision of Drug and Cosmetic Acts & Rules (through Form 10 or Form 11) during Import?**

**Ans:** No.

**56. Whether Empty Specimens collection tubes without needle used for the collection of Blood, Urine, Stool, Sputum, Semen,,etc for purpose of specimens collection are being regulated under the provision of Drug and Cosmetic Acts & Rules (through Form 10 or Form 11) during Import?**

**Ans:** No

**57. Whether there is a requirement of posting of In-Vitro Diagnostic devices for HBsAg, HIV and HCV on CDSCO website for use in blood banks.**

**Ans:** No, In – Vitro Diagnostic devices for HBsAg, HIV and HCV manufactured / Imported under valid license issued by licensing authority as specified under Drugs and Cosmetics Rules may also be used in Blood Bank, as the criteria like Sensitivity (%) and Specificity (%) for evaluation of the HBsAg, HIV and HCV diagnostic kits for the Transfusion purpose (Blood Banks) and Diagnostic purpose are same. Therefore, there is no requirement for approving / posting on CDSCO website about the details of Indigenous or Importer, Kits details on website, regarding its approval for use in Blood Bank.

**58. Whether Raw material for diagnostic kits & reagents which are further used in the manufacturing of the finished in vitro diagnostic kits are being regulated under the provision of Drug and Cosmetic Acts & Rules (through Form 10 or Form 11) during Import?**

**Ans:** No, such cases may be examined and released at the level of ADC (I)/Incharge/Port officer of CDSCO without referring NOC from CDSCO (HQ)

**59. Whether In-vitro diagnostic kits/reagents /samples intended for Research Use only, for the purpose of Accreditation / Certification of Hospital/Laboratories like College of American Pathologists (CAP) Accreditation, etc. and for External Quality Assurance (EQAS) during import are being regulated under the provision of Drug and Cosmetic Acts & Rules (through Form 10 or Form 11) during Import?**

**Ans:** No, such cases may be examined and released at the level of ADC (I)/Incharge/Port officer of CDSCO without referring NOC from CDSCO (HQ)

**60. Whether uncut sheets/semi-finished diagnostic kit, Bulk reagents like Calibrators, controls, diluents are being regulated under the provision of Drug and Cosmetic Acts & Rules (through Form 10 or Form 11) during Import?**

**Ans:** Yes

**61. Whether In-Vitro diagnostic Kits / Reagents used in the clinical investigation / clinical trial purposes are considered as Research Use Only (RUO) products?**

**Ans:** No: Any In-Vitro diagnostic Kits / Reagents that are intended for use in a clinical investigation or clinical diagnostic use outside an investigation (for example, in clinical diagnosis) should not be considered RUO.

**62. Whether Glucometers used for blood glucose monitoring are regulated under Drugs and Cosmetics Act and Rules?**

**Ans:** As per current provisions of Drugs and Cosmetics Act and Rules Glucometers used for blood glucose monitor (instrument) are not regulated. However, test strips and reagents are regulated under Drugs and Cosmetics Act and Rules.

**63. Whether all Serodiagnostic test kits are prohibited?**

**Ans:** No; only “Serodiagnostic test kits for diagnosis of tuberculosis” are prohibited to Import, Manufacture, Sale, Distribution and Use in the country under Section 10A and Section 26A of the Drugs and Cosmetics Act, 1940 Gazette notification(s) GSR432(E) & GSR433(E) dated June 7, 2012.

**64. Whether permission under Rule 37 of the Drugs and Cosmetics Act requirements is applicable for cases where the reagents are imported in bulk packs under Form 10 license mentioning Bulk or the use of product in manufacturing?**

**Ans:** No; however, in such cases, the exemption is only applicable if the applicant holds the valid manufacturing license for the finished product.

**65. Whether both legal (If any) and actual manufactures name and address should be stated in the Free Sale Certificate issued by the National Regulatory agency for the purpose of registration / Import of Diagnostic Kits/Reagents in India?**

**Ans:** Yes.

**66. Any changes in name and/or address of Indian agent/ Importer or change in constitution after issue of Registration Certificate/ Import License are required to be communicated to the Licensing Authority?**

**Ans:** Yes, Indian agent/ Importer shall inform the licensing authority immediately in writing and shall submit fresh application as per Rules.

**67. Any changes in name and/or address of legal and/or actual manufacturer or change in constitution after issue of Registration Certificate/ Import License are required to be communicated to the Licensing Authority?**

**Ans:** Yes, the manufacturer or his authorized agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and / or address of the registered office / factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of

three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises.

**68. Whether acquisition/merger of one company by another company is considered as change in constitution of the company?**

**Ans:** Yes

**69. What are the changes that require an applicant to make a fresh Registration?**

**Ans:** The following changes requires a fresh registration –

- 1) Any change with respect to manufacturer (legal/ actual) like change in constitution, change in name, change in address, etc.
- 2) Any change with respect to importer/ Indian Agent like change in constitution, change in name, etc.

