

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA v.2.0

7. PREANALYTICAL PHASE

7.6. SPECIMEN COLLECTION

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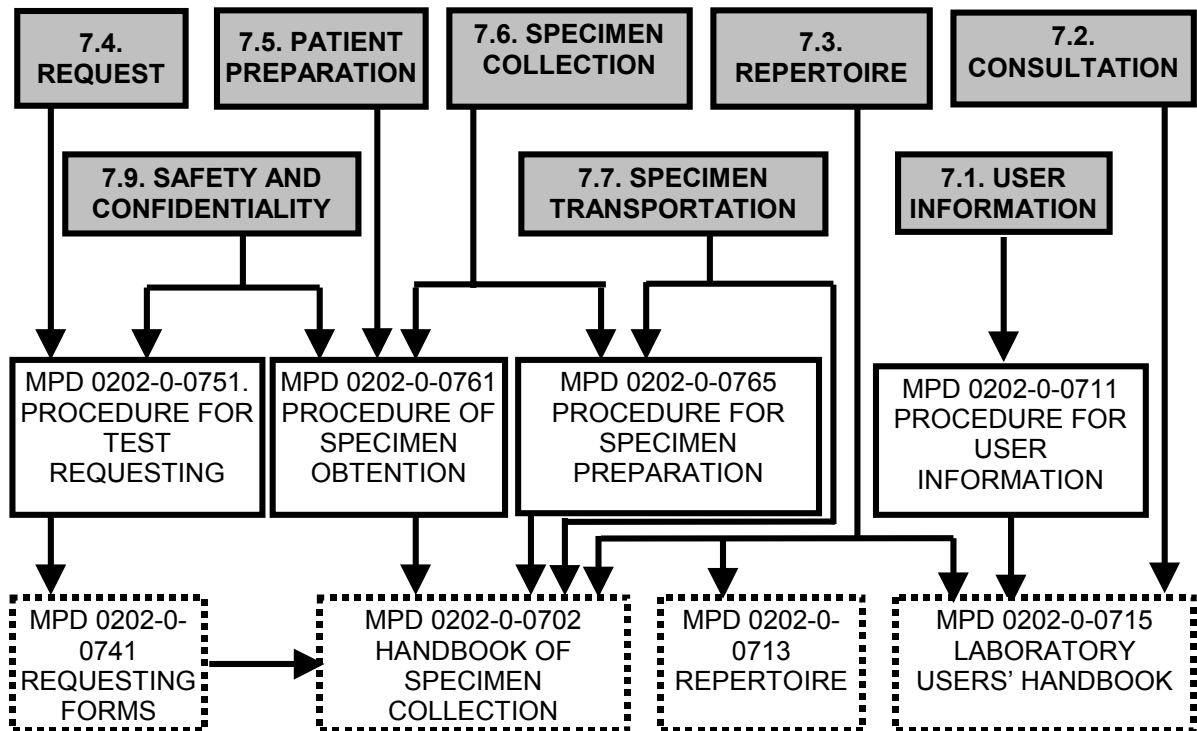
1. INTRODUCTION

There should be a procedure describing all aspects of blood and other specimen collection including patient identification, patients position, sampling technique, and biological safety aspects.

There should be a procedure for unique identification of specimens and subdivided specimens including labelling and date and time registration of specimen and requests.

There should be a list containing for each test information about the type of specimen, the type of tube and anticoagulant, collecting temperature and the amount of specimen needed.

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.		5.7. Sampling. 5.7.1. to 5.7.3.

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

- Jansen RTP, Blaton V, Burnett D, Huismann 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/TC 212/WG 1., Quality management in the clinical laboratory. Revised ISO/CD 15189, 5.4.

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3. ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998. 5.7.1., 5.7.2., 5.7.3.
4. Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. ed. Utrecht: NVKC 1996,
5. Burnett D. Understanding accreditation in laboratory medicine. London: Association of Clinical Biochemists, 1996, 140-157.

1.5. RELATED DOCUMENTS

QM 07-03. Preanalytical phase. Repertoire

QM.07-04. Preanalytical phase. Request procedures

QM 07-08. Preanalytical phase. Experimental assays.

MPD 0202-0-0701 Laboratory users' handbook

MPD 0202-0-0702 Handbook of specimen collection

MPD 0202-0-0761 Procedure for specimen collection

MPD 0202-0-0765 Procedure for specimen preparation

MPD 0202-0-0703 Procedure for requesting, collection and register of irregular specimens.

Handbook of laboratory information system

1.6. ABBREVIATIONS

LIS: Laboratory Information 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,

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that may be regarded as a set of elements and a set of relationships between these elements.

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2. SAMPLING METHODS

2.1. GENERAL

The Clinical Chemistry Department admits the following specimens for examination:

- (a) blood for whole blood, leucocytes, serum, plasma rich in platelets or plasma tests;
- (b) urine
- (c) spinal fluid;
- (d) pleural fluid;
- (e) articular fluid;
- (f) ascitic fluid;
- (g) amniotic fluid;
- (h) faeces;
- (i) breast tissue;
- (j) renal calculi.

