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1. HISTORICAL REVISION SUMMARY

Table 1. Chronological Summary of Previous Versions

Version #	Effective Date	Originator	Summary
4.0	Current	(b) (6)	Updated to accommodate the transition from LIMS v6 to LIMS v8 and the addition of a new (b) (4)
3.0	04-Sep-2019	(b) (6)	Updated to accommodate procedures for new (b)(4) method and paperless processes
2.0	10-Mar-2017	(b) (6)	Updated references section
1.0	16-Jan-2017	(b) (6)	New Document

2. PURPOSE

This document describes the data review process for all Direct Luminex Immunoassay (dLIA) data packages or electronic batches that utilize Vaccine Research & Development (VRD) LabWare Laboratory Information Management System (LIMS) version 8 (v8) or a subsequent version of VRD LabWare LIMS.

3. SCOPE

This procedure applies to VRD personnel who perform data review for Direct Luminex Immunoassays in support of clinical and non-clinical studies. The calculation of assay results and the transfer of these results to VRD LabWare LIMS v8, or subsequent versions, for authorization are in the scope of the procedure. For the remainder of this document, the term VRD LabWare LIMS is inclusive of v8 through the most current version of LIMS.

Table 2. Vaccine Research Functional Units

Functional Units	Location
Vaccine Research & Development	Pearl River

4. GLOSSARY

Table 3. Terms and Definitions

TERM	DEFINITION
Assay Plate	96-well microtiter plate used to perform the Luminex assay
Batch	(b) (4)
Bio-Plex	Bio-Rad proprietary Luminex Suspension Array System and Software
BLQ	Below Limit of Quantitation

Table 3. Terms and Definitions

TERM	DEFINITION
CSV	Comma-separated values file
DAP	Data Analysis Portal
dLIA	Direct Luminex ImmunoAssay
(b) (4)	
Lab Authorize	The action to approve the data results in VRD LabWare LIMS
LDR	Laboratory Deviation Report
LIMS	Laboratory Information Management System
LLOQ	Lower limit of Quantitation
Metadata	Assay-related information captured in VRD LabWare LIMS (eg, reagents, equipment, instruments)
MFI	Median Fluorescent Intensity
NR	Not Reported or Not Reportable
QCS	Quality Control Serum
QNS	Quantity Not Sufficient
(b) (4)	
RSS or STD	Reference Standard Sample
SAS	Statistical Analysis System

5. GENERAL

The dLIA measures antigen-specific antibodies in unknown serum samples. Specific antibodies from the serum samples are detected using (b)(4) reporter antibody. The fluorescence signal is directly proportional to the amount of antigen specific antibodies present in the serum.

- For assay plates prepared with the (b)(4) or (b)(4) methods, (b) (4) is equivalent to one batch.
- For assay plates prepared with the (b)(4) method, one batch contains (b) (4) (b) (4)
- For clinical and toxicology studies, the data reviewer must be qualified on this procedure and NOT be the same analyst who has performed laboratory activities (eg, robot operator) to generate the raw data and/or who has carried out the primary documentation review, if required, upon completion of the appropriate test method.
- It is acceptable for the data reviewer to sign off on batch-related comments in VRD LabWare LIMS when necessary.

- Following the successful upload of raw data, the results are calculated in Pfizer's proprietary SAS®-based data analysis program. The results output file is examined, and the data is entered into VRD LabWare LIMS. The data reviewer verifies that the results are correctly entered and authorizes the batch results in VRD LabWare LIMS.

- In the event that VRD LabWare LIMS is unavailable, sample preparation and assay completion worksheets should be filled out to capture the required metadata. These worksheets must be scanned into VRD LabWare LIMS and associated with the appropriate batch(es) during the data review procedures.

6. RESPONSIBILITIES

- All personnel and positions referred to in this procedure are considered to have an alternate.

- An alternate must ensure that they are trained and knowledgeable with the process.

