DEMO OF ISO 15189:2022 DOCUMENT KIT

Totally editable documentation package for quick process improvement to implement the system

Completely editable document toolkit

(Quality Manual, procedures, exhibits, standard operating procedure, blank forms, audit checklists, etc.)

Buy at: www.joinconsultant.com

Chapter-1.0 CONTENTS OF ISO 15189:2022 DOCUMENT KIT (More than 170 document files)

A. This editable documentation kit has 7 main directories in Word/Excel, as below:

ISO 15189:2022 Editable Document kit for Medical Laboratories

Sr. No.	List of Directory	Document of Details
1.	**Quality Manual**	**01 files in MS Word**
2.	**Procedures**	**31 Procedures in MS Word**
3.	**Standard operating procedure**	**40 Standard operating procedure in MS Word**
	Collection (CCC)	08 Standard operating procedure in MS Word
	Operation (OPN)	16 Standard operating procedure in MS Word
	Testing (EXM)	16 Standard operating procedure in MS Word
4.	**Exhibits**	**06 exhibits in MS Word**
5.	**Formats**	**94 formats in MS Word / Excel**
	Clinical Biochemistry (CBC)	20 formats in MS Word / Excel
	Collection (CCC)	07 formats in MS Word / Excel
	Customer service (CSD)	09 formats in MS Word
	Front Office & Patient Registration (FPR)	04 formats in MS Word
	HR and Training (TRG)	11 formats in MS Word
	Operation (OPN)	04 formats in MS Word
	Purchase (PUR)	09 formats in MS Word
	Quality control (QCD)	17 formats in MS Word / Excel
	System Formats (SYS)	11 formats in MS Word
	Stores(STR)	02 formats in MS Word
6.	**Audit checklist**	**More than 350 questions**
7.	**Sample Risk Template**	**01 File in MS Excel**

Total 170 files in editable form; Quick Download by e-delivery

B. Documentation:-

Our document kit is having sample documents required for ISO 15189:2022 certification as listed below. You need to study it do necessary changes as per your company need and within 4 days your entire editable documents with all necessary details are ready and many medical laboratories are accredited globally in 1st trial with the help of our documents from any kind of stringent accreditation assessment.

Under this directory further files are made in word Document as per the details listed below. All the documents are related to any kind of medical laboratories.

1. QualityManual:

It covers sample copy of quality manual for medical laboratory. It describes how all requirement of ISO 15189:2022. It covers list of procedures as well as overview of medical laboratories and covers tier1 of ISO 15189:2022 documents.

(A) Table of Contents

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2. Procedures (31 Procedures):

It covers sample copy of mandatory procedures covering all the details of ISO 15189:2022standard.

List of procedure

1. Procedure for Receipt, handling, storage and disposal of samples in line with the legal requirements
2. Procedure for Control of documents

3. Procedure for Establishment and review of agreements for providing medical laboratory services to its customers / patients
4. Procedure for Selecting and evaluating referral laboratories and consultants
5. Procedure for Purchasing
6. Procedure for Management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties
7. Procedure for Identification and control of non–conformities
8. Procedure for Corrective action
9. Procedure for Preventive action
10. Procedure for Control of records
11. Procedure for Internal audit
12. Procedure for Management review
13. Procedure for Personnel and training
14. Procedure for Facility maintenance and environment
15. Procedure for Selection, purchasing and management of equipment
16. Procedure for Safe handling, transport, storage and use of equipment to prevent its contamination or deterioration
17. Procedure for Calibration of equipment
18. Procedure for Reception, storage, acceptance testing and inventory management of reagents and consumables
19. Procedure for Pre–examination process
20. Procedure for Collection and handling of primary samples
21. Procedure for Transportations of samples
22. Procedure for Sample receipt
23. Procedure for Pre–examination handling, preparation and storage
24. Procedure for Validation of examination procedures
25. Procedure for Ensuring the quality of examination results
26. Procedure for Review of examination results
27. Procedure for Identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples
28. Procedure for reporting the results
29. Procedure for Release of examination results
30. Procedure for Confidentiality of patient's information
31. Procedure for Risk analysis

3. Standard operating procedure (40 SOPs):

It covers sample copy of standard operating procedures covering all the details of ISO 15189:2022 standard.

