

Tips on Using Home-use In Vitro Diagnostic Medical Devices



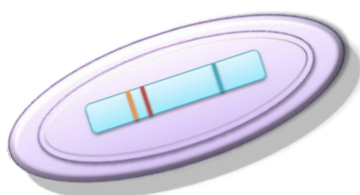
What is In Vitro Diagnostic (IVD) Medical Device?

The term “medical device” generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of disease and injuries of human beings. IVD medical devices used for examination of human specimens¹ to provide information for diagnostic, monitoring or compatibility purposes are also included under the scope of medical devices.

Traditionally, IVD medical devices have been designed exclusively for use in a healthcare setting and by a healthcare professional. Due to the advancement of technology in recent years, more and more home-use IVD medical devices are available on the market, such as home-use blood glucose meters and their test strips, urine test strips and pregnancy test kits.

Home-use IVD Medical Devices

Home-use IVD medical devices are for use by the general public. These devices are therefore designed to have relatively simple and easy operating procedures and test result interpretation as compared with professional/ laboratory IVD medical devices providing similar functions. With reference to the test results, lay users can monitor their health conditions (e.g. diabetics can use home-use blood glucose meters to test their blood glucose levels; please refer to our [“Know more about Home-use Blood Glucose Meter”](#) for details) and seek subsequent clinical consultation or treatment where necessary.



¹ Human specimens include blood, secretions (e.g. saliva and gastric juice), excretions (e.g. urine) and faeces, etc.

Potential Risks from the Use of Home-use IVD Medical Devices

The performance of home-use IVD medical devices is affected by a number of factors and their improper use may lead to inappropriate response of the users thus posing risks to their health. Some common problems are as follows:

1. The device fails to operate properly because it has not been appropriately maintained;
2. Users fail to conduct the test correctly owing to poor user techniques and/or failure to follow proper operating procedures;
3. Users act on inaccurate test results (e.g. *false negative*²/ *false positive*³ and inconsistent results) which arise from the inherent limitations of the device;
4. Users fail to interpret the test results correctly due to insufficient knowledge on the tests taken or inadequate training in test results interpretation; and
5. Users fail to take necessary follow-up measures timely on the basis of the test results.

Safe Use of Home-use IVD Medical Devices

1. Store and maintain the device according to the manufacturer's instructions;
2. Follow the directions of use when conducting the test, including device settings and specimen collection;
3. Understand the purpose of the test, its limitations, the meaning of test results and whether the test suits the user's needs before conducting the test;
4. Take appropriate follow-up measures in accordance with the test results obtained (e.g. consulting a doctor for further investigations following positive result in a faecal occult blood test);
5. Seek medical advice in case of doubt or occurrence of suspicious symptoms, despite a normal test result; and
6. **NEVER replace doctor's diagnosis** by home-use IVD test results, as these results are for general monitoring and reference only.

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² False negative result means a test result that is incorrect and fails to recognise an existing condition or disease.

³ False positive result means a test result that is incorrect and indicates a condition or disease that does not exist.