Table 4. Roles and Responsibilities

Role	Responsibilities
Analyst	• Ensures the authenticity, integrity, completeness, accuracy, quality and compliance of dLIA meta-data.
Data Reviewer	• Ensures the authenticity, integrity, completeness, accuracy, quality and compliance of dLIA meta-data. • Processes data with Pfizer's proprietary, custom SAS® program. • Performs results entry in VRD LabWare LIMS. • Creates replicate tests in VRD LabWare LIMS. • Performs lab authorization of batches in VRD LabWare LIMS. • Initiates LDRs, as required.
Supervisor	• Ensures that the data reviewer is properly trained on the appropriate SOPs. • Ensures all LDRs associated with data packages are closed in the appropriate time frame.

7. SAFETY

N/A

8. MATERIALS/EQUIPMENT

8.1. Hardware

- Computer

8.2. Software

- Active Pfizer Computer Account
- VRD LabWare LIMS user account with a Lab Reviewer or Lab Manager role; access to VRD LabWare LIMS production environment
- Access to the appropriate assay specific link(s) in the Data Analysis Portal

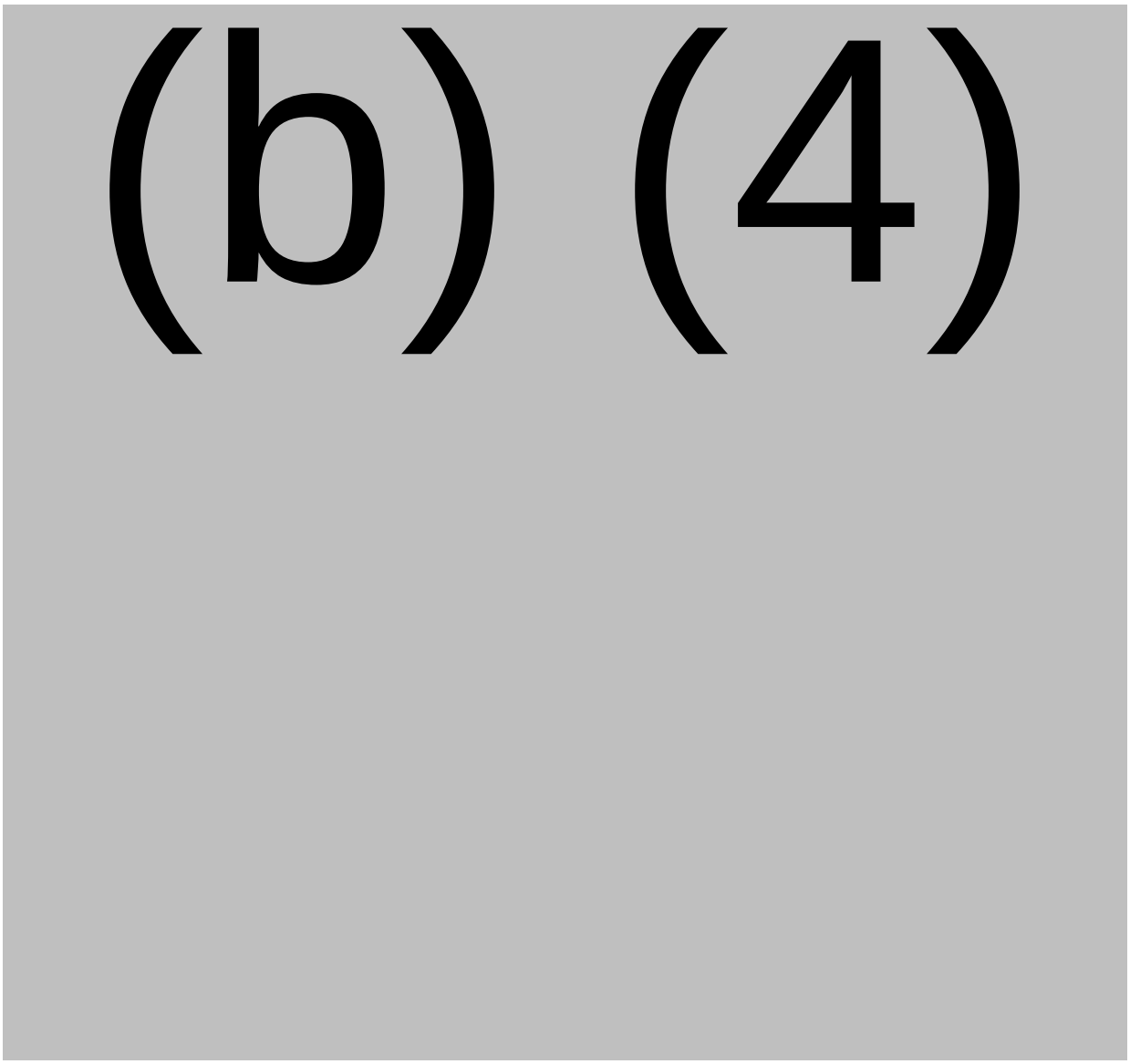
9. PROCEDURE

Data review encompasses three major tasks:

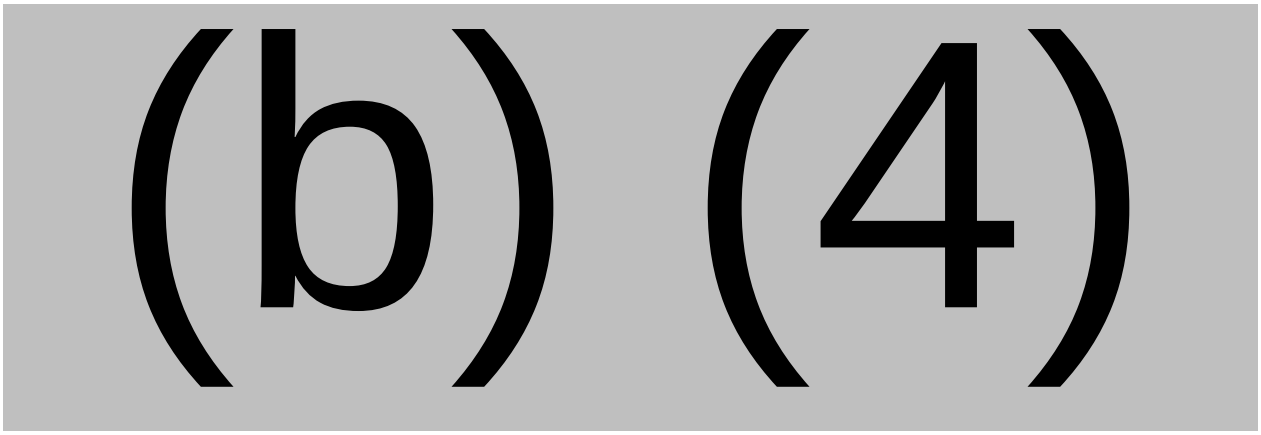
- Review of metadata entered in VRD LabWare LIMS; in the event that VRD LabWare LIMS is unavailable for metadata entry, the data reviewer should review the sample preparation and assay completion worksheets
- Calculation of Assay Results
- Upload of Assay Results to VRD LabWare LIMS and review of Assay Results in VRD LabWare LIMS

9.1. Review of VRD LabWare LIMS Metadata

(b) (4)



9.2. Calculation of Assay Results – SAS Analysis



(b) (4)

9.3. Assay Results Review

(b) (4)

(b) (4)

(b) (4)

