Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Certificate of Analysis

P.O.
Material: Commission-No.
10446691
Kit-Lot: Customer-Order-No.
539080A
Total lot size: Customer-No.
5441 PC
Delivery amount: Storage at:
                                + 02℃ to 08℃
Release date:
2023-10-19
Manufacturing date: Expiration date:
2023-03-15   2025-03-14
Legal Material Number:
OWZG23
Released by:
Stefan Barth

Customer
To whom it may concern

Material:	**10446691**
	MULTIFIBREN U
Inspection ID-No.:	**400000665768**

Kit components:

Level	Material-No. Material-Name	Lot	Release date
0010	11530442 Multifibren U	539080	2023-05-17

Material:	**10446691**
	MULTIFIBREN U
Inspection ID-No.:	**400000665768**

Inspection results:

Material-No.	**Lot**
11530442	**539080**
Multifibren U	

Function test

Create a reference with fibrinogen calibrators on BCS or BCS XP System according to current instruction for use and software version. Verification of the fibrinogen content with 9 vials of Multifibren U from controls.

Control Plasma N

Result Unit	**Assigned Value**	**Upper Limit**	**Lower Limit**
2.54 g/l	-	3.00 g/l	2.00 g/l

Control Plasma P

Result Unit	**Assigned Value**	**Upper Limit**	**Lower Limit**
0.93 g/l	-	1.30 g/l	0.50 g/l

Stability

Dissolve 3 vials of Multifibren U according to instruction for use and store closed for 8h at + 37°C. After storage, determination of the fibrinogen content under application of the reference curve, which was created above.

Control Plasma N

Result Unit	**Assigned Value**	**Upper Limit**	**Lower Limit**
2.65 g/l	-	3.00 g/l	2.00 g/l

Control Plasma P

Result Unit	**Assigned Value**	**Upper Limit**	**Lower Limit**
0.95 g/l	-	1.30 g/l	0.50 g/l

This document was generated by means of electronic data system, which was designed and validated to comply with the FDA21 CFR Part 11 electronic records and signature. This

document indicates an electronic   signature for batch release.
This lot has been tested and approved for release and shipment by the responsible Siemens
Healthcare Diagnostics Quality department.

_____ S. Barth _____

COA Verification
Stefan Barth / Quality Assurance