

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

Certificate of Analysis

| | |
|------------------------|--------------------|
| P.O. | |
| Material: | Commission-No. |
| 10446238 | |
| Kit-Lot: | Customer-Order-No. |
| 563122B | |
| Total lot size: | Customer-No. |
| 4739 PC | |
| Delivery amount: | Storage at: |
| | + 02°C to 08°C |
| Release date: | |
| 2023-10-27 | |
| Manufacturing date: | Expiration date: |
| 2023-07-28 | 2025-07-27 |
| Legal Material Number: | |
| ORKL17 | |
| Released by: | |
| Stefan Barth | |

Customer
 To whom it may concern

Material: 10446238
 STANDARD HUMAN PLASMA
Inspection ID-No.: 40000667970

Kit components:

| Level | Material-No. Material-Name | Lot | Release date |
|-------|-----------------------------------|--------|--------------|
| 0010 | 11530297 Standard Human Plasma | 563122 | 2023-10-13 |

Material: 10446238
 STANDARD HUMAN PLASMA
Inspection ID-No.: 40000667970

Inspection results:

| Material-No. | Lot |
|-----------------------------------|--------|
| 11530297 Standard Human Plasma | 563122 |

PT with Thromborel S

Creation of a reference curve with PT Multi Calibrator with Thromborel S, with subsequent measurement of the test lot which is to be approved.

Standard Human Plasma

| Result Unit | Assigned Value | Upper Limit | Lower Limit |
|-------------|----------------|-------------|-------------|
| 12.4 S | - | 13.5 S | - |

Standard Human Plasma

| Result Unit | Assigned Value | Upper Limit | Lower Limit |
|-------------|----------------|-------------|-------------|
| 84.4 % | - | 105.6 % | 70.4 % |

Fibrinogen with Dade Thrombin Reagent

Creation of a reference curve with Standard Human Plasma and Dade Thrombin Reagent, with subsequent measurement of the test lot which is to be approved.

Standard Human Plasma

| Result Unit | Assigned Value | Upper Limit | Lower Limit |
|-------------|----------------|-------------|-------------|
| 2.43 g/l | - | 2.83 g/l | 2.03 g/l |

AT III with BC AT III (A)

Creation of a reference curve with Standard Human Plasma and Berichrom AT III, with subsequent measurement of the test lot which is to be approved.

Standard Human Plasma

Material: 10446238
 STANDARD HUMAN PLASMA
Inspection ID-No.: 40000667970

| Material-No. | Lot | | | |
|-----------------------------------|--------------------|-----------------------|--------------------|--------------------|
| 11530297 Standard Human Plasma | 563122 | | | |
| | Result Unit | Assigned Value | Upper Limit | Lower Limit |
| | 92.5 % | - | 105.6 % | 70.4 % |

Test material: Thromborel S

| | Result Unit | Assigned Value | Upper Limit | Lower Limit |
|--------------------------|-------------|----------------|-------------|-------------|
| Inspection remark 565742 | Used | - | - | - |

Test material: OQUS
Dade Thrombin Reagent

| | Result Unit | Assigned Value | Upper Limit | Lower Limit |
|--------------------------|-------------|----------------|-------------|-------------|
| Inspection remark 567424 | Used | - | - | - |

Test material: Berichrom AT III (A)

| | Result Unit | Assigned Value | Upper Limit | Lower Limit |
|-------------------------|-------------|----------------|-------------|-------------|
| Inspection remark 01040 | Used | - | - | - |

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.



COA Verification
 Stefan Barth / Quality Assurance