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Centralised and Point of Care Solutions

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Roche Cardiac System – Traceability of Test Strip Calibration

1. Intention

This report shows the concept of traceability for blood measurements developed for the Roche CARDIAC tests (Troponin T, NT-proBNP, D-Dimer, CK-MB, Myoglobin) on the cobas h 232 instrument.

2. Traceability Chain

Roche CARDIAC tests for Troponin T, NT-proBNP, CK-MB are traceable to the manufacturer selected measurement procedure Elecsys® laboratory platform.

Roche CARDIAC tests for D-Dimer and Myoglobin are traceable to the manufacturer selected measurement procedure Tina-quant laboratory platform.

An international standardized reference material is not available for any of the analytes.

The process of calibration to the reference method Elecsys®/Tina-quant is also described in the Standardization Transfer Protocol (see attachment).

The traceability chain for the Roche Cardiac tests on the Roche cobas h 232 instrument can be displayed as follows:

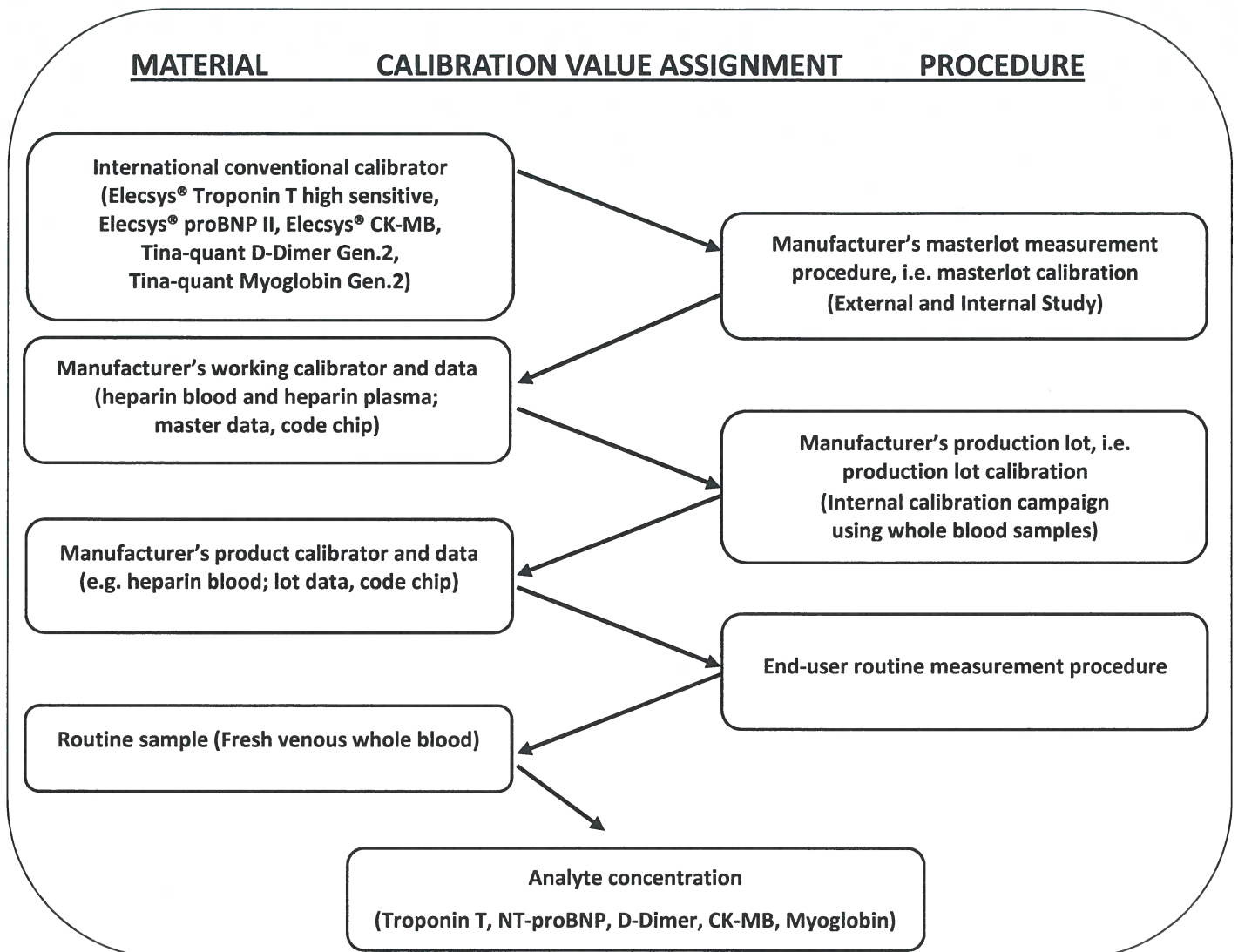


Figure: Traceability chain for a measurement result of the Roche CARDIAC tests on the Roche cobas h 232 instrument.

