

ACCELERATING APPROVAL FOR SARS-COV-2 ANTIVIRALS WITH CONTRACT TESTING

INFECTIOUS AGENTS

SARS-COV-2 Omicron & Delta Variants

PRODUCT IN DEVELOPMENT

Antiviral

ASSAY SERVICES

TCID50, LOD, LLOQ

SCOPE

Five GCLP clinical trial test cycles with >3000 total patient samples tested for viral load and recovery of infectious virus.

OBJECTIVES

Demonstrate the efficacy of a novel antiviral compound to decrease viral load.

CHALLENGES

The client required a Contract Research Organization (CRO) partner capable of storing, processing, titrating, and propagating large sample quantities following GLP/GCLP procedures for patient anonymity, while rapidly and efficiently supplying assay data.

RESULTS

Meeting or exceeding all data delivery milestones, Microbiologics tested over 3,000 patient samples in our state-of-the-art BSL-3 laboratory with remarkable precision and efficiency. During the study, Microbiologics reduced the agreed upon turnaround time for QC reviewed data and QA reviewed data release by over 30%. Surpassing client expectations for assay success rates, Microbiologics helped the client clear this segment of the FDA approval process below budget and ahead of schedule.

>95%

passing rates for all our TCID50 clinical testing runs

>97%

passing rates for all our virus recovery and propagation runs

≤10%

sample retesting rates across all four clinical studies

100%

on time delivery for biweekly QC reviewed data release

100%

on time delivery for QA reviewed data to client database within 4 weeks