



21120.554 Real-time PCR and RT-PCR Results Calculation and Rounding 2.0

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Copy of version 2.0 (approved and current)

Last Approval or
Periodic Review Completed 04-Jun-2020

Next Periodic Review
Needed On or Before 04-Jun-2021

Effective Date 10-Jun-2019

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Printed By (b) (6)

Organization Viracor

Comments for version 2.0

- Removed IBT from company
- Updated for new (HTLV on DNA Blood Mini platform) and discontinued assays (HBV on Qiagen platform, and RVP on Luminex platform)

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Periodic review	(b) (6)	04-Jun-2020 16:40	2.0	(b) (6)	
Approval	(b) (6)	03-Jun-2019 6:32	2.0	(b) (6)	
Approval	(b) (6)	30-May-2019 16:02	2.0	(b) (6)	
Approval	(b) (6)	28-May-2019 7:59	2.0	(b) (6)	

(b) (6)					
Periodic review	(b) (6)	14-Mar-2019 11:42	1.3	(b) (6)	
Periodic review	(b) (6)	13-Mar-2018 19:01	1.3	<div>(b) (6)</div> <div>SOP needs updated to refer only to current assays.</div>	
(b) (6)					
Periodic review	(b) (6)	08-Mar-2017 9:00	1.3	(b) (6)	
Periodic review	(b) (6)	16-Mar-2016 11:09	1.3	(b) (6)	
Periodic review	(b) (6)	18-Mar-2015 9:52	1.3	(b) (6)	
Periodic review	(b) (6)	05-Mar-2014 11:23	1.1	(b) (6)	
Periodic review	(b) (6)	04-Mar-2013 16:06	1.0	(b) (6)	
Approval	(b) (6)	05-Mar-2012	1.0	(b) (6)	Recorded when document uploaded to (b) (4)

Approvals and periodic reviews that occurred before this document was added to the (b) (4) Document Control system may not be listed.

Prior History

Migrating into (b) (4). Format changes and removal of (b) (4) numbers.

Replaces QS-Post-001 V2.0 (503003.001 v9) Entry into (b) (4) system. Updated for new HCV reporting ranges and deletion of discontinued assays.

Replaces QS-Post-0001 V5.0, (503003.001) Updated with new correction factor for bone marrow processing changes and clarification of resulting of qualitative and quantitative tissue results.

3/6/2013 - Replaced with current document (incorrect version was uploaded). This version of the document was approved by correct approvers and training was completed by appropriate associates.

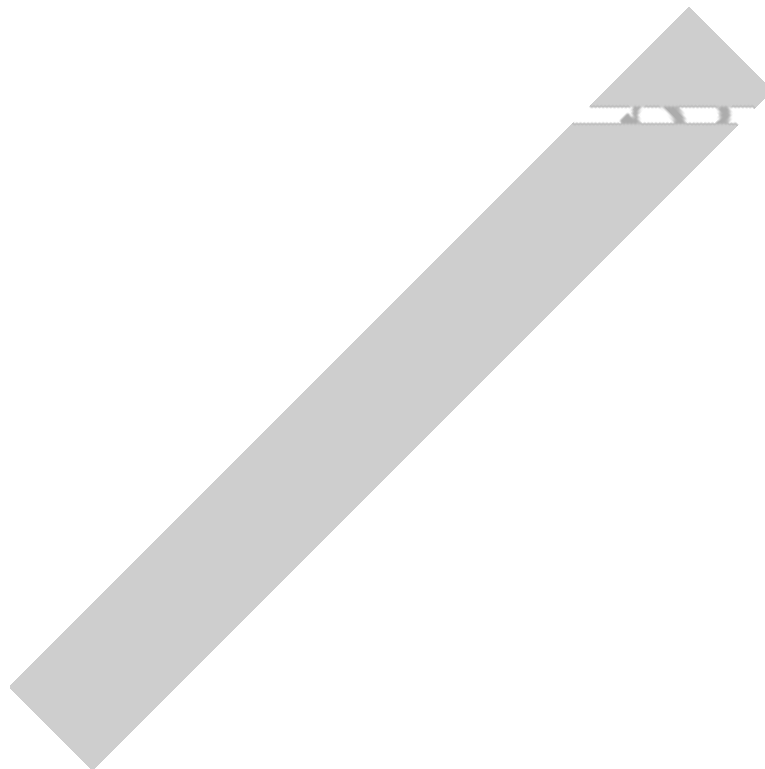
Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.0	Approved and Current	Major revision	27-May-2019	10-Jun-2019	Indefinite
1.3	Retired	Minor revision	01-Jul-2014	01-Jul-2014	10-Jun-2019

1.2	Retired	Minor revision	01-Jul-2014	01-Jul-2014	01-Jul-2014
1.1	Retired	Minor revision	06-Mar-2013	06-Mar-2013	01-Jul-2014
1.0	Retired	First version in Document Control	16-Nov-2012	05-Mar-2012	06-Mar-2013

Linked Documents

- 21120.577 Rounding and Reporting Rules for qPCR and RT-PCR assays
- 21120.725 Correction Factors for Specimen Input and Elution Volume Changes



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Objective	This SOP outlines the calculation and rounding requirements for qPCR and RT-PCR assay final results for reporting.
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Scope The scope of this SOP includes calculation and rounding steps for results for all qPCR and RT-PCR tests not resulted through the automated results transfer system. Calculation and rounding steps included in this SOP are automatically applied to samples resulted through the automated result transfer system for those designated with correction factors in the Map Maker System. Additional result calculation and rounding requirements which may be required for BioPharma samples will be detailed in client-specific work instructions.

Date this test was initially placed in service: March 5, 2012

Responsibilities Clinical Laboratory Scientists are responsible for performing procedures as stated in this SOP as directed by Clinical Laboratory Management.

Procedure For calculation of tissue results extracted using *Qiagen AllPrep DNA-RNA Extraction*

If tissue sample is ordered as a quantitative test (b) (4), use the excel program located in "(b) (4) /LAB/Useful Documents/quantitative tissue calculator" folder on the intranet for determining reportable results for positive tests on tissues. (b) (4)

(b) (4) Rounding and reporting rules for quantitative tissue results are defined in 21120.554 *Rounding and Reporting Rules for qPCR and RT-PCR Assays*.

If the tissue sample is ordered as a qualitative test, use the qualitative ranges listed in 21120.554 *Rounding and Reporting Rules for qPCR and RT-PCR Assays* to determine result. If the β -actin result is (b) (4)

For all other qPCR and RT-PCR assays

(b) (4)

Extraction Method	Volume Specimen Extracted (μL)	Elution Volume (μL)
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(b) (4)

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Extraction Method	Volume Specimen Extracted (μL)	Elution Volume (μL)
(b) (4)		

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Extraction Method	Volume Specimen Extracted (μL)	Elution Volume (μL)
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(b) (4)		

(b) (4)

Rounding and reporting rules are defined in 21120.577 *Rounding and Reporting Rules for qPCR and RT-PCR Assays*.

For assays with volume changes of any other process volume including: volume of standards in the qPCR or RT-PCR reaction and volume of DNA in the qPCR or RT-PCR reaction, the calculation methodology is as follows:

Calculation requirements explanation: (b) (4)

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