Sincerely,





Attachment: Standardization Transfer Protocol Roche Cardiac POC Troponin T (REF 07007302190)

ANALYTE	Troponin T , human heart			
REFERENCE METHOD	METHODS AND MATERIALS	RATIONALE	COMMUTABILITY	STABILITY
REFERENCE MATERIAL	Elecsys® Troponin T high sensitive (Cat. No. 0509 2744) Not available	-	Manufacturer-selected measurement procedure	-
MASTER CALIBRATOR	Master Lot CARDIAC POC Troponin T. Calibrated with native human heparinized whole blood samples from intended use population, standardized to Elecsys® Troponin T high sensitive values.	Clinical relevant measuring range and sample material; established procedure.	-	Stability at <-15°C is monitored and shown by real time stability testing in QC.
CALIBRATOR (factory calibration, no user calibration)	Calibration process: 36 Human whole blood samples spiked with native Troponin T from plasma pools to standardize lots to Master Lot CARDIAC POC Troponin T. Troponin T, human heart in: Human plasma pools; Storage:< -60°C	Blood calibrator matrix simulates native patient blood samples; established procedure.	Human plasma pools. Read off on Elecsys® Troponin T high sensitive	No intended storage; fresh blood samples only.
CONTROLS	CARDIAC POC Troponin T Control: analyte-free buffered human serum spiked with Troponin T lyophilized, storage: 2 - 8° C.	Stability achieved as lyophilisate, universal concept for the analytes.	Commutability shown in standardisation	Stability at 2 - 8°C of lyophilized controls is monitored and shown by real time stability testing.

STATISTICAL METHODS	statistical rationale: according to internal Standard Operation Procedure
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Attachment: Standardization Transfer Protocol Roche Cardiac T Quantitative (REF 0487772190)

ANALYTE	Troponin T, human heart			
REFERENCE METHOD	METHODS AND MATERIALS	RATIONALE	COMMUTABILITY	STABILITY
REFERENCE MATERIAL	Elecsys® Troponin T high sensitive (Cat. No. 0509 2744) Not available	-	Manufacturer-selected measurement procedure	-
MASTER CALIBRATOR	Master Lot Cardiac Troponin T. Calibrated with native human heparinized whole blood samples from intended use population, standardized to Elecsys® Troponin T values.	Clinical relevant measuring range and sample material; established procedure.	-	Stability at <-15°C is monitored and shown by real time stability testing in QC.
CALIBRATOR (factory calibration, no user calibration)	Calibration process: 36 Human whole blood samples spiked with native Troponin T from plasma pools to standardize lots to Master Lot Cardiac Troponin T. Troponin T, human heart in: Human plasma pools; Storage:< -60°C	Blood calibrator matrix simulates native patient blood samples; established procedure.	Human plasma pools. Read off on Elecsys® Troponin T.	No intended storage; fresh blood samples only.
CONTROLS	CARDIAC Control Troponin T: analyte-free buffered human serum spiked with Troponin T lyophilized, storage: 2 - 8° C.	Stability achieved as lyophilisate, universal concept for the analytes.	Commutability shown in standardisation	Stability at 2 - 8°C of lyophilized controls is monitored and shown by real time stability testing.

STATISTICAL METHODS	statistical rationale: according to internal Standard Operation Procedure
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Attachment: Standardization Transfer Protocol Roche Cardiac proBNP+ (REF 05533643190)

ANALYTE		N-terminal pro B-type natriuretic peptide (NT-proBNP)		
	METHODS AND MATERIALS	RATIONALE	COMMUTABILITY	STABILITY
REFERENCE METHOD	Elecsys® proBNP II (Cat. No. 0484-2464)	-	Manufacturer-selected measurement procedure	-
REFERENCE MATERIAL	Not available	-	-	-
MASTER CALIBRATOR	Master Lot CARDIAC proBNP+ Calibrated with native human heparinized whole blood samples from intended use population, standardized to Elecsys® proBNP II values.	Clinical relevant measuring range and sample material; established procedure.	-	Stability at <-15°C is monitored and shown by real time stability testing in QC.
CALIBRATOR (factory calibration, no user calibration)	Calibration process: 48 Human whole blood samples spiked with NT-proBNP from plasma pools to standardize lots to Master Lot Cardiac proBNP+. NT-pro BNP in: Human plasma pools; Storage:< -60°C	Blood calibrator matrix simulates native patient blood samples; established procedure.	Human plasma pools. Read off on Elecsys® proBNP	No intended storage; fresh blood samples only.
CONTROLS	CARDIAC Control proBNP: analyte-free buffered horse serum spiked with synth. pro BNP peptide lyophilized, storage: 2 - 8° C.	Stability achieved as lyophilisate, universal concept for the analytes.	Commutability shown in standardisation	Stability at 2 - 8°C of lyophilized controls is monitored and shown by real time stability testing.
STATISTICAL METHODS	statistical rationale: according to internal Standard Operation Procedure			



Attachment: Standardization Transfer Protocol Roche Cardiac D-Dimer (REF 04877802190)

