Ortho Clinical Diagnostics

403, Leela Business Park, Andheri Kurla Road,
Andheri East, Mumbai – 400059
T : +91 22 6787 9300
F : +91 22 6787 9333

Calibration Certificate

The below mentioned instrument has been calibrated and tests performed to check the system performance.

Instrument	: VITROS V5600
Serial No	: 5600 0703
Customer Name	: Central Clinical Laboratory Pravara Rural Hospital-Loni
Calibration performed on	: 29/11/2021

The system's calibration includes optics calibration and checking the reproducibility performance of the instrument as per the guidelines provided by the manufacturer.

Next Calibration will be performed in **MAY 2022**.

For **Ortho Clinical Diagnostics India Pvt Ltd.**

Mitesh Shah

Date: 29/11/2021

Sr.Zonal Service Manager-Ortho Care
Pune

Ortho Clinical Diagnostics

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Andheri East, Mumbai – 400059
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Calibration Certificate

The below mentioned instrument has been calibrated and tests performed to check the system performance.

Instrument	: VITROS V5600
Serial No	: 5600 1041
Customer Name	: Central Clinical Laboratory Pravara Rural Hospital-Loni
Calibration performed on	: 26/11/2021

The system's calibration includes optics calibration and checking the reproducibility performance of the instrument as per the guidelines provided by the manufacturer.

Next Calibration will be performed in **MAY 2022**.

For **Ortho Clinical Diagnostics India Pvt Ltd.**

Mitesh Shah **Date: 26/11/2021**

Sr.Zonal Service Manager-Ortho Care
Pune

Service Report

Ortho Clinical Diagnostics
INDIA Pvt. Ltd.

SOP-OCDIN-019/F02
Revision-02

Report No: 3624

Customer's Name: Pravara Medical Trust
Contact Person: Dr. Jangle (Biochemistry Lab)
Address: At post Loni, Tal. Rahata, Dist. Ahmednagar.

SOLD ☐ ❑ Warranty ❑ AMC/CMC ❑ Charge Call

RRC ☑

Nature of Call:
☐ Service Call ☐ Follow up ☑ Modification ☐ Application ☑ Preventive Maintenance
☐ Telephone ☑ eConn Proactive ☐ UPS ☐ Printer ☐ Other _____

Observed damage before service:
NA

Instrument Particulars:
Model Vitros 5600
J Number J56001041
Serial Number 56001041

Problem reported:
Error Code : xpm; Ecompres; Intellicheck; XMF6, XME6
Description : Preventive Maintenance;
Econ alert for compressor & intellicheck.
Modification # F6 Software update 3.7.1
Modification # E6 wear pads.

Call Details : Status after call :
Functioning well ☑
Incomplete but operative ☐
Needs spares ☐
Complaint forwarded to L.S. ☐
Requires follow-up ☐
Complaint escalated to _____ ☐
METER COUNT _____
SO No. 98191413

Call Details :
Complaint Forwarded by : Self
Complaint Call Date : 22/11/2021 Time: 20:15
Travel Duration (To & Fro): 2 1 Hr.
Call Attended Date : 25/11/2021 Time: 17:10
Start Time : 24/11/2021 17:15
End Time : 26/11/2021 19:00
Actual Work Hours: 14 Hr. 15 mins. + 2 Hrs.
☐ Solved over Phone. Date : _____
Time: _____

Diagnosis :
Software update v.3.7.1, mod# E6, replace air filter (canister) & preventive maintenance

Action taken / Action required:
Done backup. Updated slo version to 3.7.1. Cleaned the system. Cleaned all the modules. Done adjustments & performance tests. Run maintenance pack. Requested user to run control & samples.

For Customer Only :
Job complete ☐
Job incomplete ☐
Satisfied ☐
Unsatisfied ☐
Comments : _____
Customer's Signature & Date : 29/11/21

For Engineer Only :
Engineer's Name : Mitesh C. Shah / Kedar More
Engineer's Code : AINFE09 / AINFE10
Comments : System working ok.
Engineer's Signature & Date : 26/11/2021

Spares details:

Part No.	Description	Qty.	Source	SPR No.	Remarks
J61063	FAN Assy, 12 V DC	02	Company ☑	1000133742	Replaced
1C3537	IR wash cam	01	Customer ☐	1000133742	Replaced
T24980	Bearing flgd	03		1000133742	Replaced
J31939	Linear stepper mtr.	02		1000133742	Replaced
J60628	Roller, Kicker Bearing	02		1000133742	Replaced
J23940	ERE Tubing	01		1000133742	Replaced
J27110	Evap cap	01		1000133742	Replaced
J29532	Intake Filter	02		1000133742	Replaced

Service charge: NA J19057 WW Filter-02, J66860 Shuttle Body-01, J09974 SR Disp. Tip 01
Spares to be invoiced ☐ Service to be charged ☐ 1H5419 vapor adsorption 01, J37201 Hinge 01

Address : 403, Leela Business Park, Andheri Kurla Road, Andheri (East), Mumbai - 400059

Customer Copy

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: GLU
FLUID: Serum KIT LOT: 0110 CAL DATE/TIME: 17/12/2021 10:24:20
Status: Passed REAGENT GEN/LOT: 00098952
OP ID:
SITE TEMP: 28.4C SUPPLY HUMIDITY: 13

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: 0.267241				
SLOPE: 97.6219	1	1	33	0.270005
CURVATURE/SLOPE2: 0.424132	2	2	293	1.12527
	3	3	565	1.57205

End of Report PRINT DATE/TIME: 4/4/2022 11:21:39

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: CREA CAL DATE/TIME: 30/11/2021 14:19:18
FLUID: Serum KIT LOT: 0110 REAGENT GEN/LOT: 15319728
Status: Passed
OP ID:
SITE TEMP: 26.8C SUPPLY HUMIDITY: 16

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE	RESPONSE
INTERCEPT:	-0.0343734			mg/dL	
SLOPE:	112.430	1	1	0.6	0.003698
CURVATURE/SLOPE2:	0.000000000000	2	2	1.5	0.009392
SUB DEP DENS:	0.425994	3	3	13.2	0.065449

End of Report PRINT DATE/TIME: 4/4/2022 11:23:20

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: ALTV
FLUID: Serum KIT LOT: 0320
Status: Passed
OP ID:
SITE TEMP: 27.7C

CAL DATE/TIME: 30/3/2022 17:07:23
REAGENT GEN/LOT: 56064173

SUPPLY HUMIDITY: 9

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE U/L	RESPONSE
INTERCEPT:	0.324064				
SLOPE:	99.9461	1	1	9	0.011655
CURVATURE/SLOPE2:	-0.0798065	2	2	216	0.139018
SUBS DEPL DENS:	0.508329	3	3	761	0.416151
DELTA DENSITY:	NA				
1ST POINT REF:	3.17388				

End of Report

PRINT DATE/TIME: 4/4/2022 11:24:37

CALIBRATION REPORT

SYSTEM NAME: 5600703

ASSAY: AST
FLUID: Serum
Status: Passed
OP ID:
SITE TEMP: 28.7C

KIT LOT: 0320

CAL DATE/TIME: 9/3/2022 11:11:58
REAGENT GEN/LOT: 73285153

SUPPLY HUMIDITY: 13

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE U/L	RESPONSE
INTERCEPT:	1.54187				
SLOPE:	96.7002	1	1	15	0.005061
CURVATURE/SLOPE2:	2.09016	2	2	208	0.072773
SUBS DEPL DENS:	0.489897	3	3	690	0.217001
DELTA DENSITY:	NA				
1ST POINT REF:	7.03519				

End of Report

PRINT DATE/TIME: 5/4/2022 11:12:27

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: TBIL CAL DATE/TIME: 10/1/2022 12:34:57
FLUID: Serum KIT LOT: 0460 REAGENT GEN/LOT: 14483001
Status: Passed
OP ID:
SITE TEMP: 29.9C SUPPLY HUMIDITY: 35

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE	RESPONSE 1	RESPONSE 2
INTERCEPT: -3.43022			mg/dL		
SLOPE: 30.3032	1	1	1.1	0.190473	0.199040
CURVATURE/SLOPE2: 6.71292	2	3	9.8	0.408122	0.328641
	3	2	17.6	0.516902	0.418307

End of Report PRINT DATE/TIME: 4/4/2022 11:23:36

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: Bu CAL DATE/TIME: 20/10/2021 11:47:15
FLUID: Serum KIT LOT: 0460 REAGENT GEN/LOT: 02079935
Status: Passed
OP ID:
SITE TEMP: 28.4C SUPPLY HUMIDITY: 35

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE	RESPONSE 1	RESPONSE 2
INTERCEPT: 2.41299			mg/dL		
SLOPE: 237.587	1	1	0.6	0.136440	0.162043
CURVATURE/SLOPE2: -186.980	2	2	6.8	0.654255	0.581417
	3	3	9.7	0.482628	0.322557
	4	4	21.7	0.808774	0.545860

End of Report PRINT DATE/TIME: 4/4/2022 11:35:01

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: Bc CAL DATE/TIME: 20/10/2021 11:47:15
FLUID: Serum KIT LOT: 0460 REAGENT GEN/LOT: 02079935
Status: Passed
OP ID:
SITE TEMP: 28.4C SUPPLY HUMIDITY: 35

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE	RESPONSE 1	RESPONSE 2
INTERCEPT:	-3.78743			mg/dL		
SLOPE:	-133.900	1	1	0.1	0.136440	0.162043
CURVATURE/SLOPE2:	254.194	2	3	1.0	0.482628	0.322557
		3	4	8.0	0.808774	0.545860
		4	2	20.1	0.654255	0.581417

End of Report PRINT DATE/TIME: 4/4/2022 11:34:40

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: ALKP CAL DATE/TIME: 21/2/2022 15:54:28
FLUID: Serum KIT LOT: 0320 REAGENT GEN/LOT: 65242735
Status: Passed
OP ID:
SITE TEMP: 28.2C SUPPLY HUMIDITY: 11

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE	RESPONSE
INTERCEPT:	6.29555			U/L	
SLOPE:	96.6893	1	1	21	0.000478
CURVATURE/SLOPE2:	-0.170077	2	2	128	0.004588
SUBS DEPL DENS:	0.263819	3	3	1298	0.042905
DELTA DENSITY:	NA				
1ST POINT REF:	8.87934				

End of Report PRINT DATE/TIME: 29/4/2022 10:24:22

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: TRIG CAL DATE/TIME: 14/12/2021 10:24:10
FLUID: Serum KIT LOT: 0230 REAGENT GEN/LOT: 07049833
Status: Passed
OP ID:
SITE TEMP: 27.2C SUPPLY HUMIDITY: 35

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE	RESPONSE
INTERCEPT: -2.56962			mg/dL	
SLOPE: 90.1671	1	1	27	0.292350
CURVATURE/SLOPE2: 2.14201	2	3	200	0.892900
	3	2	463	1.58789

