

# SHIELD<sub>x</sub> - Harmonizing Standards Application to Accelerate Innovation

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*SHIELD<sub>x</sub> Team Lead/OIR RWE Representative*

*OHT 7: Office of In Vitro Diagnostics and Radiological Health (OIR)  
Center for Devices and Radiologic Health (CDRH)  
Food and Drug Administration (FDA)*

# Goal



Describe the same test  
data the same way.



*Systemic Harmonization and Interoperability Enhancement for Lab Data*



SHIELD<sub>x</sub> is a public-private partnership focused on the **adoption/development, harmonized application and implementation** of diagnostic data standards to advance innovation.

**SHIELD Stakeholders (>70 institutions engaged):**

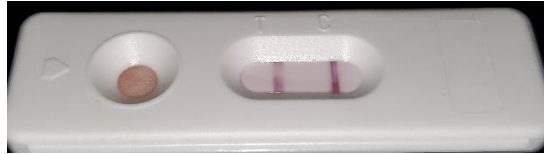
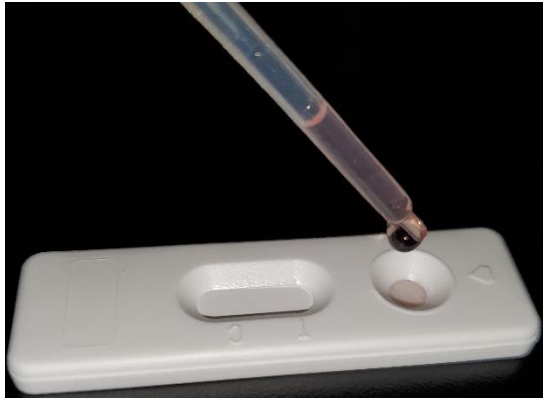
FDA (CDRH, CDER, CBER), CDC, NIH, ONC, CMS, VA, CAP, IVD Manufacturers, EHR Vendors, Laboratories, Standards Developers, PEW Charitable Trusts, NEST/MDIC, Academia

## **in vitro diagnostics (IVDs) utility:**

- 1<sup>o</sup> *in vitro* diagnostics (IVDs) products are... intended for use in diagnosis of disease or other conditions... [21 CFR 809.3](#)
  
- 2<sup>o</sup> generate data used to drive:
  - Epidemiology/outbreak monitoring
  - Healthcare research and innovation
  - Regulatory decisions
  - Clinical Decision Support (CDS)
  - Artificial Intelligence (AI)
  - Public health reporting
  - Signal detection
  - more

# What IVDs Do?

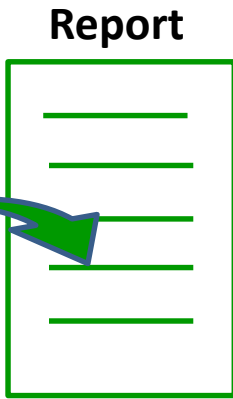
**Each IVD asks a 'question' of a specimen to get an 'answer'.**



1) **Collect and process** specimen (e.g., blood specimen collection).

2) **Ask Question:**  
Does the venous blood specimen have:

