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NGS Dx & EU Regulation

Thermo Fisher Scientific

NGS Dx: Intended Use

The Oncomine Dx Target Test is a qualitative *in vitro* diagnostic test that uses high throughput parallel sequencing technology intended to detect sequence variations using the Ion PGM Dx instrument system. The Oncomine Dx Target Test is indicated as an aid in characterizing sequencing variations in 46 genes on DNA and RNA isolated from FFPE specimens. Furthermore, the device is indicated as a companion diagnostic to identify four gene markers. The Oncomine™ Dx Target Test has been validated using the Ion PGM™ Dx Instrument System and is intended for *in vitro* diagnostic use by trained personnel in a professional laboratory environment.

The Oncomine Dx Target Test is approved by US FDA (PMA) and a self-declared CE IVD in the EU.

NGS Dx: Classification in the EU

IVDR Article 47 Devices are divided into class A, B, C and D, taking into account the intended purpose of the devices and their inherent risks. Classification is carried out in accordance with Annex VIII.

IVDR Annex VIII

Rule 3 (i) Devices are classified as class C if they are intended for human genetic testing

Rule 5 (b) Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures are Class A

EU IVDD: Self-Regulated for Instrument and Assay

EU IVDR: Class A for Instrument (to be confirmed); Class C for Assay

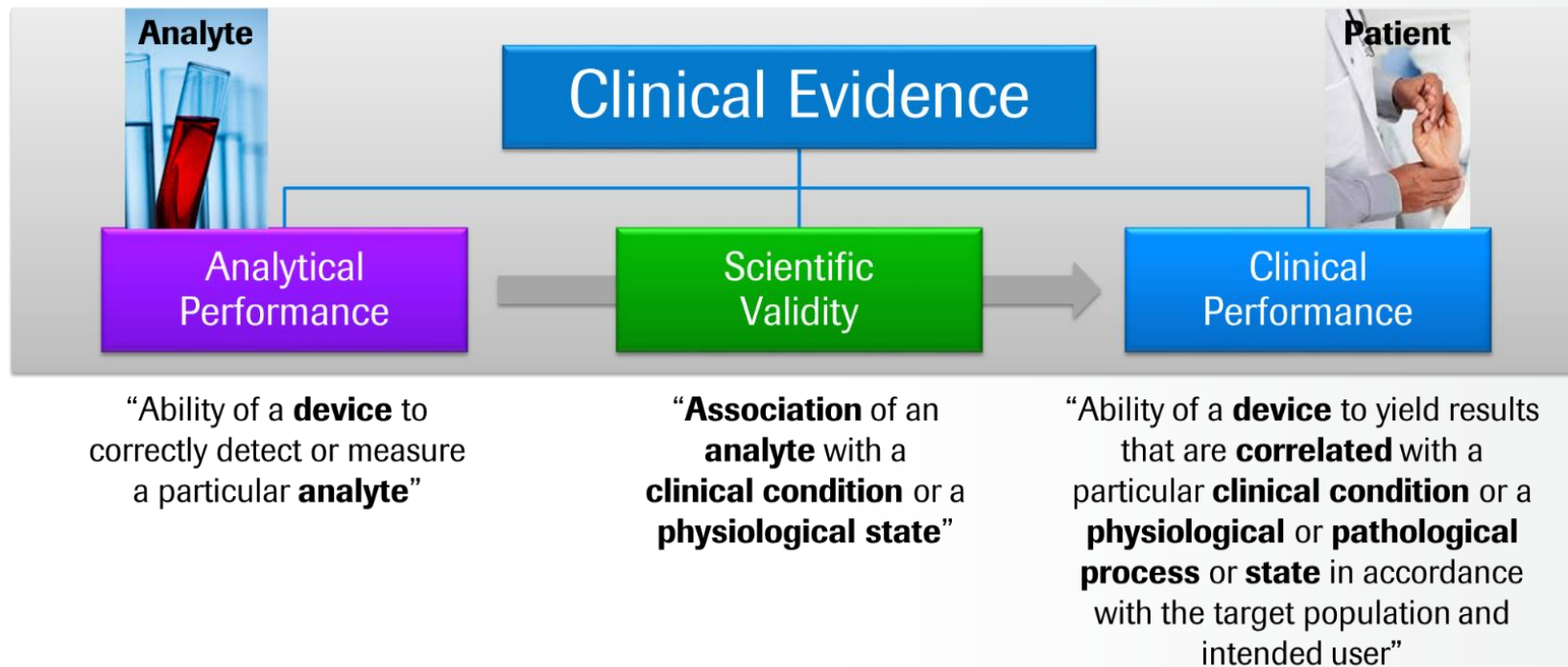
NGS Dx: EU Technical Documentation

- Previously referred to as a product's Technical File in IVDD
- Follow IVDR Annex II as a checklist for the Technical Documentation
 - Device Description/Specification, including variants and accessories
 - Information to be supplied by the manufacturer
 - Design and Manufacturing Information
 - General Safety and Performance Requirements
 - Benefit Risk Analysis and Risk Management
 - **Performance Evaluation (Product Verification and Validation)**

NGS Dx: Performance Evaluation

Performance Evaluation is a continuous process by which data are assessed and analyzed to demonstrate the scientific validity, analytical performance, and clinical performance of the device for its intended purpose

Performance Evaluation



NGS Dx - Regulatory Prospective

- During the CE Marking process and market authorizations in various countries for NGS Dx system, it's seen various regulatory requirements in terms of classification, performance and clinical data in different jurisdictions. In some countries /regions, there is no specific NGS standard or guidance.
- Due to the complexity and novelty of NGS technology, a harmonized NGS guideline will help regulator and industry to determine the requirements for device characteristics and to justify sufficient analytical and performance/clinical data to demonstrate conformity with the relevant general safety and performance requirements.