List of standard operating procedure (SOPs)

1. Collection & Transport of Specimens for Biochemistry Examinations
2. Patient Preparation Instructions
3. Needle Stick Injury – Care & Precaution
4. Specimen Acceptance & Rejection Criteria
5. Treatment and Disposal of Biomedical Waste
6. House Keeping Procedure
7. Personnel Safety Procedure
8. Sample Preparation and Storage
9. Sample collection
10. Sample rejection
11. General departmental procedure
12. Quality control procedure
13. Equipment maintenance & operating procedure
14. Measurement of Uncertainty
15. Monitoring Turn-Around-Time
16. Critical Alert Level Values / Panic Values
17. Repeat Test
18. Data backup plan
19. Generation of test results
20. Housekeeping
21. Personal protection and safety
22. Treatment and Disposal of Biomedical Waste
23. Data backup plan, Linearity and range of testing, Accuracy& Precision
24. Equipment calibration plan procedure
25. Test procedure – Serum – Alanine Amino TransferaseCobas c501
26. Test procedure – Serum – Albumin – Cobas c501
27. Test procedure – Serum – Bicarbonate – Cobas c311
28. Test procedure – Serum – Bilirubin Total – Cobas c501
29. Test procedure – Serum – Calcium – Cobas c501
30. Test procedure – Serum – Creatinine – Cobas c501
31. Test procedure – Serum – GGT – Cobas c501
32. Test procedure – Serum – Glucose – Cobas c501
33. Test procedure – Serum – HDL Cholesterol – Cobas c311
34. Test procedure – Serum – Phosphours – Cobas c501
35. Test procedure – Serum – Aspartate Amino Transferase – Cobas c501
36. Test procedure – Serum – TGL – Cobas c501
37. Test procedure – Serum – Total Cholesterol – Cobas c501
38. Test procedure – Serum – Total Protein – Cobas c501
39. Test procedure – Serum – Urea – Cobas c501
40. Test procedure – Serum – Uric Acid – Cobas c501

4. Exhibits (06 Exhibits):

It covers sample copy of exhibits covering all the details of ISO 15189:2022 standard.

List of Exhibits

1. Skill Requirements
2. Codification System
3. Calibration Periodicity
4. Secrecy Rules
5. Recommended conditions for sample collection, transport and storage for conventional cytogenetic analysis
6. Minimum retention period for identified records

5. Blank Formats (94 Formats):

It covers sample copy of blank forms required to maintain records as well as establish control and make system in the medical laboratories. The samples given are as a guide and not compulsory to follow and medical laboratories is free to change the same to suit own requirements.

List of Formats

1. Accident / Incident Record
2. Equipment Maintenance Breakdown Record
3. Calibration Register - Clinical Chemistry
4. PT / EQAS / ILC / corrective action report
5. Critical Alert Results Register
6. Equipment History Record
7. Equipment Maintenance Log
8. Housekeeping Record
9. Kit in Use Log Form
10. LJ chart Template for Lab Mean
11. LJ chart Template for Product Insert Mean
12. Non Conformance Register
13. Record Label
14. Repeat Test Result Register
15. Sample integrity register
16. Sample Rejection Register
17. Sample storage and discadal register
18. Monitoring STAT
19. Monitoring TAT
20. Temperature Log Form - Room
21. Bleeding Time & Clotting Time Register
22. Housekeeping Register
23. Non Conformance Register
24. Sample Collection Register
25. Sample rejection Register
26. Sample Rework Register
27. Temperature Log Form – Room
28. Request for examination – serum / fluoride plasma
29. Request for examination – urine
30. Request for examination – Serum
31. Request for examination – whole blood / serum
32. Request for examination – whole blood with EDTA
33. Customer feedback form
34. Complaint register
35. Complaint report
36. Inward register
37. Test Instruction Slips
38. Final Test Report
39. HIV Consent Form
40. Test Amendments Form
41. Training Calendar
42. Training Report

43. Induction training report
44. Job Description and Specification
45. Skill Matrix
46. Confidentiality Agreement
47. Appointment Letter
48. Employees Competence Report
49. ISO 15189 effectiveness check report
50. Employee history card
51. Immunization report
52. Equipment history card
53. Preventive maintenance schedule
54. Equipment wise preventive maintenance checkpoints
55. Disposal of non–conformities
56. Purchase order
57. Indent (purchase requisition)
58. Approved vendor list cum open purchase order
59. Supplier registration form
60. Open purchase order
61. Material specification sheet
62. Evaluation for Referral Lab
63. Stock register
64. Supplier evaluation form
65. Four Year Plan for Quality Control
66. Re–test plan / execution report
67. Z score report
68. Uncertainty of Measurement
69. Re - Test Analysis
70. Critical consumables
71. Environment condition monitoring report
72. pH Meter Calibration Report
73. Inspection report
74. Normality record sheet
75. Intermediate check report – weighing balance
76. Intermediate check report – oven
77. Housekeeping checklist
78. Checklist for Medical Laboratory Collection Centre / Facility
79. Quality control plan method
80. Design / Planning of the method validation
81. Validation report
82. Master List Cum Distribution List of Documents
83. Change Note
84. Corrective action report
85. Master List of Records
86. Quality objectives (key performance indicator)
87. Audit Plan / Schedule
88. Internal audit non–conformity report
89. Clause wise document wise audit review report
90. Preventive Action Report
91. Calibration status of equipment
92. Audit Observation Report
93. Goods inward register
94. Stock register