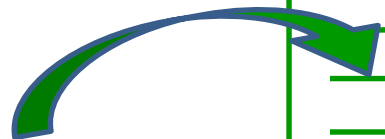
3) **Provide Answer:**



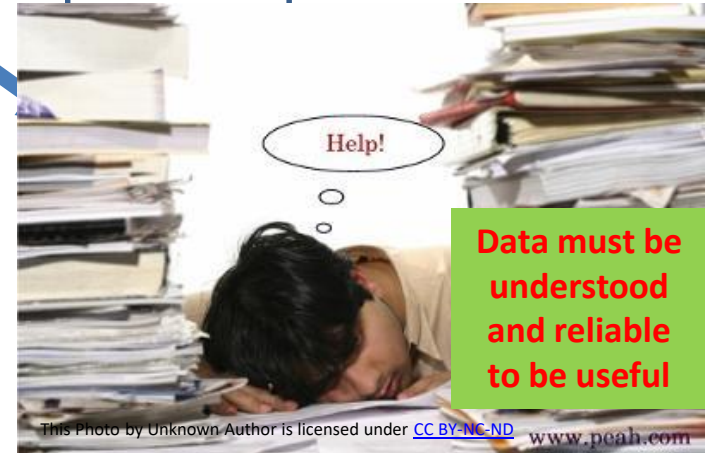
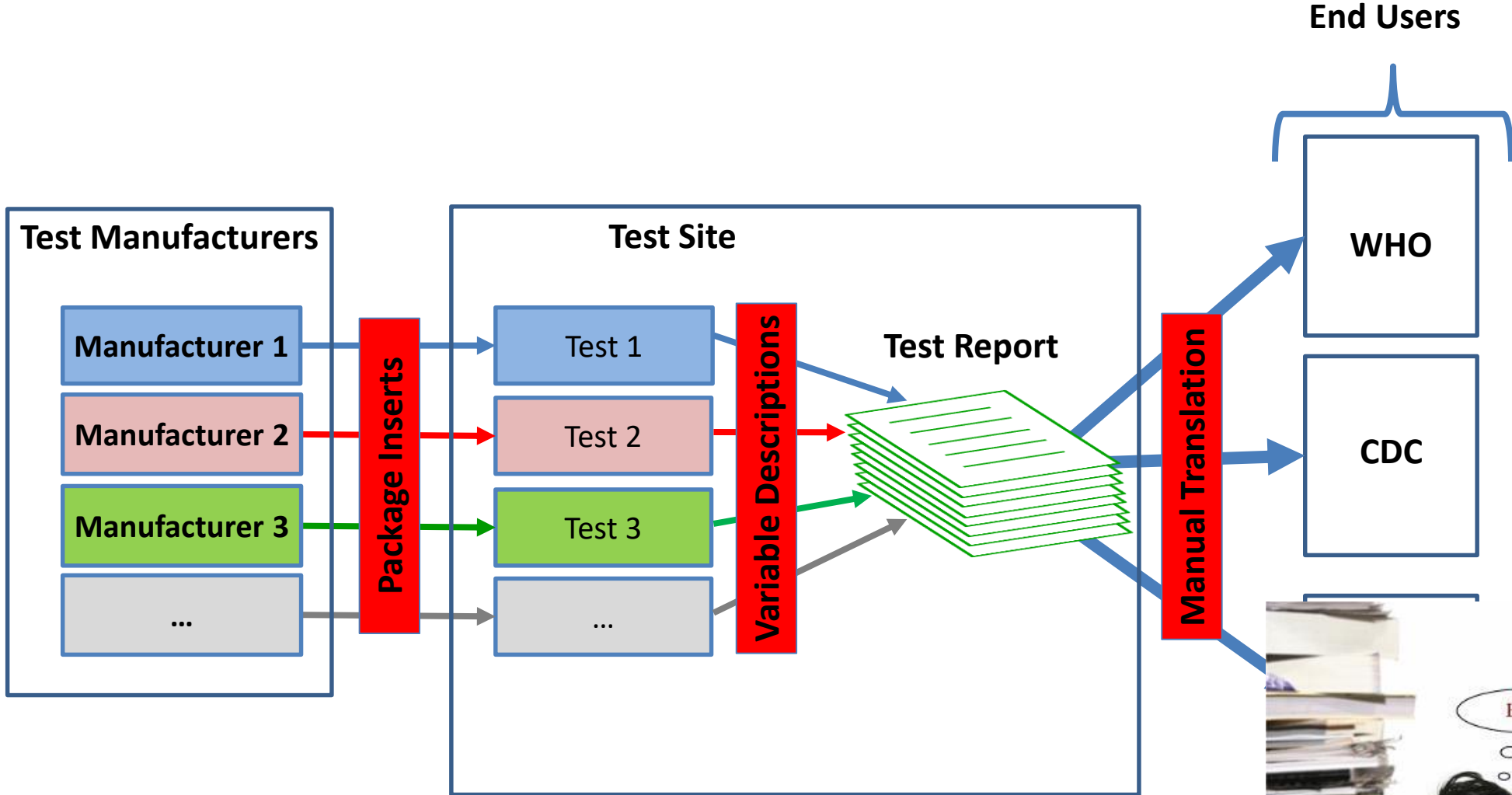
Ebola Virus Antigens (by immunoassay)?



