

(logo company)	Personnel management (title)	PR 01 (codification)
16/09/2026 (print date)	1/4 (page x of y)	001 (revision)

Personnel management

1. Purpose

- 1.1 Objective
- 1.2 Scope
- 1.3 Glossary

2. Responsibility

3. Documents

4. Requirements of the ISO 15189:2022 standard

5. Procedure

- 5.1 Onboarding and integration
- 5.2 Job-specific training
- 5.3 Competence assessment
- 5.4 Granting of authorization
- 5.5 Maintenance of competence

History

All	Creation	01/01/2026
Page	Changement	Date

Author / function	Verified / function	Approved / function
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(logo company)	Personnel management (title)	PR 01 (codification)
16/09/2026 (print date)	2/4 (page x of y)	001 (revision)

1. Purpose

1.1 Objective

The purpose of this procedure is to ensure and demonstrate that every person performing tasks that impact the quality of examinations possesses the required competence, training, and authorization.

1.2 Scope

This procedure describes the processes for managing laboratory personnel, from defining hiring needs to the annual monitoring of competence. It applies to all personnel, whether permanent or temporary (interns, fixed-term contract staff, casual staff, external service providers), and covers all roles:

- administrative and secretarial staff
- sample collection staff (nurses, authorized technicians)
- laboratory technicians
- quality team and biomedical engineers/technicians
- medical biologists

1.3 Glossary

PCR – polymerase chain reaction

HIV – human immunodeficiency virus

2. Responsibility

The personnel manager is responsible for drafting and updating this procedure and ensuring its implementation. They are supported by the director.

3. Documents

- Declaration of no conflict of interest
- Confidentiality agreement
- Organizational chart
- Duty Schedule Log
- Welcome booklet
- Job descriptions
- Competence matrix
- Personnel authorization log
- Training log
- Personnel file

4. ISO 15189 (2022 version) Requirements

§ 6.2 Personnel

§ 6.2.1 General

Author / function	Verified / function	Approved / function
/	/	/

(logo company)	Personnel management (title)	PR 01 (codification)
16/09/2026 (print date)	3/4 (page x of y)	001 (revision)

§ 6.2.2 Competence requirements

§ 6.2.3 Authorization

§ 6.2.4 Continuing education and professional development

5. Process

5.1 Induction and onboarding

Presentation of the welcome booklet, introduction to the team and the premises. Signing of work instructions, confidentiality agreements (medical secrecy), declarations of no conflict of interest, and safety protocols (single document, biological/chemical risks).

5.2 On-the-job training

The new employee is guided by a mentor (an experienced colleague). They follow a personalized training plan based on the department's procedures. During this phase, the employee performs tasks under the direct supervision of their mentor; they cannot validate results independently.

5.3 Competence assessment

At the end of the training period, the biologist in charge of the department assesses the employee's grasp of the material. This assessment is based on objective criteria: performance on blind samples, direct observation of technical procedures, and a theoretical quiz on protocols.

5.4 Granting of authorization

If the assessment is successful, the biologist or laboratory director signs the authorization form. This document explicitly specifies the tasks the employee is authorized to perform independently (e.g., authorized to perform the HIV PCR technique and technically validate the results).

5.5 Maintenance of competence

Authorization is not permanent. Each year, the laboratory re-evaluates competence maintenance (analyzing error rates, tracking continuing education) during the annual individual performance review.

In the event that an employee loses their competence (prolonged absence, maternity leave, long-term sick leave) or demonstrates a performance issue (leading to recurring nonconformities):

- in the event of prolonged absence (> 6 months): authorization is automatically suspended. Upon return, the employee undergoes an accelerated reintegration process (refresher training on updated procedures), validated by a competence re-assessment before authorization is reactivated

Author / function	Verified / function	Approved / function
/	/	/

(logo company)	Personnel management (title)	PR 01 (codification)
16/09/2026 (print date)	4/4 (page x of y)	001 (revision)

- in the event of a detected performance issue: immediate withdrawal of authorization for the specific technique by the biologist. A corrective training plan (re-mentoring) is scheduled. The employee works under supervision again until a new assessment confirms their return to autonomy

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