California Department of PublicHealth
Branch Laboratory

POWERED BY

PerkinElmer®

LDT Validation Summary

Valencia Branch Laboratory

24 MAY 2021

01

Regulations

Analytic Performance Specifications

Federal Regulations 42 CFR 493.1253 Standard: Establishment and verification of performance specifications

- Performance characteristics performed through EUA and LDT Validation

(i) Accuracy

Performed as a part of the LDT validation

(ii) Precision

Performed as a part of the LDT validation

(iii) Analytical sensitivity

Performed as part of the LDT validation

(iv) Analytical specificity to include interfering substances

Performed as a part of the EUA submission (Right to Reference)

(v) Reportable range of test results for the test system

Not applicable to this assay, qualitative test

(vi) Reference intervals (normal value)

Not applicable to this assay, qualitative test

(vii) Any other performance characteristic required for test performance

Bridging studies with MTM and VTM were performed

FDA Guidelines for Validation

Coronavirus EUA LDTs

(i) Limit of Detection

LoD finding studies determined 120 copies/mL as the LoD for the *N* and *ORF1ab* genes in this lab.

(ii) Clinical Evaluation

60 previously tested clinical samples (30 samples previously tested as negative and 30 previously tested as positive) were tested.

(iii) Inclusivity

Studies indicate target genes are *N* and *ORF1ab*.

(Right of reference)

(iv) Cross Reactivity

Cross-reactivity of the EUA Coronavirus Nucleic Acid Detection Kit was evaluated using both *in silico* analysis and by testing cross-reactivity test panels.

(Right of reference)

- CDPH guidelines lead to LDT validation
- Validation Report provides objective evidence that the assay is validated

EUA Verification to LDT Validation

Dilution

There was no change in dilutions.

AJ Thermocycler

AJ Thermocycler – authorized for use after original validation performed

Heat Inactivation

A heat inactivation process (70°C for 45 min) was added and validated to accommodate for future changes in transport media.

Reagent Changes

There were no reagent (chemistry) changes.

Equipment

No changes to extraction equipment.

Media

The media noted in the IFU is VTM. Bridge study demonstrated that performance equivalent when using MTM.

Verification & Requirements

Lab Director, CDPH Lab Directors, and CA-LFS determined necessary requirements

Data

Fulfillment of the requirements for laboratory licensure.

Ct Values

PKI scientific team made changes to positivity rate classification as per CDPH's directions.

RT-PCR

Analytik Jena qTower^{3}84G Real-Time PCR systems added to EUA by FDA .

Comparative Assay

Samples used in comparative assay tested for accuracy and precision for validation of EUA Coronavirus Kit.

Emergency Procurement

CHHS and CDPH determined type of collection kits, media, sample tubes based on Emergency Procurement supply chain availability, sample stability, and cost.

Federal Regulations 42 CFR 493.1253

MTM Qualification Heat Inactivation

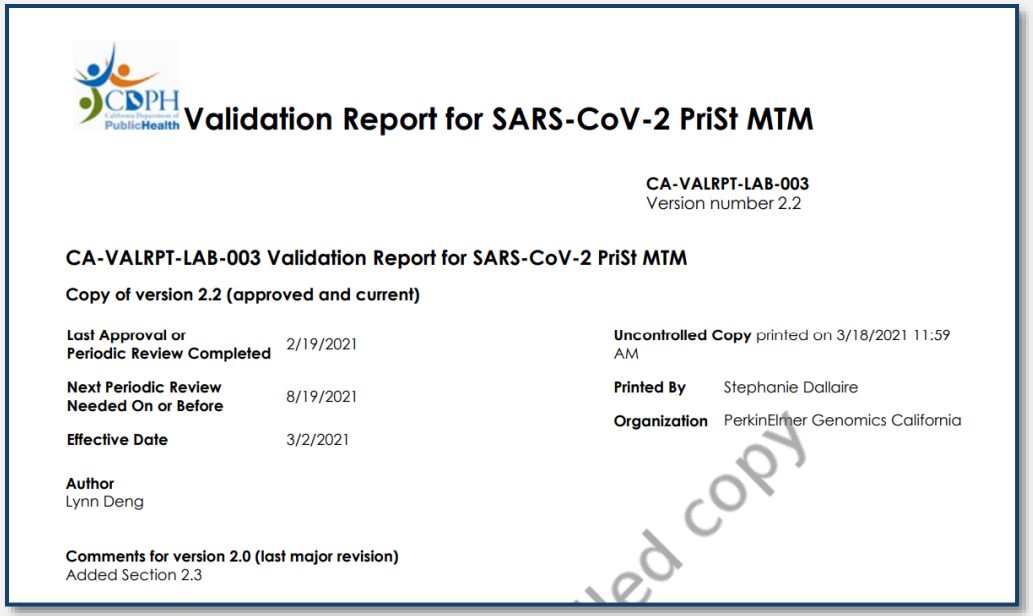
Contrived and Clinical Samples

Previously tested clinical samples

SeraCare AccuPlex SARS-CoV-2 controls

Bridging studies with MTM and VTM

Bridge studies on Heat Inactivation with MTM and VTM



CDPH Public Health

Validation Report for SARS-CoV-2 PriSt MTM

CA-VALRPT-LAB-003
Version number 2.2

CA-VALRPT-LAB-003 Validation Report for SARS-CoV-2 PriSt MTM

Copy of version 2.2 (approved and current)

Last Approval or Periodic Review Completed 2/19/2021

Next Periodic Review Needed On or Before 8/19/2021

Effective Date 3/2/2021

Author
Lynn Deng

Uncontrolled Copy printed on 3/18/2021 11:59 AM

Printed By Stephanie Dallaire

Organization PerkinElmer Genomics California

Comments for version 2.0 (last major revision)
Added Section 2.3

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (CDPH)
VALENCIA BRANCH LABORATORY (VBL)
LABORATORY DEVELOPED TEST (LDT) for SARS-CoV2 VALIDATION REPORT

Due to the FDA Guidelines for Covid-19 Pandemic, CDPH VBL is following these requirements by the FDA for EUA LDT

EMERGENCY USE AUTHORIZATION (EUA)

Validation Summary

Summary of Validation

Assay used in CDPH Valencia Branch Laboratory is a validated LDT

Performance of this LDT assay has been validated by establishing performance characteristics per 42 CFR Part 493, and by following FDA guidelines for validation of Coronavirus LDTs.