

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA v.2.0

## 7. PREANALYTICAL PHASE

### 7.4. REQUEST PROCEDURES

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CIRCULATION LIST:	NAME	POSITION

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## 1. INTRODUCTION

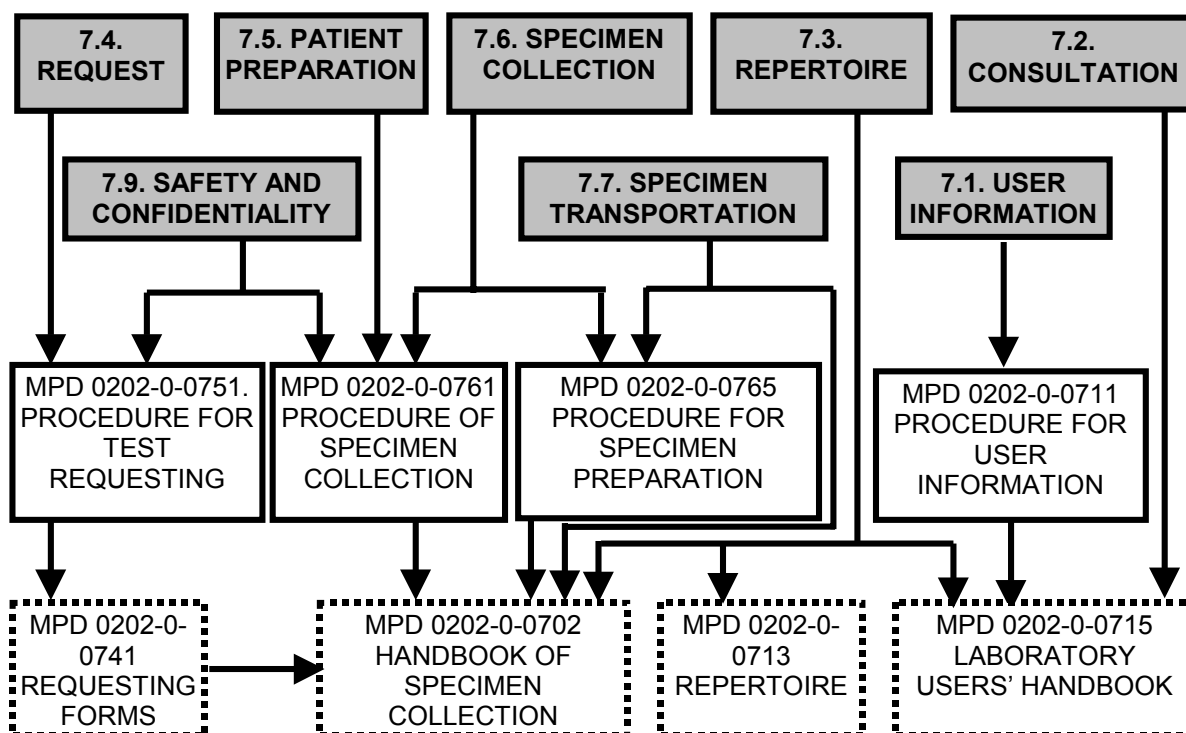
There should be procedures for urgent and routine requests.

The request form should be designed with a view to obtaining necessary information for identification of the patient, the requesting physician, requested tests and clinical information.

The request form should facilitate efficacy by its layout (e. g. disease oriented).

In the request form specific requirements for the patient for individual tests (e. g. fasting) should be indicated.

### 1.1. SCOPE



### 1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
5.4. Pre-examination procedures. 5.4.1; 5.4.5.; 5.4.12	7.2. Client related process.	

### 1.3. PUBLICATION CREDITS

EC4 WG

### 1.4. REFERENCES

- Jansen RTP, Blaton, V, Burnett D, Huisman W, Queraltó JM, Zérah S, Allman B. European Communities Confederation of Clinical Chemistry. Essential criteria for quality systems of medical laboratories. Eur J Clin Chem Clin Biochem 1997; 35(2): 123-132.
- ISO/DIS 15189 – Quality management in the medical laboratory (December 1998). 5.4.1, 5.4.5, 5.4.12.
- ISO.DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000. 7.2.


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4. Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2<sup>nd</sup> rev. ed. Utrecht: NVKC 1996,
5. Burnett D. Understanding accreditation in laboratory medicine. London: Association Of Clinical Biochemists, 1996, 160-170.

