BIOGENIX

POLICY AND PROCEDURE FOR CONTROL OF RECORDS

	NAME	DESIGNATION	SIGNATURE	DATE
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1. TABLE OF CONTENT

1 REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

2 REVIEW HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3 POLICY STATEMENT

Control of records is done following this procedure.

4 PURPOSE

The purpose of this Policy Procedure is to ensure that necessary records and documents of Laboratory are adequately protected and maintained and to ensure that records that are no longer needed by BIOGENIX Laboratory or are of no value are archived and discarded at the proper time. This Policy and procedure is also for the purpose of aiding employees of BIOGENIX Lab in understanding their obligations in retaining electronic documents - including e-mail, Web files, text files, sound and movie files, PDF documents, and all Microsoft Office or other formatted files. The management and staff of BIOGENIX laboratory are aware of **ISO 15189:2012** Medical Lab- Requirements for quality and competence, Clause **4.13**. All the requirements are based on 4.13 which states documents and records are managed from creation, archive, retention, storage and permanent destruction according to established processes that reflect the organization's commitment to quality as well as meeting accreditation and legal requirements. The laboratory management provides orientation and training to all the staff on the control of documents and records.

5 SCOPE

5.1. Scope: This Policy applies to all physical records generated in the course of BIOGENIX laboratory operation, including both original documents and reproductions. It also applies to the electronic documents described above.

5.2. Target Audience: BIOGENIX Laboratory staff

6 DEFINITIONS

6.1. Document: a paper or set of papers with written or printed information;

6.2. Archive: documents that are no longer need to use regularly;

6.3. Retention: continued use, existence, or possession of something.

7 ACRONYMS

7.1. DOH: Department of Health AbuDhabi

8 RESPONSIBILITIES

The responsibilities are shared at all level as mentioned below, management and director responsibility, quality manager responsibility and staff responsibility to control of document and records.

8.1. Laboratory director and Laboratory Management:

8.1.1. The Lab. director and Management is responsible for the approval of documents, record and forms;

8.1.2. Overseeing the accurate and complete creation of records;

8.1.3. Lab director and management is responsible to inform the staff in timely manner about any new or changed documents happened at DOH or any external service agreement and supplier or referral or referring lab.;

8.1.4. Ensuring that staff members has immediate access to current copies of the documents required to perform their duties;

8.1.5. Make sure hard copies are up to date with Quality manual, Procedures and master Index.

8.1.6. Responsible for storing the documents.

8.2. Quality manager responsibilities are:

8.2.1. Numbering new procedures and records;

8.2.2. Uploading, publishing and auditing document control system for recent activity as it pertains to the laboratory's electronic documents;

8.2.3. Archiving and retiring old procedures;

8.2.4. Ensuring the destruction of documents when appropriate and reporting to the lab director;

8.2.5. Storage and ability to retrieve of all required documents and records**;**

8.2.6. To maintain the master list of documents and distribution control list that indicates the status and distribution of all documents under the document control system. Prompt removal of obsolete documents from the workplace;

8.3. BIOGENIX laboratory Staff responsibilities:

8.3.1. The staffs are responsible for security of the documents related to their sections.

8.3.2. Reading and understanding all documents pertaining to their jobs;

8.3.3. Upon receiving any new documents, staff reads and put their signature with date and returns back to quality manager to keep a record.

9 PROCEDURE

9.1. Establishing Record

9.1.1. Records maintained by each Department in Biogenix laboratory are identified. The identification Convention being Organization /RECI/Department/Record Number For Example: **Record: BG/REC/GEN/000**

9.1.2. Clinical and diagnostic records and reports

9.1.2.1. These are hard copy reports or electronic records archived through the G42 Lab central server of the results of pathological investigation(s) sent or made available to the requesting clinicians, with the expectation that they will be stored within the patient's individual clinical record. With respect to computer-generated records, the same criteria that cover conventional records apply, unless they have been converted to hard copy records and preserved as such. Extra care is needed to prevent corruption, loss or deterioration of data stored in the hospital server.

9.1.3. Laboratory records: reports, documentation:

9.1.3.1. These include request forms; protocols of procedures; day books; worksheets; batch records; graphic output from instruments; bound copies of reports/records; near-patient test data; correspondence; records of telephoned reports; equipment maintenance logs; quality control and quality assurance records; standard operating procedures; accreditation documents and records of inspections.

9.1.3.2. Where these items are held in electronic form, usually as digital images, the same criteria that cover conventional records apply. However, extra care is needed to prevent corruption or deterioration of data. Suitably secure backup systems should be employed. Machine data are backed up daily in an external memory drive.

