

To Whom It May Concern

ISO 15189:2012 REQUIREMENTS REG. "CALIBRATION & VERIFICATION PROCEDURES"¹

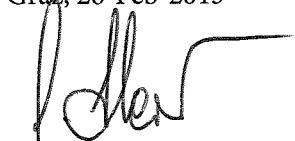
All Roche Diagnostics products which are distributed and for which a Free-Sales-Certificate is issued, are CE-marked. The In-Vitro-Diagnostics Directive of the European Union² requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the In-Vitro-Diagnostics Directive. This means that all processes in the development and manufacturing of Roche Diagnostics products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 9001:2008³, ISO 13485:2003 + AC: 2007⁴, and QSReg⁵.

The mentioned regulations require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated⁶. This status has to be assured by scheduled maintenance and by regular qualification resp. validation reviews and updates.

All physical quantities, calibrators and controls used in Roche Diagnostics systems are fully traceable to certified standards or reference materials. The performance of all Roche Diagnostics systems at the customer site is assured if regular QC measurements, cleaning and maintenance procedures as described in the instructions for use or service documentation are performed. By having controlled internal procedures and by running the tasks required in the respective user documentation, all Roche Diagnostics systems will perform as specified during their defined lifetime.

Additional calibration or verification procedures are NOT required of the user in order to assure the specified performances of every Roche Diagnostics system. Only if a user deviates from these manufacturer's recommendations does he have to establish site-specific calibration and verification procedures as part of his accreditation process.

Graz, 26-Feb-2013



Dr. Johann Harer

Head of Quality Management & Regulatory Affairs

¹ ISO 15189:2012, Medical laboratories - Requirements for quality and competence

² Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

³ ISO 9001:2008, Quality Management Systems - Requirements

⁴ ISO 13485:2003 + Cor.1:2009, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes)

⁵ Quality System Regulations, 21 CFR Part 820, requirements on medical devices

⁶ 21 CFR Part 809, 21 CFR Part 210, 21 CFR Part 11; GAMP 5 guideline; Annex 15 to the EU Guide to cGMP

 * HITACHI AUTOMATIC ANALYZER *

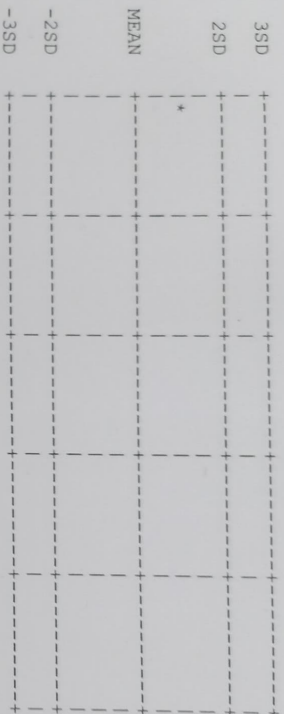
NAME RAND-BIO-2 DATE 28/06/21 09:14:11
 S.NO. C028059 0001-5 OPERATOR ID bmserv
 LOT 1390UN

TEST	RATIO COI/MES	RESULT	UNIT	MODULE	ALARM
GLUC3		104.1	mg/dL	C	
ALB2		4.60	g/dL	C	
ALP2L		151	U/L	C	
ALTL		32.3	U/L	C	
ASTL		31.7	U/L	C	
BILD2		0.903	mg/dL	C	
BILT3		1.413	mg/dL	C	
CA2		8.62	mg/dL	C	
CHOL		150.3	mg/dL	C	
CREJ		1.57	mg/dL	C	
GGT2		52.2	U/L	C	ReagEX
TP2		5.87	g/dL	C	
TRIGL		93.5	mg/dL	C	
UA		6.0	mg/dL	C	
UREA		46.3	mg/dL	C	
PHOS		4.42	mg/dL	C	
AMYLASE		85	U/L	C	ReagEX
TEST039 - HDL		65.4	mg/dL	C	
TEST042		199.24	U/L	C	

