

		12 Month	Replace
35	Replace HEPA filter		
36	Check and record 5V1	6 Month	Check/Adj/Record
37	Check and record 5V2	6 Month	Check/Adj/Record
38	Check and record 12V	6 Month	Check/Adj/Record
39	Check and record 24V1	6 Month	Check/Adj/Record
40	Check and record 24V2	6 Month	Check/Adj/Record
41	Check Gear Pump pressure, adjust if necessary	6 Month	Check
42	Check Rinse nozzle dispense volumes	6 Month	Check
43	Perform a Cell Blank	6 Month	Check
44	Perform an Air Purge and IS + REF Prime	6 Month	Check
45	Perform ISE check x20	6 Month	Check
46	Perform a Mech Check x10	6 Month	Check
47	Copy the bk1 backup file on the cobas® link	6 Month	Check
48	Run Controls to verify analyzer performance	6 Month	Check

Work performed per requirements

FSR Name: W NEET

Date: _____

FSR Signature: _____

[Handwritten Signature]

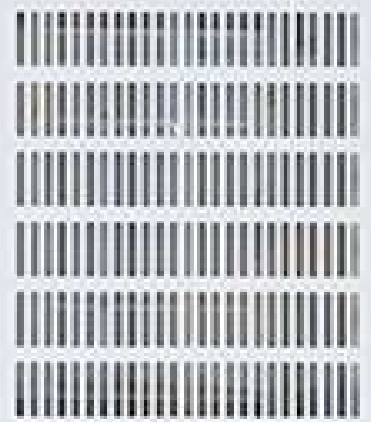
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HITACHI

cobas c 311





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

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

Account Name:

Account Number:

Analyzer S/N:

Current Year:

Service Order
Number

Instrument Test
Counts

PM Date

First PM:

Second PM:

1st PM 2nd PM

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

29	Clean ISE Sipper nozzle and replace tubing	6 Month	Clean/Replace	<input type="checkbox"/>	<input checked="" type="checkbox"/>	VDC
30	Replace ISE Sipper nozzle	12 Month	Replace	<input type="checkbox"/>	<input checked="" type="checkbox"/>	VDC
31	Clean the ISE waste vessel	6 Month	Clean	<input type="checkbox"/>	<input checked="" type="checkbox"/>	VDC
32	Check Vacuum Pump tubing and connections	6 Month	Check	<input type="checkbox"/>	<input checked="" type="checkbox"/>	VDC
33	Check Vacuum tank for liquid accumulation	6 Month	Check	<input type="checkbox"/>	<input checked="" type="checkbox"/>	VDC
34	Check Vacuum Pump Diaphragm	12 Month	Check/Replace	<input type="checkbox"/>	<input checked="" type="checkbox"/>	VDC
35	Replace HEPA filter	12 Month	Replace	<input type="checkbox"/>	<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 type="checkbox"/>	<input checked="" type="checkbox"/>	
42	Check Rinse nozzle dispense volumes	6 Month	Check	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
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46	Perform a Mech Check x10	6 Month	Check	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
47	Copy the bk1 backup file on the cobas ® link	6 Month	Check	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
48	Run Controls to verify analyzer performance	6 Month	Check	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

Work performed per requirements

FSR Name: Puneet Billowria

Date: 04/12/2021

FSR Signature:

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