End of Report PRINT DATE/TIME: 4/4/2022 11:32:16

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: CHOL CAL DATE/TIME: 24/1/2022 12:31:37
FLUID: Serum KIT LOT: 0230 REAGENT GEN/LOT: 08459641
Status: Passed
OP ID:
SITE TEMP: 26.1C SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE	RESPONSE
INTERCEPT: 3.07877			mg/dL	
SLOPE: 96.9900	1	1	45	0.494310
CURVATURE/SLOPE2: 0.129873	2	2	184	0.900709
	3	3	410	1.29231

End of Report PRINT DATE/TIME: 4/4/2022 11:31:16

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: Mg CAL DATE/TIME: 1/4/2022 15:09:50
FLUID: Serum KIT LOT: 0110 REAGENT GEN/LOT: 32068342
Status: Passed
OP ID:
SITE TEMP: 28.1C SUPPLY HUMIDITY: 33

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE	RESPONSE
INTERCEPT:	0.382835			mg/dL	
SLOPE:	108.008	1	1	0.8	0.969862
CURVATURE/SLOPE2:	99.0107	2	2	3.8	1.35466
		3	3	9.6	1.95383

End of Report PRINT DATE/TIME: 4/4/2022 11:29:11

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: dHDL
FLUID: Serum KIT LOT: 2540
Status: Passed
OP ID:
SITE TEMP: 27.1C

CAL DATE/TIME: 5/1/2022 12:34:55
REAGENT GEN/LOT: 11322283
SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: -0.511405				
SLOPE: 100.498	1	1	7	0.337742
CURVATURE/SLOPE2: 3.33635	2	2	34	0.591347
	3	3	108	0.836992

End of Report

PRINT DATE/TIME: 4/4/2022 11:33:00

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: URIC
FLUID: Serum KIT LOT: 0110
Status: Passed
OP ID:
SITE TEMP: 26.6C

CAL DATE/TIME: 30/11/2021 14:20:25
REAGENT GEN/LOT: 05489467

SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: 0.0466648				
SLOPE: 103.999	1	1	0.9	0.227342
CURVATURE/SLOPE2: 10.2910	2	2	5.8	0.697498
	3	3	16.6	1.36498

End of Report

PRINT DATE/TIME: 4/4/2022 11:27:59

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: PHOS
FLUID: Serum KIT LOT: 0110
Status: Passed
OP ID:
SITE TEMP: 28.3C

CAL DATE/TIME: 9/12/2021 10:43:57
REAGENT GEN/LOT: 12483461

SUPPLY HUMIDITY: 35

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: 0.597449				
SLOPE: 88.2428	1	1	1.2	0.212526
CURVATURE/SLOPE2: 226.099	2	2	5.6	0.466079
	3	3	12.9	0.672439

End of Report

PRINT DATE/TIME: 4/4/2022 11:30:40

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: UREA
FLUID: Serum KIT LOT: 0110
Status: Passed
OP ID:
SITE TEMP: 26.7C

CAL DATE/TIME: 30/11/2021 14:19:47
REAGENT GEN/LOT: 01318070

SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL(A)	RESPONSE
INTERCEPT: 0.113747				
SLOPE: 100.413	1	1	8	0.151459
CURVATURE/SLOPE2: 5.92787	2	2	105	0.950080
	3	3	236	1.74326

End of Report

PRINT DATE/TIME: 4/4/2022 11:22:14

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: AMYL
FLUID: Serum KIT LOT: 0320
Status: Passed
OP ID:
SITE TEMP: 28.5C

CAL DATE/TIME: 7/10/2021 10:51:00
REAGENT GEN/LOT: 60169168

SUPPLY HUMIDITY: 35

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE U/L	RESPONSE
INTERCEPT:	9.29706				
SLOPE:	106.919	1	1	51	0.009868
CURVATURE/SLOPE2:	2.79488	2	2	392	0.047469
SUB DEP DENS:	1.18899	3	3	997	0.094086

End of Report

PRINT DATE/TIME: 4/4/2022 11:25:44

CALIBRATION REPORT SYSTEM NAME: 5600703

ASSAY: Ca CAL DATE/TIME: 30/11/2021 14:21:03
FLUID: Serum KIT LOT: 0110 REAGENT GEN/LOT: 03039170
Status: Passed
OP ID:
SITE TEMP: 26.5C SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE	RESPONSE
INTERCEPT: -0.00562739			mg/dL	
SLOPE: 89.1140	1	3	1.7	0.698419
CURVATURE/SLOPE2: 0.000000000000	2	2	9.0	1.15114
	3	1	13.9	1.38325

End of Report PRINT DATE/TIME: 4/4/2022 11:28:35

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: GLU
FLUID: Serum KIT LOT: 0110 CAL DATE/TIME: 17/12/2021 10:33:26
Status: Passed REAGENT GEN/LOT: 00098952
OP ID:
SITE TEMP: 29.7C SUPPLY HUMIDITY: 13

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: 1.63615				
SLOPE: 96.2517	1	1	33	0.266175
CURVATURE/SLOPE2: 0.584552	2	2	293	1.12835
	3	3	565	1.57345

End of Report PRINT DATE/TIME: 4/4/2022 11:10:25

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: CREA
FLUID: Serum KIT LOT: 0110
Status: Passed
OP ID:
SITE TEMP: 27.6C

CAL DATE/TIME: 30/11/2021 14:31:11
REAGENT GEN/LOT: 15319728

SUPPLY HUMIDITY: 13

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE	RESPONSE
INTERCEPT:	-0.0541661			mg/dL	
SLOPE:	111.969	1	1	0.6	0.003826
CURVATURE/SLOPE2:	0.000000000000	2	2	1.5	0.009536
SUB DEP DENS:	0.430258	3	3	13.2	0.065823

End of Report

PRINT DATE/TIME: 4/4/2022 11:14:01

CALIBRATION REPORT

SYSTEM NAME: 5601041

ASSAY: ALTV
FLUID: Serum
Status: Passed
OP ID:
SITE TEMP: 26.8C

KIT LOT: 0320

CAL DATE/TIME: 27/11/2021 17:35:12
REAGENT GEN/LOT: 56060225

SUPPLY HUMIDITY: 13

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE U/L	RESPONSE
INTERCEPT:	0.180227				
SLOPE:	100.658	1	1	9	0.011726
CURVATURE/SLOPE2:	0.252039	2	2	216	0.137514
SUBS DEPL DENS:	0.505881	3	3	761	0.404376
DELTA DENSITY:	NA				
1ST POINT REF:	3.15859				

End of Report

PRINT DATE/TIME: 4/4/2022 11:15:50

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: AST
FLUID: Serum KIT LOT: 0320
Status: Passed
OP ID:
SITE TEMP: 29.1C

CAL DATE/TIME: 9/3/2022 11:47:24
REAGENT GEN/LOT: 73285153
SUPPLY HUMIDITY: 13

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE	RESPONSE
INTERCEPT:	1.44557			U/L	
SLOPE:	98.6854	1	1	15	0.005001
CURVATURE/SLOPE2:	0.983398	2	2	208	0.072998
SUBS DEPL DENS:	0.489488	3	3	690	0.226543
DELTA DENSITY:	NA				
1ST POINT REF:	7.03013				

End of Report

PRINT DATE/TIME: 4/4/2022 11:14:34

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: TBIL
FLUID: Serum KIT LOT: 0460
Status: Passed
OP ID:
SITE TEMP: 30.3C

CAL DATE/TIME: 10/1/2022 12:54:51
REAGENT GEN/LOT: 14483001

SUPPLY HUMIDITY: 35

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE	RESPONSE 1	RESPONSE 2
INTERCEPT: -3.55472			mg/dL		
SLOPE: 31.8012	1	1	1.1	0.189014	0.197460
CURVATURE/SLOPE2: 3.80023	2	3	9.8	0.408233	0.329984
	3	2	17.6	0.520751	0.424288

End of Report

PRINT DATE/TIME: 4/4/2022 11:14:17

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: Bu
FLUID: Serum KIT LOT: 0460
Status: Passed
OP ID:
SITE TEMP: 28.5C

CAL DATE/TIME: 20/10/2021 11:56:17
REAGENT GEN/LOT: 02079935

SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE	RESPONSE 1	RESPONSE 2
INTERCEPT: 2.86560			mg/dL		
SLOPE: 249.097	1	1	0.6	0.130505	0.164592
CURVATURE/SLOPE2: -207.053	2	2	6.8	0.641979	0.556780
	3	3	9.7	0.476381	0.314441
	4	4	21.7	0.789259	0.520370

End of Report

PRINT DATE/TIME: 4/4/2022 11:21:30

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: Bc
FLUID: Serum KIT LOT: 0460 CAL DATE/TIME: 20/10/2021 11:56:17
Status: Passed REAGENT GEN/LOT: 02079935
OP ID:
SITE TEMP: 28.5C SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE 1	RESPONSE 2
INTERCEPT: -4.57232					
SLOPE: -135.721	1	1	0.1	0.130505	0.164592
CURVATURE/SLOPE2: 275.017	2	3	1.0	0.476381	0.314441
	3	4	8.0	0.789259	0.520370
	4	2	20.1	0.641979	0.556780

End of Report PRINT DATE/TIME: 4/4/2022 11:21:57

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: ALKP
FLUID: Serum KIT LOT: 0320 CAL DATE/TIME: 21/2/2022 16:04:11
Status: Passed REAGENT GEN/LOT: 65242735
OP ID:
SITE TEMP: 28.9C SUPPLY HUMIDITY: 13

PARAMETERS		LEVEL	BOTTLE	CALIB VALUE U/L	RESPONSE
INTERCEPT:	5.71241				
SLOPE:	97.6871	1	1	21	0.000493
CURVATURE/SLOPE2:	0.310304	2	2	128	0.004533
SUBS DEPL DENS:	0.251355	3	3	1298	0.040835
DELTA DENSITY:	NA				
1ST POINT REF:	8.60456				

End of Report PRINT DATE/TIME: 29/4/2022 10:31:37

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: TRIG
FLUID: Serum KIT LOT: 0230 CAL DATE/TIME: 15/12/2021 09:53:55
Status: Passed REAGENT GEN/LOT: 07049833
OP ID:
SITE TEMP: 28.3C SUPPLY HUMIDITY: 35

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: -23.8010				
SLOPE: 109.158	1	1	27	0.361645
CURVATURE/SLOPE2: -1.55834	2	3	200	0.886041
	3	2	463	1.62546

End of Report PRINT DATE/TIME: 4/4/2022 11:20:19

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: CHOL
FLUID: Serum
Status: Passed
OP ID:
SITE TEMP: 27.3C

KIT LOT: 0230

CAL DATE/TIME: 24/1/2022 12:41:31
REAGENT GEN/LOT: 08459641

SUPPLY HUMIDITY: 33

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: 5.02189				
SLOPE: 93.7497	1	1	45	0.490888
CURVATURE/SLOPE2: 0.812442	2	2	184	0.904349
	3	3	410	1.29182

