

Diagnosics During and Beyond the Pandemic

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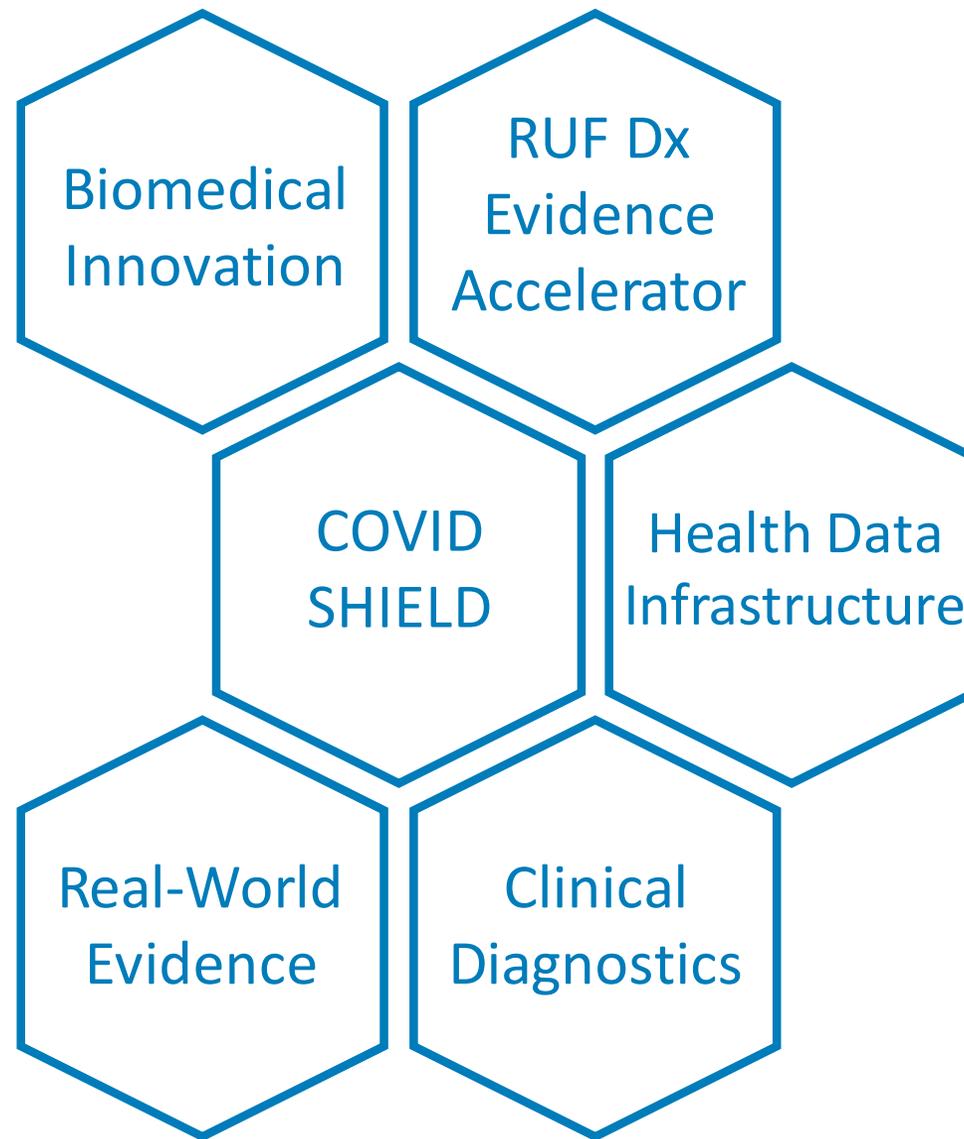
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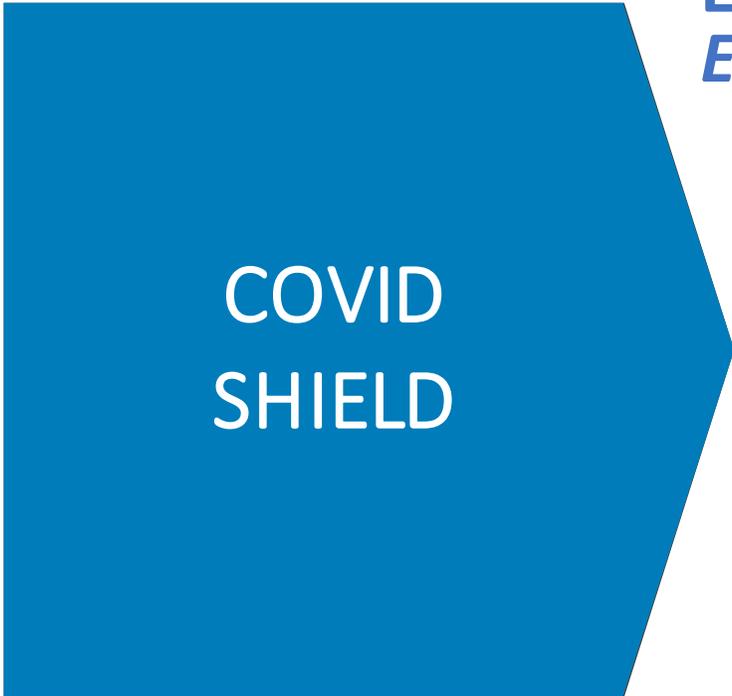
Protecting & Promoting Public Health *During a Pandemic*