6. Audit checklist (more than 350 questions)

It covers sample audit questions based on all the ISO 15189 requirements. It helps the auditor to make own audit checklist for quick and perfect auditing to ensure all the ISO 15189 requirements are fulfilled by the medical laboratories.

7. Sample risk template

The ready to use risk template in editable form is given to prepare the risk document for the organization. It is given in excel and can be use as ready to use template.

Chapter-2.0 ABOUT COMPANY

Joinconsultant is a progressive company promoted by a group of qualified engineers and management graduates having rich experience of over 25 years in ISO consultancy and management areas. The company serves the global customers through on-site and off-site modes of service delivery systems. We offer a full range of consulting services geared towards helping all types of organizations to achieve competitiveness, certification and compliance to international standards and regulations. So far, we have **more than 2700 clients in more than 36 countries**. **Our readymade training kit and editable documentation kit help the clients in making their documents with ease and complying with the related ISO standard faster.**

1. Our promoters and engineers have rich experience of providing management training and ISO series consultancy for **more than 2700 companies** globally. We have clients **in more than 36 countries.**
2. We are a highly qualified team of 80 members (M.B.A., Degree Engineers). Our Director has rich professional experience in this field (since 1991).
3. We have 100% success rate in ISO series certification for our clients from reputed certifying bodies. We possess a branded image and are a leading name in the global market.
4. We suggest continual improvement and cost reduction measures as well as provide highly informative training presentations and other products that give you payback within 2 months against our cost.
5. So far, we have trained more than 50000 employees in ISO series certification.
6. We have spent more than 60000 man-days (170 man-years) in the preparation of ISO documents and training slides.

Joinconsultant is committed for:

1. Personal involvement and commitment from the day one
2. Optimum charges
3. Professional approach and globally helped many companies for this standard.
4. Hard work and updating the knowledge of team members
5. Strengthening clients by system establishment and providing best training materials in any areas of management to make their house in proper manner
6. Establishing strong internal control with the help of system and use of the latest management techniques.

Chapter-3.0 USER FUNCTION

3.1 Hardware and Software Requirements

A. Hardware

- Our documentation kit can better perform with P4 and higher computers with a minimum of 10 GB hard disk space.
- For better visual impact, you may keep the setting at high color.

B. Software

- Documents are written in MS-Office 2007 and Windows XP programs. You are, therefore, required to have MS-Office 2007 or higher versions with Windows XP.

3.2 Features of Documentation kit

- The kit contains all necessary documents as listed, and complies with the requirements of system standards.
- The documents are written in easy to understand English language.
- This kit will save much time in typing and preparing your documents at your own.
- The kit is user-friendly to adopt and easy to learn.
- The contents of this kit are developed under the guidance of experienced experts.
- The kit provides a model of the management system that is simple and free from excessive paperwork.

Chapter-4.0 BENEFITS OF USING OUR DOCUMENT KIT

1. By using these documents, you can save a lot of your precious time while preparing the ISO 15189 documents.
2. The kit takes care of all the sections and sub-sections of ISO 15189 standards and helps you to establish better system.
3. This document kit enables you to change the contents and print as many copies as you need. The users can modify the documents as per their industry requirements and create their own ISO 15189 documents for their organization.
4. It will save much cost in document preparation.
5. You will get a better control in your system due to our proven formats.
6. You will also get a better control in your system as our proven documents and templates are developed under the guidance of experts and globally proven consultants. The team has a rich experience of more than 25 years in the ISO consultancy.
7. Our products are highly sold across the globe and are used by many multinational companies. They have got total satisfaction as well as experienced value for money.
8. In the preparation of documentation kit, our team has verified and evaluated the entire content at various levels. More than 1000 hours have been spent in the preparation of this documentation kit.
9. The entire kit is prepared by a globally proven team of leading ISO consultants.

Chapter-5.0 METHOD OF ONLINE DELIVERY

On completion of the secured purchase, we provide a username and password to download the product from our FTP server. We provide instant online delivery of the kit to the users by sending an e-mail of username and password.

For purchase,

Visit our website for more details on the documentation kit:

https://www.joinconsultant.com