End of Report

PRINT DATE/TIME: 4/4/2022 11:20:06

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: Mg
FLUID: Serum KIT LOT: 0110
Status: Passed
OP ID:
SITE TEMP: 28.8C

CAL DATE/TIME: 16/9/2021 11:21:29
REAGENT GEN/LOT: 32068342
SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: 0.361532				
SLOPE: 101.621	1	1	0.8	0.976550
CURVATURE/SLOPE2: 103.589	2	2	3.8	1.38205
	3	3	9.6	1.99126

End of Report

PRINT DATE/TIME: 4/4/2022 11:19:19

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: dHDL
FLUID: Serum KIT LOT: 2540
Status: Passed
OP ID:
SITE TEMP: 28.2C

CAL DATE/TIME: 5/1/2022 12:42:27
REAGENT GEN/LOT: 11322283
SUPPLY HUMIDITY: 31

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: -0.244157				
SLOPE: 93.8445	1	1	7	0.342356
CURVATURE/SLOPE2: 9.57231	2	2	34	0.598629
	3	3	108	0.836760

End of Report

PRINT DATE/TIME: 4/4/2022 11:20:43

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: URIC
FLUID: Serum KIT LOT: 0110
Status: Passed
OP ID:
SITE TEMP: 27.3C

CAL DATE/TIME: 27/11/2021 16:02:07
REAGENT GEN/LOT: 05489467

SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: -0.00268656				
SLOPE: 102.623	1	1	0.9	0.236541
CURVATURE/SLOPE2: 8.31990	2	2	5.8	0.707108
	3	3	16.6	1.38348

End of Report

PRINT DATE/TIME: 4/4/2022 11:18:04

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: PHOS
FLUID: Serum KIT LOT: 0110
Status: Passed
OP ID:
SITE TEMP: 29.0C

CAL DATE/TIME: 9/12/2021 10:53:30
REAGENT GEN/LOT: 12483461

SUPPLY HUMIDITY: 35

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: 0.546283				
SLOPE: 86.2334	1	1	1.2	0.217389
CURVATURE/SLOPE2: 213.892	2	2	5.6	0.473451
	3	3	12.9	0.680923

End of Report

PRINT DATE/TIME: 4/4/2022 11:19:40

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: UREA
FLUID: Serum KIT LOT: 0110
Status: Passed
OP ID:
SITE TEMP: 27.6C

CAL DATE/TIME: 30/11/2021 14:31:37
REAGENT GEN/LOT: 01318070
SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL(A)	RESPONSE
INTERCEPT: 0.209745				
SLOPE: 99.6223	1	1	8	0.149922
CURVATURE/SLOPE2: 7.26464	2	2	105	0.949782
	3	3	236	1.73500

End of Report

PRINT DATE/TIME: 4/4/2022 11:13:12

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: AMYL
FLUID: Serum KIT LOT: 0320 CAL DATE/TIME: 7/10/2021 10:58:30
Status: Passed REAGENT GEN/LOT: 60169168
OP ID:
SITE TEMP: 28.5C SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE U/L	RESPONSE
INTERCEPT: 11.1882				
SLOPE: 112.761	1	1	51	0.009416
CURVATURE/SLOPE2: 2.95956	2	2	392	0.045173
SUB DEP DENS: 1.18001	3	3	997	0.091037

End of Report PRINT DATE/TIME: 4/4/2022 11:17:14

CALIBRATION REPORT SYSTEM NAME: 5601041

ASSAY: Ca
FLUID: Serum KIT LOT: 0110
Status: Passed
OP ID:
SITE TEMP: 27.5C

CAL DATE/TIME: 30/11/2021 14:32:53
REAGENT GEN/LOT: 03039170
SUPPLY HUMIDITY: 34

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: 0.0384845				
SLOPE: 95.6149	1	3	1.7	0.683448
CURVATURE/SLOPE2: 0.000000000000	2	2	9.0	1.12001
	3	1	13.9	1.33930

End of Report

PRINT DATE/TIME: 4/4/2022 11:18:35

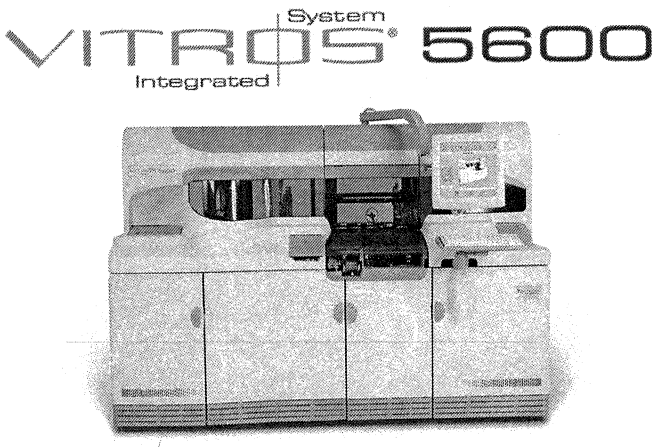
0703

Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS® 5600 INTEGRATED SYSTEM



Manufactured by:

Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. APPROVAL OF THE IQ PROCEDURE:

Both Central Clinical Laboratory Pravara Rural Hospital and Ortho Clinical Diagnostics are responsible for installation of VITROS® 5600 Immunodiagnostic System bearing Sr. No **J5600-0703** in Central Clinical Laboratory, Pravara Rural Hospital as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : *Mitesh Shah* Signature:

Designation : Sr. Zonal Manager Date: 23/06/2018

Company : Ortho Clinical Diagnostics

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K. N. Hotkar. Signature:

Designation : Asso. professor. Date: 23/06/2018.

Department : Biochemistry

Name : Mr. Bhawas S.R. Signature :

Designation : Sr. Lab. Tech. Date : 23/06/2018

Department : Biochemistry

Customer Authorizations:

Name : Dr. S.N. Jangle, Sir

Designation : Prof. & Head. Dept. of Biochemistry.

Signature : S.N Jangle

Date : 23/06/2018

PROFESSOR & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736,(M.S.)INDIA

II. INSTRUCTIONS:

1. This document is to be completed at the time the system is installed to its location and set up for operation.

2. An authorized Ortho Clinical Diagnostics representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification.

3. Employees of Central Clinical Laboratory Pravara Rural Hospital will verify each result and sign in the each page. The member of the validation team will carry out this procedure.

4. ALL deviations from normal specification during installation will be noted under COMMENTS. All resolution to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this protocol for the same.

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS® 5600 Immunodiagnostic System, and the Sr. No. 56000703 located at

This protocol will define the documentation that will be used to evaluate the instrument's installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Installation checks will also be performed to verify that the Instrument has been installed with proper connections and utilities.

Trained, knowledgeable personnel will perform Installation Qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

IV. ANCILLARY INFORMATION

a. Certification of Purchase Order Compliance

I certify to the best of my knowledge, the instrument VITROS® 5600 Immunodiagnostic System and **Sr. No.** 56000703 ----- installed on 20/06/2018.

Verified By: Mitesh C. Shah Date: 20/06/2018

b. Utilities

Sr. No	Utility		Verified by & date
1.	**Environmental condition:** As per requirement (To be free from Dust, Electrical & magnetic Interferences and free from vibration)	Yes / No	Mitesh C. Shah 20/06/2018
2.	**Adequate space for installation:** (Length 110 inches x Width 35 inches x Height 84 inches)	Yes / No	Mitesh C. Shah 20/06/2018
3.	**Electrical Outlets:** Actual Voltage on site [200 Vac – 240 Vac] **Electrical Input:** Voltage supplied through ON LINE UPS (232Vac @ 50Hz frequency, Earthing < 2.0Vac)	Yes / No	Mitesh C. Shah 20/06/2018
4.	**Capacities:** • 90 samples (80 Routine positions & 10 STAT positions are available) • 150 Reagent Positions are available.	Yes / No	Mitesh C. Shah 20/06/2018
5.	**Temperature:** 15° C to 30° C 15% to 75% relative humidity	Yes / No	Mitesh C. Shah 20/06/2018

The instrument has been verified for the following:

Sr. No.	Verification		Verified by & date
1.	Equipment is identified	Yes / No	20/06/2018
2.	Manufacturer's specifications are included	Yes / No	20/06/2018
3.	Accessories / Consumables are listed	Yes / No	20/06/2018
4.	Equipment manual from the manufacturer is documented	Yes / No	20/06/2018
5.	Manufacturer's Certificate of compliance attached	Yes / No	20/06/2018

V INSTALLATION QUALIFICATION:

A. Equipment Description

The VITROS® 5600 Integrated System is a Random access, walk away system intended for use in the *in vitro* quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Chemistry Products MicroSlides, VITROS Chemistry Products MicroTip reagents and VITROS Immunodiagnostic Products Reagents.

Instrument Identification		Verified by	Date
Equipment Name :	**Automated Integrated System**	Mitesh C. Shah	20/06/2018
Model :	VITROS® 5600	Mitesh C. Shah	20/06/2018
Manufacturer :	Ortho Clinical Diagnostics, Inc., US	Mitesh C. Shah	20/06/2018
Marketed by :	Ortho Clinical Diagnostics India Pvt. Ltd.	Mitesh C. Shah	20/06/2018
Serial Number :	5600 0703	Mitesh C. Shah	20/06/2018
Lab Id :	No. 1	Mitesh C. Shah	20/06/2018
Software Name :	QNX	Mitesh C. Shah	20/06/2018
Software Version :	V. 3.3.1	Mitesh C. Shah	20/06/2018
Size (in inches) :	Adequate for installation: (Length 170 x Width 83 x Height 84).	Mitesh C. Shah	20/06/2018
Power :	1600W@ 50Hz of 220Vac – 240Vac	Mitesh C. Shah	20/06/2018

B. Accessories/Consumables

The following accessories were supplied with the instrument. Check (√) 'verified by' in case they are found to be in order.

Description	Quantity	Verified	Date
User Training Manual	1	✓	20/06/2018
Application Software-Revelation	1	✓	20/06/2018
Universal Sample Tray	9	✓	20/06/2018
Backup DVD R/w	3	✓	20/06/2018
Printer Cable	1	✓	20/06/2018
Printer Software	1	✓	20/06/2018
Power Cords	3	✓	20/06/2018
Printer	1	✓	20/06/2018
Air filter	1	✓	20/06/2018
Waste can 5L	1	✓	20/06/2018

C. **List of Manuals :**

Ortho Clinical Diagnostics has supplied following manual.

D. **Maintenance :**

The instrument listed within this document will be placed under the control of the purchasing institution with respect to proper maintenance procedures as detailed in the Training and Reference Guide. The maintenance procedures will be filed separately.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period Johnson and Johnson Ltd offers several levels of Maintenance Agreements and Performance Testing services to assist you in maintaining GLP/GMP compliance. Contacting your local representative and requesting the additional Service Agreement can supply additional information.