- In Vitro Diagnostics in the era of COVID-19
 - Emergency Use
 - Viral nucleic acid, direct antigen, antibody
- Balance of risks and benefits
 - Safety & innovation
- Testing as part of a larger strategy
 - Hierarchy of controls & risk mitigation
 - Infection control practices

How will
diagnostics be
used and how
might they change
over the course of
the pandemic?

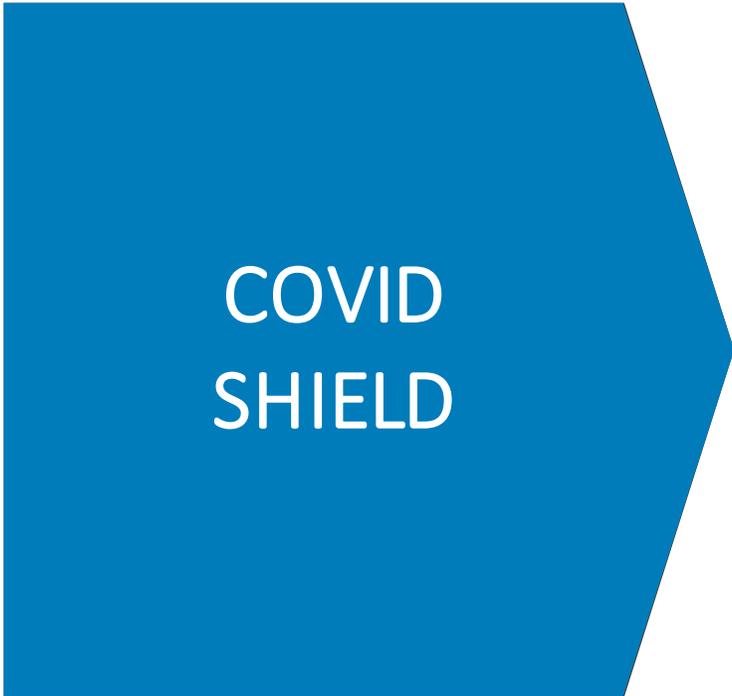


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COVID
SHIELD

Semantic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD): *Enables mission critical downstream activities*

- Improve the speed and accuracy of reporting
- Improve diagnostic data quality
- Identify shortages
- Improve downstream integration into and across healthcare system platforms (e.g. EHRs)
- Support clinical trials by linking diagnostics, interventional, and therapeutic data over time
- Assess test quality and performance, including clinical validity, by linking lab/Dx data with clinical and outcomes data by leveraging and harmonizing RWD and RWE prospectively

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COVID
SHIELD

- SARS-CoV-2 Dx Data Harmonization – Mapping Tool at CDC’s Division of Laboratory Systems website:

[LOINC LIVD Test Code Mapping for SARS-CoV-2 Tests](#)
- Test developers or manufacturers may contact FDA at SHIELD-LabCodes@fda.hhs.gov for information about verifying codes with CDC and its partners in this project, and to provide feedback

Regan Udall Foundation Diagnostics Evidence Accelerator: *Using RWD to Evaluate COVID-19 Diagnostic Testing*

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RUF Dx
Evidence
Accelerator

- While traditional test methods are underway, studies using RWD may provide important complementary information about real world patterns of use, test performance, and immunity
- Contemporary retrospective and prospective RWD sources are of progressively higher quality, and new methods have improved reliability of results
- A coordinated program of diagnostic testing research using RWD could rapidly generate useful evidence to inform clinical, public health, and policy decisions