Ebola Virus Antigens Detected



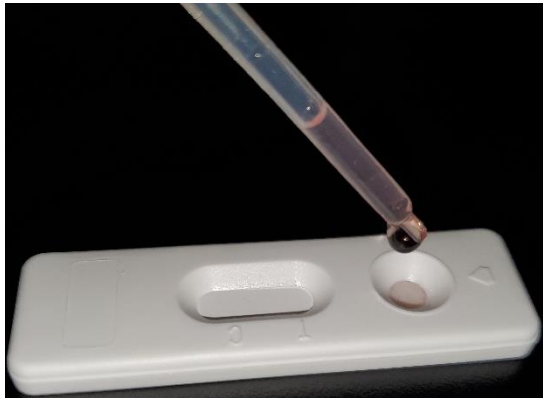
# Currently: Same Test Represented Different Ways



**Data must be understood and reliable to be useful**

# Describing the Same Test the Same Way

**Each IVD asks a 'question' of a specimen to get an 'answer'.**

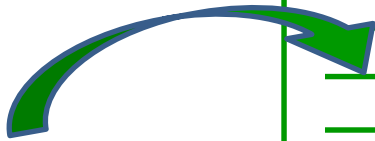
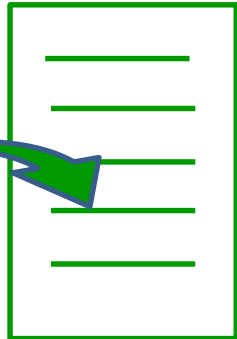


1) **Collect and process** specimen  
(e.g., blood specimen collection).

2) **Ask Question:**  
Does the venous blood specimen have:

