

Overview of IVD Regulations in Korea

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**IVD Hot Topics*



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Definition of IVD & Classification of IVD



IVD Definition & Classification in Korea

What is IVD in Korea?

- A device, whether used alone or in combination, intended by the manufacturer for the in-vitro test of specimens derived from the human body or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrator, control, etc.

How is IVD classified in Korea?

- IVD is classified with 4 classes based on potential risk of test result effecting individual and public health.
- Harmonized with GHTF/IMDRF rules



Classification of IVD in S.Korea

Enforcement Decree of MDA

High Risk in
both
Indiv. & public
health

High Risk Indiv.
& Moderate
Risk Pub.

Moderate Risk
in both Indiv. &
Pub.

Low Risk in both
Indiv. & public
health

Class 4

HIV, HBV, HCV, HTLV, ABC
Rh(D) test for Blood
Screening

Class 3

High risk infection
agent(SDT, Influe, Malaria,
etc), Cancer marker, Heart
disease marker, etc

Low risk infection
agent(helico bactor, c.
difficile, etc), GOT, GPT, g-
protein, creatinine,
pregnancy test, etc,
H&E, Media, etc.

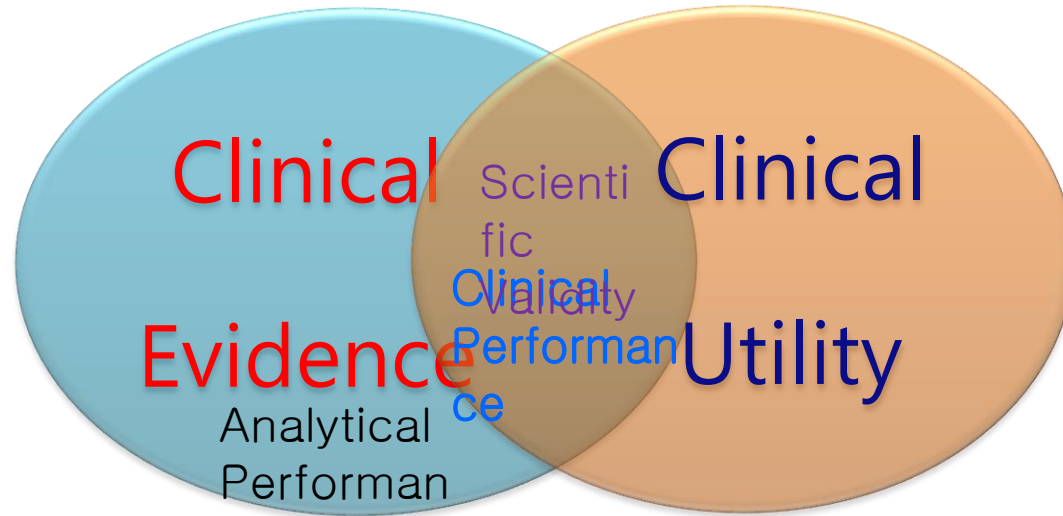


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The Requirements of IVD Approval



IVD should be approved with Clinical Evidence

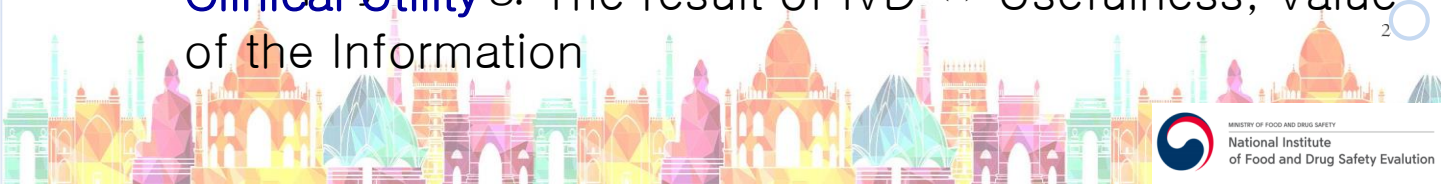


Scientific Validity : An analyte ↔ a clinical condition/physiological state

Analytical Performance : The result of IVD ↔ detection or measurement of analyte

Clinical Performance : The result of IVD ↔ a clinical condition/physiological state

Clinical Utility : The result of IVD ↔ Usefulness, Value of the Information



General Review of Technical File

Technical Document ?

Documents related to quality of medical devices, such as, functions, safety. etc.

