

**DUKE****DOCUMENT NUMBER:** COMM-QA-016 FRM2**DOCUMENT TITLE:**

Weekly QC Document Control FRM2

DOCUMENT NOTES:**Document Information****Revision:** 04**Vault:** COMM-QA-rel**Status:** Release**Document Type:** COMM-QA**Date Information****Creation Date:** 12 Jul 2021**Release Date:** 01 Sep 2021**Effective Date:** 01 Sep 2021**Expiration Date:****Control Information****Author:** LE42**Owner:** RB232**Previous Number:** COMM-QA-016 FRM2 Rev 03 **Change Number:** COMM-CCR-189

COMM-QA-016 FRM2

Weekly QC Document Control

Site/Location:	Month:	Year:
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Document #	Revision #	Effective Date	Document Type				Prior versions have been destroyed			Date/Initials <small>Current: First date location staffed. New/ Revised: Effective Date or a comment is required</small>
			Current	New	Revised	Archived	Current/New N/A	Revised/Archived Yes	No	
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Weekly Verification – All Printed documents are verified as the current, released version from MasterControl?				
<u>Week 1</u> <input type="checkbox"/> Yes <input type="checkbox"/> No, DEV #:	<u>Week 2</u> <input type="checkbox"/> Yes <input type="checkbox"/> No, DEV #:	<u>Week 3</u> <input type="checkbox"/> Yes <input type="checkbox"/> No, DEV #:	<u>Week 4</u> <input type="checkbox"/> Yes <input type="checkbox"/> No, DEV #:	<u>Week 5</u> <input type="checkbox"/> NA <input type="checkbox"/> Yes <input type="checkbox"/> No, DEV #:
Date/Initials:	Date/Initials:	Date/Initials:	Date/Initials:	Date/Initials:

Monthly Review: _____ QSU Review: _____

Comments: _____

Summary – Use of this Form

This form is a monthly record of all forms currently printed and in-use, plus a record of any new or revised forms that go into use during the month. This is intended to prevent the use of any expired form, and to confirm that new or revised forms go into use on their Effective Date. Also, any Deviation relevant to a listed form is referenced on this form.

Instructions for Completing Weekly QC Document Control

In this field...	Record
Site/Location:	Record collection site name, laboratory location, or work area containing pre-printed documentation.
Month:	Record current month.
Year	Record current year.
Document #	Record SOP number (including FRM number) for any document that is printed in advance when it is not possible to print on an as-needed basis. All currently in-use documents should be listed each month, as well as any New or Revised document that go into effect during the month.
Revision #	Record current Revision number of referenced document.
Effective Date	Record Effective Date for referenced document.
Document Type	<ul style="list-style-type: none"> For a document currently in use without revision, check Current. For a new document put into effect during this month, check New. For a document that has been revised and put into effect during this month, check Revised. For a document that has been archived, check Archived.
Prior versions have been destroyed	<ul style="list-style-type: none"> If this document type is Current or New, check NA. If this document type is Revised or Archived, destroy all copies of the prior version. Check Yes to confirm that all previous versions at site have been destroyed on this new form's Effective Date. If previous version is not destroyed on the new form's Effective Date, check No and record a comment and/or Deviation number under Weekly Verification for this week.
Date/Initials	Date and initial for review of the associated document. If the document type is New or Revised, this date must match Effective Date for the document. If this date does not match, a comment is required to explain the difference, and a deviation may be required. If this document is Current (currently in use at site), this date should be the first day of the month when the collection site, lab, or work area is staffed.
Weekly Verification	Weekly, verify that all printed documents are the current, released version from MasterControl as listed in the table and that all previous versions were destroyed. If no, list deviation number.
Monthly Review:	The monthly review will be performed by the supervisor or designee. Initial and date.

COMM-QA-016 FRM2 – Example Weekly QC Document Control

Site/Location: <i>CCBB Laboratory Distribution Area</i>	Month: <i>September</i>	Year: <i>2020</i>
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Document #	Revision #	Effective Date	Document Type				Prior versions have been destroyed			Date/Initials <small>Current: First date location staffed. New/ Revised: Effective Date or a comment is required</small>
			Current	New	Revised	Archived	Current/New N/A	Revised/Archived Yes	No	
<i>CCBB-DIST-004 FRM2</i>	<i>03</i>	<i>02/08/2017</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>SR 09/01/2020</i>
<i>CCBB-DIST-004 FRM3</i>	<i>02</i>	<i>01/01/2015</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>SR 09/01/2020</i>
<i>CCBB-DIST-012 FRM3</i>	<i>03</i>	<i>10/01/2012</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>SR 09/01/2020</i>
<i>CCBB-DIST-012 JA3</i>	<i>04</i>	<i>10/01/2012</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>SR 09/01/2020</i>
<i>CCBB-DIST-012 JA7</i>	<i>01</i>	<i>05/30/2012</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>SR 09/01/2020</i>
<i>CCBB-DIST-012 JA8</i>	<i>01</i>	<i>02/01/2013</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>SR 09/01/2020</i>
<i>CCBB-DIST-012 JA9</i>	<i>02</i>	<i>06/17/2016</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>SR 09/01/2020</i>
<i>CCBB-DIST-035 JA1</i>	<i>01</i>	<i>09/06/2016</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>SR 09/01/2020</i>
<i>CCBB-DIST-035 JA2</i>	<i>01</i>	<i>09/10/2020</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>RG 09/10/2020</i>
<i>CCBB-DIST-004 FRM2</i>	<i>04</i>	<i>09/20/2020</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>RG 09/21/2020</i>
<i>CCBB-DIST-004 FRM3</i>	<i>03</i>	<i>09/27/2020</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>RG 09/27/2020</i>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Weekly Verification – All Printed documents are verified as the current, released version from MasterControl?				
<u>Week 1</u> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No, DEV #:	<u>Week 2</u> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No, DEV #:	<u>Week 3</u> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No, DEV #: 0686	<u>Week 4</u> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No, DEV #:	<u>Week 5</u> <input checked="" type="checkbox"/> NA <input type="checkbox"/> Yes <input type="checkbox"/> No, DEV #:
Date/Initials: <i>KV 09/07/2020</i>	Date/Initials: <i>KV 09/14/2020</i>	Date/Initials: <i>KV 09/21/2020</i>	Date/Initials: <i>KV 09/28/2020</i>	Date/Initials: <i>KV 10/01/2020</i>

Monthly Review: *KV 10/01/2020* QSU Review: *LE 10/03/2020*

Comments: *Prior version of CCBB-DIST-004 FRM2 not destroyed on effective date of new version, See Dev-0686 for details.*

Signature Manifest**Document Number:** COMM-QA-016 FRM2**Revision:** 04**Title:** Weekly QC Document Control FRM2**Effective Date:** 01 Sep 2021

All dates and times are in Eastern Time.

COMM-QA-016 FRM2 Weekly QC Document Control FRM2**Author**

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Lisa Eddinger (LE42)		02 Aug 2021, 09:35:42 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		02 Aug 2021, 09:58:18 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Richard Bryant (RB232)		02 Aug 2021, 10:15:08 AM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandra Mulligan (MULLI026)		18 Aug 2021, 08:30:40 PM	Approved