3) **Provide Answer:**

Report



IVD Test



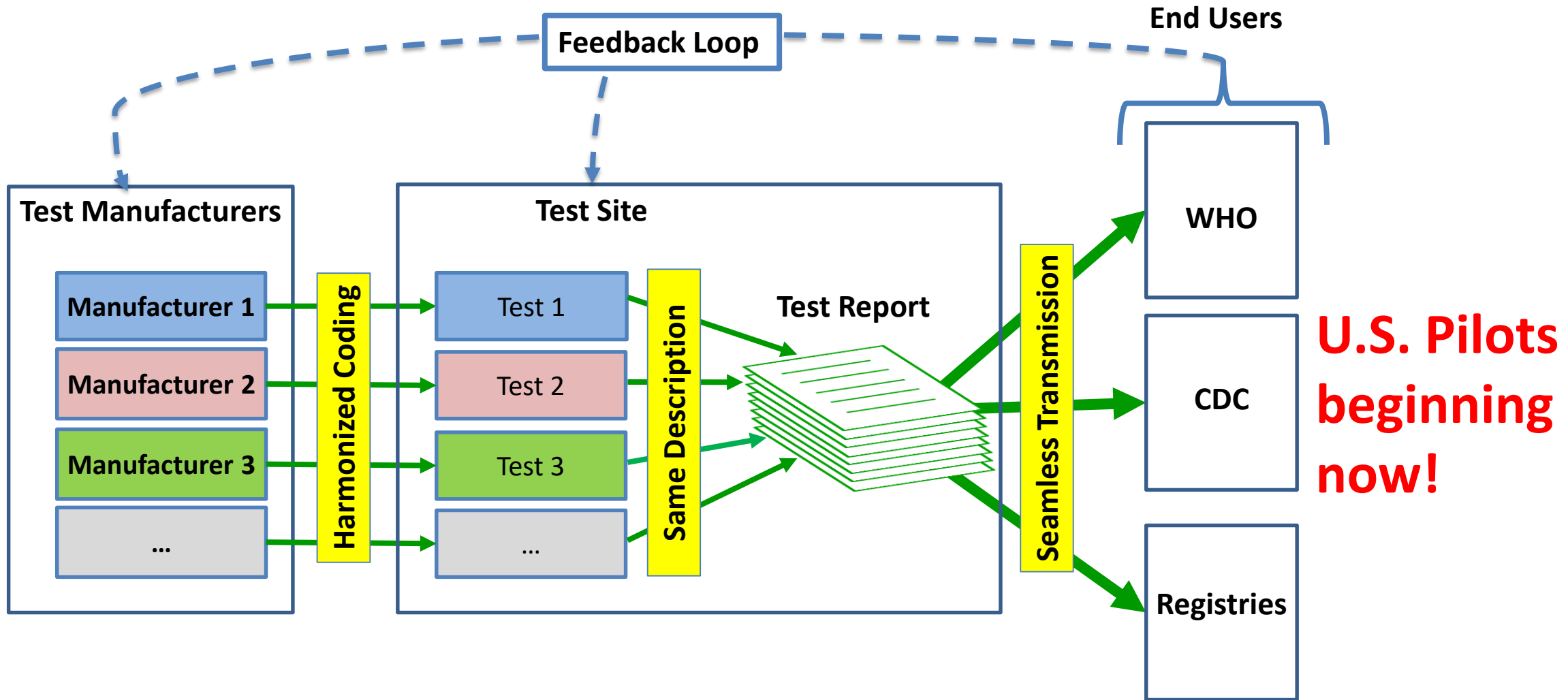
Ebola Virus Antigens  
(by immunoassay)?



Ebola Virus Antigens  
Detected

# Goals: Semantic Interoperability

(Describing the same test the same way)



## Plan:

Ecosystem supports manufacturers/industry to provide vetted and harmonized descriptive IVD codes (*vetted through a sole authoritative source*) to labs to improve utility for consumers.



# Goals: Semantic Interoperability

FDA

(De

Logical Observation Identifiers Names  
and Codes for *In Vitro*  
Diagnostic Tests

Guidance for Industry and  
Food and Drug Administration Staff

Document issued

For questions about this document,  
contact the Director at (301) 796-3345.



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research

<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM610636.pdf>

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From Regenstrief  
Guide for  
LOINC Microbiology

Edited by: Swapna Abhyankar, MD  
Mary Zabriskie, MLS(ASCP)  
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Harmonized and  
Structured  
Transmission

Digital File  
LOINC

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<http://ivdconnectivity.org/livd/>