VI. INSTALLATION PROCEDURE

(The following steps Performed at the time of original installation at the initial location)

1. Locating & unpacking the instrument.
2. Reaffix/verify the circuits boards & CPU
3. Nominal Line voltage frequency selection of transformer.
4. Load Supply & Power ON the system.
5. System Configuration.
6. Systems Tests & Adjustments.
7. Subsystems Performance Verification & calibration
8. Setting and installing printer.

The Above mentioned steps has completed successfully by trained field Engineer as described below.

VI.1 Locating & unpacking the VITROS® 5600 instrument:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf)

- Check the Tip & Tell Label.
- Verify the serial no / J number of the system match those indented for delivery.
- Place the pallet in a position with a minimum of 7 m (24 ft.) of clearance in front of the end with the LABELS
- Remove the STRAPPING and the RAMPS from the pallet..
- Assemble the 2 piece RAMP and hok the RAMPS to the end of the pallet
- Move the system down the ramps. Do the same for the second half of the system.
- Place the instrument in the lab leveled floor.
- Join the two halves of the system as per manufacturer's instructions.
- Remove the packing material from
    - VERSATIP supply carousel
    - Under side of sample supply cover

- SR metering Nozzle
- Well Wash Nozzles
- Beneath SR Pumps
- Luminometer & Micro ImmunoAssay VERSATIP ring
- Supply 4 load doors & Reagent Well shuttle
- SR carousel
- Remove the wire Tie, tape & Foam from UIA REAGENT METERING ARM.
- Remove the moisture separators behind the compressor installed on it bracket.
- Remove the Foam supporting from the compressor.

VI.2 Reaffix/verify the circuits boards & CPU:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf)

- Open the right side front door and open the card rack metal cover.
- Remove the RC labeled DSP boards and reaffix it back.
- Open the right side rear panel and open the card rack metal cover.
- Remove the UC labeled DSP boards and reaffix it back.
- Open the Middle front door and open the CPU top cover & verify the boards.

VI.3 Nominal Line voltage / frequency selection of transformer:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf)

- Connect the Primary T2_H6 on Label no H6 for 0Vac.
- Connect the Primary T2_H# on label no H2 for 230Vac.
- Connect the Secondary T2_X1 on label no X1 for 230Vac.
- Connect the Secondary T2_X# on label no X2 for 200Vac.
- Connect the Secondary T2_X3 & T2_X3 on label no X3 for 0Vac.

VI.4 Load Supply & Power ON the system:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf)

- VersaTip & Sample Trays.
- Signal Reagent & Universal Reagent.
- Check the supply and Earthing voltage.
- Switch **ON** the Instrument.

VI.5 System Configuration.: (\6902906_3600-RefGd_Ltr-EN.pdf)

Click on Set Access Level from Status Menu and type password

Option -> Configure System ->

- **Configure Current Date & Time:**

  Select the format and set the **Date and Time.**

- **Configure System Name & J Number**

  Enter the System Name & J number.

- **Configure the Screen Saver**

  Set the Screen saver delay time.

- **Configure the Site Temperature**

  Set the site temperature tolerance for the nominal site temperature.

  Status -> Diagnostics -> Select the required task

- **Touch Screen Calibration:**

  Touch "Calibrate Touch screen" at the bottom of the DIAGNOSTICS Menu.

  Touch center of the target appear on the screen.

  When you have finished, touch "Save Calibration"

- **Country Code Selection:**

  Touch "Diagnostics" then Select "V-Docs"

  Press [Alt] and [S] to Access the service Scripts.

Select "Configure Country Code"

Select the appropriate country from the List.

Select " Set country code"

Touch "Return".

Touch "Shut Down". Configure the Language from the System Menu button.

Touch "Final Shutdown". Then reset the system.

VI.6 **System Tests and Adjustments:** (\6902906_3600-RefGd_Ltr-EN.pdf)

Adjustments are diagnostic functions used to fine-tune or define various system Parameters to ensure proper system performance. With the exception of the IRS Calibration, all other adjustments are available only to trained service personnel.

- MicroImmunnoassay (μIA) Metering
- MicroSensor
- MicroWell Reagent Metering
- MicroWell Wash Metering
- Signal Reagent Metering
- Luminometer
- Scrap Run

VI.7 Subsystems Performance Verification & Calibration : (\.6902906_3600-RefGd_Ltr-EN.pdfpdf)

- Well Wash Dispense & Aspiration Calibration.
- Signal reagent Dispense calibration.
- 30PSI & 10PSI calibration.
- Soak Volume Verification
- IRS Calibration

VI.8 **Setting and installing printer:** (\.6902906_3600-RefGd_Ltr-EN.pdf)

- Remove the Packing material form the printer and assemble the accessories.
- Connect the USB cable and Switch ON the Printer.
- Set report control and print the test page.

VII. Installation Report :

Activity	Observation	Remarks	Verified By / Date
Locating & unpacking the instrument.	Instrument was located and unpacked	**Ok**	Mitesh C. Shah 21/06/2018
Reaffix/verify the circuits boards & CPU	Reaffixed/verified the circuits boards & CPU	**Ok**	Mitesh C. Shah 21/06/2018
Nominal Line voltage frequency selection of transformer.	Nominal Line voltage frequency was sated.	**Ok**	Mitesh C. Shah 21/06/2018
Load Supply & Power ON the system.	Supply Loaded & Powered ON the system.	**Ok**	Mitesh C. Shah 21/06/2018
System Configuration.	System was configured as per the requirement.	**Ok**	Mitesh C. Shah 21/06/2018
System Tests and Adjustments	System Tested and Adjustments done.	**Ok**	Mitesh C. Shah 21/06/2018
Subsystems Performance Verification & calibration	Subsystems Performance Verified & calibrated successfully.	**Ok**	Mitesh C. Shah 21/06/2018
Setting and installing printer	Printer was installed and connected to the system.	**Ok**	Mitesh C. Shah 21/06/2018

VIII. COMMENTS :

Deviation:

NA

Impact On Operation:

NA

Corrective Action:

NA

IX. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outlined in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been / not been addressed. The system is ready for Operation Qualification.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : *Mitesh Shah* Signature:

Designation : Sr. Zonal Manager Date: 23/06/2018

Company : Ortho Clinical Diagnostics

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K. N. Hotkar. Signature:

Designation : Asso. professor Date: 23/06/2018

Department : Biochemistry

Name : Mr. Bhawar S.B. Signature :

Designation : Sr. Lab. Technician. Date : 23/06/2018

Department : Biochemistry

Customer Authorizations:

Name : Dr. S.N. Jangle Sir

Designation : Prof. & Head Biochemistry

Signature : S.N.Jangle

Date : PROFESSOR & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736,(M.S.)INDIA

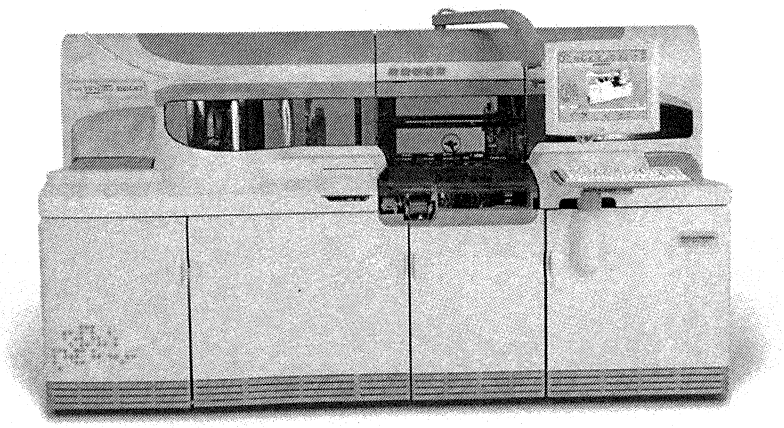
0703

Ortho Clinical Diagnostics

OPERATIONAL QUALIFICATION

For

VITROS® 5600 INTEGRATED SYSTEM



Manufactured by:

Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. APPROVAL OF THE OQ PROCEDURE:

Both Central Clinical Laboratory Pravara Rural Hospital and Ortho Clinical Diagnostics are responsible for installation of VITROS® 5600 Immunodiagnostic System bearing Sr. No **J5600-0703** in Central Clinical Laboratory, Pravara Rural Hospital as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : *Rathod Vijaykumar* Signature:

Designation : Territory Manager Date: 07/07/2018

Company : Ortho Clinical Diagnostics

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K. N. Hotkar Signature:

Designation : Asso. Prof. Date: 07/07/2018

Department : Biochemistry

Name : Mr. Bhawar S.R. Signature :

Designation : Sr. Lab. Technician Date : 07/07/2018

Department :

Customer Authorizations:

Name : Dr. S. N. Jangle, Sir

Designation : Prof. & Head Biochemistry

Signature : S.N.Jangle

Date : 07/07/2018

PROFESSOR & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736,(M.S.)INDIA

II. INSTRUCTIONS:

1. This document is to be completed at the time the system is installed to its location and set up for operation.
2. An authorized Ortho Clinical Diagnostics representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification.
3. Employees of Central Clinical Laboratory Pravara Rural Hospital will verify each result and sign in the each page. The member of the validation team will carry out this procedure.
4. ALL deviations from normal specification during installation will be noted under COMMENTS. All resolution to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this protocol for the same.

III. SCOPE

This Operational Qualification protocol will be performed on the VITROS® 5600 Integrated System, bearing Sr. No. J5600 0703 located at Department of Biochemistry.

This protocol will define the documentation that will be used to evaluate the instrument's operational check in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been operated in accordance with the intended usage.

Operational checks will also be performed to verify that the Instrument has been operated with proper information / sequence and utilities.

Trained, knowledgeable personnel will perform operational Qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

IV. OPERATIONAL QUALIFICATION:

A. Instrument Identification

		Verified Date
1. Model Name	VITROS® 5600 Integrated System	20/6/18
2. Serial Number	J5600 0703	20/6/18

B. Following is a list of tests to be performed and verified:

Test No.	Test Name	Test purpose	Initial / Date
01	System centers Overview	To make the operator to identify the instrument subsystem.	2/7/18
02	Start up & Shutdown	To make the equipment ready for operation.	2/7/18
03	User Inter Face Overview	Different functionality of software utility available for the operator interaction.	2/7/18
04	Sample programming and Analysis	To process samples either by manual assigning or through LIS.	2/7/18
05	Performing Calibration	To calibrate the system for every new lot of assay or after calibration expiry.	2/7/18
06	Maintenance & System clean	To perform maintenance process to keep the system operating properly.	2/7/18
07	Reagent Management & supply	To update & monitor the status of reagents required for assay processing.	3/7/18
08	Performing Quality control	To confirm that systems, reagents and consumables are acceptable and working within specifications for each assay used	3/7/18
09	Result Review	To review the processed results in the system.	3/7/18
10	Result Intellicheck.	To check the Intellicheck function of the system.	3/7/18
11	Option & Configuration	To setup the system as per Laboratory requirement.	4/7/18

Test: 1 : **System Hardware Overview**

Purpose : To make the operator to identify the instrument subsystem.