It is laboratory policy that no more specimen material should be taken from patients than is strictly necessary. The minimum specimen volume is stated in the *MPD 0202-0-0701 Laboratory users' handbook*.

In addition, when a service request is received, the computer system determines not only the type but also the number of specimen tubes which need to be filled, rounded up to the next full tube.

Venous blood specimens are taken using a closed vacuum sampling system.

2.2. SPECIMEN IDENTIFICATION

A label bearing the following information is attached to every specimen:

Specimen number	As soon as a service request is received, a six-figure specimen number is issued. The first two figures in the specimen number represent the date in the current month; the third figure indicates the origin and general practitioner/specialist; the last three figures form a serial number for the day in question. (See the Document <i>Handbook of the Laboratory Information System</i> .) The specimen number remains "alive" until all the results have been entered into the computer. At the end of each day, the computer checks all the live specimen numbers to see whether the results have been entered, and transfers completed data sets to the patients' historical files. Once a data set has been transferred, the specimen number is still displayed, but it is no longer possible to access data on the patient using the specimen number in question. The specimen number is then released for reuse.
Material code	
Name, date of birth and sex of the patient	
Department and room number (in-patients)	
Doctor's code	

Manuscript labels bearing patients' names and dates of birth are attached to specimens taken at external specimen collection centres.

More details regarding specimen labels are given in the *Handbook of the Laboratory Information System (LIS)*.

2.3. SPECIMEN COLLECTION AND PREPARATION

The specimen collection procedures are contained in documents *MPD 0202-0-0761 Procedure for specimen collection* and *MPD 0202-0-0765 Procedure for specimen preparation*, where distinction is made between the following types of specimen collection:

- (a) Blood sampling by phlebotomy
- (b) Capillary blood sampling
- (c) Blood culture sampling
- (d) Sweat sampling
- (e) Preparation of diffusion specimens

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(f) Preparation of a large drop specimen

The document *MPD 0202-0-0761 Procedure for specimen collection* contains a list of the materials to be obtained for each type of test, and the specimen tubes or containers to be used. The document includes similar information regarding material that is not obtained by laboratory staff (urine, arterial blood, liquor, gastric juice, semen, etc).

Special requirements relating to the collection of specimens from individual patients and relevant clinical data given on the service request form have to be entered into the Laboratory Information System and, if indicated by the Clinical Chemists, reported with the result.

All the information is summarized in the *MPD 0202-0-0702 Handbook of specimen collection*.

3. IDENTIFICATION OF SPECIMENS AND SUBDIVIDED SPECIMENS

3.1. PROCEDURES

There is a procedure (*MPD 0202-0-0761 Procedure for specimen collection*) for unique identification of specimens and subdivided specimens including labelling and date and time registration of specimen and requests and procedures of specimen collection. The contents are, at least:

- (a) Handbook of specimen collection;
- (b) Responsibilities of specimen collection;
- (c) Procedures for specimen collection;
- (d) Specimen identification.

There is a procedure (*MPD 0202-0-0765 Procedure for specimen preparation*) for treatment (centrifugation, separation, division, etc.) of specimens.

3.2. CHECKS

Before taking blood specimens in the Outpatients' Specimen Collection Unit or in the ward, laboratory staffs have to compare the patient data given in the specimen collection listing generated by the LIS with the data on the patient's ID bracelet.

Outpatients are asked to give their names and dates of birth, which are compared with the information printed onto the analytical service request forms.

Each specimen transferred to the laboratory has to be accompanied by an analytical service request form onto which the patient data card has been printed; the specimen must also bear the same identification details as are on the accompanying analyst service request form.

The data on the specimen and on the analytical service request form is checked; when the request is entered into the LIS, the data is compared with that stored on computer.

4. LIST OF SPECIMEN TYPES

The *MPD 0202-0-0761 Procedure for specimen collection* and the *MPD 0202-0-0702 Handbook of specimen collection* includes a detailed list of specimen types, amount, as well as the preferred anticoagulant (and the type of tube) and the temperature to be kept before it has been delivered.

Test	Type of specimen	Type of tube	Type of anticoagulant	Temperature	Amount of specimen

5. IRREGULAR REQUESTS

The procedure *MPD 0202-0-0761 Procedure for specimen collection* and *MPD 0202-0-0765 Procedure for specimen preparation*, contain information concerning requests of analytical services:

- (a) orally;
- (b) additions to previous requests;
- (c) experimental tests;

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(d) research protocols.

See also QM 07-08. *Experimental assays.*

6. SPECIMENS AND SAMPLES NOT ACCEPTABLE

The Clinical Chemistry Department does not accept specimens or samples without the appropriate accompanying form or not clearly identified. See QM.07-04. *Preanalytical phase. Request procedures.*

7. RESPONSABILITIES ON "SPECIMEN COLLECTION"

Specimens are obtained by personnel belonging to the Nurse Department.

The Quality Officer of the Clinical Chemistry Department is responsible of writing, maintaining, and updating the information required for the specimen collection for the laboratory analytical services. This information is compiled and publicized by the Quality Officer.

8. DOCUMENT MANAGEMENT

Updated documents concerning the specimen collection for analytical services 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 specimen collection for analytical services are revised at least once a year.

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