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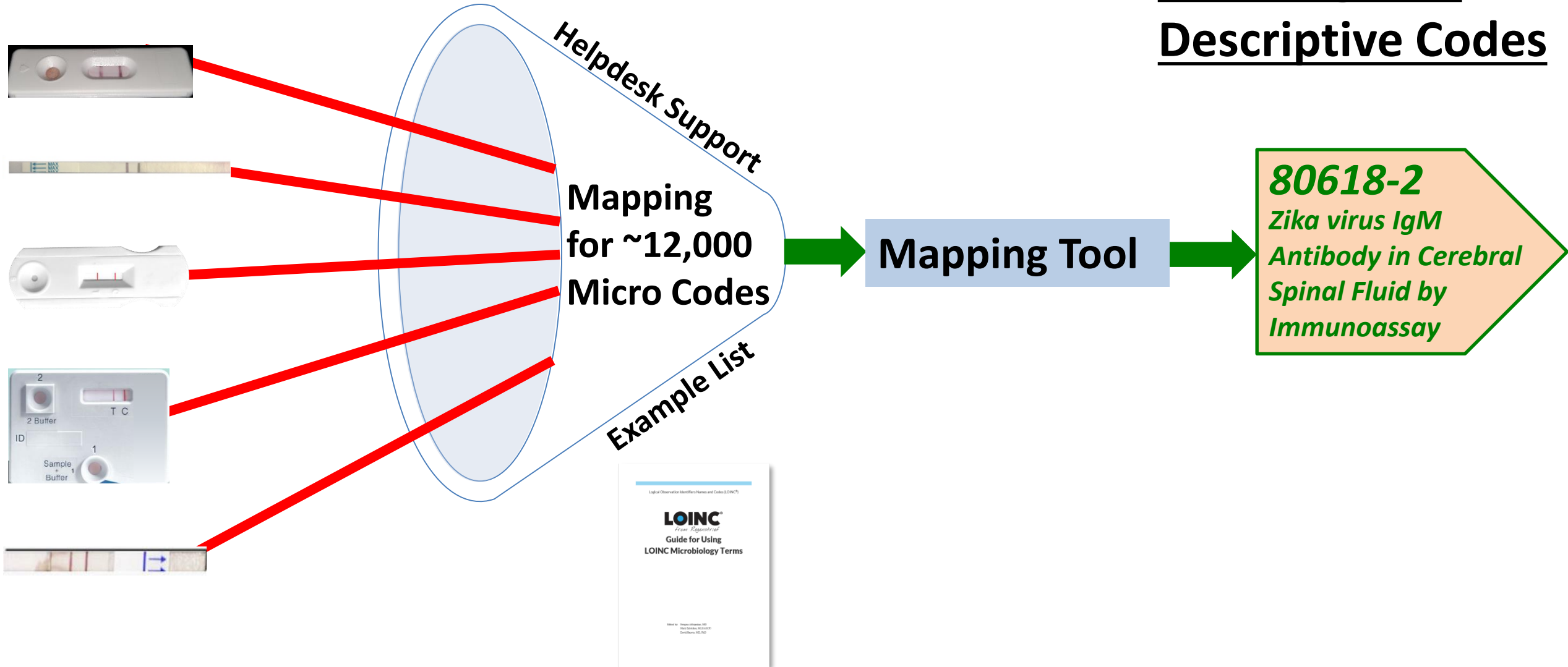
Ecosystem supports manufacturers/industry to provide vetted and harmonized descriptive IVD codes (*vetted through a sole authoritative source*) to labs to improve utility for consumers.