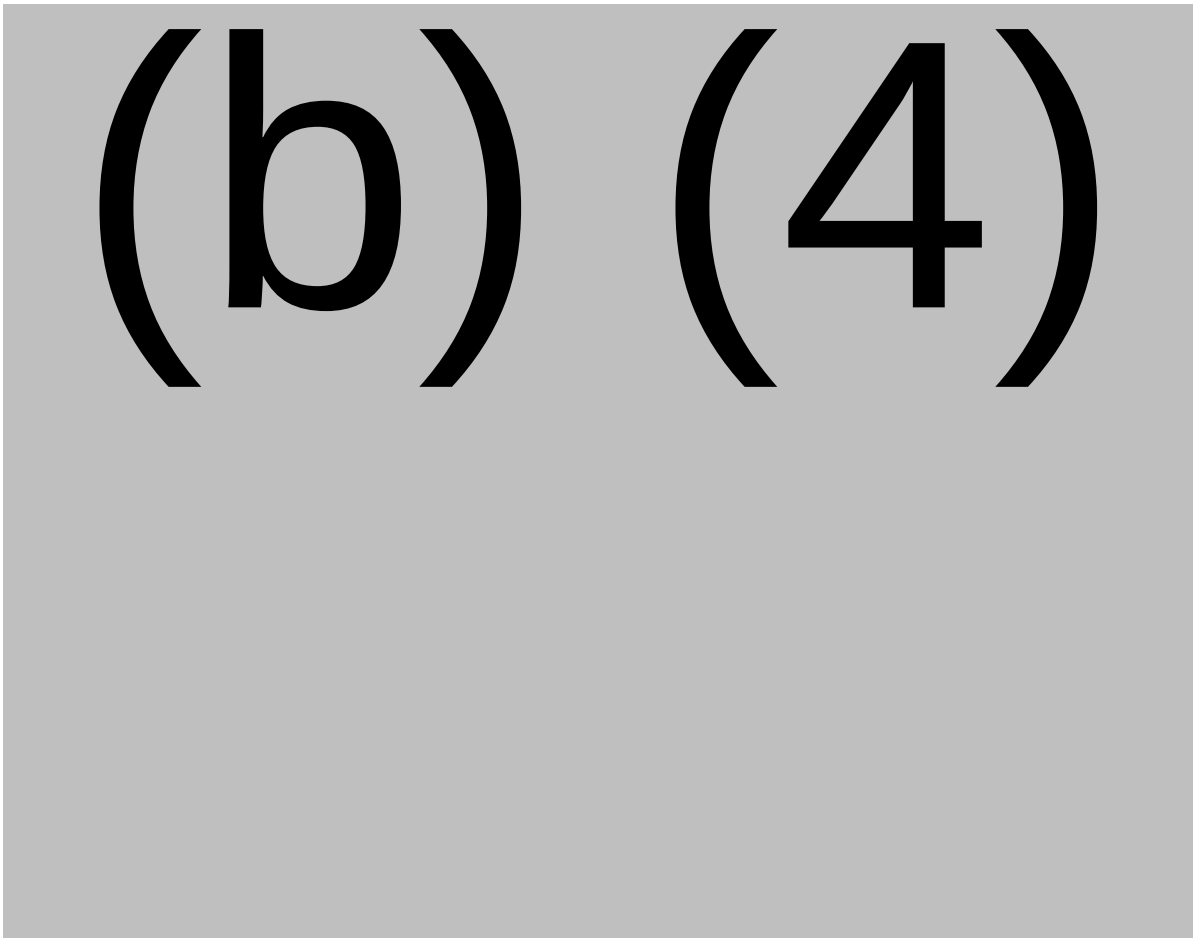


Table 5. Review Rules for Repeat Tests

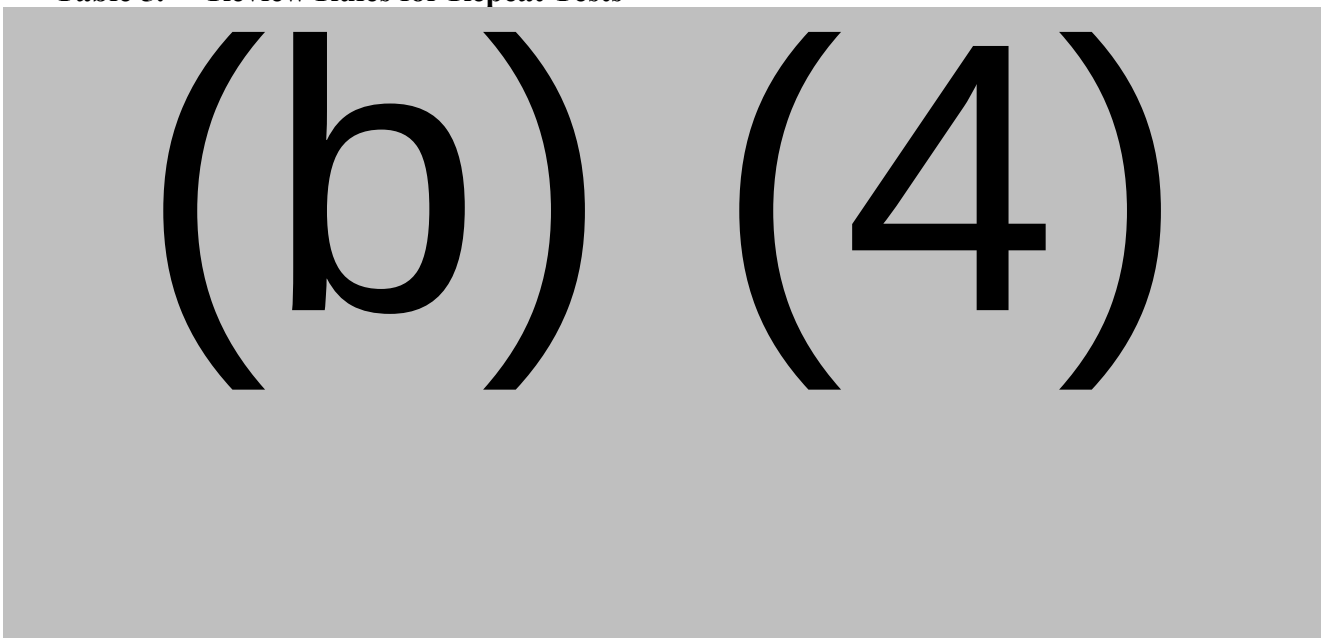


