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January 14, 2022

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khalid@macagain.net

RE: CEASE AND DESIST: Failure to Comply with COVID-19 Reporting Requirements

Dear Khalid Ansari and Macagain Corporation:

This office represents the Colorado Department of Public Health and Environment (CDPHE). It has come to CDPHE's attention that Macagain Corp (Macagain), in the state of Colorado, administered and continues to administer COVID-19 rapid tests and collected and continues to collect samples for PCR testing. However, Macagain has failed to report the results of these rapid tests and/or PCR tests to CDPHE as required by Amended Public Health Order 20-33 (PHO 20-33) and CDPHE's reporting regulations.

You are therefore ordered to **CEASE and DESIST** all testing operations in the state of Colorado pending resolution of the demands stated herein.



STATE OF COLORADO

DEPARTMENT OF LAW

Pursuant to C.R.S. § 24-33.5-704(2), Governor Polis issued Executive Order D 2021 122, which extended the state of disaster emergency in Colorado due to the presence of COVID-19. That executive order has since been extended and amended and continues to have the full force and effect of law. PHO 20-33 is issued pursuant to the Governor's directive and CDPHE's power "to investigate and control the causes of epidemic and communicable diseases affecting the public health." C.R.S. § 25-1.5-102(1)(a)(I).

PHO 20-33 requires that "[a]ll laboratories, local public health agencies, providers, point of care testing services, and any other entity performing COVID-19 testing of any kind shall report all test result information to CDPHE." Entities testing in Colorado are required to submit test results through CDPHE's electronic laboratory reporting platform or through other CDPHE-approved methods. Results shall include patient information, provider information, test result information, and any other information deemed necessary by CDPHE.

CDPHE regulations further require testing entities to report COVID-19 test results. COVID-19 is listed as a "reportable disease" in CDPHE's epidemic and communicable disease control regulations. 6 C.C.R. § 1009-1 Appendix A. As a reportable disease, COVID-19 test results "shall be reportable in accordance" with the Department's reporting regulations. 6 C.C.R. § 1009-1:1.

To that end, CDPHE's reporting regulations require any "person providing testing" to report cases of disease to CDPHE. 6 C.C.R. § 1009-1:2. CDPHE's laboratory reporting regulation further requires that COVID-19 cases "shall be reported...by the laboratory, or by an outpatient clinic that performs laboratory testing on site, whether or not associated with a hospital." 6 C.C.R. § 1009-1:3. "[O]ut-of-state laboratories that maintain an office or collection facility in Colorado or arrange for collection of specimens in Colorado; and in-state laboratories that send specimens to out-of-state referral laboratories" are also required to comply with CDPHE reporting regulations. *Id*.

It is unlawful to violate, disobey, or disregard the provisions of the public health laws or the lawful order or regulation issued pursuant thereto, or to fail to make or file reports relating to the existence of disease or other facts relating to the public health. C.R.S. § 25-1-114(1)(a). Your failure to report COVID-19 test results violates PHO 20-33 and the regulations above.

As a result of your noncompliance, you are ordered to **immediately CEASE** and **DESIST all COVID-19 testing operations in the state of Colorado** pending resolution of the following demands. Before restarting testing operations, you must provide to CDPHE:

- 1. A list of the total number of rapid tests that you administered in the state of Colorado and the total number of samples that you collected in the State of Colorado that were then sent for PCR testing to another location;
- 2. The contact information, including name of testing organization, CLIA identification number, and other identifying information, of any entity that you sent samples to perform PCR testing;
- 3. The required information set forth in PHO 20-33, section 2, for each test identified in response to the first demand listed above;
- 4. The number of samples that you collected in the State of Colorado that you have not yet sent for PCR testing;
- 5. The patient information, as required in section 2 of PHO 20-33, for each sample that you have not yet sent for PCR testing; and
- 6. All internal reporting policies and procedures concerning the administration of COVID-19 rapid tests and the collection of PCR testing.

Please contact us by January 21, 2022, at 9:00 a.m. to confirm your intentions to comply with applicable public health orders and reporting regulations and to resolve the demands as stated herein.

Failure to comply with this cease-and-desist order may result in CDPHE taking immediate judicial action, including requesting the entry of a temporary restraining order and subsequent preliminary injunction.

Sincerely,

FOR THE ATTORNEY GENERAL

s/ Jennifer L. Weaver

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