- Including information on raw materials, structure, intended use, instruction for use, principles of functions, precautions for use, test standards, etc.**



Data on raw materials, Characteristics, Intended use, Operation method, mechanism, precautions, test specification, etc.



Technical Documents supporting Clinical Evidence

Clinical Evidence for IVD Approval should be supported by 7 Technical Documents

● Development Process, Detection Principle & Method, Usage Status

● Materials & Manufacturing method

● Intended Use

● Storage Method & Stability

● Performance Test data

- **Analytical** : Sensitivity(cut-off, LOD, etc.), Specificity(interference, cross-reactivity), Accuracy, Precision(repeatability),

etc.

- **Clinical** : Sensitivity, Specificity

- **QC** : final QC SOP, Test result, The information of Standard material

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IVD Industry in S.Korea



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Expansion of IVD Industry in Korea

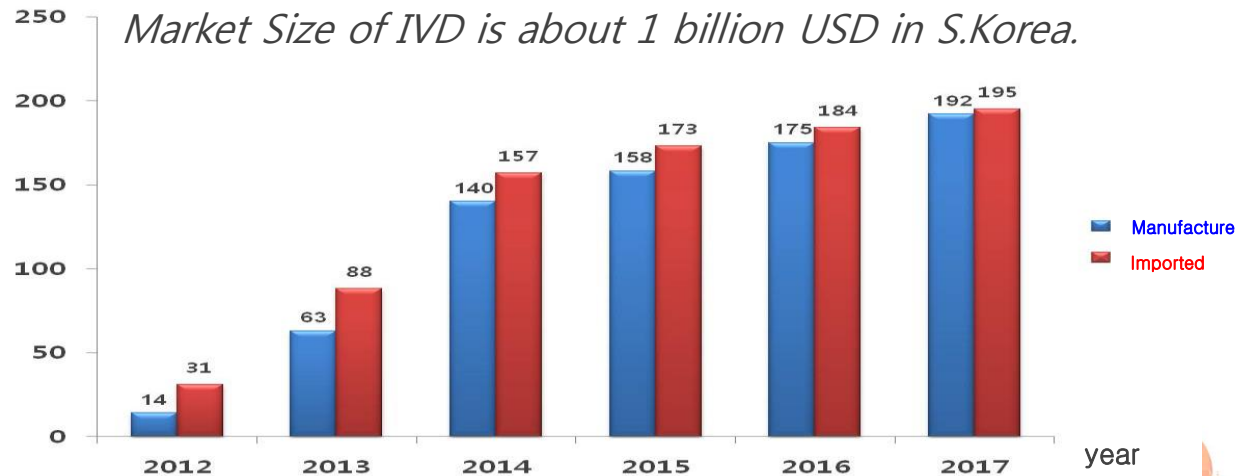
- The Number of IVD companies

('17.10.31.)

Total	Manufactured	Imported
387	192	195

- The number of IVD companies has been increasing

Market Size of IVD is about 1 billion USD in S.Korea.



Total Number of IVD's approved in S.Korea

- Approved IVD in S.Korea

('17.10.31.)

	Total	Class 1	Class 2	Class 3	Class 4
Manufactured	4,112	911	1,280	1,530	457
Imported	9,527	2,465	5,200	1,677	185
Total	13,539	3,380 (25.0%)	6,580 (48.6%)	3,237 (23.9%)	342 (2.5%)



※ HOT Topics of IVD in Korea

● IVD Devices Act ('18)

- Plan to Establish New LAW for IVD Devices

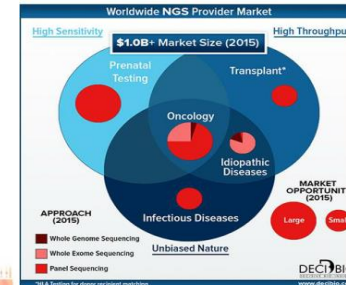
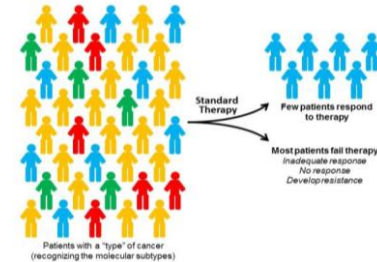
● For the Era of Precision Medicine

- Personalized Medicine

ex) IVD-CDx, IVD-MIA & Algorithm

● Lab. Developed Test(LDT) related

Next Generation Sequencing(NGS)



Thank you



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