



(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to develop a plan to improve the development and distribution of diagnostic tests during a public health emergency, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. MILLER-MEEKS introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to develop a plan to improve the development and distribution of diagnostic tests during a public health emergency, and for other purposes.

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 “Diagnostics Testing
5 Preparedness Plan Act of 2025”.

1 **SEC. 2. IMPROVING DEVELOPMENT AND DISTRIBUTION OF**
2 **DIAGNOSTIC TESTS.**

3 Section 319B of the Public Health Service Act (42
4 U.S.C. 247d–2) is amended to read as follows:

5 **“SEC. 319B. IMPROVING DEVELOPMENT AND DISTRIBUTION OF**
6 **DIAGNOSTIC TESTS.**

7 “(a) **DIAGNOSTIC TESTING PREPAREDNESS PLAN.**—
8 The Secretary shall develop, make publicly available, and
9 update a plan for the rapid development, validation, au-
10 thorization, manufacture, procurement, and distribution
11 of diagnostic tests, and for rapid scaling of testing capac-
12 ity, in response to chemical, biological, radiological, or nu-
13 clear threats, including emerging infectious diseases, for
14 which a public health emergency is declared under section
15 319, or that has significant potential to cause such a pub-
16 lic health emergency.

17 “(b) **PURPOSES.**—The purpose of the plan under sub-
18 section (a) shall be to—

19 “(1) facilitate the development and utilization
20 of diagnostic tests;

21 “(2) describe the processes for the rapid devel-
22 opment, validation, authorization, manufacture, pro-
23 curement, and distribution of diagnostic tests, and
24 for rapid scaling of testing capacity; and

25 “(3) facilitate coordination and collaboration
26 among public and private entities to improve the

1 rapid development and utilization of diagnostic test-
2 ing during a public health emergency.

3 “(c) CONSIDERATIONS.—The plan under subsection
4 (a) shall take into consideration—

5 “(1) domestic capacity, including any such ca-
6 pacity established through partnerships with public
7 and private entities pursuant to subsection (e), to
8 support the development, validation, manufacture,
9 procurement, and distribution of tests, and the rapid
10 scaling of testing capacity;

11 “(2) novel technologies and platforms that—

12 “(A) may be used to improve testing capa-
13 bilities, including—

14 “(i) high-throughput laboratory
15 diagnostics;

16 “(ii) point-of-care diagnostics; and

17 “(iii) rapid at-home diagnostics;

18 “(B) improve the accessibility of diagnostic
19 tests; and

20 “(C) facilitate the development and manu-
21 facture of diagnostic tests;

22 “(3) medical supply needs related to testing, in-
23 cluding diagnostic testing, equipment, supplies, and
24 component parts, and any potential vulnerabilities
25 related to the availability of such medical supplies

1 and related planning needs, consistent with section
2 2811(b)(4)(J);

3 “(4) strategies for the rapid and efficient dis-
4 tribution of tests locally, regionally, or nationwide
5 and appropriate scaling of laboratory testing capac-
6 ity; and

7 “(5) assessment of such strategies through
8 drills and operational exercises carried out under
9 section 2811(b)(4)(G), as appropriate.

10 “(d) COORDINATION.—To inform the development
11 and update of the plan under subsection (a), and in car-
12 rying out activities to implement such plan, the Secretary
13 shall coordinate with industry, such as device manufactur-
14 ers, clinical and reference laboratories, and medical prod-
15 uct distributors, States, local governmental entities, In-
16 dian Tribes and Tribal organizations, and other relevant
17 public and private entities.

18 “(e) CAPACITY BUILDING.—The Secretary may con-
19 tract with public and private entities, as appropriate, to
20 increase domestic capacity in the rapid development, vali-
21 dation, authorization, manufacture, procurement, and dis-
22 tribution of diagnostic tests, as appropriate, to State,
23 local, and Tribal health departments and other appro-
24 priate entities for immediate public health response activi-
25 ties to address an infectious disease with respect to which

1 a public health emergency is declared under section 319,
2 or that has significant potential to cause such a public
3 health emergency.

4 “(f) DEADLINES FOR PLAN.—

5 “(1) PUBLIC RELEASE.—Not later than one
6 year after the date of enactment of the Diagnostics
7 Testing Preparedness Plan Act of 2025, the Sec-
8 retary shall publicly release the plan developed under
9 subsection (a).

10 “(2) UPDATES.—The Secretary shall update
11 such plan not less frequently than once every 3 years
12 after the date of the initial public release of the
13 plan.”.