TABLE OF CONTENTS

LIST OF TABLES

1. HISTORICAL REVISION SUMMARY

Table 1. Chronological Summary of Previous Versions

Version #	Effective Date	Originator	Summary
3.0	Current	(b) (6)	Updated to accommodate procedures for new (b) (4) method and paperless processes.
2.0	10-Mar-2017		Updated references section.
1.0	16-Jan-2017		New Document

2. PURPOSE

This document describes the data review process for all Direct Luminex Immunoassay data packages that utilize LabWare v6 LIMS.

3. SCOPE

This procedure applies to the Vaccine Research & Development (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 LabWare v6 LIMS for authorization are in the scope of the procedure.

Table 2. Vaccine Research Functional Units

Functional Units	Location
Vaccine Research & Development	Pearl River

4. GLOSSARY

Table 3. Terms and Definitions

Term	Definition
CSV	comma-separated values file
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
DAP	Data Analysis Portal
dLIA	Direct Luminex ImmunoAssay
Lab Authorize	The action to approve the data results in LabWare v6 LIMS
LDR	Laboratory Deviation Report

Table 3. Terms and Definitions

Term	Definition
LIMS	Laboratory Information Management System
LLOQ	Lower limit of Quantitation
Metadata	Assay-related information captured in LabWare LIMS (e.g. reagents, equipment, instruments)
MFI	Median Fluorescent Intensity
QCS	Quality Control Sample
QNS	Quantity Not Sufficient
(b) (4)	
RSS or STD	Reference Standard Sample

5. GENERAL

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

- For assay plates prepared with the (b) (4) methods, (b) (4) assay plate is equivalent to one batch.
- For assay plates prepared with the (b) (4) method, (b) (4) batch contains up to (b) (4) assay plates.
- 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 LabWare v6 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 LabWare v6 LIMS. The data reviewer verifies that the results are correctly entered and authorizes the results in LabWare v6 LIMS.
- In the event that LabWare v6 LIMS is unavailable, sample preparation and assay completion worksheets should be filled out to capture the required metadata. These worksheets must be scanned into LabWare v6 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 data.
Data Reviewer	• Ensures the authenticity, integrity, completeness, accuracy, quality and compliance of dLIA data. • Processes data with Pfizer's proprietary, custom SAS® program. • Performs results entry in LabWare v6 LIMS. • Creates replicate tests in LabWare v6 LIMS. • Performs lab authorization of batches in LabWare v6 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 prior to final QA authorization.

7. SAFETY

N/A

8. MATERIALS/EQUIPMENT

8.1. Hardware

- Computer

8.2. Software

- Active Pfizer Computer Account.
- LabWare v6 LIMS user account with a Data Reviewer or Lab Manager role; access to LabWare v6 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 LabWare v6 LIMS; in the event that LabWare v6 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 LabWare v6 LIMS and review of Assay Results in LabWare v6 LIMS

9.1. Review of LabWare v6 LIMS Metadata

(b) (4)

(b) (4)

9.2. Calculation of Assay Results – SAS Analysis

(b) (4)

9.3. Assay Results Review

(b) (4)

