

116TH CONGRESS  
2D SESSION

# S. 3512

To clarify the authority for regulating laboratory-developed testing procedures.

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## IN THE SENATE OF THE UNITED STATES

MARCH 17, 2020

Mr. PAUL introduced the following bill; which was read twice and referred to  
the Committee on Health, Education, Labor, and Pensions

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## A BILL

To clarify the authority for regulating laboratory-developed  
testing procedures.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Verified Innovative  
5       Testing in American Laboratories Act of 2020” or the  
6       “VITAL Act of 2020”.

7       **SEC. 2. LABORATORY-DEVELOPED TESTING PROCEDURES.**

8       (a) FINDINGS.—Congress finds the following:

9               (1) Laboratory testing services are an integral  
10       part of medical decision making, health manage-  
11       ment, and public health surveillance.

1           (2) Provision of laboratory services is a profes-  
2           sional health care activity, which is regulated under  
3           the Public Health Service Act (42 U.S.C. 201 et  
4           seq.).

5           (3) As witnessed with the 2020 COVID–19  
6           pandemic, undue regulation of laboratory-developed  
7           testing procedures may hamper the medical manage-  
8           ment and public health response to infectious disease  
9           outbreaks and pandemics, leading to delays in access  
10          to testing and the ability to meet needed capacity to  
11          stem community spread.

12          (b) SENSE OF CONGRESS.—It is the sense of Con-  
13          gress that—

14               (1) the Federal Government should work to—

15                   (A) ensure that patients receive the most  
16                   appropriate tests and procedures for medical  
17                   evaluations or treatment of clinical conditions;

18                   (B) ensure that laboratory-developed test-  
19                   ing procedures are accurate, precise, clinically-  
20                   relevant, and monitored for continued quality  
21                   performance;

22                   (C) enable laboratory professionals to pro-  
23                   vide professional services without undue restric-  
24                   tions;

(D) ensure that regulatory oversight of laboratory tests does not limit patient access, impede innovation, constrain flexibility or adaptability, or limit a test's sustainability as a result of being unduly burdensome or beyond the fiscal capacity of the laboratory to reasonably validate and perform, or the health care system to financially support;

(E) preserve the ability of the laboratory community to provide surge capacity in public health emergencies, including biological, chemical, radiological, and nuclear threats, infectious disease outbreaks, or other emergent situations; and

(F) safeguard, strengthen, and expand the existing Laboratory Response Network, including public health laboratories, sentinel laboratories, national laboratories, commercial reference laboratories, academic medical center laboratories, and hospital-based laboratories; and

(2) laboratories using laboratory-developed testing procedures should adhere to personnel requirements required under section 353 of the Public Health Service Act (42 U.S.C. 263a), including such

1 requirements relating to qualified professionals who  
2 direct and supervise laboratories and consult on di-  
3 agnosis, treatment, and management of patient care,  
4 and render opinions to clients concerning diagnosis,  
5 treatment, and management of patient care required  
6 under such section 353.

7 (c) AUTHORITY OVER LABORATORY-DEVELOPED  
8 TESTING PROCEDURES.—All aspects of a laboratory-de-  
9 veloped testing procedures shall be regulated by the Sec-  
10 retary of Health and Human Services under section 353  
11 of the Public Health Service Act (42 U.S.C. 263a), and  
12 no aspects of laboratory-developed testing procedures shall  
13 be regulated under the Federal Food, Drug, and Cosmetic  
14 Act (21 U.S.C. 301 et seq.), including during a public  
15 health emergency declared under section 319 of the Public  
16 Health Service Act (42 U.S.C. 247d).

17 (d) DEFINITION.—In this section, the term “labora-  
18 tory-developed testing procedure” means a professional  
19 medical service that utilizes a laboratory examination in  
20 the context of clinical care or public health services and  
21 that meets the standards for establishment of performance  
22 specifications established by regulation under section  
23 353(f) of the Public Health Service Act (42 U.S.C.  
24 263a(f)) applicable to—

1           (1) laboratory modifications of test systems ap-  
2           proved, cleared, or authorized by the Food and Drug  
3           Administration under section 510(k), 513, 515, or  
4           564 of the Federal Food, Drug, and Cosmetic Act  
5           (21 U.S.C. 360(k), 360e, 360e, 360bbb-3);

6           (2) methods developed or performed, and re-  
7           sults produced and interpreted, within a laboratory  
8           or laboratories under common ownership or within  
9           the same organization, certified as required under  
10          section 353(c) of the Public Health Service Act (42  
11          U.S.C. 263a(c));

12          (3) standardized methods such as those that  
13          are available in textbooks and peer-reviewed publica-  
14          tions; or

15          (4) methods in which performance specifications  
16          are not provided by the manufacturer of test sys-  
17          tems or components.

18          (e) PUBLIC MEETING.—Not later than 90 days after  
19          the date of enactment of this Act, the Administrator of  
20          the Centers for Medicare & Medicaid Services shall hold  
21          a public meeting to solicit recommendations on updating  
22          the regulations under section 353 of the Public Health  
23          Service Act (42 U.S.C. 263a).

24          (f) REPORT TO CONGRESS.—Not later than 180 days  
25          after the date of enactment of this Act, the Secretary of

1 Health and Human Services shall report to the Committee  
2 on Health, Education, Labor, and Pensions of the Senate  
3 and the Committee on Energy and Commerce of the  
4 House of Representatives, the following:

5 (1) Recommendations to update section 353 of  
6 the Public Health Service Act (42 U.S.C. 263a) and  
7 the regulations promulgated under such section, tak-  
8 ing into consideration input and recommendations  
9 from the Clinical Laboratory Improvement Advisory  
10 Committee, to reflect the current state of the field  
11 of clinical laboratory testing.

12 (2) An assessment of the availability and utili-  
13 zation of laboratory-developed testing procedures  
14 during the 2020 COVID–19 pandemic response that  
15 includes—

16 (A) validation criteria and process, and av-  
17 erage length of time from validation to achiev-  
18 ing emergency use authorization under section  
19 564 of the Federal Food, Drug, and Cosmetic  
20 Act (21 U.S.C. 360bbb–3) before, and after,  
21 February 29, 2020;

22 (B) the number of patients and samples  
23 tested by laboratories using such testing proce-  
24 dures; and

1                   (C) recommendations to ensure that dur-  
2                   ing future infectious disease outbreaks, the pub-  
3                   lic health system and clinical laboratories do  
4                   not encounter delays to testing.

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