### 1.5. RELATED DOCUMENTS

MPD 0202-0-0751 Procedure for test requesting  
MPD 0202-0-0703 Procedure for requesting forms  
MPD 0202-0-0741 Requesting forms  
MPD 0202-0-0701 Laboratory users' handbook  
MPD 0202-0-0702 Specimen collection handbook

### 1.6. ABBREVIATIONS

**LIS:** laboratory information system  
**PMS:** hospital patient management system

### 1.7. RELATED DEFINITIONS

**measurable quantity:** (measurable property, quantity) attribute of a phenomenon, body, or substance that may be distinguished qualitatively and determined quantitatively. NOTE 1: Phenomenon, body, or substance corresponds to the concept of system as used in clinical laboratory sciences. Qualitatively refers to the need to define a quantity before it can be measured. NOTE 2: Measurable quantity is described by three concepts, here called kind-of-quantity, **component**, and **system**. NOTE 3: "**quantity**" is often used as a short term.

**measurand:** particular quantity subject to measurement. EXAMPLE Vapour pressure of a given specimen of water at 20 °C. NOTE The specification of a measurand may require statements about other quantities such as time, temperature and pressure.

**quantity:** short term of **measurable quantity**.

**sample:** one or more parts taken from a system and intended to provide information on the system, often to serve as a basis for a decision on the system or its production. EXAMPLES: A volume of serum taken from a larger volume of serum; a simple random subset of measured values of a measurable quantity taken from a set of such values. NOTE 1: The single part forming a cohesive entity and taken from one place and at one time is also called a "sampling unit" or an "item". NOTE 2: Unless otherwise specified, the sample is assumed to be representative of a "static system", that is a system having no appreciable change in relevant measurable quantities during the time of consideration. NOTE 3: When a "dynamic system" is concerned, as is often the case in the clinical laboratory sciences, the calendar time of sampling is a mandatory item of specification to the system of interest. Such a special type of sample has been called a "**specimen**", but this term is not used here. The term specimen has also been used in laboratory medicine as a synonym for a sample, as defined here, of biological origin, or for an entire macroscopic parasite. NOTE 4: The system from which a sample is taken may not be of the same type as that of the measurand. EXAMPLE: A given blood sample may serve for measurement of pH in plasma and haemoglobin concentration) in erythrocytes. NOTE 5: The definition given above covers a sample from any type of system. ISO gives two definitions that apply more to data and materials respectively. (a) sample: One or more sampling units taken from a population and intended to provide information on the population; (b) sample: Representative quantity of material extracted from a batch of reference material). NOTE 6: In some countries the term specimen is used for primary sample (or a subsample of it) which is the sample prepared for sending to or as received by the laboratory and intended for measurement.

**sampling:** process of drawing or constituting a sample.

**sampling procedure:** operational requirements and or instructions relating to the use of a particular sampling plan, that is the planned procedure of selection, withdrawal, and preparation of one or more samples from an inspection lot to yield knowledge of the characteristic(s) of the lot. NOTE: In laboratory medicine, the "inspection lot" usually is a person.

**specimen:** in some countries the term specimen is used for primary sample.

**system:** demarcated part or phenomenon of the perceivable or conceivable universe, material or immaterial, that may be regarded as a set of elements and a set of relationships between these elements.

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## 2. SUBMISSION OF REQUESTS

### 2.1. REQUEST INFORMATION

Requests are made using specific forms. The request form in the Clinical Chemistry Department is the equivalent of a referral letter from one doctor to another and can be regarded as the first step in a consultation between the requesting doctor and the laboratory.

Details are included in *MPD 0202-0-0751 Procedure for test requesting* and *MPD 0202-0-0703 Procedure for requesting forms*.

Information which is required for a number of specific purposes, includes:

Information	Reason
patient's name unit number date of birth gender	Identification and (age, sex) interpretation of results
Return address (e.g. ward, clinic, surgery; telephone/page number if urgent)	Delivery of report
Name of clinician (and telephone/ page number)	Liaison, Auditing, Billing
Clinical details (including drug treatment)	Justification of request Audit Interpretation Selection of appropriate tests Choice of analytical method (to avoid drug interference)
Test requested	Instruction to analyst
Specimen(s) required	Instruction to phlebotomist
Date (and time if appropriate)	Identification Interpretation (with timed/sequential requests) Audit
from <i>Clinical Biochemistry</i> , edited by Marshall WJ and Bangert SK Churchill Livingstone (1995)	

### 2.1. ELECTRONIC REQUESTS

If computer terminals connected with the laboratory information system (LIS) are available in the wards, requests are made on the LIS. When such systems are in use the patient's identification details are normally obtained from the patient master index of the hospital patient management system (PMS) or from the LIS patient database which can in turn be refreshed periodically by information from the PMS.

If a request for the testing of a specimen other than blood (e.g. urine, faeces or liquor) is input directly into the laboratory host computer by a hospital department, a summary service request form is generated by the LIS. This form is printed out on the requesting department's printer and sent to the laboratory with the specimen.

Further information on the management and operation of LIS and PMS is given in the section on computers in the laboratory.

### 2.3. WRITTEN REQUESTS

The general form used by the institution is given in *MPD 0202-0-0741 Requesting forms*, which contains a display of the forms currently in use and the dates they entered use.

