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**Letter to the Editor**

# An Overview of a New Approach in Evaluation, Verification and Validity of In Vitro Diagnosis (IVDs) Performance in Iran

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## Dear Editor-in-Chief

According to many questions arising in clinical laboratories community on quality assessment and performance of In Vitro Diagnosis (IVDs) process in Iran, we are publishing a descriptive detailed process of Ministry of Health & Medical Education (MHME) role in achieving a permit for importing or local production of IVDs, supervisions on distribution, consumption, post marketing monitoring, limitations, and future prospects of Reference Health Laboratory (RHL) and its role in improving each step.

The quality assessment & performance of IVDs program, is among other important quality assurance issues in medical laboratories of Iran started at RHL of MHME many years ago. At that time the results of a data set produced by RHL was the base for introducing and choosing of a product in the market. However, in recent years, issues such as introducing different technologies, competition of companies (local manufactures /importers), variety in clinical assessment analysis along with significant technical performance differences among IVDs in conducted analytical and clinical studies, and also different relevant certificates and approvals in a product technical file, have caused the clinical laboratories & technology management office to breakdown the evaluation process and consider other effective parameters to improve the investigation steps. These processes which at present are being proceeded in Medical Equipment office (MEO) with RHL cooperation for reviewing the technical file and performance evaluation are as follows (1-3):

1- A company Registration

All legal & real people according to law may act in manufacturing, and in IVDs importing. The necessary steps are:

- Introduce themselves to MEO and present a sample of the company's stamp with necessary documents indicating authorization of them.
- Fill out necessary application forms.
- Pass the training courses with at least minimum acceptable score.
- Receive an activity I.D from MEO after presenting all necessary documents and permits.

2- IVD Registration

The applicant at this step presents an appropriate request for reviewing the IVD/s technical file to MEO. The technical file should be in special format and contain(2,3) the following items:

- Executive Summary
- Device Description
- Design Philosophy
- Marketing History
- Standards Lists

- Performance Evaluation Documents
- Common Technical Specifications (CTS)
- Risk Management
- Labeling
- Quality Management System (ISO 13485)
- International Certificates: FDA, CE or CE Declaration of Conformity (whether or not).

Each of the above sections reveals important information on a product quality and performance specifications. For example, marketing history has a valuable impact indicating the product has already been distributed in regulated international markets. Furthermore, if validity of international certificates is suspected, it is clarified through communication with issuing agencies.

The responsibility of RHL, as mentioned earlier, is reviewing the technical file of products in details by its expert technologist, and performance evaluation in cases that is needed. If the gathered data are complete and adequate, they are presented at "Registry Committee" and the final result is then reported to MEO.

The members of IVDs Registry Committee, held 2-3x monthly at RHL, are RHL general director and representatives from two offices as fixed members. In addition, experts from other related organs may be invited to attend the relevant sessions of the committee. The final decision of committee is categorized in four different groups:

- To evaluate a product technically at RHL or other collaborating laboratories based on RHL protocol.
- To receive an import permit for a limited number of products after necessary quality and IVDs performance evaluation in collaborating laboratories at specific time period determined by RHL.
- To confirm and register without initial technical evaluation process. Products from distinct companies/manufactures having national /international valid certificates, long satisfactory marketing history are considered in this group. Their evaluation is through post marketing surveillance (PMS).
- To return unacceptable product files to requesting company by MEO.

3-Post Marketing Monitoring of IVDs

Medical device manufactures and distributers should ensure that the products comply with certain requirements and regulations and do not endanger health or safety in a community once they are on the market (2,3). These requirements include such things as established and defined tracking system, reporting of device malfunctions, serious injuries, post market surveillance studies, post approval studies in order to improve calibration- upgrading- traceability- product development protocol services including installation-training, maintenance- and product recall.

One of the problems influencing the quality of clinical laboratory data randomly in Iran is related to devices that are already available in the market and they tend to fail customer or user expectation for quality or to meet performance specifications. In such cases they are subjected to" Complaint Reporting" to responsible organs and health care professionals. Any indication of complaint (oral, written,…) may be submitted to MEO and RHL, handled effectively, thoroughly analyzed and the manufactures or distributers be informed of the result/s. Then necessary corrective or preventative actions shall be taken that are of help to reduce the quality risks involved in IVDs quality and performance.

Efficiency and quality of this system depend on many factors such as professional commitment, technical management expertise, and technical personnel as if carelessness in finding and reporting quality based deficiencies of a product may rise and lead to health safety problems. In addition, it may cause an unnecessary assessment procedure to begin.

## *The Challenges & Future Prospects of RHL*

In fact what has been achieved so far at clinical laboratories & technology management of MHME with MEO and RHL collaborating and help of other organs like CDC, Pasteur institute of Iran, is strengthening the process of quality control activities that have been started many years

ago in different sections of clinical laboratories in Iran. The focus of all these activities is to assure the quality performance of IVDs; including instruments/equipment, reagents, control materials, and other factors that should be taken in account in pre analysis, analysis, and post analysis procedures. The progress and continuity of these activates are not possible unless with cooperation and harmonization of all other related and involved organs, for example, consumers, manufactures, importers, distributers, and related government organizations. On the way, however, there are obstacles such as inadequate and unavailable standards and guidelines, limited information sources in IVDs technology, competitions among importing companies for product registry purposes, and ways of product availability in the markets that could influence indirectly the RHL following plans:

- Determination of technical specifications acceptable for product registry purposes.
- Preparation of a format for IVDs technical file
- Promotion, supervision and controlling GMP of high risk class products for local manufacture
- Supervision for proper distribution of IVDs
- Supervision and promotion on improving the customer compliances system and monitoring through PMS
- Determination of guidelines for manufactures support with cost effective purposes.

Thus RHL has purposed key points in three levels of promotion and improvement regarding IVDs technology and management to MHME:

1. Conformity with universal standards in IVDs with emphasis on promoting local production quality.
2. Continuous strengthening of IVDs quality control assurance evaluation process.
3. Consumer encouragement to cooperate & inform relevant organs of compliances.

It is hoped RHL role to be effective in harmonizing even more.

## Conflict of Interest

None Disclosed.

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