Individual QC Chart

06/04/22 14:39

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST ALB2 UNIT g/dL



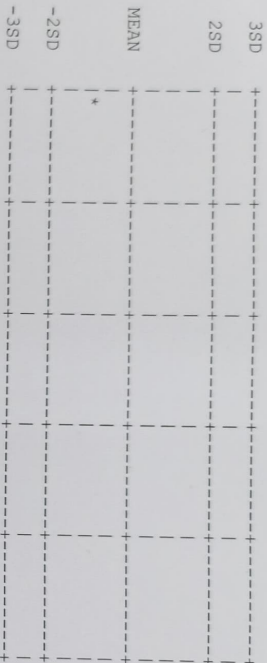
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT
 1*28/06 09:17 bmserv 4.60 g/dL

TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN	SD	CV(%)	RESULT
ALB2	C	RAND-BIO-2	1390UN	4.33	0.33	145	4.450	0.087	1.96	4.38

MODULE C CONTROL RAND-BIO-2 LOT 1390UN

TEST ALLT

UNIT U/L



R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 28/06 09:18 bmserv 32.3 U/L

TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN	SD	CV(%)	RESULT
ALLT	C	RAND-BIO-2	1390UN	36	3.50	392	33.93	1.77	5.22	32.2

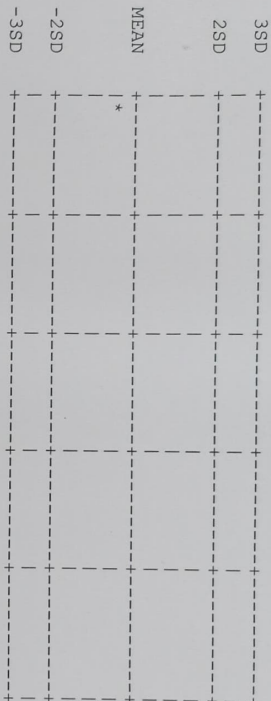
Individual QC Chart

06/04/22 14:40

MODULE C CONTROL RAND-BIO-2 LOT 1390UN

TEST ASTL

UNIT U/L



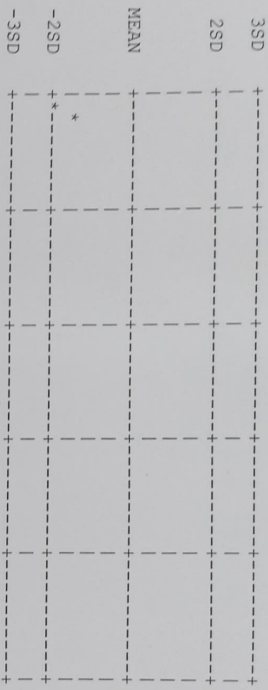
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT
 1 28/06 09:18 bmserv 31.7 U/L

TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN SD	CV(%)	RESULT
ASTL	C	RAND-BIO-2	1390UN	34	3.50	365	31.32	3.58	30.3
							1.12		

Individual QC Chart

06/04/22 14:41

MODULE C CONTROL RAND-BIO-2 IOT 1390UN TEST BIID2 UNIT mg/dL



R.PACK IOT

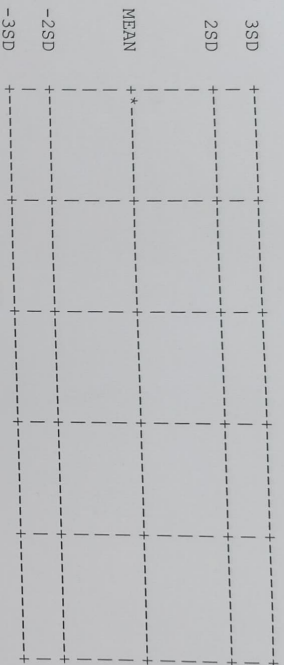
DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 28/06 09:18 bmserv 0.903 mg/dL 28/06 17:11 bmserv 0.938 mg/dL

TEST BIID2	MODULE C	CONTROL RAND-BIO-2	IOT 1390UN	T.MEAN 1.12	T.SD 0.12	N 365	MEAN SD 1.0199	CV(%) 7.31	RESULT 0.855
							0.0746		