Instructions for service users are contained in the *MPD 0202-0-0701 Laboratory users' handbook* and *MPD 0202-0-0702 Specimen collection handbook*.

The written request form has two copies. The Clinical Chemistry Department keeps the first copy. The Accounting Department receives the second copy.

#### 2.3.1. MAIN SERVICE REQUEST FORM

The Main Service Request Form can be used for most types of test.

The form is used by medical specialists to request both in-patient and outpatient tests.

Outpatients attending the Outpatients' Specimen Collection Unit bring the forms with them.

#### 2.3.2. MINOR SERVICE REQUEST FORM

The Minor Service Request Form is used to request blood sugar tests and tests on materials other than blood.


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The form is normally handed in together with the specimen and has space for recording the results of certain tests.

The form is used by medical specialists to request both in-patient and outpatient tests.

### 2.3.3. GENERAL PRACTITIONER'S SERVICE REQUEST FORM

The General Practitioner's Service Request Form is diagnosis oriented.

The form is used by general practitioners to request outpatient tests. Outpatients or patients attending the external specimen collection centres bring the forms with them.

### 2.3.4. AMINO ACID SERVICE REQUEST FORM

The Amino Acid Service Request Form is used by internal and external medical specialists to request both in-patient and outpatient tests.

### 2.3.5. MICROBIOLOGICAL LABORATORY TESTS

Forms requesting medical microbiological laboratory tests have to be sent in by the service user with the specimen material.

## 2.4. TELEPHONE REQUESTS

Between 5.00 p.m. and 7.30 a.m., urgent in-patient tests can be requested by telephoning the Laboratory Technician on duty; during office hours such tests can be requested from the Urgent Specimen Collection Service.

It is possible to arrange by telephone for a specimen to be taken from a patient at his or her home. Following approval ' the Clinical Chemist, someone from the External Specimen Collection Service goes to the patient's home and takes the specimen, then brings it to the laboratory, together with the appropriate service request form.

A doctor can also use the telephone to request additional tests on serum obtained from a patient up to seven days earlier, provided that there is sufficient serum left in the primary specimen tube and that the outcome of the test would not be adversely affected by the storage period and Service requests temperature (4 °C)

## 3. REQUESTS OUTSIDE OFFICE HOURS (STAT)

Only a limited range of services is available outside office hours. The same test methods are used outside office hours as at other times.

Request forms for time-dependent tests have to be submitted to the laboratory in advance.

Details are included in *MPD 0202-0-0751 Procedure for test requesting* and *MPD 0202-0-0703 Procedure for requesting forms*.

## 4. URGENT, IRREGULAR AND PRIORITY REQUESTS

Only the types of test specified in the relevant list can be requested on an urgent basis, and medical specialists may only submit urgent requests. The relevant service request form has to be signed. The medical specialist requesting the test marks the request form "PRIORITY" and signs it.

When computer makes an urgent request, the system generates an Urgent Service Request Form, which is printed out on the laboratory printer.

The procedure *MPD 0202-0-0751 Procedure for test requesting* contains details about special requests: additions, experimental, research, etc.

## 5. PROCEDURES FROM EXTERNAL ANALYTICAL SERVICES REQUESTS

The Clinical Chemistry Department accepts request from external institutions provided that the accompanying request form includes:

- (a) unequivocally patient identification;
- (b) gender and birthday;
- (c) origin;
- (d) clear identification of requesting authorized person for requesting analytical services;

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- (e) ~~address, telephone number (or e-mail);~~
- (f) specimen and anatomical place where it was obtained;
- (g) examinations requested;
- (h) date, time and person who obtained the specimen;
- (i) date, time and person who admitted the specimen in the Clinical Chemistry Department;
- (j) other relevant information, like drugs, diets, etc....

## 6. SPECIMENS AND SAMPLES NOT ACCEPTED

The clinical Chemistry Department does not accept requests or specimens with clear identification.

Difficult collection or instable specimens (like spinal fluid) are processed but results are not issued until a responsible person from the requesting department identifies or provides enough information. This fact is recorded in the appropriate register.

## 7. RESPONSABILITIES ON "REQUESTING"

The Director of the Clinical Chemistry Department is responsible of the requesting policy of laboratory services users.

The writing, revision and maintenance of documents concerning the consultation by users is responsibility of the Quality Officer.

Design of requesting forms is made by the person appointed by the Director of the Clinical Chemistry Department.

## 8. DOCUMENT MANAGEMENT

Updated documents concerning the request of analytical services procedures are available in the document volume of the LIS.

One copy of these procedures is kept in the Quality System Files. Staff members of the Clinical Chemistry Department receive an update copy as soon as it is available.

## 9. REVIEW OF DOCUMENTS

Documents concerning the request of analytical services are revised at least once a year.


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