

Scope: Institution / Department (Name the department or unit issuing the SOP)

Standard Test Procedure (TP): EU-SOP-TP-001/Version 1.0

Title: SOP format to describe a test procedure

(e.g. ABO typing)

Valid from: Effective date.

Expiry date.

A document control procedure must be established to guarantee a regular review

of documents and to keep the history of documents (previous versions).

Replaces Version: Document-Code and Document-Version

Changes: - Please describe/list the relevant changes that have been made in

comparison to the previous version of the document

- Reasons for changes

Distributor: Original: Quality management office

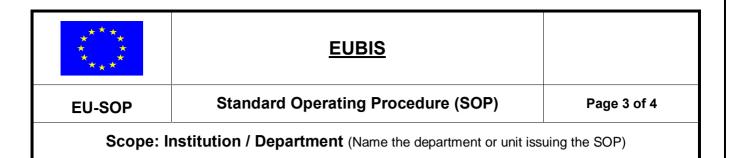
Copy-Identification Number (Example): 1, 2, 3 etc.

the use of electronic copies is optional

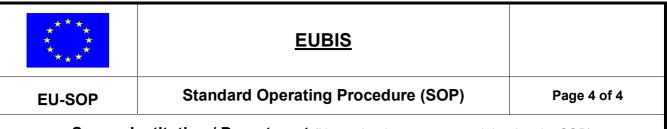
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EU-SOP	Standard Operating Procedure (SOP)	Page 2 of 4
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- 1. Objective
- 2. Area of application
- 3. Roles covered by the SOP (job description, personnel responsibilities)
- 4. Analyt
- 5. Abbreviation
- 6. Test Method
- 7. Test Principle
- 8. Reference Range
- 9. Measuring Range
- **10. Units**
- 11. Conversion Facor or Formula
- 12. Test Material
- 13. Minimum Sample Volume
- 14. Minimum Test Sample Volume



- 15. Pre-analytic Requirements
- 16. Calibration
- 17. Sample Storage before Analysis
- 18. Equipment (Test)
- 19. Reagenz (including Manufaturer/Ordering Number or Source)
- 20. Test Procedure (optional Tables/Figures and Flow Charts)
- 21. Sources of Variability
- 22. Suitability of Test (Indications)
- 23. Criteria for Technical Authorisation
- 24. Procedures for Non Conformance
- 25. Interpretation and Documentation
- 26. Sample storage after Analysis
- 27. Test Validation Records
- 28. Quality Control (Internal / External)



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29. References / Literature

30. Annex