

S 1666

VITAL Act of 2021

Congress: 117 (2021–2023, Ended)

Chamber: Senate

Policy Area: Health

Introduced: May 18, 2021

Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (May 18, 2021)

Official Text: <https://www.congress.gov/bill/117th-congress/senate-bill/1666>

Sponsor

Name: Sen. Paul, Rand [R-KY]

Party: Republican • **State:** KY • **Chamber:** Senate

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 18, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Verified Innovative Testing in American Laboratories Act of 2021 or the VITAL Act of 2021

This bill expressly shifts the regulation of laboratory-developed testing procedures from the Food and Drug Administration (FDA) to the Centers for Medicare & Medicaid Services (CMS). Under current law, the FDA regulates the safety and effectiveness, as well as quality of design and manufacture, of laboratory-developed tests, while the CMS regulates clinical laboratories and testing processes. Historically, the FDA has exercised enforcement discretion and not enforced certain statutory and regulatory requirements with respect to these tests.

The CMS must hold a public meeting to solicit recommendations to update existing regulations related to clinical laboratories, and the Department of Health and Human Services must report specified information to Congress, including an assessment of the availability and use of laboratory-developed testing procedures during the COVID-19 (i.e., coronavirus disease 2019) response.

Actions Timeline

- **May 18, 2021:** Introduced in Senate
- **May 18, 2021:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.