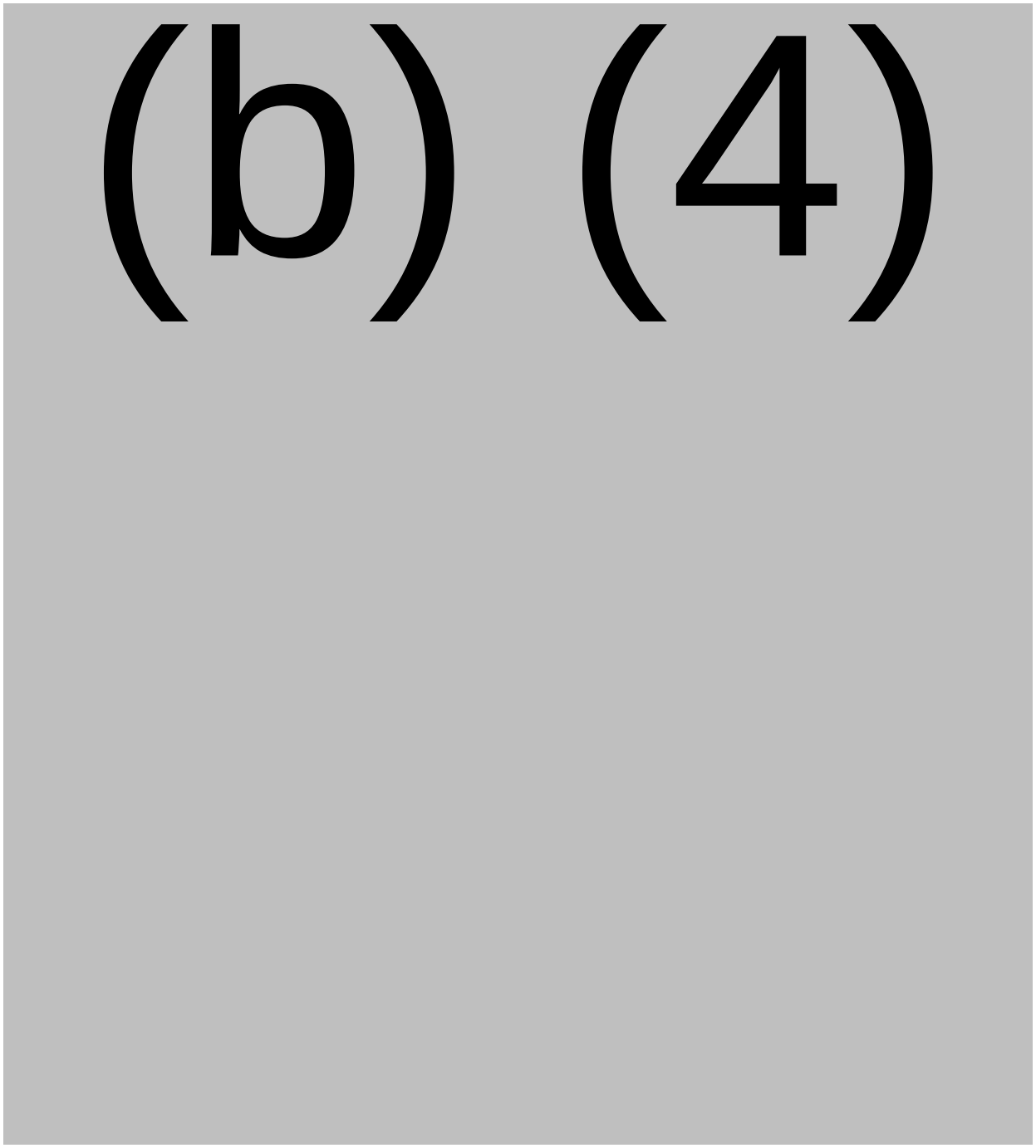


Table 5. Review Rules for Repeat Tests

