

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

Customer
To whom it may concern

Certificate of Analysis

P.O.	
Material:	Commission-No.
10445724	
Kit-Lot:	Customer-Order-No.
569960	
Total lot size:	Customer-No.
11438 PC	
Delivery amount:	Storage at:
	+ 02°C to 08°C
Release date:	
2023-11-20	
Manufacturing date:	Expiration date:
2023-11-02	2025-11-01
Legal Material Number:	
B4234-25	
Released by:	
Stefan Barth	

Material: 10445724
Dade Owren's Veronal Buffer
Inspection ID-No.: 400000671207

Kit components:

Material: 10445724
Dade Owren's Veronal Buffer
Inspection ID-No.: 400000671207

Inspection results:

Material-No.	Lot
10445724 Dade Owren's Veronal Buffer	569960

pH Value

The measurement of pH occurs in the temperature range between + 15 to + 25°C.

Result Unit	Assigned Value	Upper Limit	Lower Limit
7.45	-	7.45	7.25

Conductivity

Result Unit	Assigned Value	Upper Limit	Lower Limit
15.35 mS/cm	-	15.70 mS/cm	15.10 mS/cm

Function test on CA-1500 (test lot)

Determination of the fibrinogen content on a Sysmex CA-1500 System device with Thrombin reagent (test lot).

Ci-Trol 1

Result Unit	Assigned Value	Upper Limit	Lower Limit
263.0 mg/dl	-	274.0 mg/dl	214.0 mg/dl

Data-Fi Abnormal Fibrinogen Control

Result Unit	Assigned Value	Upper Limit	Lower Limit
122.0 mg/dl	-	132.0 mg/dl	92.0 mg/dl

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