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RUF Dx Evidence Accelerator

- **TEST:** To generate evidence on real world test performance of SARS-CoV-2 molecular diagnostics, direct antigen, and antibody tests
- **PATIENT:** To improve understanding of the pathophysiology of disease including the development of antibodies, immune response, and immunity in patients with SARS-CoV-2 infection (by diagnostic testing and/or clinical assessment)
- **POPULATION:** To estimate the prevalence of SARS-CoV-2 infection, recovery (presence and persistence of antibodies over time) and reinfection for different populations, analyzed by geography, public health interventions, and other characteristics
- **SYSTEM:** To promote the uptake of COVID SHIELD data standards within clinical labs to improve the ability to address diagnostic testing questions

Rapid Acceleration of Diagnostics (RADx): *Key Component of Operation Warp Speed*

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Biomedical
Innovation

- Fast-track technology development program that leverages NIH Point-of-Care Technology Research Network ([POCTRN](#))
- Innovative solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches as soon as late summer 2020
- Early & advanced stage transformative technologies to improve analytical performance, enhance operational performance, and improve access and reduce cost of testing
- Driving toward at-home or at-anywhere diagnostics coupled with digital health tools

Data & Public Health Decision-Making: *Evidence-based decision making relies on comprehensive, high quality data*



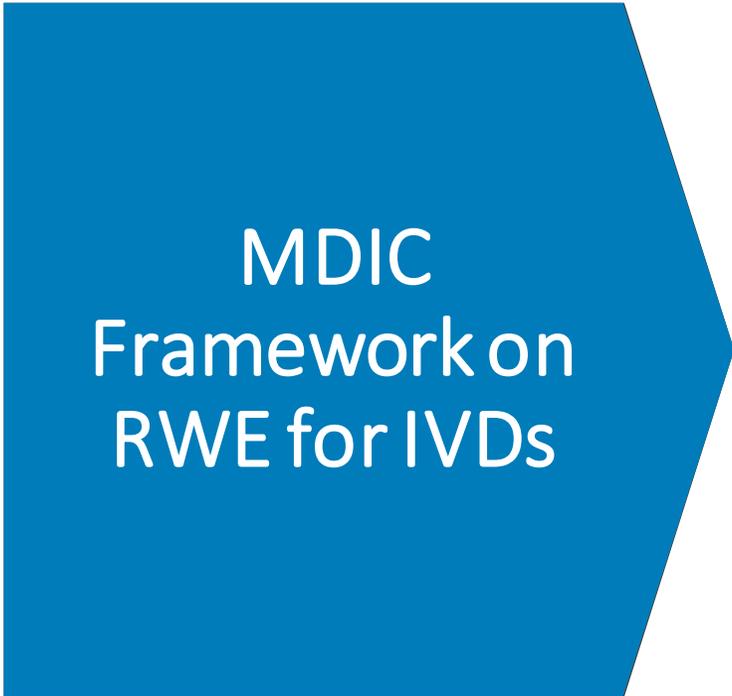
Health Data Infrastructure

- Core data elements across different categories must be harmonized and integrated (e.g. diagnostic, specimen, clinical, demographic data)
- Increasing granularity of data at different levels enables evidence-based decision-making
 - Federal / National: real-time, high-level tracking, policy-making, resource utilization, security
 - State / Local: Contact tracing, containment of outbreaks, mitigation
 - Patient/ Physician: prevention, diagnosis, treatment, recovery

[HHS Announces New Laboratory Data Reporting Guidance for COVID-19 Testing \(June 4, 2020\)](#)

- *COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115*

Real-World Clinical Evidence Generation: Advancing Regulatory Science and Patient Access for In Vitro Diagnostics (IVDs)

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MDIC Framework on RWE for IVDs

- Focuses on the use and potential value of RWE to support regulatory decision-making for medical devices
- Support FDA and industry when considering when and how RWD, appropriate designs, and statistical methods including modeling to generate RWE might be incorporated into product development and regulatory decision-making
- Highlights issues pertinent to clinical validation of RWD in pre-market and post-market regulatory decision-making of IVD devices

FDA Resources & Additional Information

*Under Heading: Specialty Technical Topics Subheading:
In Vitro Diagnostics*



& Devices

Questions about COVID-19 IVD EUAs: CDRH-EUA-Templates@fda.hhs.gov

EUA webpage: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

FAQs on COVID-19 Testing: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2>

Serology Testing Performance: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance>

Questions about laboratory data harmonization for COVID-19 testing: SHIELD-LabCodes@fda.hhs.gov

HHS Laboratory Data Reporting Guidance for COVID-19 Testing: <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>



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