**70. Whether the Importer who is having valid Form-10 license but there is some small change in the name of importer or address of Importer still can he import till another license is granted.**

**Ans:** No, at the time of import, the label of the product should comply with details as specified in the Form-10 for the product.

**71. If there is a change in the Indications and/ or Intended use of registered Notified IVDs, does the applicant need to submit a fresh application including Power of Attorney incorporating the changed Indications and/ or Intended use of the registered Notified IVDs?**

**Ans:** Yes, revised Power of Attorney is required to be submitted, reflecting the changes/ modification to indications.

**72. What is the procedure for expanding/ modifying the currently registered indications?**

**Ans:** The process for change notification to CDSCO and approval will be followed in such case. Revised Power of Attorney including the expanded/ modified indication will need to be submitted to the CDSCO.

**73. Whether any minor change which is notified to the Regulatory Authority but CDSCO's response is awaited can be imported in India?**

**Ans:** No

**74. What is the time line for response to a change notification?**

**Ans:** 90 working days.

**75. What are the Labeling requirements for IVD in India?**

**Ans:** Labeling should comply with requirements of the Rule 96 of Drugs and Cosmetics Act and Rules

**76. At the time of submitting applications for registration/ re-registration/Import of IVDs, are original labels as per Rule 96 to be submitted to the CDSCO?**

**Ans:** Original labels as per Rule 96 are required, however applicants may submit coloured copy of original label incorporating all details as per Rule 96.

**77. What are mandatory addresses on the labels of IVDs being imported/ marketed in India?**

**Ans:** The label of IVDs being imported must include the names and addresses of the legal manufacturer, actual manufacturer and the name and address of importer on which the Import License in Form 10 has been issued.

**78. Can the importers of IVDs can incorporate India-specific requirements on labels after/post landing in India at customs warehouse or place approved by the Licensing Authority?**

**Ans:** Yes, importers of IVDs are currently allowed to incorporate India-specific requirements like name and address of importer, import License Number on imported IVDs post landing in India at customs warehouse or place approved by the CDSCO prior to release into market.

**79. Whether shelf life of the IVDs can be stated on the label instead of date of manufacture?**

**Ans:** Yes

**80. Whether Certificate of Exportability (which reflects that the proposed products may not be freely sold in the country of origin but can be exported), is acceptable as Free Sale Certificate?**

**Ans:** No

**81. Whether NOC from the office of DCGI is required for the approval of manufacturing license from the state licensing authority for the Notified diagnostic kits / reagents and new diagnostic kits / reagents (First in India)?**

**Ans:** Yes, this office is presently issuing NOC for manufacturing of Notified diagnostics kits and New diagnostic kits / reagents (First in India) on the basis of examination of the following documents:-

- Detailed manufacturing process.



- Developmental studies.
- Stability data
- Testing protocols for raw materials and finished products
- In- house specification
- Labeling Details
- Evaluation Reports.
- Experts opinion(First in India) etc.

**82. How should the documents be notarized?**

**Ans:** The notary should ensure that documents are properly authenticated by signing each document/page or by providing notarization page (Declaration from notary) having name/number of certificate/documents along with pages eg.

“This part includes certificate X (pages), Certificate Y (pages)” etc. and should be intact (Authorized by notary tamper proof) and stapling or pasting not accepted.

**83. What is the time limit for submission of Query Response?**

**Ans:** There is no time limit for submission of Query Response as per the provision of Drugs and Cosmetics Act and Rules, however, it should be reasonable and justifiable.

**84. Where can I submit my enquiries related to registration, Import and Manufacture of IVDs?**

**Ans.**All enquiries regarding the submission and approvals can be sent to the Drugs Controller General India ([dci@nb.nic.in](mailto:dci@nb.nic.in)) - CDSCO, FDA Bhawan, ITO, Kotla Road, New Delhi - 110002. Phone: 91-11-23236965 / 23236975. Fax: 91-11-23236973.

**85. Can Third party/ Authorized Consultant ask the status of the application?**

**Ans:** No, only either applicant or his authorized Regular employee may ask the status of their application if it is beyond the time limit prescribed under Drugs and Cosmetics Act and Rules.

**86. Who is authorized to make a Technical Presentation, on behalf of applicant, when asked by the CDSCO?**

**Ans:** Only Subject Expert or Technical Person of the company who is equally competent to make technical presentation.

**87. Can import of the IVDs with brand name be done in case the Import License (Form-10) reflecting the product (IVDs) with generic name or vice versa?**

**Ans:** No

**88. Can an importer import a IVDs having residual shelf life less than 60 % for Commercial or testing purpose?**

**Ans:** No

**89. Can one time permission for import of IVDs be granted without having valid Import License in Form-10?**

**Ans:** No

**90. What are the regulatory requirements for Import, Manufacture and labeling of Veterinary IVDs?**

**Ans:** Same as IVDs meant for human beings.

**91. Is there a need to register notified products that are imported and locally processed for 100% export only and which will not be marketed in India?**

**Ans:** No, However the importer shall comply with requirements specified by DGFT from time to time.