

NAME
S.NO.
LOT

PCC 2
C004068 001
41010520

DATE 11/12/20 10:20:19
OPERATOR ID bmserv

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
Na	126 L	mmol/L	(128-	144) Cal.E
K	6.20 L	mmol/L	(6.39-	7.19) Cal.E
Cl	94.5 L	mmol/L	(98-	110) ISE.E



To Whom It May Concern

For ISO 15189:2012 and ISO 15189:2014 accredited Laboratories - requirements regarding "Calibration & Verification Procedures" [1]

All In vitro Diagnostics Products which are manufactured and distributed by Roche Diagnostics GmbH and for which a Free-Sales-Certificate is issued, are CE-marked.

The In-Vitro-Diagnostics Directive of the European Union [2] 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 development and manufacturing of Roche Diagnostics GmbH products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 13485:2012 [3] + AC:2012 and 21 CFR Part 820 [4].

The mentioned regulations and standards require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated. 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 Diagnostic systems are fully traceable to certified standards or reference materials. The performance of all In-vitro diagnostics systems of Roche Diagnostics GmbH at the customer site is assured if regular Quality Control 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 In-vitro diagnostics systems of Roche Diagnostics GmbH will be performed as specified during their defined lifetime.

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

Mannheim, 18 December 2017

Roche Diagnostics GmbH

Roche Diagnostics GmbH

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Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Ursula Redeker, Sprecherin; Edgar Vieth - Aufsichtsratsvorsitzender: Dr. Severin Schwan

- [1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories – Requirements for quality and competence
- [2] Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices
- [3] EN ISO 13485:2012 + AC:2012 Medical devices – Quality management systems-Requirements for regulatory purposes
- [4] CFR Part 820, Quality System regulations 21 Requirements on medical devices

Roche Professional Services (ISO 9001:2015 certified)

Customer Support Center No: 1800-123-7599 /Toll No: +91-44-30413900



Date: 11.12.2020

Date: 11.12.2020

Disclaimer

1. This Service report has been signed by the authorized representative of your organization.
2. Discrepancies if any must be intimated within a period of seven (7) days of the receipt of the email, in the absence of which the report will be final and conclusive.
3. This report shall be governed by the laws of India and the courts at Mumbai shall have the exclusive jurisdiction to deal with the disputes arising hereunder.

**cobas c 311 analyzer
Preventative Maintenance Reference Guideline**

Account Name: Hira Clinical mLab
Analyzer S/N: 1340-07

Account Number: RR

Current Year: 2020

Service Order
Number

First PM: ord-0014532064

Instrument
Test Counts

11-12-2020

Second PM: NA

NA

1st PM 2nd PM

1	Remove and clean covers	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2	Vacuum dust from analyzer	6 month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3	Flush ISE valves	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4	Photometer: Check, replace ABS Lamp if necessary	6 Month	Check/Replace	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5	Clean Sample Probe, check spring function	6 Month	Check/Clean/Replace	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6	Clean Sample Probe Rinse Well	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7	Clean Sample Arm sensors	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8	Check Sample Arm tubing	6 Month	Check	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9	Clean Reagent Probe and check spring function	6 Month	Clean/Check/Replace	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10	Clean Reagent Probe Rinse Well and Cap Piercer	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
11	Clean Reagent Arm sensors	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
12	Clean Cassette sensor and Barcode Reader Window	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
13	Clean Cassette Input Shutter Solenoid	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
14	Decontaminate system/Incubation bath	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
15	Replace Heat Cut filter	12 Month	Replace	<input checked="" type="checkbox"/>	<input type="checkbox"/>
16	Replace Rinse Mechanism nozzle tips	12 Month	Replace	<input checked="" type="checkbox"/>	<input type="checkbox"/>
17	Check Reaction cells for dirt or scratches	6 Month	Check/Replace	<input checked="" type="checkbox"/>	<input type="checkbox"/>
18	Clean Reaction Disk Home Position and count sensor	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
19	Replace USM Cell Cover	12 Month	Replace	<input checked="" type="checkbox"/>	<input type="checkbox"/>
20	Clean Sample Area	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
21	Inspect Rinse Mechanism tubing/Vacuum Vessels	6 Month	Check/Clean/Replace	<input checked="" type="checkbox"/>	<input type="checkbox"/>
22	Clean and lubricate Sample Arm shafts	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
23	Clean and lubricate Probe Guard assembly	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
24	Clean and lubricate the Rinse Mechanism	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
25	Clean and lubricate Reagent Arm bearings	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
26	Clean and lubricate Pipettor Assemblies	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
27	Decontaminate Sample and Reagent lines	6 Month	Clean	<input checked="" type="checkbox"/>	<input type="checkbox"/>
28	Replace Seals in the Syringe Assemblies	6 Month	Replace	<input checked="" type="checkbox"/>	<input type="checkbox"/>



