Document Title:

Exact Sciences Laboratories Policy for COVID-19 Specimen Rejection

Policy

The Exact Sciences Laboratories policy for COVID-19 specimen rejection is that each patient specimen must meet the minimum requirements for patient identification, collection and transport in order to be tested by the clinical laboratory. Exact Sciences Laboratories (ES Labs) reserves the right to reject any specimens that do not meet the requirements set forth in this policy; the health care provider and/or its facility will be notified and patient recollection will be needed in these instances.

Purpose

The purpose of this policy is to establish a framework for COVID-19 specimen rejection practices which addresses regulatory requirements under the Clinical Laboratory Improvement Amendments (CLIA), College of American Pathologists (CAP), and state permits such as New York State Department of Health (NYSDOH).

Scope

This policy applies to clinical laboratory staff, most specifically, pre-processing & processing personnel, clinical laboratory management and the Medical Director. Only trained employees should execute this policy.

Definitions

Defined Term	Definition / Explanation
CAP	College of American Pathologists
CLIA	Clinical Laboratory Improvement Amendments
COVID-19	Coronavirus Disease 2019
ES Labs	Exact Sciences Laboratories
NYSDOH	New York State Department of Health

Responsibility

The Laboratory Director (or designee), SVP of Operations (or designee) and Non-technical leadership (or designee are responsible for oversight, and the Laboratory Director is responsible for biennial review of this policy.

Exceptions: Exact Sciences Corporate is not governed by this policy.

Supporting Documents

Table of Supporting Documents	
Document Title	**Document #**
COVID-19 Specimen Accessioning	SOP-2063
SARS-CoV-2 (N gene) Test Information for Laboratory Manuals (US)	FRM-2051-a
SARS-CoV-2 (E, N, RdRP gene) Test Information for Laboratory Manuals (US)	FRM-2051-b

Attachments

Attachment 1: COVID-19 Specimen Rejection Details

Revision History

Revision #	Revision Details
1.0	Initial document creation
2.0	Edits made to Attachment 1, aligned minimum requirements to be applicable to all specimens, removed discussion of exception handling.
2.1	Removed Exception Handling from the Title, Policy and Purpose sections.

Attachment 1: COVID-19 Specimen Rejection Details

Each COVID-19 specimen must meet the minimum requirements for patient identification, collection method & process, and appropriate transport in order to be tested by the clinical laboratory. Specimens that do not meet the below listed criteria will be rejected accordingly and the provider or submitter will be notified of the need for recollection.

Requirement: Specimen Identification

The following patient identifiers must be present: first name, last name and date of birth. Specimens will be rejected if these identifiers are not clearly evident from the collection device/tube, the paperwork or electronic information provided via interface.

Requirement: Specimen Collection

Specimens must be collected in manner appropriate for the type and consistent with the SARS-CoV-2 Test Information Laboratory Manuals (US).

Additionally, the following collection information must be present: date of collection and time of collection*. Specimens will be rejected if this information is not clearly evident from the collection device/tube, the paperwork, or electronic information provided via interface.

Requirement: Specimen Transport

Specimens will be rejected if they do not meet necessary temperature requirements for the collection device that was used for the specific specimen.

Additionally, specimens will be rejected if they are received in the following conditions:

- outside of the 72-hour stability requirement,
- the collection device is broken or leaking

** If the time of collection is not provided, the lab will default to 12:00am on the date of collection for stability determination.*