	QUALITY POLICY	UDX-PO-00001-EN	
	Política de Calidad	Rev: 002	1 / 2

# Quality Policy


(Política de Calidad)

Doc Name: **Quality Policy**  
 Doc No: **UDX-PO-00001-EN**  
 Rev: **002**  
 Language: **English**  
 Doc Type: **Policy (PO)**  
 Doc Date: **04/05/2018**  
 Release Date: **04/05/2018**  
 Manager: **Christian Hense**

<b>Author:</b>	<b>Reviewer:</b>	<b>Approver:</b>
Alejandro Martín Macías	Paola Hurtado Castillo	Christian Hense

## Change History

Revision	Date	Approval	Changes
001	02/11/2016	ALG, CHE	New document
002	04/05/2018	CHE	Added Multi-“omics” techniques

	QUALITY POLICY	UDX-PR-00001-EN	
	Política de Calidad	Rev: 002	2 / 2

Universal Diagnostics S.L. (UDX) is an innovative biomedical start-up specialized in the development of diagnostic tests for the early detection of cancer and precancerous states using multi-“omics” techniques.

Top Management is convinced that the main strategy to win the battle against cancer is its early detection. Therefore, they consider it a priority to ensure that research, development, manufacturing and marketing of IVD medical devices for the performance of the diagnostic test in the clinical laboratory are developed with the greatest efficiency and effectiveness, striving for excellence. Hence, Top Management commits to fulfil the following purposes of quality policy:

- Achieve customers and stakeholders’ (patients, employees, physicians, investors and collaborators) satisfaction, know and meet their expectations as well as respond to their needs.
- Establish a high level of collaboration with suppliers, customers and stakeholders such as investors, collaborators and physicians.
- Increase personal and professional satisfaction, promote teamwork in a suitable environment and enhance training, raising awareness and involving all UDX’s personnel on the continuous improvement of processes and the achievement of objectives.
- Eliminate or minimize the risks associated with the products / services to provide customers and end users with the maximum level of safety.
- Establish a vigilance system for their own products to detect, classify, record, assess, manage and solve any incident affecting the product on the market.
- Ensure compliance with legal and regulatory requirements applicable to the company, its products and services and compliance with ISO 9001 and ISO 13485 standards.
- Ensure continuous improvement of the Quality Management System (QMS) through the periodic review and adaptation of the objectives, indicators and quality policy to maintain the effectiveness of the QMS and provide the safety and effectiveness of their products.
- Ensure compliance with good professional practice, the performance of appropriate analyses according to their intended use and the continuous improvement of the quality of laboratory services.