ANALYTE	D-dimer			
	METHODS AND MATERIALS	RATIONALE	COMMUTABILITY	STABILITY
REFERENCE METHOD	Tina-quant D-Dimer Gen.2 (REF 04912551190)	-	Manufacturer-selected measurement procedure	-
REFERENCE MATERIAL	Not available	-	-	-
MASTER CALIBRATOR	Master Lot Cardiac D-Dimer. Calibrated with native human heparinized whole blood samples from intended use population, standardized to Tina-quant D-Dimer values.	Clinical relevant measuring range and sample material; established procedure.	-	Stability at <-15°C is monitored and shown by real time stability testing in QC.
CALIBRATOR (factory calibration, no user calibration)	Calibration process: 36 Human whole blood samples spiked with D-Dimer Antigen to standardize lots to Master Lot Cardiac D-Dimer. D-Dimer in: Buffered diluted solution of D-Dimer Antigen; Storage: -20°C	Blood calibrator matrix simulates native patient blood samples; established procedure.	Buffered diluted solution of D-Dimer Antigen (Ref.No 12206145001)	No intended storage; fresh blood samples only.
CONTROLS	CARDIAC Control D-Dimer (OEM: LSI Medience Corporation): solution spiked with human D-Dimer lyophilized, storage: 2 - 8° C.	Stability achieved as lyophilisate, universal concept for the analytes.	Commutability shown in standardisation	Stability at 2 - 8°C of lyophilized controls is monitored and shown by real time stability testing.

STATISTICAL METHODS statistical rationale: according to internal Standard Operation Procedure


Attachment: Standardization Transfer Protocol Roche Cardiac CK-MB (REF 04877900190)

ANALYTE	creatinine kinase MB isoenzyme			
REFERENCE METHOD	METHODS AND MATERIALS	RATIONALE	COMMUTABILITY	STABILITY
REFERENCE MATERIAL	Elecsys® CK-MB (Cat. No. 0589-4808) Not available	-	Manufacturer-selected measurement procedure	-
MASTER CALIBRATOR	Master Lot Cardiac CK-MB. Calibrated with native human heparinized whole blood samples from intended use population, standardized to Elecsys® CK-MB values.	Clinical relevant measuring range and sample material; established procedure.	-	Stability at <-15°C is monitored and shown by real time stability testing in QC.
CALIBRATOR (factory calibration, no user calibration)	Calibration process: 36 Human whole blood samples spiked with human CK-MB from CK-MB, Antigen, ZLF to standardize lots to Master Lot Cardiac CK-MB. CK-MB in: Buffered diluted solution of CK-MB, Antigen, ZLF; Storage:< -60°C	Blood calibrator matrix simulates native patient blood samples; established procedure.	Buffered diluted solution of CK-MB, Antigen, ZLF	No intended storage; fresh blood samples only.
CONTROLS	CARDIAC Control CK-MB: analyte-free buffered human serum spiked with human CK-MB from CK-MB, Antigen, ZLF, storage: 2 - 8° C.	Stability achieved as lyophilisate, universal concept for the analytes.	Commutability shown in standardisation	Stability at 2 - 8°C of lyophilized controls is monitored and shown by real time stability testing.

STATISTICAL METHODS	statistical rationale: according to internal Standard Operation Procedure
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Attachment: Standardization Transfer Protocol Roche Cardiac Myoglobin (REF 04877799190)

ANALYTE	Myoglobin			
	METHODS AND MATERIALS	RATIONALE	COMMUTABILITY	STABILITY
REFERENCE METHOD	Tina-quant Myoglobin Gen.2 (REF04580010190)	-	Manufacturer-selected measurement procedure	-
REFERENCE MATERIAL	Not available	-	-	-
MASTER CALIBRATOR	Master Lot Cardiac Myoglobin. Calibrated with human heart heparinized whole blood samples from intended use population, standardized to Tina-quant Myoglobin values.	Clinical relevant measuring range and sample material; established procedure.	-	Stability at <-15°C is monitored and shown by real time stability testing in QC.
CALIBRATOR (factory calibration, no user calibration)	Calibration process: 36 Human whole blood samples spiked with a plasma diluted solution of human heart Myoglobin from Co. Scipps to standardize lots to Master Lot Cardiac Myoglobin. Myoglobin in: Plasma diluted solution of human heart Myoglobin from Co. Scipps ; Storage: < -60°C	Blood calibrator matrix simulates native patient blood samples; established procedure.	Plasma dilution of human heart Myoglobin from Co. Scipps	No intended storage; fresh blood samples only.
CONTROLS	CARDIAC Control Myoglobin (OEM: DENKA SEIKEN): solution spiked with human Myoglobin lyophilized, storage: 2 - 8° C.	Stability achieved as lyophilisate, universal concept for the analytes.	Communtability shown in standardisation	Stability at 2 - 8°C of lyophilized controls is monitored and shown by real time stability testing.

STATISTICAL METHODS	statistical rationale: according to internal Standard Operation Procedure
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