# Simplified Process for IVD Code Assignment

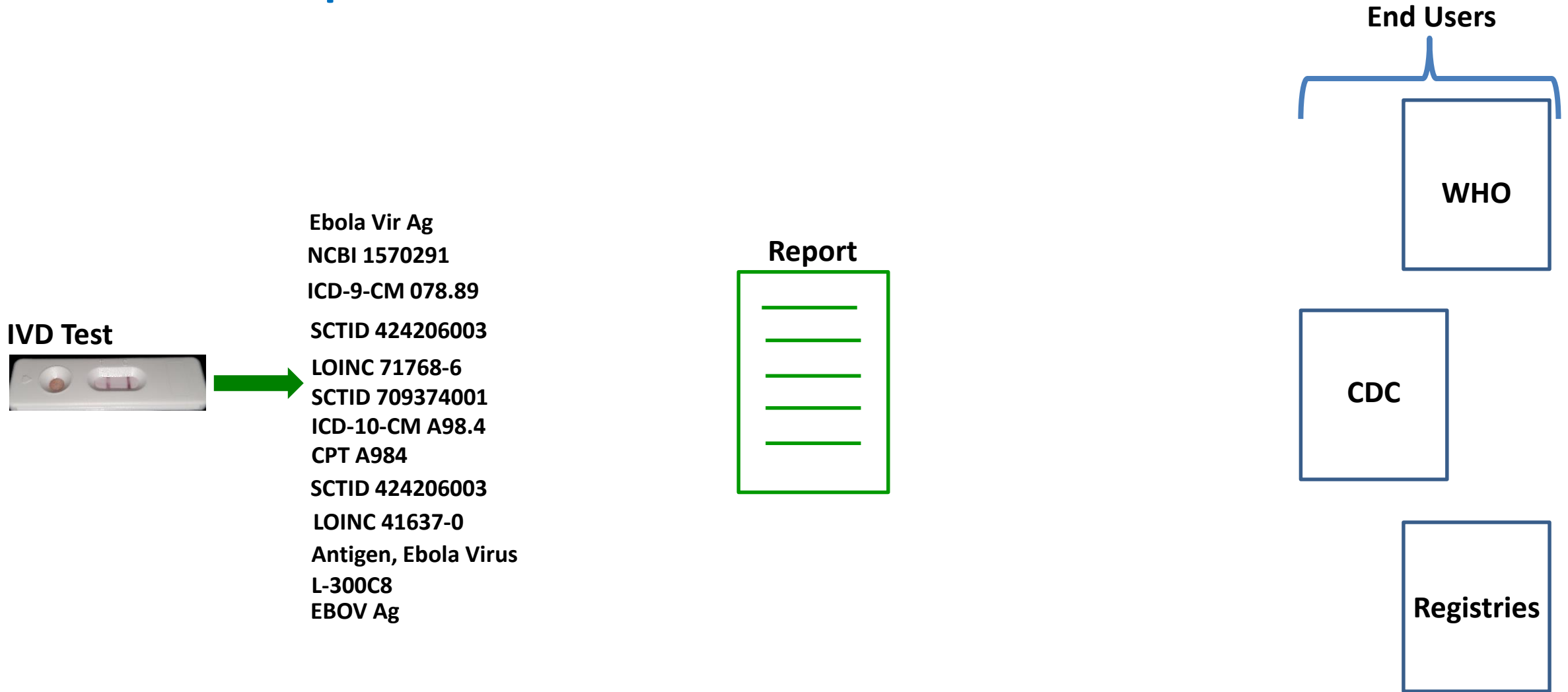


Same IVD Type

Unambiguous  
Descriptive Codes



# Empowering Future Possibilities: Simplified Data Collection/Transmission



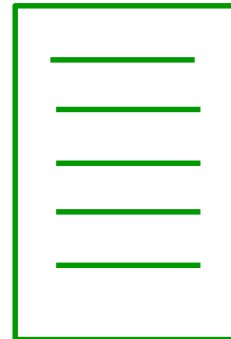
# Empowering Future Possibilities: Simplified Data Collection/Transmission

