DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Carl Perez Telephone: 301-796-9102 Industry Information: www.fda.gov/oc/industry	June 16-17, 2025
	FEI NUMBER 3006579817

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ahmed Kilani, Ph.D., MT(ASCP), President and Laboratory Director

FIRM NAME	STREET ADDRESS
Clongen Laboratories, LLC	211 Perry Parkway, Suite 6
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Gaithersburg, MD 20877	Release testing facility

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1
Quality oversight is inadequate. Specifically,

a. There is a lack of a separate and independent quality assurance unit needed to perform objective review.

b. Internal audits are not performed at the defined frequency according to the Quality Manual.

c. No independent review of final test reports and associated test data is performed.

d. An administrative staff member was identified as acting Quality Assurance Manager, and no evidence was found that this individual performs any quality assurance activities as defined by Quality Manual and confirmed per employee.

e. SOP ADMIN006, How to Write a Standard Operating Procedure, does not require review and approval of any technical or QA procedures. No evidence was found of any QA review of any controlled SOPs.

f. Per the Clongen Quality Manual, (b) (4) review is required to be conducted by the Laboratory Director and the Quality Assurance Manager to assess current policies, practices and procedures to determine effective changes. Clongen stated that (b) (4) review has not been performed since 2023. However, that is no evidence of any reviews being performed.

OBSERVATION 2
Written procedures are not established for critical laboratory tasks. Specifically, for:

a. Sample receiving and (b) (4) when receiving sample shipments from (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Digitally signed by Carl A. Perez -S Date: 2025.06.17 12:56:20 -04'00' Digitally signed by DONALD B. ERTEL -S Date: 2025.06.17 13:01:34 -04'00' Hyesuk Kong -S Digitally signed by Hyesuk Kong -S Date: 2025.06.17 13:04:45 -04'00' KEVIN MATTHEWS -S Digitally signed by KEVIN MATTHEWS -S Date: 2025.06.17 13:13:20 -04'00'	Carl Perez, Consumer Safety Officer CDR Donald Ertel, Branch Chief Kevin Matthews, Consumer Safety Officer Hyesuk Kong, Biologist	06/17/2025

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CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Carl Perez Telephone: 301-796-9102 Industry Information: www.fda.gov/oc/industry	June 16-17, 2025
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b. Generation of the final test report for (b) (4) mycoplasma test results.

c. Mitigation and recovery steps in the event of failure of the freezers used for sample storage.

d. Receiving, tracking and management of reagent inventories.

e. Cleaning program of the laboratory areas and equipment.

OBSERVATION 3
Equipment is not qualified or monitored for its intended use. Specifically,

a. Technician was observed using out of calibration equipment (pipette and thermomixer) during the extraction step for mycoplasma testing on June 16, 2025. (b) (4) of (b) (4) pipettes on a rack were discovered to be out of calibration.

b. Preventive maintenance (PM) and calibrations requirements are not established and routinely performed on critical equipment including the (b) (4) PCR System (ID# (b) (4)), (b) (4) Thermomixers # (b) (4) (b) (4) gel imaging system (ID #(b) (4)), Electropheresis (b) (4) (ID #(b) (4), and (b) (4) (ID # (b) (4)).

c. Qualification studies were not initially performed on the (b) (4) and (b) (4) freezers prior to use.

OBSERVATION 4
Quality control documentation and practices are inadequate. Specifically,

a. Test runs are not documented during performance including (b) (4) of electrophoresis gels, critical test parameter checks, and reagents lot numbers and expirations.

b. Quality control of positive controls is recorded on an (b) (4) with no record of (b) (4) (b) (4)

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	Digitally signed by Carl A. Perez -S Date: 2025.06.17 12:56:49 -04'00' Digitally signed by DONALD B. ERTEL -S Date: 2025.06.17 13:02:03 -04'00' Hyesuk Kong -S Digitally signed by Hyesuk Kong -S Date: 2025.06.17 13:05:30 -04'00' KEVIN MATTHEWS -S Digitally signed by KEVIN MATTHEWS -S Date: 2025.06.17 13:13:43 -04'00'	Carl Perez, Consumer Safety Officer CDR Donald Ertel, Branch Chief Kevin Matthews, Consumer Safety Officer Hyesuk Kong, Biologist	06/17/2025

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c. Receipt and identification of samples is tracked in non-validated excel spreadsheet database with no data verification checks.

d. While observing test performance on June 17, 2025:

i. Container for in-use (b) (4) was observed to be mislabeled with erroneous lot number and expiration date.

ii. (b) (4) has no identification (b) (4)

e. Errors were discovered in multiple completed Master Mix Reaction Worksheet (Attachment A to SOP (b) (4) SOP008, Protocol for PCR Setup and Reporting of Results) without any corrections or secondary review.

OBSERVATION 5

Employee training and qualification is inadequate. Specifically, administrative staff member performs essential tasks such as (b) (4) with no evidence of training on updated procedures or non-existing procedures.

OBSERVATION 6

A quality agreement defining the roles and responsibilities of each involved party is not established. Specifically, there is no quality agreement established with (b) (4) regarding mycoplasma release testing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Digitally signed by Carl A. Perez -S Date: 2025.06.17 12:58:31 -04'00' Digitally signed by DONALD B. ERTEL -S Date: 2025.06.17 13:02:28 -04'00' Hyesuk Kong -S Digitally signed by Hyesuk Kong -S Date: 2025.06.17 13:06:16 -04'00' KEVIN MATTHEWS -S Digitally signed by KEVIN MATTHEWS -S Date: 2025.06.17 13:11:08 -04'00'	Carl Perez, Consumer Safety Officer CDR Donald Ertel, Branch Chief Kevin Matthews, Consumer Safety Officer Hyesuk Kong, Biologist	06/17/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."