



Certificate of Analysis

Product name

KIT C4800 HCV GT AMP/DET 120T CE-IVD

Material No.

06984274190

Lot No.

N04779

Date of Manufacturing

2025-03-21

Expiry Date

2026-02

Parameter	Result	Unit
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Components

1

C48HCV-GTADKit120T

PASS

The visual inspection should be as follows:

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 HCV GT MMX R2A, 0.5 mL

Black microtube and cap with a white insert, containing a clear, faint blue to faint purple liquid, fitted firmly into a labeled adapter.

10 x ADAPTER c4800 HCV GT MMX R2B, 0.5 mL

Black microtube and cap with a yellow insert, containing a clear, faint blue to faint purple liquid, fitted firmly into a labeled adapter.

10 x ADAPTER c4800 HCV GT MMX R2C, 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.

PCTR-GT1-R2A-Ch1-Ct

5

#InRng

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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
PCTR-GT4-R2B-Ch5-Ct	5	#InRng
PCTR-GT6-R2C-Ch0-Ct	5	#InRng
PCTR-AllHCV1-R2A-Ch3-Ct	5	#InRng
PCTR-AllHCV2-R2B-Ch3-Ct	5	#InRng
PCTR-AllHCV3-R2C-Ch3-Ct	5	#InRng
PCTR-GT1a-R2B-Ch0-CC Neg	100	%
PCTR-GT1b-R2B-Ch1-CC Neg	100	%
PCTR-GT2-R2A-Ch5-CC Neg	100	%
PCTR-GT3-R2A-Ch0-CC Neg	100	%
PCTR-GT5-R2C-Ch1-CC Neg	100	%
GT1bTR-GT4-R2B-Ch5-CC Neg	100	%
GT1bTR-AllHCV1-R2A-Ch3-CC Pos	100	%

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GT1bTR-AllHCV2-R2B-Ch3-CC Pos	100	%
GT1bTR-AllHCV3-R2C-Ch3-CC Pos	100	%
GT1bTR-GT1-R2A-Ch1-CC Neg	100	%
GT1bTR-GT1a-R2B-Ch0-CC Neg	100	%
GT1bTR-GT1b-R2B-Ch1-CC Pos	100	%
GT1bTR-GT2-R2A-Ch5-CC Neg	100	%
GT1bTR-GT3-R2A-Ch0-CC Neg	100	%
GT1bTR-GT5-R2C-Ch1-CC Neg	100	%
GT1bTR-GT6-R2C-Ch0-CC Neg	100	%
GT4TR-GT4-R2B-Ch5-CC Pos	100	%
GT4TR-AllHCV1-R2A-Ch3-CC Pos	100	%

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GT4TR-AllHCV2-R2B-Ch3-CC Pos	100	%
GT4TR-AllHCV3-R2C-Ch3-CC Pos	100	%
GT4TR-GT1-R2A-Ch1-CC Neg	100	%
GT4TR-GT1a-R2B-Ch0-CC Neg	100	%
GT4TR-GT1b-R2B-Ch1-CC Neg	100	%
GT4TR-GT2-R2A-Ch5-CC Neg	100	%
GT4TR-GT3-R2A-Ch0-CC Neg	100	%
GT4TR-GT5-R2C-Ch1-CC Neg	100	%
NC-GT1-R2A-Ch1-CC Neg	100	%
NC-GT1a-R2B-Ch0-CC Neg	100	%
NC-GT1b-R2B-Ch1-CC Neg	100	%
NC-GT2-R2A-Ch5-CC Neg	100	%

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NC-GT3-R2A-Ch0-CC Neg	100	%
NC-GT4-R2B-Ch5-CC Neg	100	%
NC-GT5-R2C-Ch1-CC Neg	100	%
NC-GT6-R2C-Ch0-CC Neg	100	%
NC-AllHCV1-R2A-Ch3-CC Neg	100	%
NC-AllHCV2-R2B-Ch3-CC Neg	100	%
NC-AllHCV3-R2C-Ch3-CC Neg	100	%
GT4TR-GT6-R2C-Ch0-CC Neg	100	%

This lot meets our specification

Disposition by

Noor Eldabagh

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

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