Reference : Operator Reference Guide - Pages 4-1 to 4-5

Summary:

For better understanding purpose, Instrument has been divided into several parts according to its operation mode, so we call this partition as centers. And those centers are named as mention below.

Procedure:

This will list the available system centers in the instrument and its subsystem contend to operator understanding. The operator has to overview the Service V-Docs to get an idea about the system centers overview.

- Sampling Centers
  - Sample Supply
  - Primary Tip sealer
  - Micro sensor subsystem
- Micro Immunoassay Center
  - Micro Immunoassay Metering & Reagent Metering
  - Micro Immunoassay Versa Tip Ring
  - Micro Well Incubator
  - Micro Well Wash Assembly
  - Signal Reagent Assembly
  - Luminometer
- Command Center
  - Master Computer & Monitor
  - Keyboard & Touch system
- System Frame and Cabinetry

Test: 2 : **Starting Up and Shutting Down**

Purpose : To make the instrument 'READY' for operation

Reference : Operator Reference Guide - Pages 3-0 to 3-25

Summary:

Instrument will check status of different parts of the instrument automatically after booting up to system status screen; if there is an error code posted, initialize the system and follow corrective action instructions provided for the error code.

Procedure:

Starting Up the System

- Check the room temperature and switch on the Air Conditioner.
- Check the UPS.
- Switch on the Printer & Load the paper.
- Switch on the VITROS® 5600 Integrated System by lift the main switch up and hold it for about 5 sec.
- Wait for the instrument to get ready after initialization.
- The machine is ready for next step if it displays "READY" on the status console.
- If not, initialize by pressing the initialize button on the error code screen.
- Follow the instructions provided for the error codes.

Shutting Down the system

- Touch **Shutdown** in the main menu.
- Press '**Y/N**' to continue the shutdown process.
- Desire normal shutdown or final shutdown and then select desired menu.
- If, you selected **Final Shutdown,** press the RESET button to restart the instrument, or press the Main power switch down to make it OFF.

Observation	System status console shows "Ready". Instrument is ready for operation	**Remarks**	**Initial/Date**
		Pass	2/7/18

Test: 3 : **User Interface Overview**

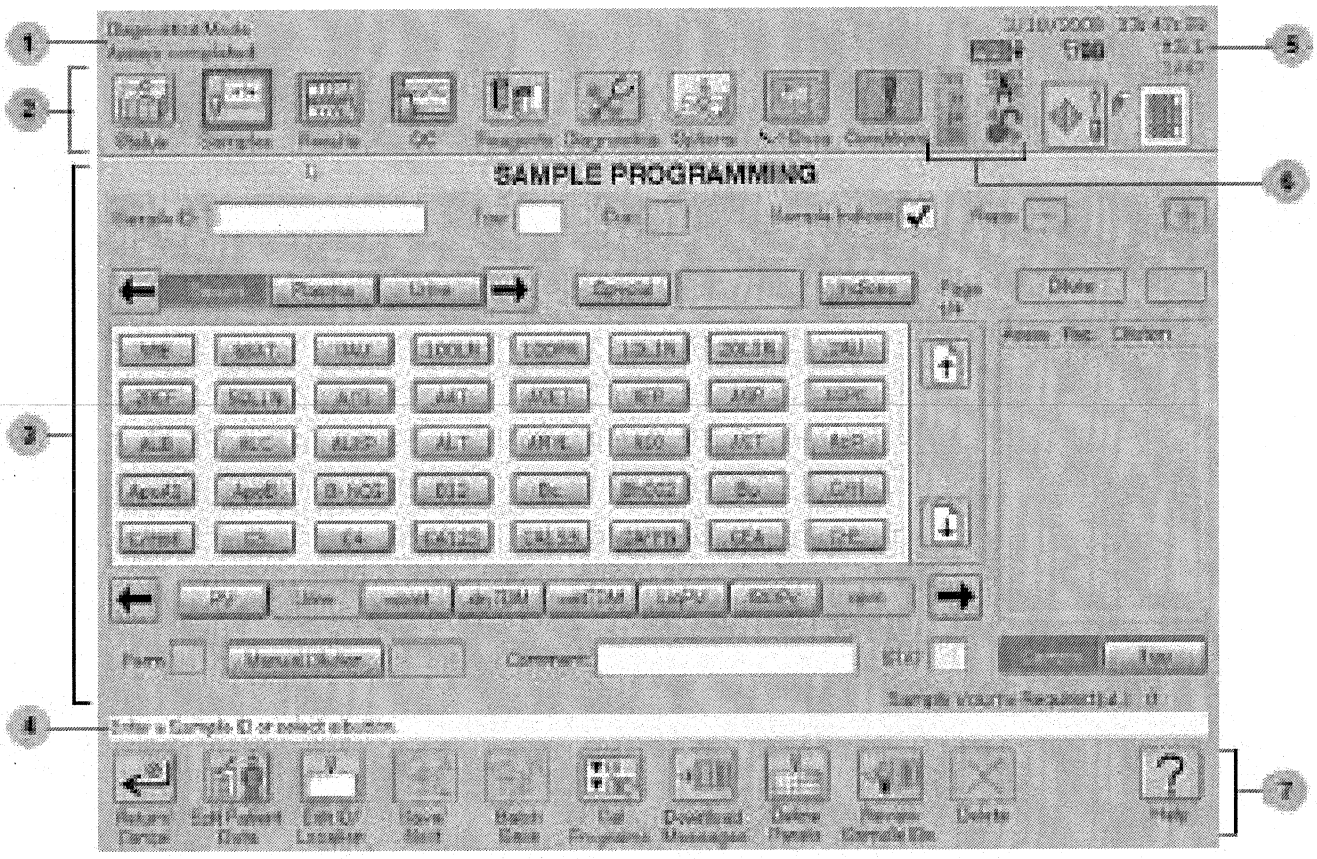
Purpose : To make the operator to understand the system screens.

Reference : Operator Reference Guide - Pages 6-0 to 6-12

Summary:

The System status screen will make the operator to understand of different functionality of software utility available for the operator. This will helps operator to check system status as well as to instruct any commands to the system for required operation.

Procedure:



The above (as shown in the Previous Page) picture is actual system software screen and the number in the blue circle is to identify the several functionality of the software icons designed for the operator to interact with the system. We call these software icon as mentioned below.,

1. Status Line
2. Status Console
3. Function Screen
4. Prompt Line
5. Time, Date and Version Display
6. Status Indicators
7. Process Buttons

Test: 4 **: Sample programming and Analysis**

Purpose : To program and process the samples

Reference : Operator Reference Guide (pages 9-1 to 9-13)

Summary: The operator can process assay by assigning program manually in the Universal Sample tray in **'Sample Program'** menu or they can download sample program through **'LIS'**. Sample programming is the process of selecting assays and programming characteristics for samples. The system uses the sample program to meter appropriate sample and select the right reagent for the assay, process and then report results with the correct identification.

Procedure:

Sr. No.	Activity	**Observation**	Remarks Pass / Fail	Done By Date
01	Sample Programming methods & Overview	Desire the sample Programming method.	Pass	3/7/2018
02	Loading and Processing of samples	Tray cover opened and samples loaded in sample tray placed in sample supply.	Pass	3/7/2018
03	Programming samples	Sample program assigned for selected tray.	Pass	3/7/2018
04	Processing samples	Samples are processed automatically by the system.	Pass	4/7/2018
05	Unloading the samples	Tray cover opened and processed sample tray unloaded.	Pass	4/7/2018
06	Viewing samples in process	Sample under process are displayed on the 'View Sample Status' Screen.	pass	4/7/2018

Test: 5 : **Performing Calibration**

Purpose : To calibrate the system for every new lot of assay

Reference : Operator Reference Guide (pages 10-1 to 10-9)

Summary: The system requires its own calibration for every individual assay to measure the analytic concentration as well as to accept reagent pack status ready for processing. Assay calibration is a process that relates the response of the system to analyte concentration or activities. Calibration is performed periodically to adjust for changes in the system, assay protocols, or assay reagent lots.

The system requires calibration for individual assays when:

- A new assay is uploaded to the system
- The calibration expires (up to 28 days after it is processed, depending on the assay; refer to the package insert for expiration information)
- An assay reagent lot number changes
- Government regulations specified
- An assay's protocol changes

You also may need to perform calibration when:

- Certain service procedures are performed
- Quality control performance is out of range

Procedure:

Sr. No.	Activity	**Observation**	Remarks	Done By
			Pass / Fail	Date
01	Load New ADD via CD or Downloaded file (New Gen Lot, Protocol , reagent lot calibration , Diluents lot information).	Calibrator identified and updated for protocol & master calibration data.	Pass	Vijay 3/7/2018
02	Preparing calibrators.	Calibrators are ready for processing.	Pass	3/7/2018
03	Performing Calibration with Bar code label.	System recognizes the barcode and processing the calibration automatically.	Pass	3/7/2018
04	Performing Calibration with Sample processing screen.	In the sample programming, the calibration program is assigned and processed the calibration assigned for each assay.	Pass	3/7/2018
05	Calibration report.	Calibration completed successfully. Report printed.	Pass	4/7/2018

Test: 6 : **Maintenance & System Clean**

Purpose : Clean appropriate modules to maintain Accuracy and precision.

Reference : Operator Reference Guide 16-13 to 16-17

Summary:

Maintenance procedures are tasks that are performed to keep the system operating properly. Maintenance protocols to be performed according to the recommended schedule (daily, weekly, monthly, or as required). Ensure that we need to use 70% Isopropyl alcohol to disinfect the appropriate module to keep cleanliness and maintain the accuracy & precision.

