



BIOGENIX

# POLICY PROCEDURE TO ABIDE BY U.A.E GOVERNMENT & DOH REGULATION

NAME		DESIGNATION	SIGNATURE	DATE
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# POLICY PROCEDURE TO ABIDE BY U.A.E. GOVERNMENT AND DOH REGULATIONS

CODE: BG/PP/GEN/038

## BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 01/07/2020

PAGE: 2 of 7

NEW REVIEW DATE: 30/06/2022

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## 2. REVISION HISTORY

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





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## 4. POLICY STATEMENT

It is mandatory for every employee of BIOGENIX laboratory to know the UAE government and HAAD regulations and follow them without any violations. BIOGENIX laboratory should conduct its activities in a manner consistent with relevant federal and state laws and regulations governing the operation of clinical laboratories.

## 5. PURPOSE

This policy is to ensure all the employees abide by the UAE government DOH regulations in the BIOGENIX Laboratory.

## 6. SCOPE

- 6.1 The scope of this policy and procedure extends to all the UAE government/DOH regulations pertaining to laboratory function in the BIOGENIX Laboratory.
- 6.2 Target Audience: All BIOGENIX Laboratory staff

## 7. DEFINITIONS

- 7.1 N.A.

## 8. ACRONYMS

- 8.1. **DOH** – Department of Health Abu Dhabi
- 8.2. **UAE** - United Arab Emirates

## 9. RESPONSIBILITIES

- 9.1 It is the responsibility of the Laboratory Director to make sure that all laboratory employees are aware of all the government regulations and implement them.
- 9.2 All BIOGENIX Laboratory staffs should make sure that they abide by the regulations.

## 10. PROCEDURE

- 10.1. **Regulatory Compliance**





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- 10.1.1. BIOGENIX Laboratory develops, implements, and maintains policies, processes, and procedures throughout the organization that are designed to meet relevant requirements.
- 10.1.2. Our laboratory provide services only according to appropriate local laws and DOH regulations. Such laws and regulations may include subjects such as certificates of need, licenses, permits, accreditation, record-keeping, confidentiality, patient's rights and medical staff clinical privileges. The organization is subject to numerous other laws in addition to these healthcare regulations.
- 10.1.3. We comply with all applicable laws and regulations. All laboratory employees, medical staff members and contract service providers must be knowledgeable about and ensure compliance with all laws and regulations; and should immediately report violations or suspected violations to the Laboratory Director or member of management.
- 10.1.4. Requests for information is answered with complete, factual, and accurate information. We cooperate with and be courteous to all government inspectors and provide them with the information to which they are entitled during an inspection.
- 10.1.5. During a government inspection, we never conceal, destroy, or alter any documents, lie, or make misleading statements to the government representative. We don't attempt to cause another colleague to fail to provide accurate information or obstruct, mislead, or delay the communication of information or records relating to a possible violation of law.
- 10.1.6. In order to ensure that we fully meet all regulatory obligations, Employees must be informed about stated areas of potential compliance concern. DOH routinely notifies laboratory services of areas in which insufficient attention is being accorded to comply with government regulations. We should be diligent in the face of such guidance about reviewing these elements of our system to ensure their correctness.
- 10.1.7. We provide employees with the information and education they need to fully comply with all applicable laws and regulations.

## 11. CROSS REFERENCE

- 11.1. HAAD clinical laboratory standards, Version 1.0, Health policy and regulation, Health Authority of Abu Dhabi.
- 11.2. ISO15189Accreditation Medical laboratories Requirements for quality and competence of medical laboratories:2012





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## 12. RELEVANT DOCUMENTS & RECORDS

12.1 N/A

