



Certificate of Analysis

Product name

KIT COBAS 4800 HCV 120T CE-IVD

Material No.

06979602190

Lot No.

N21023

Date of Manufacturing

2026-01-09

Expiry Date

2027-09

Parameter**Result****Unit**

Components

1

5X LOD-Sens Repts-Pos

100

%

C4800-HCVKIT-120T

PASS

The visual inspection should be as follows:

10 X ADAPTER c4800 HCV 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.

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.

Issue date 2026-02-25

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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
HC-Accuracy	100	%
HC-Prec-SD	0.05	
LC-Accuracy	100	%
LC-Prec-SD	0.07	
NHP-Negativity-TND	100	%

This lot meets our specification

Disposition by

Theresa Lapinski

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

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