

## S 3512

VITAL Act of 2020

**Congress:** 116 (2019–2021, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Mar 17, 2020

**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. (Mar 17, 2020)

**Official Text:** <https://www.congress.gov/bill/116th-congress/senate-bill/3512>

### Sponsor

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

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

### Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Cruz, Ted [R-TX]	R · TX		Mar 19, 2020

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 17, 2020

### Subjects & Policy Tags

**Policy Area:**

Health

### Related Bills

*No related bills are listed.*

## **Verified Innovative Testing in American Laboratories Act of 2020 or the VITAL Act of 2020**

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**

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- **Mar 17, 2020:** Introduced in Senate
- **Mar 17, 2020:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.