Individual QC Chart

06/04/22 14:42

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST CHO2I UNIT mg/dL



TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN	SD	CV(%)	RESULT	UNIT
1	28/06	09:18	bmserv	150.3	mg/dL						
				152	9.50	371	149.90	4.31	2.88	150.8	mg/dL

Individual QC Chart

06/04/22 14:43

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST CREJ2 UNIT mg/dL



R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 28/06 09:19 bmserv 1.57 mg/dL

TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN	SD	CV(%)	RESULT
CREJ2	C	RAND-BIO-2	1390UN	1.50	0.15	378	1.477	0.057	3.86	1.44

Individual QC Chart

06/04/22 14:43

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST GLUC3 UNIT mg/dL



R.PACK LOT		DATE	TIME	OP.ID	RESULT	UNIT	DATE	TIME	OP.ID	RESULT	UNIT
1	28/06	09:17	bmserv	104.1	mg/dL		28/06	16:52	bmserv	111.7	mg/dL

TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN	SD	CV(%)	RESULT
GLUC3	C	RAND-BIO-2	1390UN	111	8.30	387	106.02	6.18	5.83	106.1

Individual QC Chart

06/04/22 14:44

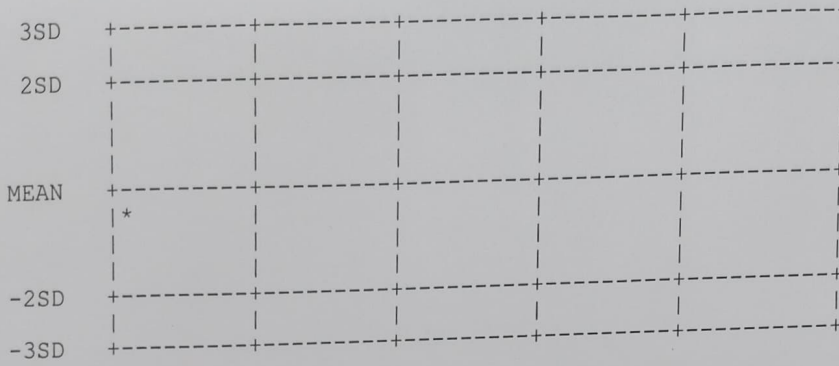
MODULE C

CONTROL RAND-BIO-2

LOT 1390UN

TEST HDLC4

UNIT mg/dL



R.PACK LOT
 DATE TIME OP.ID RESULT UNIT
 1 28/06 09:19 bmserv 65.4 mg/dL

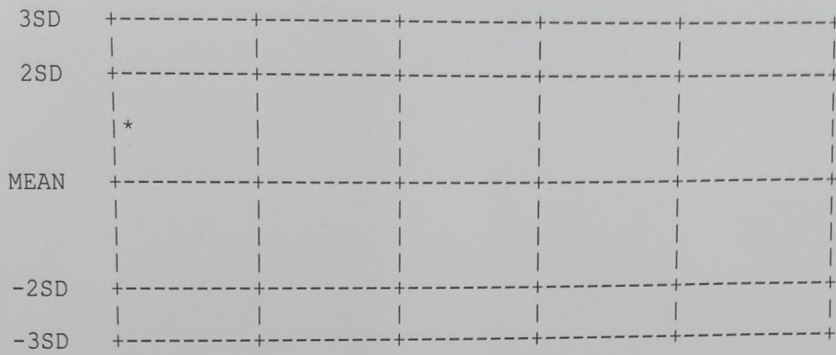
DATE TIME OP.ID RESULT UNIT

TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN	SD	CV(%)	RESULT
HDLC4	C	RAND-BIO-2	1390UN	69.1	5.20	360	67.68	2.53	3.74	67.0