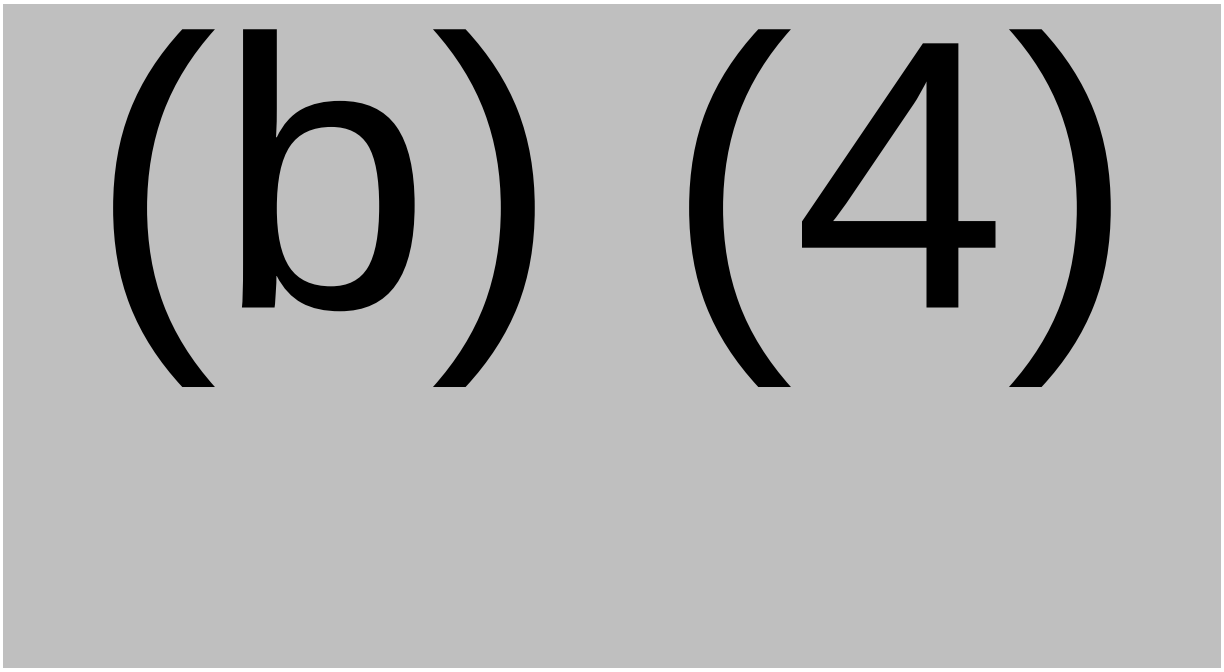
(b) (4)

9.4. LabWare v6 LIMS

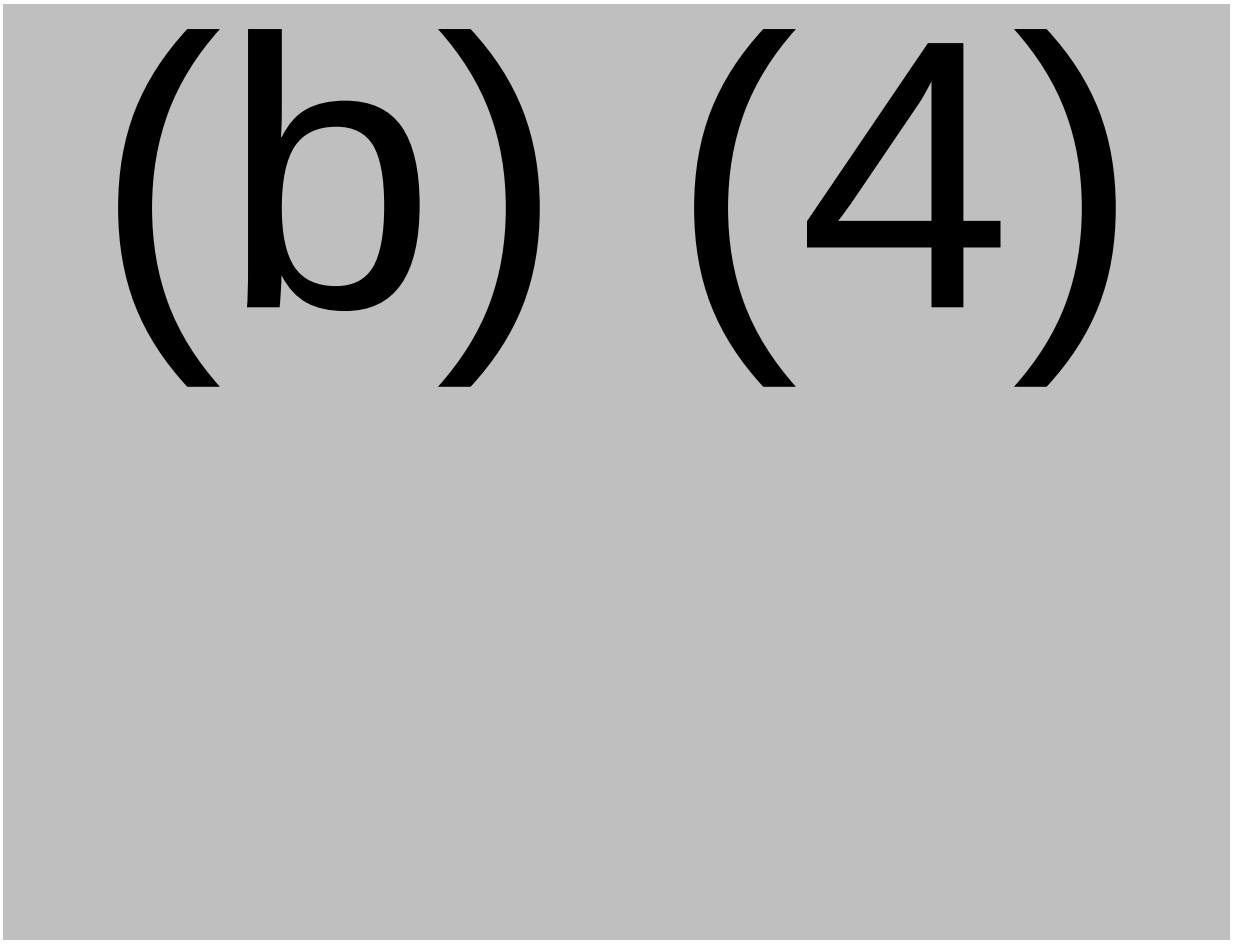
(b) (4)

