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Handling of Point-Of-Care-Testing labmed Recommendations

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1. Introduction

The need to ensure that laboratory analyses are performed directly where patients are cared for, arose in the context of new trends in healthcare. This is known as point-of-care testing (POCT) or near-patient testing (near-patient analysis).

At the same time, the rapid technological developments have generated devices that are easy to use and deliver results of analysis of whole blood samples within the shortest time. This makes it possible to perform the analysis at the bedside, in emergency and intensive care units, in hospital units, in doctors' medical practices or at home of patients. The need to obtain high quality results is still the major focus, however with shorter response times, lower costs and optimal staff assignment.

POCT is not a replacement of the central laboratory services and remains an addition, although certain laboratory tests can be performed by POCT at the patient directly or in its proximity.

2. Biomedical Scientists (BMS)

BMS are specialists in healthcare, who are educated and trained in quality control procedures and quality control regulations of laboratory analytics. They guarantee the quality of the measurements, regardless of where they are performed. Advances in technology allow the realization of laboratory analyses also by non-laboratory personnel. BMS, however, are still responsible for maintaining the necessary quality control and quality assurance programs.

Thus the tasks of the BMS are expanded - they take over the role of «advisors» for the application and the monitoring of the Point-of-care analyses.

3. The medical laboratory

The medical laboratory carries the responsibility to ensure that non-laboratory technical personnel is trained and instructed sufficiently for the use of POCT tests. The appropriate proof of qualification of the instructed personnel is an integrated part of the training program. The medical laboratory will be responsible for the definition of adequate analyses, the creation of necessary work instructions and the data backup.

4. Costs

The total costs for POCT must be evaluated carefully, including the expenses for health and safety measures. Preventive measures must be taken to avoid unnecessary analyses. Advantages and disadvantages of POCT must be listed carefully taking into account potential savings in patient costs and duration of stay. Treatments, which additional costs grow by POCT, must be examined particularly critical under the aspect of increased health care costs.

5. General recommendations

1. POCT tests must be performed by qualified and properly trained personnel; whenever possible, personnel trained in laboratory medicine should be employed.

2. BMS are responsible for supervising the POCT program and must be included in the decision making (selection and introduction of tests).

3. The POCT offer is based on an analysis of needs and will be established in collaboration with the laboratory and medical and nursing services. The offer should only include clinically relevant analyses and will be limited to cases requiring urgent action as a consequence of a POCT result.

4. The central medical laboratory must develop a quality assurance and quality improvement program. Regular competency testing of the POCT analysis performing personnel are part of this program and must be made periodically by the qualified personnel of the medical laboratory.

5. Medical laboratories have experience in the training of biomedical analysts and they should apply it in the training of non-laboratory professionals. The appropriate training programs should be structured and completed under supervision of the laboratory technical personnel.

6. BMS and the medical laboratory are responsible for the selection and introduction of POCT devices.

7. Precise equipment and operating instructions, created by the laboratory personnel, ensure uniform execution analyses.

8. Service and maintenance work are prescribed by the medical laboratory; these guidelines must be followed and their execution must be documented.

9. The medical laboratory must ensure that the legal and normative requirements (e.g. accreditation standards) are fulfilled. Processes for the documentation and traceability of all the results must be clearly defined.

10. Particular attention must be paid to the consideration of pro and cons of POCT (speed, quality of results, costs).

6. Recommendations for POCT procedure should be applied according to the instructions of the medical laboratories.

1. The training of non-laboratory personnel must fulfil the minimum requirements and ensure the following conditions:
    a. Sufficient knowledge about the applied method to ensure the proper and safe application
    b. Understanding of the importance of regular and recorded control on the correct operation of the analytical equipment.
    c. Taking the responsibility for ensuring the operational capability of the analytical equipment.
    d. Recognition of malfunctions of the analytical equipment.
    e. Basic knowledge of the significance of abnormal results.

2. Written records containing the following minimum information must be available at the site of the test execution:
    a. List of persons trained for the appropriate test.
    b. Accurate description of the method and approach of the test.
    c. Journal, in which all calibrations, maintenance, quality controls, lot numbers of reagents and results are registered.

3. The medical laboratory, medical and nursing staff must agree concerning acquisition, employment, maintenance and replacement of the analysis systems. Ease of use, automatic calibration, self-cleaning, standard functions and compatibility of results with those of existing systems in medical laboratories are reviewed by qualified personnel of the laboratory. The medical laboratory is responsible for the acquisition, storage and control of equipment and devices.

4. All results must be documented and transferred into the patient's history in a way that its source is seen as POCT investigations.

5. All results must be entered in the laboratory information system and marked accordingly. The validation of the results is done by the medical laboratory.

6. Unexpected results must be checked in the appropriate, qualified medical laboratory.

7. The protocols must be adapted to the national/local quality requirements and must correspond to the national/local regulations for analysis systems of the medical in-vitro-diagnostics.