Individual QC Chart

06/04/22 14:45

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST PHOS2 UNIT mg/dL



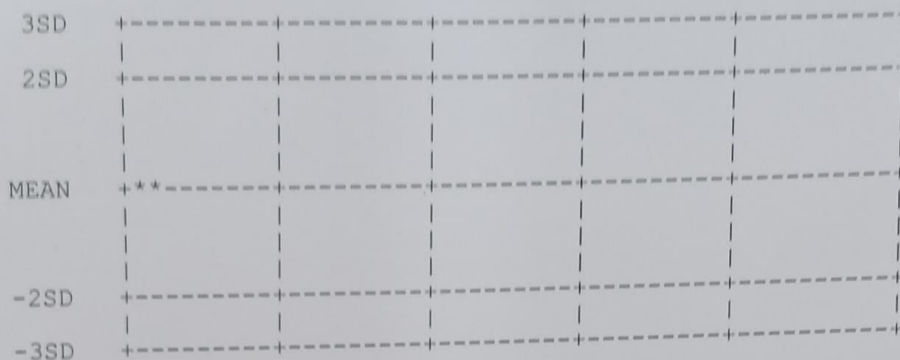
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 28/06 09:19 bmserv 4.42 mg/dL

TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN	SD	CV(%)	RESULT
PHOS2	C	RAND-BIO-2	1390UN	4.15	0.31	38	4.242	0.093	2.19	4.21

Individual QC Chart

06/24/22 14:45

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST TP2 UNIT g/dL

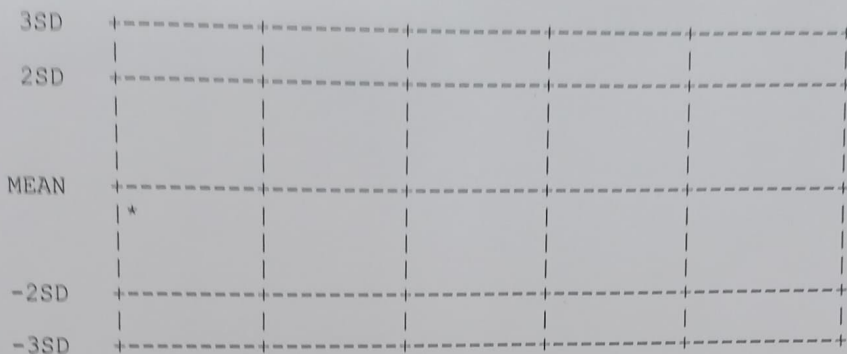


R.PACK LOT		DATE	TIME	OP.ID	RESULT	UNIT	DATE	TIME	OP.ID	RESULT	UNIT
1	28/06	09:18	bmserv	5.87	g/dL		28/06	11:56	bmserv	5.94	g/dL
TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN	SD	CV(%)	RESULT	
TP2	C	RAND-BIO-2	1390UN	5.80	0.58	366	5.855	0.113	1.93	5.83	

Individual QC Chart

06/04/22 14:45

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST TRIGL UNIT mg/dL



R. PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 28/06 09:19 bmserv 93.5 mg/dL

TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN SD	CV(%)	RESULT
TRIGL	C	RAND-BIO-2	1390UN	96.5	7.65	382	94.50 4.28	4.53	95.1

