The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
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To: Laboratories and Facilities Conducting COVID-19 RT-PCR Testing and Genomic Analysis

From: Catherine M. Brown, DVM, MSc, MPH
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RE: Availability of SARS-CoV-2 Residual Clinical Specimens and Public Health Reporting of Variants of Concern

Date: February 8, 2021

The Department of Public Health (DPH or the Department) is statutorily mandated to conduct investigations as to the causes of disease and especially of epidemics, G.L. c. 111 §5, and has regulatory authority to conduct certain surveillance activities. COVID-19, the disease caused by the SARS-CoV-2 virus, is a disease dangerous to the public health pursuant to GL c. 111 s. 6 and 105 CMR 300. The Department is authorized to obtain medical records and other information that the Department deems necessary to carry out its responsibilities to investigate, monitor, prevent and control diseases dangerous to the public health. 105 CMR 300.191.

In furtherance of the Department's mandate, it is necessary that the Department receive particular reporting of information on SARS-CoV-2 variants of concern and be granted access to residual clinical specimens of SARS-CoV-2.

Laboratories are requested to report: 1) the identification of atypical SARS-CoV-2 RT-PCR tests indicative of gene target failure; and 2) the identification, based on genomic analysis, of any variants of concern as defined by the U.S. Centers for Disease Control and Prevention (CDC) and as may be listed by the CDC from time to time here: Emerging SARS-CoV-2 Variants | CDC website, to the Department by providing their facility name, phone and email contact information, and description of results by email to MASPHL.sequencing@mass.gov. This initial email must not contain any confidential information, including but not limited to, individual identifiers or protected health information (PHI). Upon receipt of this email the Department will contact the laboratory directly. Laboratories should be prepared to either provide, or direct

the Department to someone who can provide, any and all demographic and epidemiologic information on the person the original sample came from.

Additionally, laboratories are requested to make residual samples available following diagnostic SARS-COV-2 RT-PCR testing to the Department upon request.

Specifically, this information is necessary for the Department's investigation into the existence of diseases dangerous to the public health in order to determine the causes and extent of such diseases and to formulate prevention and control measures; identification of cases and contacts; counseling and interviewing individuals as appropriate to assist in positive identification of exposed individuals and to develop information relating to the source and spread of illness; monitoring the medical condition of individuals diagnosed with or exposed to diseases dangerous to the public health; collection and/or preparation of data regarding immunity levels in segments of the population and other relevant epidemiological data; and/or, ensuring that diseases dangerous to the public health are subject to the requirements of 105 CMR 300.200 and other proper control measures. 105 CMR 300.190 et seq.

HIPAA covered entities are reminded that the HIPAA Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities, such as the Department, who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. 45 CFR 164.512(b)(1)(i).