8. The protocols must be in compliance with health and safety practices and with the regulations of national/local standardisation committees of the medical laboratories.

9. The equipment must be cleaned according to the existing laboratory regulations and must be sterilized if necessary.

10. Test and consumable material and contaminants must be treated according to the relevant laboratory regulations.

11. Fields of activity

7. Fields of activity

7.1 Inside Hospital

Hospitals need point-of-care testing (POCT) in the divisions of care, emergency services, anaesthesia, intensive care and ambulant treatment. The area of application is the same as in the central laboratory, but closer to the patient. These decentralized provided services complement those of the medical laboratory, which continues its analytic activity as a centre for the entire hospital.

BMS are, together with the laboratory director, responsible for safety and quality of all laboratory tests, which are offered in a hospital.

The same requirements are valid for the decentralized analytics, as well as for the central medical laboratory, which therefore assumes the professional responsibility for the entire POCT offers in a hospital. This contains among other things, the selection and standardisation of methods and equipment, the training, the application of used methods and instruments as well as the appropriate measures for quality assurance.

All analytic activities require knowledge of preanalytical factors, that can influence the results.Due to their qualification, Biomedical Scientists are best suited to judge the impact of the following factors on the laboratory test results:

- identity of the patient
- biological fluctuations and age depending values
- sampling techniques
- storage and transport of biological material

Due to their education and professional experience in medical laboratories, BMS are trained in:

- ensuring the identity of the samples
- quality control procedures
- execution, evaluation and monitoring of internal and external quality controls
- calibration and maintenance of the equipment.
- Selection and standardization of methods and devices.

7.2 Outside the hospital

A large number of laboratory analyses are performed in doctors' offices and outpatient clinics. These analysis centres are also subject to the legally prescribed quality control programs.

Due to their education and qualification, BMS can bring in their experience in business centres of medical quality control and support legislators and insurance companies in monitoring compliance with regulations.

Due to their education and experience, BMS are trained in the support and advice in the field of laboratory-analytical processes. They are able to analyze the needs of the different institutions and to make appropriate recommendations and suggestions for the implementation of POCT tests. They can also take over the training of various user groups (doctors, medical assistants, nursing staff).

With this advisory role, the Biomedical Scientists are in constant contact with medical laboratories, so that the necessary knowledge can be kept up to date. The main areas of activity are:

- Production and maintenance of links between the medical laboratory and the practice laboratory or outpatient clinic
- Provide individualized assistance in relation to quality control processes, like:
  – Backtracking and evaluation of results of external quality controls
  – Training in quality control
  – Advice on procedures for internal quality control
  – Support for problems in analytics
  – Support for the preparation of documents describing the procedures and instructions
  – Regular personal contact with key persons
- Organization and realization of training for non-laboratory personnel in the external institutions, with the following contents:
  – Theory and practice of laboratory work
  – Increase understanding of the importance of internal and external quality controls

BMS can bring in their knowledge in the industry (e.g. customer care) and/or more generally have an advisory function in institutions that perform POCT analyses (e.g. police, military, first aid stations, sports medicine).

8. Legal bases for the authorization to practise POCT laboratory tests

8.1 Extracts from the basic convention on the quality assurance in the medical laboratory QUALAB

- Contracting parties are service providers and payers.
- The parties aim to ensure quality assurance according to Swiss law, in particular internal and external quality control, to the service providers, which perform analyses.

- The contracting parties constitute a commission (QUALAB) with the involvement of professional societies and concerned federal agencies, the latter acting with an observer status. Organization, responsibility and competence are regulated in business regulations.

8.2 Extracts from the concept of quality assurance in the medical laboratory (concept QUALAB, version 1.1)

- The concept of quality assurance in the medical laboratory corresponds to the Swiss law, as well as to the regulations of the Swiss federal list of analysis with appendices and summarizes the regulations of the quality assurance for medically prescribed analyses in the medical laboratory. These regulations are mandatory in particular for analyses, which are accomplished debited to the basic health insurance and/or paid by it.
- The analyses in the medical laboratory are provided either by the laboratory director or by the Biomedical Scientists (or the practice assistant in the practice laboratory). Persons of other paramedical professions are authorized to perform testing in the laboratory, if they identify themselves through a proven, appropriate and equivalent training in theoretical bases and medical analytics of the practice laboratory. The details are regulated by the QUALAB.

9. Abbreviations/legend

BMS:	Biomedical Scientists
POCT:	Point-of-Care-Testing
QUALAB:	Swiss commission for quality assurance in the medical laboratory
KVG:	Federal law on health insurance
KVV:	Regulation on health insurance
UVG:	Federal law on accident insurance
IVG:	Federal law on disability insurance
MVG:	Federal law on military insurance
RK:	Swiss red cross.

10. Sources

- IFBLS = International Federation of Biomedical Laboratory Scientists (Homepage)
- Concept of quality assurance in the medical laboratory (concept QUALAB, version 1.1).

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