



Certificate of Analysis

Product name

KIT COBAS 4800 HIV-1 QT-QL 120T CE-IVD

Material No.

08792992190

Lot No.

K00278

Date of Manufacturing

2023-03-15

Expiry Date

2024-12

Parameter	Result	Unit
ERCB-Accuracy	100	%
ERCB-Prec-SD	0.06	
ERCD-Accuracy	100	%
ERCD-Prec-SD	0.05	
NHP-Negativity-TND	100	%
5X LOD-Sens Reps-Pos	100	%
C48HIV1KIT-120T	PASS	

The visual inspection should be as follows:

10 X ADAPTER c4800 HIV-1 MMX R2, 0.5 mL
Black microtube and cap with a gold insert, containing a clear, faint blue to faint purple liquid, fitted firmly into a labeled adapter.

10 X ADAPTER c4800 MMX R1, 1.75 mL
Natural microtube and cap with a teal insert, containing a clear, colorless liquid, fitted firmly into a labeled adapter.

Issue date 2023-04-19

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Roche Molecular Systems, Inc.
Quality Management
1080 U.S. Highway 202 South
Branchburg, NJ 08876-3771



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Parameter**Result****Unit**

10 X ADAPTER c4800 RNA QS, 1.75 mL
Natural microtube and cap with a purple insert,
containing a clear colorless liquid, fitted firmly into a
labeled adapter.

Calibration Coefficient Verification
Kit Calibration Coefficient values encoded in the Assay
Value Card must match the values recorded in SAP.

Components 1

This lot meets our specification

Disposition by

Dominick DeSantis

This certificate is a computer printout and has therefore not been signed by hand.

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