



Document Information:

Document Author: Limburger, Marion {DOMS~Penzberg}
Business Area / Unit: Roche Professional Diagnostics
Confidentiality: Confidential
Document Class: Device Master Record
Document Type: Device Master Record
Document Creator: Limburger, Marion {DOMS~Penzberg}
Document Lifecycle Status: Signed
Valid From: 19-Jan-2022 16:30:26 (UTC)
Valid To:
Document Title: C_08_RSP_07026773190_EN
Document Number: 0000000000001200000177459
Document Version: 03
Template: No

Global Group: Regulatory Affairs
Global SubGroup: Specification Prod. (Registr.)
Local Group: Reg. Specification
Language: English
Site: RDG Germany
Department: C_DOMS
Document Applies To: C_Standardization/ QC Penzberg
Document Description: Elecsys Anti-HAV IgM - "Only for use in Regulatory Affairs"

Electronic Signatures:

Signed By: limburgm (Marion Limburger {DOMSO})
Role: Author
Signature Differentiation: Quality Control
Signed Date: 19-Jan-2022 11:35:42 (UTC)

Signed By: petzenhs (Sabine Petzenhammer {DOMSO})
Role: Reviewer
Signature Differentiation: Quality Control
Signed Date: 19-Jan-2022 16:10:06 (UTC)

Signed By: gehrker (Ralph Gehrke {DOMS})
Role: Approver
Signed Date: 19-Jan-2022 16:23:44 (UTC)

SPECIFICATION

for

Elecsys Anti-HAV IgM

0702 6765 190

0702 6773 190

Part 1 (M)

Appearance

Streptavidin-coated microparticles

sediment with clear supernatant

648 - 792 µg/ml

Part 2 (R1)

Appearance

Monoclonal Anti-HAV antibody (mouse)

labeled with ruthenium complex;

anti-human Fcγ antibody (sheep)

pH-value (HEPES buffer)

clear solution

proved by performance test

7.0 – 7.4

Part 3 (R2)

Appearance

Biotinylated monoclonal anti-h-IgM antibody (mouse);

HAV antigen (cell culture)

pH-value

clear solution

proved by performance test

7.0 – 7.4

Part 4 (AHAVIGM Cal1)

Appearance

Human serum

clear, yellowish solution

negative for anti-HAV IgM

Part 5 (AHAVIGM Cal 2)

Appearance

Anti-HAV IgM (human) in human serum

clear, yellowish solution

approx.. 5 U/mL

Performance test

Recovery of Anti-HAV-IgM in

(based on assigned value)

PreciControl 1 Anti-HAV IgM

PreciControl 2 Anti-HAV IgM

≤ 0.4 COI

85 – 115 %

All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.

The testing methods use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

The calibrators (AHAVIGM Cal1 and AHAVIGM Cal2) have been prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.

The serum containing anti-HAV IgM and the HAV antigen (cell culture) were inactivated using β-propiolactone and UV-radiation.