



EUBIS

EU-SOP

Standard Operating Procedure (SOP)

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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
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the use of electronic copies is optional

Written by:	Reviewed and authorised by:		
Date:	Date:		
Name of person(s)	Name of person(s)		



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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 Factor or Formula

12. Test Material

13. Minimum Sample Volume

14. Minimum Test Sample Volume

File Name: EU-SOP-TP-001_V01-Test Procedure (TP)



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15. Pre-analytic Requirements

16. Calibration

17. Sample Storage before Analysis

18. Equipment (Test)

19. Reagenz (including Manufacturer/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