The State of Maryland

Executive Department

ORDER
OF THE
GOVERNOR OF THE STATE OF MARYLAND

NUMBER 20-03-23-02

INITIATING A PROCESS FOR AUTHORIZATION OF LABORATORIES IN MARYLAND TO DEVELOP AND PERFORM COVID-19 TESTING

WHEREAS, A state of emergency and catastrophic health emergency was proclaimed on March 5, 2020, and renewed on March 17, 2020, to control and prevent the spread of COVID-19 within the state, and the state of emergency and catastrophic health emergency continue to exist;

WHEREAS, Laboratories in Maryland have a critical role in disease surveillance, treatment, and suppression efforts;

WHEREAS, It is necessary to control, regulate, use, and/or ration, and/or take other appropriate actions with respect to, laboratories in Maryland to respond to the catastrophic health emergency;

WHEREAS, To respond to the catastrophic health emergency, it is necessary to designate and/or gain access to laboratories in Maryland, working collaboratively, to the extent feasible, with health care providers; and

WHEREAS, The Food and Drug Administration of the U.S. Department of Health and Human Services has provided regulatory flexibility allowing states to authorize certain laboratories to develop and perform tests for COVID-19, to facilitate rapid detection of cases and contacts, appropriate clinical management and infection control, and implementation of community mitigation efforts;

NOW, THEREFORE, I, LAWRENCE J. HOGAN, JR., GOVERNOR OF THE STATE OF MARYLAND, BY VIRTUE OF THE AUTHORITY VESTED IN ME BY THE CONSTITUTION AND LAWS OF MARYLAND, INCLUDING BUT NOT LIMITED TO TITLE 14 OF THE PUBLIC SAFETY ARTICLE, AND IN AN EFFORT TO CONTROL AND PREVENT THE SPREAD OF COVID-19 WITHIN THE STATE, DO HEREBY ORDER:

I. Laboratory Authorization Process. The Secretary of Health of the State of Maryland (the "Secretary") is hereby ordered to implement

a process to authorize laboratories in Maryland to develop and perform testing for COVID-19, consistent with the Food and Drug Administration's "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency", issued on March 16, 2020, as it may be amended, revised, or supplemented from time to time (the "Lab Authorization Process").

II. Secretary's Directives. In addition to the Lab Authorization Process, the Secretary is authorized to issue such directives as may be necessary to control and regulate the development and performance of COVID-19 testing by laboratories in Maryland.

III. Suspension of Statutes, Rules, Regulations. The effect of any statute, rule, or regulation of an agency of the State or a political subdivision inconsistent with this order is hereby suspended, including, without limitation, any statute, rule or regulation that would prevent laboratories in Maryland from developing and performing testing for COVID-19 in accordance with any directives issued by the Secretary pursuant to paragraph II above and the Lab Authorization Process.

IV. General Provisions

a. This Order remains effective until the state of emergency has been terminated and the proclamation of the catastrophic health emergency has been rescinded, or until rescinded, superseded, amended, or revised by additional orders.

b. The underlined paragraph headings in this Order are for convenience of reference only and shall not affect the interpretation of this Order.

ISSUED UNDER MY HAND THIS 23RD DAY OF MARCH, 2020, AND EFFECTIVELY IMMEDIATELY.

Lawrence J. Hogan, Jr.
Governor