The Maintenance is classified into four-category ie.,

1. Daily Maintenance
2. Weekly Maintenance
3. Monthly Maintenance
4. As required Maintenance

Daily Maintenance: Pages from 16-14 to 16-15

Sr. No.	Activity	Observation	Remarks Pass/Fail	Done By Date
01	Perform Metering Maintenance	Metering Maintenance Performed	Pass	4/7/18
02	Empty Solid and Liquid waste container	Solid & Liquid waste containers are emptied.	Pass	4/7/18
03	Remove outdated or empty reagent packs, Signal Reagent packs and Universal Wash Buffer	Outdated empty Reagent packs, SR packs and UWR bottles are removed & discarded.	Pass	4/7/18
04	Inspect sample trays and adaptors	Sample Trays are cleaned.	Pass	4/7/18
05	Clean the SR Probe assembly	SR Probes are cleaned.	Pass	4/7/18
06	Load required reagent packs, Signal Reagent pack and Universal Wash Buffer.	All the required reagent packs are loaded and updated in the system as required.	Pass	4/7/18
07	Run Q.C fluids	Q.C samples are processed successfully.	Pass	4/7/18

Weekly Maintenance: Pages from 16-15 to 16-16

Sr. No.	Activity	Observation	Remarks Pass/Fail	Done By Date
01	Clean the Micro well Incubator.	Micro well incubator – Inner ring, outer ring, middle ring, shuttle weight, drop holes, Luminometer FOB, Wash reagent and signal reagent probes are cleaned.	Pass	5/7/18
02	Clean the Primary tip sealer.	Primary Tip Sealer cleaned.	Pass	5/7/18
03	Clean the Secondary Tip Sealer.	Secondary Tip Sealer cleaned.	Pass	5/7/18
04	Clean the Sample Supply and Cap Retainer.	Cap Retainer & Sample Supply cleaned.	Pass	5/7/18
05	Clean the Touch Screen Monitor & Keyboard.	Touch Screen Monitor & Key board Clean Done.	Pass	5/7/18
06	Run the maintenance Pack for Subsystem cleaning.	Maintenance pack is loaded; subsystem cleaning done automatically by the system.	Pass	5/7/18
07	Run QC Fluids	Q.C Processed successfully.	pass	5/7/18

Monthly Maintenance: Pages from 16-15 to 16-16

Sr. No.	Activity	Observation	Remarks Pass/Fail	Done By Date
01	Clean Micro sensor Cover & Ring Area.	Micro Sensor Cover & Ring Surface cleaned.	Pass	6/7/18
02	Inspect/Clean Micro Immuno Assay reagent Supply top Cover.	Micro Immuno Assay Reagent Supply top Cover Inspected and Cleaned.	Pass	6/7/18
03	Clean VITROS Versa Tip supply Registration Rail.	Versa tip Supply Registration Rail cleaned.	Pass	6/7/18
04	Inspect Reagent cooler filter for cleanliness.	Reagent cooler filter removed & cleaned.	Pass	6/7/18
05	Replace Vapors adsorption cartridge for every two months.	Every two months once, VAC replaced.	Pass	6/7/18
06	Make a backup of Q.C, Calibration and Configuration.	Backup of QC, Calibration and Configuration made successfully.	Pass	6/7/18
07	Inspect / Clean Master Computer Filter.	Inspected and Cleaned Master computer Air Filter.	Pass	6/7/18

Test: 7 : **Managing reagents Inventory and Supply**

Purpose : To Maintain & monitor the status of reagents or supply required for assay processing.

Reference : Operator Reference Guide (pages 15-1 to 15-7)

Summary: The Reagent Management feature enables you to review current inventory Information for the reagents loaded on the system. Using this function, you can load and unload reagents as necessary. To maintain the required reagents in the system for processing, the operator should review the Reagent management screen.

Procedure:

Sr. No.	Activity	**Observation**	Remarks Pass/Fail	Done By Date
01	Review the reagent inventory to plan for the day.	The reagent inventory for the day planned.	Pass	3/7/18
02	Loading of Reagent Pack automatically	Required Reagent Packs loaded automatically by software request.	Pass	3/7/18
03	Loading of Reagent Pack with help of Manual Lot Entry button.	Requested Lot Information fed and the reagent pack loaded.	Pass	3/7/18
04	Loading of Signal Reagent automatically.	SR Pack loaded in position 1 & 2 and accepted by barcode reading.	Pass	3/7/18
05	Loading of Signal Reagent with Manual Load Button.	SR packs information fed and loading done.	Pass	3/7/18
06	Loading of Universal Wash Buffer	UWR buffer loading done through Load supply Software icons.	Pass	3/7/18
07	Unloading of Reagents	The entire Empty & expired reagents packs are unloaded by Load/Unload software icons.	Pass	3/7/18

Test: 8 : Performing Quality control

Purpose : Quality Control (QC) is important in determining the performance and accuracy of the system. To perform Quality Control, QC materials are run with either known, or unknown values along with patient samples to determine whether the system is functioning within the established ranges for your lab.

Reference : Operator Reference Guide (Pages 9-6 to 9-8)

Summary: Performing quality control procedures is an important part of using or maintaining the system. This section explains:

- When you should perform quality control
- How to choose a control fluid

The recommended frequency for processing quality control fluids is once in every 24 hours. However, the frequency with which you perform quality control procedures may vary, depending on the requirements and regulations for processing control fluids by your national, state, provincial, and local governments. Quality control procedures within your own Laboratory may also require a different frequency. You should also perform quality control procedures when:

- Assays have been calibrated
- Certain service procedures are performed, other than routine maintenance

Procedure:

Sr. No.	Activity	**Observation**	Remarks Pass / Fail	Done By Date
01	Choosing the Control fluid	Required control fluid identified.	Pass	4/7/18
02	Preparing Liquid or Lyophilized control fluids	Control fluid prepared and ready for processing.	Pass	4/7/18
03	Creating QC file.	Q.C file created for assay in the system according to control fluid.	Pass	4/7/18
04	Process QC samples	QC samples are programmed in the sample programming window and the QC samples are loaded and processed automatically	Pass	4/7/18
05	Review Q.C result.	Processed Q.C results are reviewed and found satisfactory.	Pass	4/7/18
06	Display & printing graph.	Q.C graph reviewed and printed.	Pass	4/7/18
07	Managing Quality control Reports	Required reports printed and filed.	Pass	4/7/18

Test: 9 : **Result Review.**

Purpose : To review the processed results in the system.

Reference : Operator Reference Guide (Pages 11-1 to 11-6)

Summary: The Results Review function helps to evaluate result records for patient and quality control samples. The results will be displayed along with the Reagents Lot information, Dilution information & if there is any error codes or Flags.

Result records contain the data generated by the system when assays are processed. The system can store up to 25,000 result records. When this limit is reached, new result records overwrite the oldest records. The system permanently deletes the overwritten records from computer memory.

Procedure:

Sr. No.	Activity	**Observation**	Remarks Pass / Fail	Done By Date
01	Update List.	Sample under process status displayed with all information.	Pass	3/7/18
02	Monitoring Results.	Completed Recent Assay Results displayed on the screen.	Pass	3/7/18
03	Filter Results.	Processed Assay Results displayed as per the selected criteria.	Pass	3/7/18
04	Edit Patient Data	User can Edit/Add Patient Demography information, but the Patient ID will remain same.	Pass	3/7/18
05	Retrieving and Reviewing Archive Results by Set Report Status.	Archived Results are updated successfully in the CD/Pen Drive. The same Retrieved from the CD/Pen Drive.	Pass	3/7/18
06	Managing Reports by Set Report Status.	Required Reports got printed and filed.	Pass	3/7/18
07	Integrated Codes and Flags	Reported Codes and Flags are referred in Flags and Code chart. Necessary corrective action taken.	Pass	3/7/18

Test: 10 : **Result Intellicheck.**

Purpose : To check the Integrity of Performed assays.

Reference : Operator Reference Guide (Pages 11-8 to 11-9).

Summary: The Result Intellicheck screen to view Intellicheck Technology Verifications performed for each sample and assay processed. For the selected result record, you can view verification data and detected exceptions for each analyte.

Example:

- To Analyze Intelli Report, select the sample ID listed on result review screen.
- On Review results screen, touch the 'Result Intellicheck' Icon.
- Result Intellicheck report comes on the screen.
- Check the parameters of Sample Metering, Sample + Reagent volume, Signal reagent volume and well wash verification for their acceptance.
- Take print of the Result intellicheck report.

Acceptance criteria:

Sr. No.	Parameter	Acceptance limit	Remarks Pass / Fail	Done By Date
01	**Sample Metering** • Clot • Bubble • Short sample • Viscosity • Thin layer of fluid	Against all the parameters, "No" should be displayed on screen	Pass	4/7/2018
02	**Reagent Metering** Sample + Reagent volume	No Exception. Range: 12700 – 19000	Pass	4/7/2018
03	Signal Reagent	No Exception Range: 17500 – 22800	pass	4/7/2018
04	Well wash verification	No Exception Range: 21300 – 25000	pass	4/7/2018
05	Luminometer – Self calibration	No Exception	Pass	4/7/2018

Test: 9 **: Option & Configuration**

Purpose : To setup the system as per laboratory requirement

Reference : Operator Guide (Pages 11-8 to 11-14)

Summary: The Options & Configuration function provides many features for customizing your VITROS® 5600 Integrated System. It is organized into three main groups:

- Configure Analyte Data & Review/Edit Calibration Data
- System Setup
- System Services

Selections within these groups allow you to customize analyte parameters, review calibration data, perform user calibrations, configure and set system parameters, review usage inventory, configure e-Connectivity® and network device parameters, configure printer, laboratory computer and auxiliary ports, perform backup for quality control, calibration and configuration files and perform an archive procedure for result records.

Procedure:

Sr. No.	Activity	Observation	Remarks Pass / Fail	Done By Date
01	Configure Assays	Analyte parameters are configured as desired by laboratory.	Pass	6/7/18
02	Review / Edit Calibration Data	Calibration data updated.	Pass	6/7/18
03	Configure System Setup	Required subsystem configuration is done successfully.	Pass	6/7/18
04	Configure Subsystem Setup	The required subsystem can be disabled / deactivated as per needs.	Pass	6/7/18
05	Configure Report Control	System report parameter has set for printer & LIS.	Pass	6/7/18
06	Configure Communication	System interface protocol set for Laboratory Information System (LIS), Ethernet and e-Connectivity® communications,	Pass	6/7/18
07	Configure Demography	Global demographic attributes to be used when configuring age, sex, and normal ranges for specific assay/body fluids is defined.	Pass	6/7/18
08	System Services 1.Datalogger 2.Perform Backup 3.Usage Counters 4.Option Summary 5.Load System Data	Shall be performed and reviewed as & when required.	Pass	6/7/18

V. Operational procedure:

a. Certificate of Training

1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

Mr.Vijaykumar Rathod , Territory Manager from Ortho Clinical Diagnostics has conducted the training.

Sr. No.	Training program	Initials	Date
1.	Instrument Setup		
2.	System Operation		
3.	Basic trouble shooting and Maintenance		

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

Sr. No.	Operators	Department	Initials	Date
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

b. Customer SOP / Manuals:

Title	Number	Version	Verified by	Date
Vitros 5600 Integrated System Reference Guide			Vijay	2/7/2018
Microslide Instruction for use Manual			Vijay	2/7/2018
Microtip Chemistry Instruction For Use Manual			Vijay	2/7/2018
Micro Well Instruction For Use Manual			Vijay	2/7/2018

VI. COMMENTS :

Deviation:

Impact On Operation:

Corrective Action:

IX. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outlined in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been / not been addressed. The system is ready for Operation Qualification.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : *Rathod Vijaykumar* Signature:

Designation : Territory Manager Date: 07/07/2018

Company : Ortho Clinical Diagnostics

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K. N. Hotkar Signature:

Designation : Asso. prof. Date: 07/07/2018

Department : Biochemistry

Name : Mr. Bhawar S. R. Signature :

Designation : Sr. Lab Technician Date : 07/07/2018

Department : Biochemistry

Customer Authorizations:

Name : Dr. S. N. Jangle Sir.