IVD Test

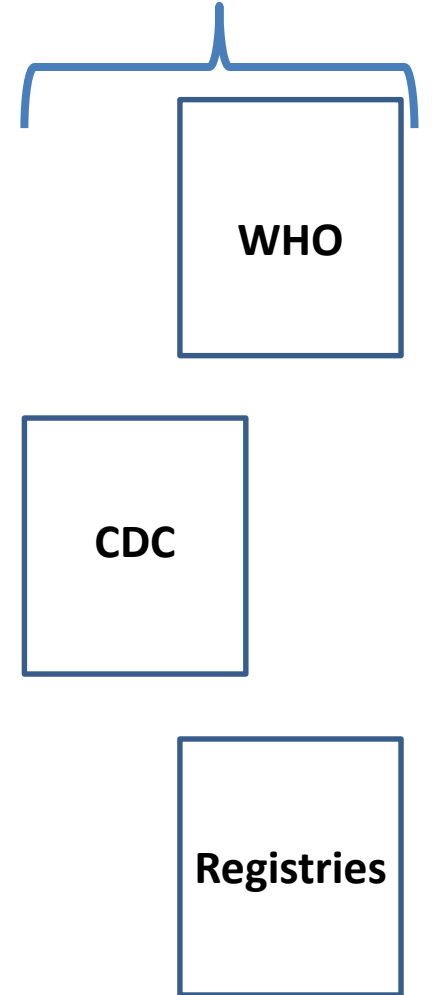


Ebola Vir Ag  
NCBI 1570291  
ICD-9-CM 078.89  
SCTID 424206003  
LOINC 71768-6  
SCTID 709374001  
ICD-10-CM A98.4  
CPT A984  
SCTID 424206003  
LOINC 41637-0  
Antigen, Ebola Virus  
L-300C8  
EBOV Ag

Report



End Users



# Empowering Future Possibilities: Simplified Data Collection/Transmission

IVD Test



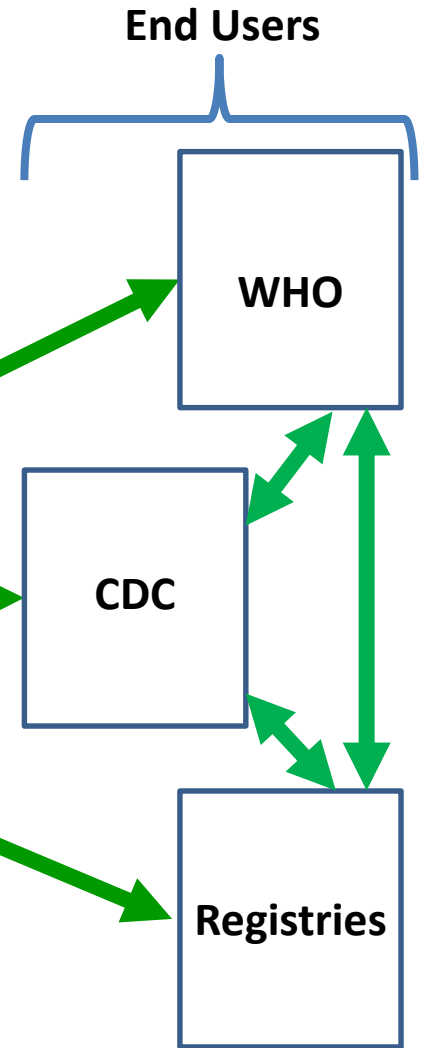
LOINC 71768-6  
SCTID 709374001

Harmonized Codes

The smartphone screen displays a form titled "Encounter Details" with the following sections:

- Case Report Date:** Tap to enter date.
- Patient Information:** Patient ID: \_\_\_\_\_ Age: \_\_\_\_\_ Occupation: \_\_\_\_\_ Location: [Location Picker] Alive/Dead: Choose one Consent:
- Clinical Signs & Symptoms:** Symptoms: Check all that apply [List of symptoms with checkboxes]
- Unexplained Bleeding:** Check all that apply [List of symptoms with checkboxes]
- Hospitalization Information:** Admission Date: Tap to enter date. Checkout Date: Tap to enter date. Location: Choose one Isolation?:
- Laboratory Testing:** Test Date: Tap to enter date. Test Results: Choose one Test Type: Choose one Specimen: Choose one
- Epidemiological Risk/Exposures**

Real-Time Transmission



To get involved/learn more, contact:

[Michael.Waters@fda.hhs.gov](mailto:Michael.Waters@fda.hhs.gov)

**THANK YOU!**

#### SUPPORT

- HHS Patient-Centered Outcome Research Trust Fund (PCORTF)
- Medical Countermeasures Initiative (MCMi)
- Presidential Advisory Council for Combatting Antimicrobial Resistant Bacteria (PACCARB)
- **DEDICATED VOLUNTEERS WHO HAVE INVESTED COUNTLESS HOURS AND CONSIDERABLE EXPERTISE**



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