9.2.Identification

9.2.1. Records are identified by its name and reference number.

9.2.2. Naming convention of the record is reviewed by the authorized person when there is a need arising.

9.3.Indexing

9.3.1. All records are indexed to facilitate identification.

9.3.2. Storage of data on electronic media is done with an index maintained by the Quality Manager.

9.4.Maintenance

9.4.1. The user maintains the established records regularly which provide the necessary information required for that activity, the list of records, the form used, the retention period.

9.4.2. Electronic records are protected by using

i. access control

ii. Backup-responsibility

9.4.3. Information in damaged records is transferred to new records or suitable repair is carried out.

9.5.Review

9.5.1. All quality records are reviewed once in a year for completeness by the Quality Manager.

9.6. Storage

9.6.1. All records are stored in secured pre-determined locations in cabinets or cupboards.

9.6.2. All records are stored for a predetermined period as per individual record requirements documented in Procedure for Document Control

9.6.3. All the details of records or original observations, derived data, graphs in various departments are in the form of work sheets, machine print outs. They are stored as up to the predetermined retention period to establish sufficient information for proof.

9.6.4. Storage of records is done in a manner to prevent loss, damage or deterioration of any kind and also for easy retrieval.

9.6.5. Regular backups of relevant technical data related to test results, where manual records are not available, are taken every day by the IT Personnel.

9.7. Access

9.7.1. Access to records is given only after the approval of the Lab. Director /Quality Manager.

9.7.2. Access to records is allowed to third parties / customers / doctors, if specified in the contract or after Lab. Director approval.

9.7.3. Copies of records are made only with the approval of the Lab. Director /Quality Manager.

9.7.4. All personnel in the department concerned have access to all records in their department.

9.7.5. The amendments to electronically stored technical records are done with the approval of the lab. Director.

9.8. Retention

9.8.1. All records and work sheets are retained in their respective departments till the end of retention period specified in Procedure for Document Control (LMC/L II/05).

9.8.2. The laboratory maintains a record system to suit its particular circumstances and comply with any existing regulations. All original observations, calculations and derived data, analyte calibration records and test report data are retained for a minimum retention period

9.9. Disposal of Records

9.9.1. All records stored manually and electronically are disposed off after the specified retention time.

9.9.2. Biogenix Laboratory Director is responsible for the ongoing process of identifying records that have met the required retention period and their destruction. Destruction of hard copy and electronic records will be accomplished by shredding and permanent electronic deletion

9.10. Suspension of Record Disposal In Event Of Litigation Or Claims. In the event Biogenix Lab is served with any subpoena or request for documents or any employee becomes aware of a governmental investigation or audit concerning Biogenix Lab or the commencement of any litigation against or concerning Biogenix Lab; such employee shall inform the Laboratory Director and any

further disposal of documents shall be suspended until shall time as the Director, with the advice of counsel, determines otherwise. The Director shall take such steps as is necessary to promptly inform all staff of any suspension in the further disposal of documents.

10 CROSS REFERENCE

10.1. HAAD standards for retention of medical records

10.2. **HAAD Standard for Medical Laboratories**

10.3. ISO 15189:2012 MEDICAL LABORATORY Requirement for Quality and Competence

10.4. CLSI Guidelines for Development of Lab Documents and records

10.5. The Royal College of Pathologists - The Retention and Storage of Pathological Records and Archives. 3rd Edition.

10.6. THE MANAGEMENT, RETENTION AND DISPOSAL OF PERSONAL HEALTH RECORDS – NHS code of practise ,2001 July, version

10.7. College of American Pathologists guidelines for retention of laboratory records and materials, Revised March 2010, Reaffirmed June 2013. http://www.cap.org/apps/cap.portaL?_nfpb=true&cntvwrPtlt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtlt&cntvwrPtlt%7BactionForm.contentReference%7D=policies%2Fpolicy_appPP.html&_state=maximized&_pageLabel=cntvwr

10.8. Retention of Laboratory records and diagnostic material, National Pathology Accreditation Advisory Council, Australia, Third Edition, 2002. http://www.health.gov.au/internet/main/publishing.nsf/Content/3FF0E46266C263FACA256F18004699EA/$File/retentionlab.pdf

11 RELEVANT DOCUMENTS & RECORDS

11.1. BG/REC/GEN/036 Document Control List

11.2. BG/REC/GEN/038 Distribution list

11.3. BG/REC/GEN/037 Document change form