MANAGEMENT OF NON-CONFORMING SAMPLE COLLECTION AND RE-SAMPLING

INDEX

1 PURPOSE

This operating instruction describes the information required for the proper management of repeat sampling and/or the delivery of a sample following the reporting of a Non-Conformity.

2 SCOPE OF APPLICATION

This operating instruction applies to all services managed within the General Clinical Laboratory.

3 REFERENCES

- PR-AQ-002 “Gestione delle non conformità”
- MD-AQ-012B “Registro raccolta Non Conformità Laboratorio”
- MD-LCG-016 “Campione inadeguato/non pervenuto”

4 DEFINITIONS / ABBREVIATIONS

Definitions:

Not applicable

Abbreviations:

GCL: General Clinical Laboratory

LIS: Laboratory Information System

NC: Non Conformity

5 ANNEXES

Nessuno

6 OPERATING PROCEDURES

Non-conformities identified in the General Clinical Laboratory are recorded by the staff on duty using the form MD-AQ-012B “Laboratory Non-Conformity Log”, classified by the relevant sector.

Corrective actions undertaken are documented in the log.

Each individual NC must be reported to the recipient using the form MD-LCG-016 “Inadequate/Not Received Sample.”

For patients attending the Phlebotomy Rooms of the various Group facilities, if the material received is deemed unsuitable and prevents the analysis from being performed, the Laboratory Secretariat will send an email to the Admissions Office reporting the relevant NC and attaching the duly completed MD-LCG-016 form.

In the case of samples or biological material considered unsuitable, the Admissions Office will be responsible for contacting the patient to inform them of the need to repeat the sampling or to provide new biological material. Upon the patient’s return, a new admission will be carried out free of charge.

The non-compliant admission will then be formally closed.

For hospitalized patients, the NC will be managed directly in the laboratory LIS.

Details concerning the management of non-conformities and the traceability of series found to be out of control are provided in procedure PR-AQ-002 “Management of Non-Conformities.”

LEGAL NOTICE

.