Policy for Changes to Test Interpretation

CA-RPT-POL-002
Version number 2.0

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Comments for version 2.0
Reworded 5.5 for clarity.

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	8/23/2021	2.0	Adam Rosendorff	
Approval	Quality Manager	8/23/2021	2.0	Lora J. H. Bean Lora Bean	
Approval	Lab Director	8/10/2021	1.0	Adam Rosendorff	
Approval	Quality Manager	8/10/2021	1.0	Lora J. H. Bean Lora Bean	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.0	Approved and Current	Major revision	8/23/2021	8/24/2021	Indefinite
1.0	Retired	Initial version	8/10/2021	8/10/2021	8/24/2021

Approved: 8/23/2021 by Adam Rosendorff

1. PURPOSE

1.1. The purpose of this document is to outline the policy for the Laboratory Director changing analytic criteria for laboratory diagnosis (e.g. Ct Cutoff) or medical interpretation of results at CDPH Branch Laboratory, Valencia CA.

2. SCOPE

1.2. This policy applies to the role of the Laboratory Director at CDPH Branch Laboratory, Valencia CA.

3. ROLES AND RESPONSIBILITIES

3.1. Laboratory Director or designee ensures laboratory performance and compliance with this policy.

4. DEFINITIONS

4.1. N/A

5. POLICY

The laboratory is a Branch Laboratory owned by the California Department of Public Health (CDPH). The Laboratory Director operates in collaboration with the CDPH Laboratory System to ensure consistent and relevant test interpretation and reporting. Therefore, in this capacity:

5.1 The Laboratory Director is the final approver for all reporting changes and interpretative decisions and enforces the associated documents, procedures, and the laboratory practices.

5.2 Any client request to change analytic threshold changes (i.e. Ct value) or medical interpretation must be evaluated for impact on patient care based on laboratory data, published studies, epidemiology data (e.g. prevalence of infection), or consensus of the professional community. The Laboratory Director ensures that the laboratory follow all required validation testing, justification of clinical appropriateness and impact, as well as document control procedures relevant to the requested changes.

5.3 Changes to analytic threshold or medical interpretation will continue to be recorded in CA-RPT-SOP-002 Analysis and Reporting of SARS-CoV-2 Assay

5.4 The Laboratory Director determines required training for the laboratory personnel required due to implemented changes.

5.5 The Laboratory Director is responsible for notifying the ordering provider.

6. REFERENCE DOCUMENTS

6.1. CFR 493.1445 -Standard; Laboratory Director Responsibilities

6.2. College of American Pathologists, TLC.10475 Laboratory Director Checklist

6.3. CA-RPT-SOP-002 Analysis and Reporting of SARS-CoV-2 Assay

7. REVISION HISTORY

Version	Summary of Changes	Date
2	Re-worded 5.5 for clarity	23Aug2021
1	New document.	August 2021