9.4.1. Upload of SAS Results

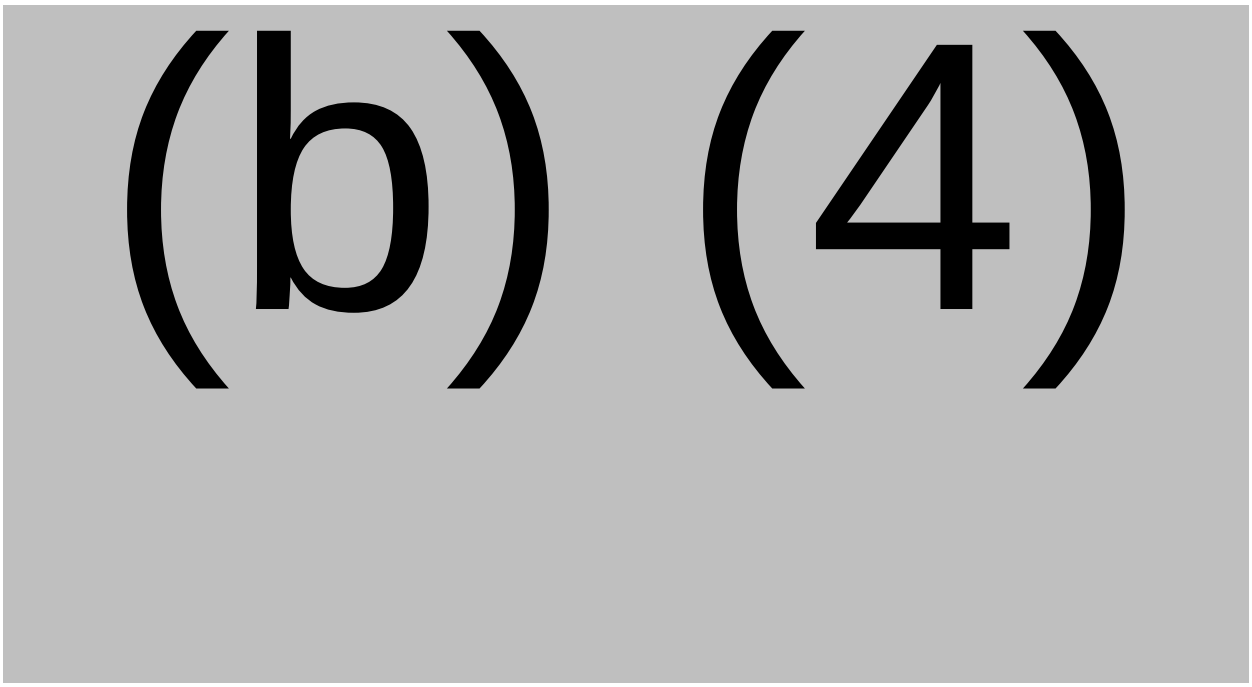
(b) (4)



