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GUIDELINES TO SUBCONTRACTING CLINICAL LABORATORY EXAMINATIONS A PROPOSAL OF THE CATALAN ASSOCIATION FOR CLINICAL LABORATORY SCIENCES

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Abstract

Clinical laboratories, acting as subcontractors, do not always supply information on the quality of their examination procedures and results. Thus, its selection by a contracting organization is often based only in economical criteria. This article gives some guidelines to subcontractors on how to describe its quality characteristics in order to be appropriately contracted.

Key words: management, subcontracting

Introduction

Most clinical laboratories refer the examination of some biological properties to another clinical laboratory acting as subcontractor, commonly named "referral laboratory" (hereafter called the subcontractor). Subcontractors do not always supply information on the quality of their examination procedures and results. Thus, the contracting organisations can not always select the subcontractor adequately; in many occasions and due to this lack of information, the selection criterion is just economical.
The object of this article is to give some guidelines to subcontractors on how to describe its quality characteristics concerning general aspects, organisation and production processes, in order to provide guidance to contracting organisations on evaluating the subcontractors and, consequently, to facilitate their selection based on quality criteria. The present guidelines are partially based on a document of the same type produced by the National Committee for Clinical Laboratory Santandards (USA) (1).

Identification of the subcontractor

The document that describes the characteristics of the subcontractor shall include its name, address, phone, fax, etc., as well as the name of its director/manager. If the subcontractor has no independent legal entity, the legal entity on which it depends on shall be also included. Other indispensable data are also the registration number and legal authorisation of the subcontractor, when applicable.

There shall also figure the mention of whether or not the subcontractor is accredited (ISO 15189:2003) or certified (ISO 9001:2000).

General characteristics

The subcontractor shall give details of the following general characteristics:

- Sample picking up system used; information whether specific containers or additives are needed; the transportation mechanism and conditions for the sample, and also the type of sample identification.
- Sample picking up schedules.
- Communication systems for requesting and reporting. Detail of languages the documents can be expressed in shall also be included.
- Sample preservation system and time and procedure to follow when additional measurements in the same sample are needed.
- Name, surnames and timetable of consultants for consulting services.
- Diagnostic algorithms used.
- Identification of other clinical laboratories acting as subcontractors of the subcontractor.

Examination procedure characteristics

A list of the characteristics to be described for each examination procedure is given in Table 1. It is recommended that the descriptors contained in that table as headlines for the characteristics of each examination procedure be used.

Pre-examination phase characteristics

The subcontractor shall specify the following pre-examination characteristics:

- Conditions that the patient shall fulfil before the samples are obtained or collected i.e. fasting hours, diet or special hygienic activities.
- Type of samples, type of collection container and required

additives.

- Conditions under which samples were obtained such as position of the patient at the moment of the withdrawal, resting time before the withdrawal or special material for the withdrawal.
- Sample preservation and transportation conditions.
- Criteria for unacceptable samples, such as serum from haemolysed blood, clotted blood or insufficient amount.
- Indication about the container where the examination is done (is it the same in which the sample is received?).
- Sample identification system used in the examination process.

Examination phase characteristics

The subcontractor shall specify the following examination characteristics:

- Examination instrument used.
- Examination method used.
- Reagent manufacturer certification (i.e. ISO 9001), if available.
- Unit of measurement, when appropriate.
- Detection limit of the measurement procedure, when appropriate.
- Measuring range, when appropriate.
- Reference limits or discrimination value (cut-off point), stratified according to biological characteristics (i.e. age and sex), when appropriate.
- Origin of the reference limits (i.e. produced in house, adopted, etc.)
- Certified reference materials to which calibrators are traceable.
- Name of the national or international external quality assessment schemes, in which the subcontracter participates.
- Number of internal control materials included per run (samples/control materials ratio)
- Day-to-day imprecision —expressed as coefficient of variation— at a concentration of clinical relevance and at a physiological concentration, indicating the values of these concentrations.
- Relative systematic error (formerly inaccuracy) at a physiological concentration. The relative systematic error will be calculated using a conventionally true value from an external quality assessment scheme. For glucose, cholesterol and triglyceride concentrations in plasma or serum and for haemoglobin concentration in blood, the conventionally true value used should be the overall consensus value (all the laboratories). For the remaining quantities, the conventionally true value should be the method consensus value.
- Whether the subcontractor contracts another clinical laboratory for the examination of a biological property.

Post-examination phase characteristics

The subcontractor shall specify the following post-examination characteristics:

- Turnaround time.
- Availability of on-line connection between the examination system and the laboratory information system.
- Criterion used to repeat a measurement, i.e. "To be repeated if the result is below 4.5 or above 85 nmol/l" or "if the result is over the reference limits" or "if the result is positive".
- Methods used to accept or reject series of results, i.e. Westgard's rule 2_{2s}, Bull's algorithm, etc.

- Immediate communication of alarming ('panic') results to the requesting laboratory. In this case, the alarming criteria used shall be specified, i.e. results above 120 nmol/l, below 2.5 nmol/l, positive results, etc.
- Eventual additional comments to the results in the clinical laboratory report, i.e. comments on the interpretation of the results, comments on endogenous interference, advice on other examinations or on frequency to repeat the examination.

References

1 National Committee for Clinical Laboratory Standards. Selecting and evaluating a referral laboratory; Approved Guideline. NCCLS Publication GP9-A. Villanova: NCCLS, 1998.

Table 1. Example of characteristics to be described by a subcontractor to offer the examination of a biological property.

Quantity: Serum—Examplenina; substance concentration
Pre-examination phase characteristics:

Patient preparation	See the Instructions Sheet num. 14
Sample, collection container and additive	Serum, 10 ml, tube with gel barrier
Obtaining and recollecting conditions	Previous resting time: 30 min
Preservation and transportation conditions	4 - 8 ºC, 2 hours max.
Criteria for sample rejection	Haemolysis
Primary container	Yes
Bar code identification	Yes

Examination phase characteristics:

Measurement done in own laboratory	Yes
Measurement system	(name/manufacturer)
Measurement method	MEIA
Certification of the reactive	ISO 9001
Measurement units	nmol/l
Detection limit	0,01
Measurement interval	0,01 - 100,00
Reference limits	0,5 - 20,0
Origin of the reference limits	Own production
Traceability of calibrators	IRP WHO 80/558
External quality assessment scheme	EQAS-Servica
Samples/control materials ratio	50 / 2
Day-to-day imprecision	6 % (to 10 nmol/l)
Day-to-day imprecision	10 % (to 0,3 nmol/l)
Relative systematic error	+ 1,5% (to 10,0 nmol/l)

Post-examination phase characteristics:

Turnaround time	2 days
On-line connection of the examination system	Yes
Criteria for repeating a measurement	< 0,5 and > 20
Series of results validation	Westgard's rule 12sx
Urgent notice of alarming results	Not