Designation : Prof. & Head Biochemistry

Signature : S. N. Jangle

Date : 07/07/2018

PROFESSOR & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736,(M.S.)INDIA

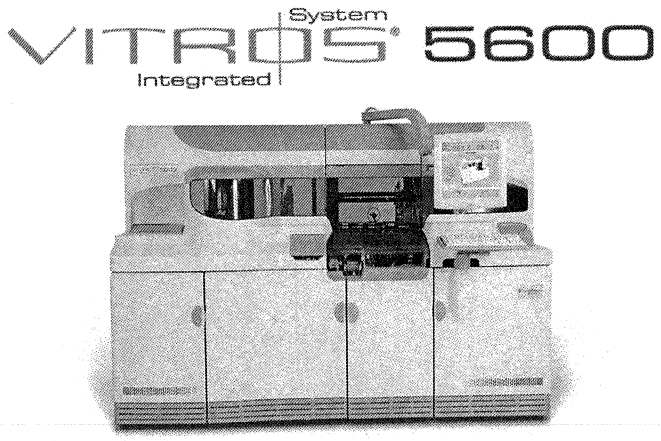
0703

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS® 5600 INTEGRATED SYSTEM



Manufactured by:

Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. APPROVAL OF THE PQ PROCEDURE:

Both Central Clinical Laboratory Pravara Rural Hospital and Ortho Clinical Diagnostics are responsible for installation of VITROS® 5600 Immunodiagnostic System bearing Sr. No **J5600-0703** in Central Clinical Laboratory, Pravara Rural Hospital as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : *Rathod Vijaykumar* Signature:

Designation : Territory Manager Date: 07/07/2018

Company : Ortho Clinical Diagnostics

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K. N. Hatkar Signature:

Designation : Asso. Prof. Date: 07/07/2018

Department : Biochemistry

Name : Mr. Bhawar S. R. Signature :

Designation : Sr. Lab Tech. Date : 07/07/2018

Department : Biochemistry

Customer Authorizations:

Name : Dr. S. N. Jangle. Sir.

Designation : Prof & Head. Biochemistry

Signature : S. N. Jangle

Date : 07/07/2018

PROFESSOR & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736,(M.S.)INDIA

II. INSTRUCTIONS:

1. This document is to be completed at the time the system is installed to its location and set up for operation.
2. An authorized Ortho Clinical Diagnostics representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification.
3. Employees of Central Clinical Laboratory Pravara Rural Hospital will verify each result and sign in the each page. The member of the validation team will carry out this procedure.
4. ALL deviations from normal specification during installation will be noted under COMMENTS. All resolution to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this protocol for the same.

III. SCOPE

This Performance Qualification protocol will be performed on the VITROS® 5600 Integrated System, and the Sr. No. --J5600703 located at

This protocol will define the documentation that will be used to evaluate the instrument's performance check in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been performed in accordance with the intended usage.

Performance checks will also be performed to verify that the Instrument has been operated with proper information/sequence and utilities.

Trained, knowledgeable personnel will perform Performance Qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

IV. PERFORMANCE QUALIFICATION

A. Instrument Identification

Verified Date

1. Model Name VITROS 5600 — 2/7/2018
2. Serial Number J56000703 — 2/7/2018

B. Following is a list of tests to be performed and verified:

Sr.No	Test Name	Test Purpose	Initial / Date
01	QC Run	To see the performance of quality control material on the equipment on selected assay parameters as per the specifications given	2/7/2018
02	Accuracy Study	To compare the obtained value with true values of processed control.	22/6/2018
03	Precision Study	To check the precision performance of the equipment	22/7/2018

C. Performance Testing:

Test I

Test Name	:	**QC Run**
Purpose	:	To see the performance of quality control material on the equipment as per the specifications given
Method	:	Microslide – Rate Chemistry & Endpoint Chemistry Microslide – Potentiometric Chemistry; Microslide – Immunorate Chemsitry; Microtip Chemistry Microsensor Chemistry Microwell - Chemiluminescence Immunoassay

Analysis of controls:

Note: Analyze controls for ALT (Microslide Rate Chemistry);
Sodium (Potentiometric Chemistry);
BuBc (Microslide End point Chemistry)
Phenytoin (Microslide – Immunorate Chemistry)
dLDL (Microtip Chemistry)
Gentamycin (Microtip Chemistry)
IgM (Microtip Chemistry)
HIT (Microsensor Chemistry)
TSH (Microwell - Immunometric assay) &
TT4 (Microwell - Competitive assay).

Sr. No.	Activity	Procedure done as per the protocol defined in Vitros 5600 V Docs – System Operation – Quality Control	Remarks Pass/Fail	Done By Date
01	Preparing Liquid or Lyophilized control fluids	"Instructions for use" of QC material	Pass	Vijay 3/7/18
02	Creating QC file	V Docs – System Operation – Quality Control – Define control fluids	Pass	3/7/18
03	QC sample programming and analysis	V Docs – System Operation – Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	3/7/18

Test II

Test Name : **Accuracy**

Purpose : To see the accuracy of obtained quality control value in comparison with the expected mean values.

Method : Microslide; Microtip; Microsensor and Microwell method as mentioned above

Analysis of controls:

Note: Analyze controls as mentioned above.

Sr. No.	**Activity**	**Procedure done as per the protocol defined in Vitros 5600 V Docs – System Operation – Quality Control**	**Remarks** / **Pass/Fail**	**Done By** / **Date**
01	Preparing Liquid or Lyophilized control fluids	'Instructions for use' of QC material	Pass	3/7/2018
02	QC sample programming and analysis	V Docs – System Operation – Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	3/7/2018
03	Accuracy Analysis	Compare the obtained Q.C value with mean of expected value as mentioned in the QC Value chart.	Pass	3/7/2018

Test III

Test Name : **Precision Study**

Purpose : To see the precision performance of the equipment

Method : Microslide – Rate Chemistry & Endpoint Chemistry
Microslide – Potentiometric Chemistry;
Microslide – Immunorate Chemsitry;
Microtip Chemistry
Microsensor Chemistry
Microwell - Chemiluminescence Immunoassay

- Analyze Vitros Performance Verifier Level 1 control for the following tests : ALT (5 x 7 times), Na+ (5 x 8 times), dLDL (6 x 6 times), BuBc (5 x 7 times)
- Analyze TDM Performance Verifier Level 3 for Phenytoin (5 x 7 times).
- Analyze TDM Performance Verifier Level 1 for Gentamycin (6 x 6 times).
- Analyze Protein Peformance Verifier Level 1 for IgM (6 x 6 times).
- Analyze Microsensor Check Fluid Level I for Hemolysis, Icterus and Turbidity (20 times each).
- Analyze all the three levels of Vitros Total Thyroid controls for Microwell – Chemiluminescence Immunoassay TT4 and TSH (10 times each).
- Calculate the Mean, SD and CV%.

Acceptance Criteria :

Sr. No.	Analyte	Control Level	Precision Limit
01	ALT	PV I	≤ 2.2 SD
02	Sodium	PV I	≤ 0.69% CV
03	dLDL	PV I	SD < 2.4
04	Bu	PV I	≤ 0.3 SD
05	Bc	PV I	≤ 0.6 SD
06	Phenytoin	TDM PV III	≤ 0.75 SD
07	Gentamycin	TDM PV I	SD < 0.11

08	IgM	Protein PV I	SD < 2.1
09	Hemolysis	MS Check Fluid Level I	SD < 4.4
10	Icterus	MS Check Fluid Level I	SD < 0.4
11	Turbidity	MS Check Fluid Level I	SD < 14.8
12	TT4	Total Thyroid Control Level 1	CV% ≤ 4.9
		Level 2	CV% ≤ 4.6
		Level 3	CV% ≤ 6.0
13	TSH	Total Thyroid Control Level 1	CV% ≤ 10.9
		Level 2	CV% ≤ 4.9
		Level 3	CV% ≤ 4.7

* Reference: The acceptance SD & CV% has been taken from Manufacturer's recommended limits.

Table for Record the Obtained Q.C Values :

Test Name: **Control Level:**

Control Lot: **Expiry Date:**

Sr. No	Obtained Q.C Value	Range of the Comparator	Mean of the Comparator	Remarks Pass / Fail	Done By Date
01					
02					
03					
04					
05					
06					
07					
08					
09					
10					

* Reference :- Attached QC Report

V. COMMENTS:

Deviation:

Impact On Operation:

Corrective Action:

IX. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outlined in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been / not been addressed. The system is ready for Operation Qualification.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : *Rathod Vijaykumar* Signature:

Designation : Territory Manager Date: 07/07/2018

Company : Ortho Clinical Diagnostics

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K. N. Hotkar Signature:

Designation : Asso. prof. Date: 07/07/2018

Department : Biochemistry

Name : Mr. Bhawar S. R. Signature :

Designation : Sr. Lab. Technician Date : 07/07/2018

Department : Biochemistry

Customer Authorizations:

Name : Dr. S. N. Jangle Sir

Designation : prof & Head Biochemistry

Signature : S N Jangle

Date : 07/07/2018

PROFESSOR & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736(M.S.)INDIA

Ortho Clinical Diagnostics

403, Leela Business Park, Andheri Kurla Road,
Andheri East, Mumbai – 400059
T : +91 22 6787 9300
F : +91 22 6787 9333

Calibration Certificate

The below mentioned instrument has been calibrated and tests performed to check the system performance.

Instrument	: VITROS V5600
Serial No	: 5600-0703
Customer Name	: PRAVARA MEDICAL TRUST-LONI
Calibration performed on	: 06.12.2018

The system's calibration includes optics calibration and checking the reproducibility performance of the instrument as per the guidelines provided by the manufacturer.

Next Calibration will be performed in JUNE **2019**.

