

By: Harrison

H.B. No. 964

A BILL TO BE ENTITLED

AN ACT

relating to the regulation of laboratory developed tests during a federally declared public health emergency.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle D, Title 2, Health and Safety Code, is amended by adding Chapter 100B to read as follows:

CHAPTER 100B. REGULATION OF LABORATORY DEVELOPED TESTS DURING
FEDERALLY DECLARED PUBLIC HEALTH EMERGENCY

Sec. 100B.001. DEFINITIONS. In this chapter:

(1) "Federally declared public health emergency"
means:

(A) a public health emergency declared by the
United States secretary of health and human services under 42
U.S.C. Section 247d; or

(B) an emergency or disaster declared, including
under a renewal of the declaration, by the president of the United
States in relation to a public health emergency described by
Paragraph (A) under:

(i) the National Emergencies Act (50 U.S.C.
Section 1601 et seq.); or

(ii) the Robert T. Stafford Disaster Relief
and Emergency Assistance Act (42 U.S.C. Section 5121 et seq.).

(2) "Laboratory developed test" means a test used in
the same clinical laboratory in Texas that designed and

1 manufactured the test to detect a pathogen or agent or to diagnose
2 a health condition caused by a pathogen or agent, and as result,
3 such test is deemed to be a test used and manufactured solely
4 intrastate.

5 Sec. 100B.002. PROHIBITED REGULATION BY UNITED STATES FOOD
6 AND DRUG ADMINISTRATION. (a) Notwithstanding any other law,
7 during a federally declared public health emergency, a clinical
8 laboratory is considered a state agency for purposes of regulation
9 by the United States Food and Drug Administration when the
10 laboratory is performing a laboratory developed test on a pathogen
11 or agent that is the basis for the emergency declaration or to
12 diagnose the health condition that is the basis for the emergency
13 declaration.

14 (b) Subsection (a) does not affect a clinical laboratory's
15 liability under any applicable state or federal law, except to the
16 extent the laboratory's liability is limited under the Public
17 Readiness and Emergency Preparedness Act (42 U.S.C. Section 247d)
18 and further does not authorize any state agency to exercise any
19 authority over laboratories that it did not possess prior the
20 issuance of the public health emergency.

21 SECTION 2. This Act takes effect immediately if it receives
22 a vote of two-thirds of all the members elected to each house, as
23 provided by Section 39, Article III, Texas Constitution. If this
24 Act does not receive the vote necessary for immediate effect, this
25 Act takes effect September 1, 2025.