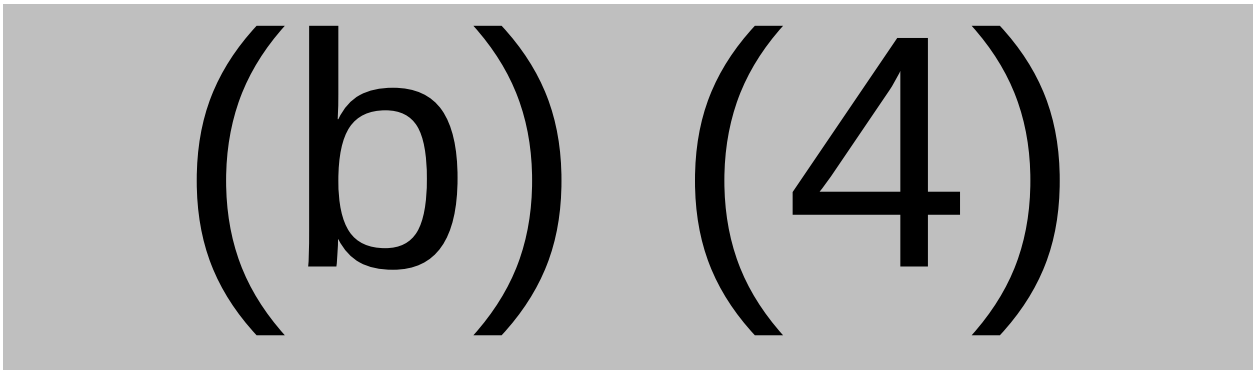
9.4.2. Result Review



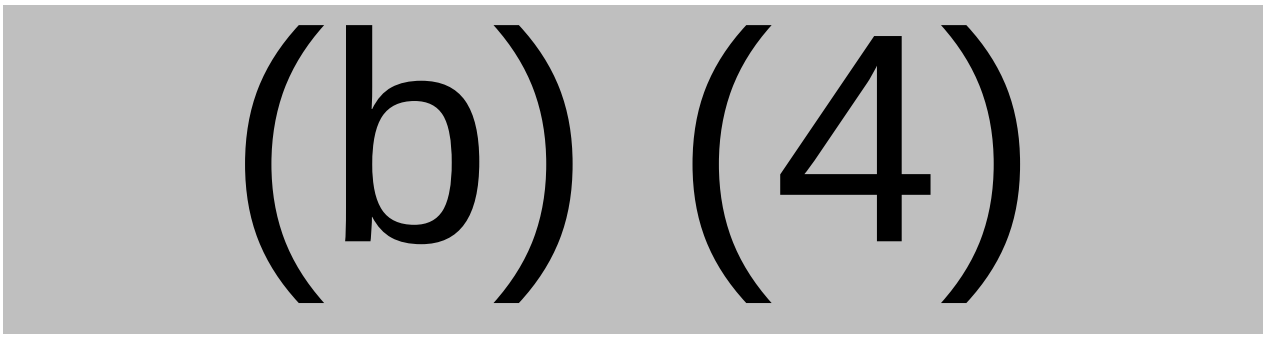
9.4.3. Apply Single Repeat Code

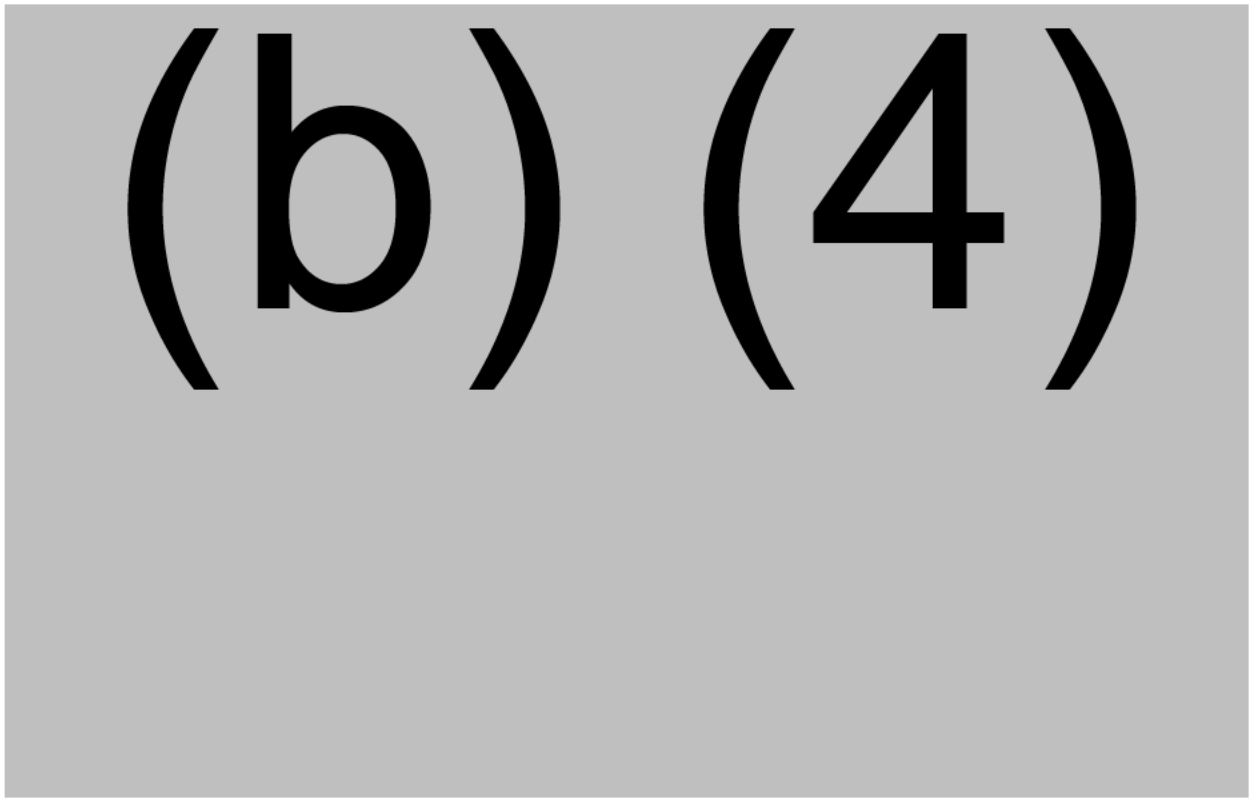


9.4.4. Complete Batch and Create Replicates



9.4.5. Lab Authorization





9.5. Deviations

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

10. REFERENCES

Table 6. General References

Document	Title
VR-SOP-QU-10004	(b) (4)
VR-TM-10148	
VR-TM-10152	
VR-TM-10199	
VR-TM-10200	
VR-TM-10207	
VR-TM-10215	
VR-TM-10220	

Table 6. General References

Document	Title
VR-TM-10225	(b) (4)
VR-TM-10260	
VR-TM-10265	
VR-TM-10274	

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-19-14295

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 QA	QA is no longer involved in review of dLIA data.
4. Glossary: Added metadata to list of terms	Metadata had not been appropriately defined.
5. General: Added clarification as to how many plates can be within each batch.	(b) (4) create (b) (4) assay plate per batch; while (b) (4) creates up to (b) (4) assay plates per batch.
9.3 Assay Results Review: Clarified appropriate review rules	Provided more detail for review associated with certain repeat codes; removed out of date repeat codes from the list
9.4.3 Apply Single Repeat Code: Indicated appropriate procedure	New functionality for data reviewers in LabWare v6 LIMS.
10. References: Updated general and form references tables	Updated to include appropriate test methods and forms.

Document Approval Record

Document Name:	VR-SOP-LC-11120
Document Title:	Data Review Procedures for Direct Luminex Immunoassays in LIMS v 6

Signed By:	Date(GMT)	Signing Capacity
(b) (6)	28-Aug-2019 19:15:11	Business Line Approver
Jones, Thomas	28-Aug-2019 20:02:26	Manager Approval
(b) (6)	28-Aug-2019 20:20:46	Final Approval
(b) (6)	29-Aug-2019 02:50:44	Author Approval