Table 5. Review Rules for Repeat Tests

(b) (4)

9.4. VRD LabWare LIMS

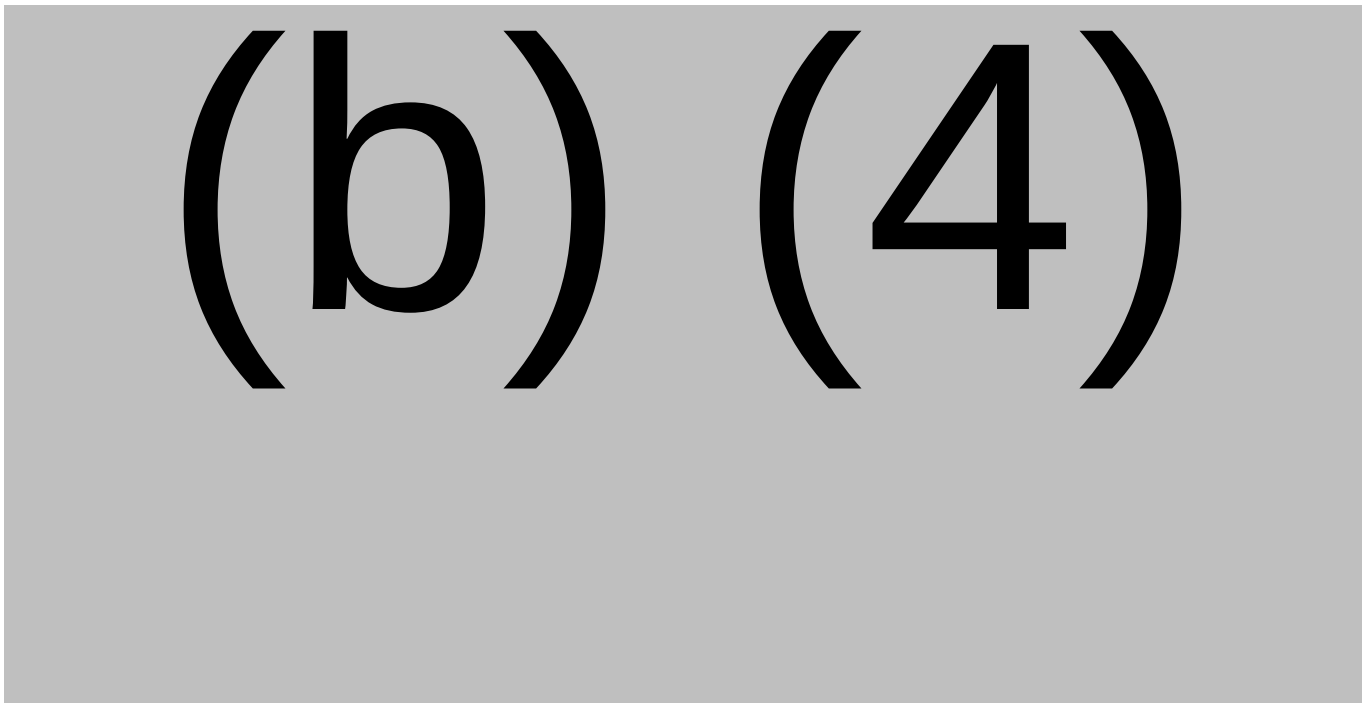
(b) (4)

