



National Committee on Vital and Health Statistics
Advising the HHS Secretary on National Health Information Policy

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Two Issues



- Testing technology & data
- Digital Exposure Notification Tools
- Both require understanding in relation to HIPAA
- Both are affected by current category confusion.....

Diagnostic

- Symptomatic or known suspected exposure
- CLIA lab, under FDA policies

Screening

- Asymptomatic without known/suspected exposure
- CLIA lab, under FDA policies

Surveillance

- Aim to characterize Incidence and prevalence in the community
- Results not returned to individuals
- CLIA not necessary

[CDC categories](#)
(consistent with
[FDA language](#))

Most EUAs are for this

This use is off-label.
Lower sensitivity tests may be appropriate.
Negative tests do not need not be confirmed with high sensitivity tests if part of routine screening.

FDA does not generally regulate

What the [FDA says](#)
about these categories

HHS: diagnostic and contact tracing

Assurance testing (they introduce in distinction to diagnostic and surveillance testing; they avoid “screening”)
This group: “routine testing in critical contexts”

Alignment with other vocab

HHS: Surveillance testing

Diagnostic

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- CLIA lab, under FDA policies

Screening

- Asymptomatic without known/suspected exposure
- CLIA lab, under FDA policies

Surveillance

- Aim to characterize Incidence and prevalence in the community
- Results not returned to individuals
- Necessary

[CDC categories](#)
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Most EUAs are for this

This use is
Lower sens
may be app
Negative te
need not be
with high se
if part of rou
screening.

In actuality, colleges,
universities,
businesses, schools,
3rd party
providers, and
potentially
individuals at home.

not generally

What the [FDA says](#)
about these
categories

HHS: diagnostic and
contact tracing

Assurance testing (they
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surveillance testing; they
avoid “screening”)
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Alignment with
other vocab

HHS: Surveillance testing

Recommendations re Testing



- Need clarification that HIPAA applies to Screening testing sites;
- Therefore need to broaden list of HIPAA Covered entities;
- Need public education that HIPAA is consistent with sharing of data with public health authorities;
- Need clarified norms for when screening positives should be confirmed with diagnostic testing.
- (We also need to clarify payment systems for screening testing.)

Ethics & Exposure Notification Tech



COVID-19 Rapid Response Impact Initiative | White Paper 22

Digital Tools for COVID-19 Contact Tracing: Identifying and Mitigating the Equity, Privacy, and Civil Liberties Concerns

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Recommendations re EN Tech



- HIPAA does not apply so we need:
 - Federal legislation to provide safeguards and hold governments and companies accountable.
 - Resources to FTC and state agencies to hold companies accountable for any privacy violations or other deceptive practices.

Seven principles for legislation

- Meaningful consent
- Transparency
- Data Minimization (Bluetooth)
- Limited Retention Period
- Prohibition on secondary uses
- Data Security (Decentralization; differential privacy)
- Equity