Individual QC Chart

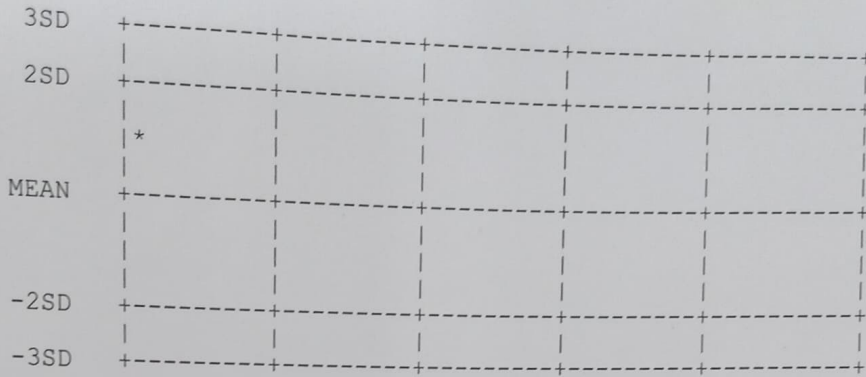
06/04/22 14:46

MODULE C

CONTROL RAND-BIO-2 LOT 1390UN

TEST UA2

UNIT mg/dL



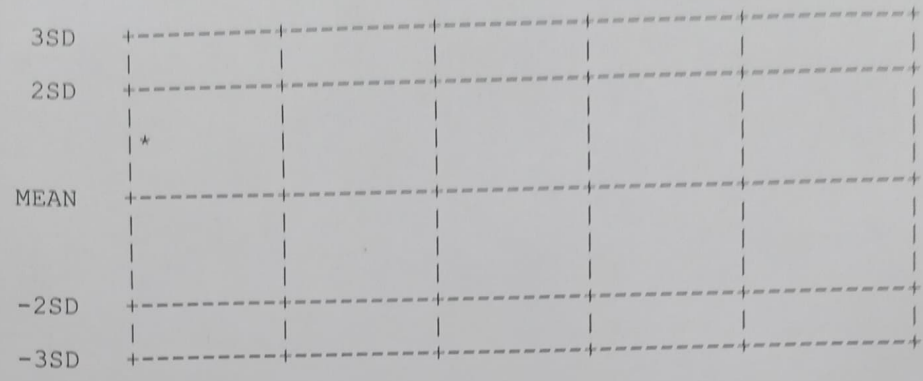
R.PACK LOT		DATE	TIME	OP.ID	RESULT	UNIT
1	28/06	09:19	bmserv	6.0	mg/dL	

TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN SD	CV(%)	RESULT
UA2	C	RAND-BIO-2	1390UN	5.68	0.37	366	5.73 0.16	2.79	6.0

Individual QC Chart

06/04/22 14:46

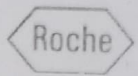
MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST UREAL UNIT mg/dL



R. PACK LOT
 DATE TIME OP.ID RESULT UNIT
 1 28/06 09:18 bmserv 46.3 mg/dL

DATE TIME OP.ID RESULT UNIT

TEST	MODULE	CONTROL	LOT	T.MEAN	T.SD	N	MEAN SD	CV(%)	RESULT
UREAL	C	RAND-BIO-2	1390UN	42.7	3.15	384	44.35 1.99	4.49	43.9



Case No.	CAS-0013301642	Instrument Model	cobas 6000 c501 module
Order No.	ORD-0017161433	Instrument Serial No.	16Z0-07
Contract Type	IN-COMPREHENSIVE	Finance Status	RENT
Lab/Inst./hosp.Name	Arth Diagnostics Pvt Ltd		
Customer No.	0052070145		
Contact Name :	Kishan Singh		
Contact Number :	+919468703577		
Address :	Plot#4C,Apex Chamber,		
City :	Udaipur		

Call Received Date/Time:	15.04.2021 16:45	Call Attended Date/Time:	27.06.2021 16:30
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Job Type	PM Visit
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Job Description	
Action Summary	Work done : Preventive Maintenance done, Calibration & Q.C. Done Customer Satisfaction Rating (1-5):5

Spare Part Replaced

Part No	Parts Description	Batch No	Batch Expiry Date	Qty	Invoice Type
07783175001 ⁽¹⁾	KIT MAINTENANCE 4 501/502 ⁽¹⁾			1	Free of charge
05521521001 ⁽¹⁾	KIT MAINTENANCE 1 501/502 ⁽¹⁾			1	Free of charge

⁽¹⁾: Customer owned

Time Report

Effective Visit Date : 27.06.2021		Complete Date : 28.06.2021
Date	Type	Time
2021.06.27	Travel Time--Standard	1
2021.06.27	Working Time--Standard	2
2021.06.28	Quality Control--Standard	0.5
2021.06.28	Travel Time--Standard	0.5
2021.06.28	Working Time--Standard	2
Total:		6

Customer's Signature Name : Singh Kishan	Service Engineer/Application Specialist Name : Manoj Vishwakarma