(b) (4)

9.4.2. Result Review

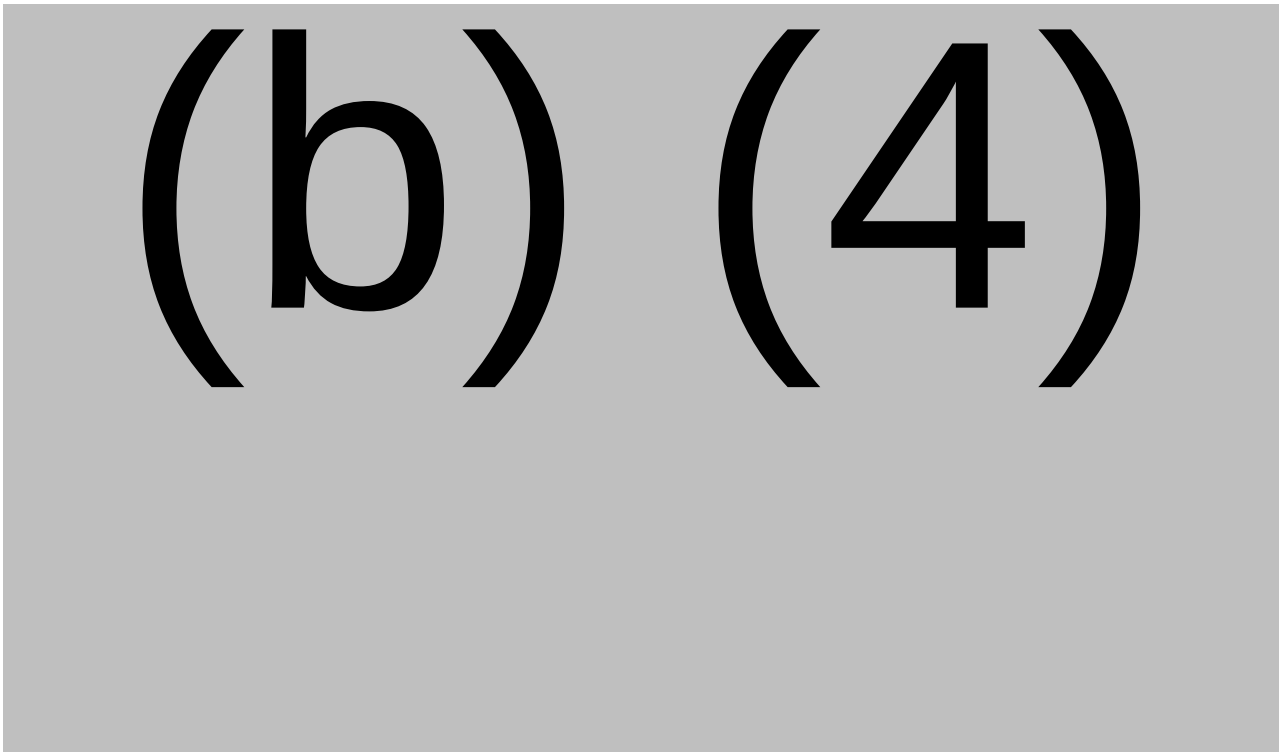
(b) (4)