Case No.	CAS-0011221422	Instrument Model	Cobas 4000 c311 stand alone system
Order No.	ORD-0014532064	Instrument Serial No.	1340-07
Contract Type	IN-COMPREHENSIVE	Finance Status	RENT
Lab/Inst./hosp.Name	HIRA CLINICAL LABORATORY		
Customer No.	0052011871		
Contact Name :	SK Hira		
Contact Number :	+919781326622		
Address :	CIVIL HOSPITAL ROAD CIVIL HOSPITAL		
City :	HOSHIARPUR		

Call Received Date/Time:	04.03.2020 17:30	Call Attended Date/Time:	11.12.2020 12:00
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Job Type	PM Visit
Job Description	
Job Summary	Cause: Preventive Maintenance. Workdone: PM carried out. Replaced PM kit 1 and 2. Photometer check done. Verification: Ran the qc and samples, instrument working is ok. All electrodes and reaction cells need to replace ASAP. Customer Satisfaction Rating (1-5): 5

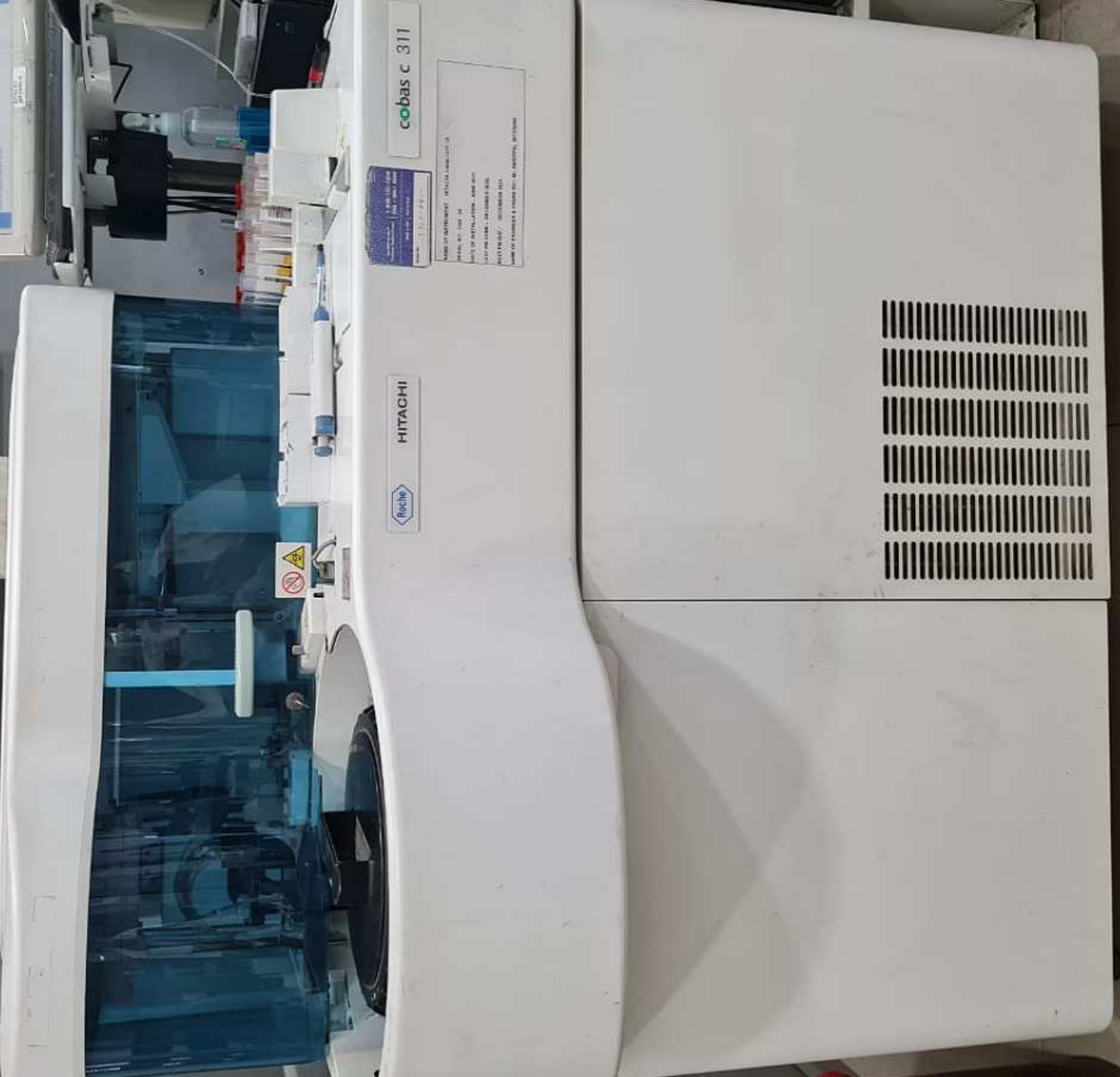
Spare Part Replaced				
Part No	Parts Description	Batch No	Batch Expiry Date	Invoice Type
05182522001 ⁽¹⁾	KIT MAINTENANCE 6 MONTHS COBAS C311 ⁽¹⁾			Free of charge
05182549001 ⁽¹⁾	KIT MAINTENANCE 1 YEAR COBAS C311 ⁽¹⁾			Free of charge

