



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: 07-Sep-2021 06:09:26 (UTC)
Valid To:
Document Title: C_08_RSP_09043284190_EN
Document Number: 0000000000001200000544129
Document Version: 01
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 FT4 IV - "Only for use in Regulatory Affairs"

Electronic Signatures:

Signed By: limburgm (Marion Limburger {DOMSO})
Role: Author
Signature Differentiation: Quality Control
Signed Date: 03-Sep-2021 06:39:40 (UTC)

Signed By: muells79 (Steffen Mueller {DOMST})
Role: Reviewer
Signature Differentiation: Quality Control
Signed Date: 07-Sep-2021 05:36:57 (UTC)

Signed By: tassonir (Richard Tassoni {DOMS})
Role: Approver
Signed Date: 07-Sep-2021 06:01:10 (UTC)

SPECIFICATION

for

Elecsys FT4 IV

0904 3284 190

0904 3276 190

Part 1 (M)

Appearance

sediment with clear supernatant
648 - 792 µg/ml

Streptavidine coated micro particles

Part 2 (R1)

monoclonal anti-T4 antibody (rabbit)

labeled with ruthenium complex

proved by performance test
6.8 - 7.2

pH value (phosphate buffer)

Part 3 (R2)

Biotinylated T4

proved by performance test
6.8 - 7.2

pH value (phosphate buffer)

Performance test

Recovery of FT4 in

(based on assigned value)

PreciControl Universal level I

90 - 110 %

PreciControl Universal level II

90 - 110 %