(b) (4)



9.4.5. Secondary Data Check

Prior to lab authorization, a secondary data reviewer should verify the information associated with each batch to ensure completeness. Secondary review should be completed within three weeks of the completion of data review. The secondary data reviewer must not be the analyst who performed the sample preparation, assay completion or the initial data review.



(b) (4)

9.4.6. Lab Authorization

(b) (4)

9.5. Deviations

Refer to VR-SOP-QU-10726 for Laboratory Deviations. (b) (4)

10. REFERENCES

Table 6. General References

Document	Title
VR-SOP-QU-10004	Documentation Practices in Vaccine Research
VR-TM-10148	(b) (4)
VR-TM-10152	
VR-TM-10199	
VR-TM-10200	
VR-TM-10207	
VR-TM-10215	
VR-TM-10220	
VR-TM-10225	
VR-TM-10260	
VR-TM-10265	
VR-TM-10274	
VR-TM-10293	Single-plex Luminex Assay for Quantitation of IgG Antibodies to SARS-CoV-2 S1 Protein in Human Serum
VR-TM-10294	Single-plex Luminex Assay for Quantitation of IgG Antibodies to SARS-CoV-2 RBD Protein in Human Serum
VR-TM-10309	Single-plex Luminex Assay for Quantitation of IgG Antibodies to SARS-CoV-2 Spike Protein in Human Serum

Table 7. Form References

Form	Title
N/A	N/A

Table 8. Specific References

Document	Title
VR-SOP-QU-10726	Laboratory Deviation Report

11. DOCUMENT VERSION MODIFICATIONS

11.1. CRIF Number: VR-CRIF-20-14684

Table 9. Detailed Changes

List detailed changes for document(s) Include section number(s) for each	List rationale for each change
Throughout Document: Removed references to LabWare v6 LIMS	LabWare v6 LIMS has been updated to LabWare v8 LIMS. For the purposes of this document, the term VRD LabWare LIMS refers to version 8.0 and all subsequent versions.
5.0 General: Removed reference to (b)(4) method	The (b)(4) sample prep method has been decommissioned.
9.3 Assay Results Review: Added detailed list of (b) (4)	All (b) (4) have been defined in detail, including the circumstances under which they should be triggered by SAS.
9.3 Assay Results Review: Added review rules associated with (b) (4)	(b) (4) is a new (b) (4) therefore specific review rules had not yet been defined.
9.4.2 Result Review: Included detailed steps associated with manual rejection of individual tests	Detailed instructions associated with manual rejection of individual tests had not previously been defined.
9.4.2 Result Review: Included detailed steps associated with manual entry of results	Detailed instructions associated with manual entry of results had not previously been defined.
9.4.5 Secondary Data Check: Included steps associated with a secondary data check	Instructions associated with a secondary data check had not previously been defined.
10.0 References: Added new test methods to the reference section	New assays have been qualified since the last update of this document.

Document Approval Record

Document Name:	VR-SOP-LC-11120
Document Title:	Data Review Procedures for Direct Luminex Immunoassays in VRD La Ware LIMS

Signed By:	Date(GMT)	Signing Capacity
Cooper, David	01-Dec-2020 19:06:24	Final Approval
(b) (6)	01-Dec-2020 19:16:53	Business Line Approver
(b) (6)	01-Dec-2020 21:29:57	Quality Assurance Approval
(b) (6)	14-Dec-2020 22:24:16	Business Line Approver
(b) (6)	16-Dec-2020 23:48:19	Final Approval
(b) (6)	17-Dec-2020 17:55:54	Manager Approval
(b) (6)	18-Dec-2020 15:06:09	Author Approval