(1): Customer owned

Time Report	
Effective Visit Date : 11.12.2020	Complete Date : 11.12.2020

Date	Type	Time
2020.12.11	Quality Control--Standard	1.5
2020.12.11	Travel Time--Standard	6
2020.12.11	Working Time--Standard	3
Total:		10.5

Customer's Signature Name : Hira SK	Service Engineer/Application Specialist Name : Amritpal Singh



HITACHI



cobas c 311

READ INSTRUCTIONS - Before installation
before use. See 14
LIST OF INSTALLATION AND USE
ACCESSORIES - ACCESSORIES
REQUIREMENTS - ACCESSORIES
NAME OF BUSINESS & PHONE NO. - ADDRESS - CITY/STATE

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NAME OF BUSINESS & PHONE NO. - ADDRESS - CITY/STATE



1st PM 2nd PM

29	Clean ISE Sipper nozzle and replace tubing	6 Month	Clean/Replace	<input type="checkbox"/>	VDC
30	Replace ISE Sipper nozzle	12 Month	Replace	<input checked="" type="checkbox"/>	VDC
31	Clean the ISE waste vessel	6 Month	Clean	<input checked="" type="checkbox"/>	VDC
32	Check Vacuum Pump tubing and connections	6 Month	Check	<input checked="" type="checkbox"/>	VDC
33	Check Vacuum tank for liquid accumulation	6 Month	Check	<input checked="" type="checkbox"/>	VDC
34	Check Vacuum Pump Diaphragm	12 Month	Check/Replace	<input checked="" type="checkbox"/>	VDC
35	Replace HEPA filter	12 Month	Replace	<input checked="" type="checkbox"/>	VDC
36	Check and record 5V1	6 Month	Check/Adj/Record	5v	VDC
37	Check and record 5V2	6 Month	Check/Adj/Record	5v	VDC
38	Check and record 12V	6 Month	Check/Adj/Record	12v	VDC
39	Check and record 24V1	6 Month	Check/Adj/Record	24v	VDC
40	Check and record 24V2	6 Month	Check/Adj/Record	24v	VDC
41	Check Gear Pump pressure, adjust if necessary	6 Month	Check	<input checked="" type="checkbox"/>	
42	Check Rinse nozzle dispense volumes	6 Month	Check	<input checked="" type="checkbox"/>	
43	Perform a Cell Blank	6 Month	Check	<input checked="" type="checkbox"/>	
44	Perform an Air Purge and IS + REF Prime	6 Month	Check	<input checked="" type="checkbox"/>	
45	Perform ISE check x20	6 Month	Check	<input checked="" type="checkbox"/>	
46	Perform a Mech Check x10	6 Month	Check	<input checked="" type="checkbox"/>	
47	Copy the bk1 backup file on the cobas® link	6 Month	Check	<input checked="" type="checkbox"/>	
48	Run Controls to verify analyzer performance	6 Month	Check	<input checked="" type="checkbox"/>	

Work performed per requirements

FSR Name: Amrit Pal Singh

Date: 11-12-2020

FSR Signature: 

Roche Diagnostics
 Technical Publications Department
 9115 Hague Rd.
 Indianapolis, IN 46250-0457 USA

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 3981-00-0510

Photometer Check

11/12/20 15:18

-----PREVIOUS DATA-----
DATE 11/12/20 07:04

340 nm	11870
376 nm	9320
415 nm	10025
450 nm	8824
480 nm	8692
505 nm	8582
546 nm	8479
570 nm	8387
600 nm	8244
660 nm	8854
700 nm	8729
800 nm	8580

-----CURRENT DATA-----
DATE 11/12/20 15:17

340 nm	12045
376 nm	9495
415 nm	10164
450 nm	8956
480 nm	8812
505 nm	8698
546 nm	8588
570 nm	8496
600 nm	8343
660 nm	8948
700 nm	8812
800 nm	8610

 * HITACHI AUTOMATIC ANALYZER *

 DATE 11/12/20 09:19:42
 OPERATOR ID HIRA

PCCC 2
 C013135 001
 41010520

NAME
 S.NO.
 LOT

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
CREJ2	3.79	mg/dL	(3.61-	4.61)
ALP2L	207	U/L	(205-	261)
UA2	10.2	mg/dL	(8.58-	10.50)
ALB2	5.10	g/dL	(4.39-	5.59)
UREAL	114	mg/dL	(109-	133)
TP2	7.14	L	(7.16-	8.40)
AMYL2	187	U/L	(169-	217)
GLUC3	251	mg/dL	(212-	260)
CHO21	169	mg/dL	(153-	189)
PHOS2	7.26	mg/dL	(6.80-	8.32)
BILD2	2.38	mg/dL	(2.16-	2.96)
TRIGL	207	mg/dL	(190-	234)
ASTL	150	U/L	(132-	168)
ALT1L	113	U/L	(109-	137)
CAL2	14.1	mg/dL	(12.7-	14.7)
CRPL3	52.16	mg/L	(45.6-	59.6)
BILT3	3.5	mg/dL	(3.32-	4.24)
GGT12	253	U/L	(242-	310)
HDLC4	57.7	mg/dL	(51.9-	71.9)