For **Ortho Clinical Diagnostics India Pvt Ltd.**

Mitesh Shah **Date: 06/12/2018**

Sr.Zonal Service Manager-Ortho Care

Pune

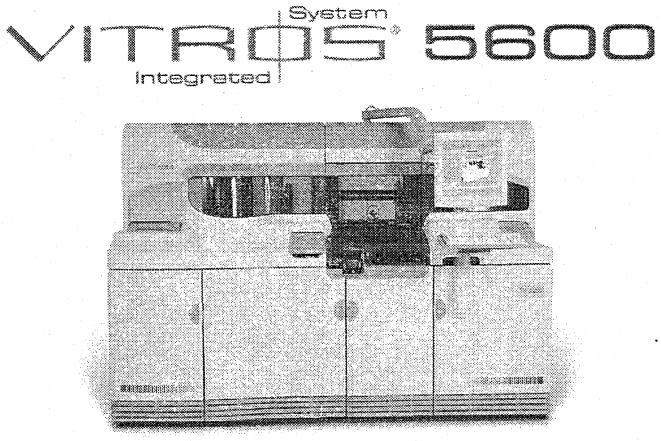
1041

Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS® 5600 INTEGRATED SYSTEM



Manufactured by:

Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. APPROVAL OF THE IQ PROCEDURE:

Both Central Clinical Laboratory Pravara Rural Hospital and Ortho Clinical Diagnostics are responsible for installation of VITROS® 5600 Immunodiagnostic System bearing Sr. No **J56001041** in Central Clinical Laboratory, Pravara Rural Hospital as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	*Mitesh Shah*	Signature:
Designation	:	Sr. Zonal Manager	Date: 05/12/2020
Company	:	Ortho Clinical Diagnostics	

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name	:	Mr. K. N. Hotkar	Signature:
Designation	:	Asso. Prof.	Date: 05/12/2020
Department	:	Biochemistry	
Name	:	Mr. Bhawar S. R.	Signature :
Designation	:	Sr. Lab Tech.	Date : 05/12/2020
Department	:	Biochemistry	

Customer Authorizations:

Name : Dr. S. N. JANGLE

Designation : Professor and Head, Biochemistry

Signature : S. N. Jangle

Date : 05/12/2020

PROFESSOR & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736,(M.S.)INDIA

II. INSTRUCTIONS:

1. This document is to be completed at the time the system is installed to its location and set up for operation.
2. An authorized Ortho Clinical Diagnostics representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification.
3. Employees of **Central** Clinical Laboratory Pravara Rural Hospital will verify each result and sign in the each page. The member of the validation team will carry out this procedure.
4. All deviations from normal specification during installation will be noted under COMMENTS. All resolution to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this protocol for the same.

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS® 5600 Immunodiagnostic System, and the Sr. No. **J56001041** located at Central Clinical Laboratory Pravara Rural Hospital.

This protocol will define the documentation that will be used to evaluate the instrument's installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.

Trained, knowledgeable personnel will perform Installation Qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated, and the appropriate course of action determined. All documents will be initialed and dated.

IV. ANCILLARY INFORMATION

a. Certification of Purchase Order Compliance

I certify to the best of my knowledge, the instrument VITROS® 5600 Immunodiagnostic System and **Sr. No. J56001041** installed on 05/12/2020.

Verified By: Mitesh Shah Date:05/12/2020

b. Utilities

Sr. No	Utility		Verified by & date
1.	**Environmental condition:** As per requirement (To be free from Dust, Electrical & magnetic Interferences and free from vibration)	Yes / No	Mitesh Shah 05/12/2020
2.	**Adequate space for installation:** (Length 110 inches x Width 35 inches x Height 84 inches)	Yes / No	Mitesh Shah 05/12/2020
3.	**Electrical Outlets:** Actual Voltage on site [200 Vac – 240 Vac] **Electrical Input:** Voltage supplied through ON LINE UPS (232Vac @ 50Hz frequency, Earthing < 2.0Vac)	Yes / No	Mitesh Shah 05/12/2020
4.	**Capacities:** • 90 samples (80 Routine positions & 10 STAT positions are available) • 150 Reagent Positions are available.	Yes / No	Mitesh Shah 05/12/2020
5.	**Temperature:** 15° C to 30° C 15% to 75% relative humidity	Yes / No	Mitesh Shah 05/12/2020

The instrument has been verified for the following:

Sr. No.	Verification		Verified by & date
1.	Equipment is identified	Yes / No	Mitesh Shah 05/12/2020
2.	Manufacturer's specifications are included	Yes / No	Mitesh Shah 05/12/2020
3.	Accessories / Consumables are listed	Yes / No	Mitesh Shah 05/12/2020
4.	Equipment manual from the manufacturer is documented	Yes / No	Mitesh Shah 05/12/2020
5.	Manufacturer's Certificate of compliance attached	Yes / No	Mitesh Shah 05/12/2020

V INSTALLATION QUALIFICATION:

A. Equipment Description

The VITROS® 5600 Integrated System is a Random access, walk away system intended for use in the *in vitro* quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Chemistry Products MicroSlides, VITROS Chemistry Products MicroTip reagents and VITROS Immunodiagnostic Products Reagents.

Instrument Identification		Verified by	Date
Equipment Name :	**Automated Integrated System**	Mitesh Shah	05/12/2020
Model :	VITROS® 5600	Mitesh Shah	05/12/2020
Manufacturer :	Ortho Clinical Diagnostics, Inc., US	Mitesh Shah	05/12/2020
Marketed by :	Ortho Clinical Diagnostics India Pvt. Ltd.	Mitesh Shah	05/12/2020
Serial Number :	56001041	Mitesh Shah	05/12/2020
Lab Id :	Biochemistry Analyzer No. 2	Mitesh Shah	05/12/2020
Software Name :	QNX	Mitesh Shah	05/12/2020
Software Version :	V	Mitesh Shah	05/12/2020
Size (in inches) :	Adequate for installation: (Length 170 x Width 83 x Height 84).	Mitesh Shah	05/12/2020
Power :	1600W@ 50Hz of 220Vac – 240Vac	Mitesh Shah	05/12/2020

B. Accessories/Consumables

The following accessories were supplied with the instrument. Check (√) 'verified by' in case they are found to be in order.

Description	Quantity	Verified	Date
User Training Manual	1	√	05/12/2020
Application Software-Revelation	1	√	05/12/2020
Universal Sample Tray	9	√	05/12/2020
Backup DVD R/w	3	√	05/12/2020
Printer Cable	1	√	05/12/2020
Printer Software	1	√	05/12/2020
Power Cords	3	√	05/12/2020
Printer	1	√	05/12/2020
Air filter	1	√	05/12/2020
Waste can 5L	1	√	05/12/2020

C. **List of Manuals :**

Ortho Clinical Diagnostics has supplied following manual.

D. **Maintenance :**

The instrument listed within this document will be placed under the control of the purchasing institution with respect to proper maintenance procedures as detailed in the Training and Reference Guide. The maintenance procedures will be filed separately.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period Ortho Clinical Diagnostics offers several levels of Maintenance Agreements and Performance Testing services to assist you in maintaining GLP/GMP compliance. Contacting your local representative and requesting the additional Service Agreement can supply additional information.

VI. INSTALLATION PROCEDURE

(The following steps Performed at the time of original installation at the initial location)

1. Locating & unpacking the instrument.
2. Reaffix/verify the circuits boards & CPU
3. Nominal Line voltage frequency selection of transformer.
4. Load Supply & Power ON the system.
5. System Configuration.
6. Systems Tests & Adjustments.
7. Subsystems Performance Verification & calibration
8. Setting and installing printer.

The Above-mentioned steps has completed successfully by trained field Engineer as described below.

VI.1 Locating & unpacking the VITROS® 5600 instrument:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf)

- Check the Tip & Tell Label.
- Verify the serial no / J number of the system match those indented for delivery.
- Place the pallet in a position with a minimum of 7 m (24 ft.) of clearance in front of the end with the LABELS
- Remove the STRAPPING and the RAMPS from the pallet..
- Assemble the 2 piece RAMP and hok the RAMPS to the end of the pallet
- Move the system down the ramps. Do the same for the second half of the system.

- Place the instrument in the lab leveled floor.
- Join the two halves of the system as per manufacturer's instructions.
- Remove the packing material from
    - VERSATIP supply carousel
    - Under side of sample supply cover
    - SR metering Nozzle
    - Well Wash Nozzles
    - Beneath SR Pumps
    - Luminometer & Micro ImmunoAssay VERSATIP ring
    - Supply 4 load doors & Reagent Well shuttle
    - SR carousel
    - Remove the wire Tie, tape & Foam from UIA REAGENT METERING ARM.
    - Remove the moisture separators behind the compressor installed on it bracket.
    - Remove the Foam supporting from the compressor.

VI.2 Reaffix/verify the circuits boards & CPU:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf)

- Open the right side front door and open the card rack metal cover.
- Remove the RC labeled DSP boards and reaffix it back.
- Open the right side rear panel and open the card rack metal cover.
- Remove the UC labeled DSP boards and reaffix it back.
- Open the Middle front door and open the CPU top cover & verify the boards.

VI.3 Nominal Line voltage / frequency selection of transformer:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf)

- Connect the Primary T2_H6 on Label no H6 for 0Vac.
- Connect the Primary T2_H# on label no H2 for 230Vac.
- Connect the Secondary T2_X1 on label no X1 for 230Vac.
- Connect the Secondary T2_X# on label no X2 for 200Vac.

- Connect the Secondary T2_X3 & T2_X3 on label no X3 for 0Vac.

VI.4 Load Supply & Power ON the system:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf)

- VersaTip & Sample Trays.
- Signal Reagent & Universal Reagent.
- Check the supply and Earthing voltage.
- Switch **ON** the Instrument.

VI.5 System Configuration.: (\6902906_3600-RefGd_Ltr-EN.pdf)

Click on Set Access Level from Status Menu and type password

Option -> Configure System ->

- **Configure Current Date & Time:**

  Select the format and set the **Date and Time**.

- **Configure System Name & J Number**

  Enter the System Name & J number.

- **Configure the Screen Saver**

  Set the Screen saver delay time.

- **Configure the Site Temperature**

  Set the site temperature tolerance for the nominal site temperature.

  Status -> Diagnostics -> Select the required task

- **Touch Screen Calibration:**

  Touch "Calibrate Touch screen" at the bottom of the DIAGNOSTICS Menu.

Touch center of the target appear on the screen.

When you have finished, touch "Save Calibration"

- **Country Code Selection:**

  Touch "Diagnostics" then Select "V-Docs"

  Press [Alt] and [S] to Access the service Scripts.

  Select "Configure Country Code"

  Select the appropriate country from the List.

  Select " Set country code"

  Touch "Return".

  Touch "Shut Down". Configure the Language from the System Menu button.

  Touch "Final Shutdown". Then reset the system.

VI.6 **System Tests and Adjustments:** (\6902906_3600-RefGd_Ltr-EN.pdf)

Adjustments are diagnostic functions used to fine-tune or define various system Parameters to ensure proper system performance. With the exception of the IRS Calibration, all other adjustments are available only to trained service personnel.

- MicroImmunnoassay (µIA) Metering
- MicroSensor
- MicroWell Reagent Metering
- MicroWell Wash Metering
- Signal Reagent Metering
- Luminometer
- Scrap Run

VI.7 Subsystems Performance Verification & Calibration : (\.6902906_3600-RefGd_Ltr-EN.pdfpdf)

- Well Wash Dispense & Aspiration Calibration.
- Signal reagent Dispense calibration.
- 30PSI & 10PSI calibration.
- Soak Volume Verification
- IRS Calibration

VI.8 **Setting and installing printer:** (\.6902906_3600-RefGd_Ltr-EN.pdf)

- Remove the Packing material form the printer and assemble the accessories.
- Connect the USB cable and Switch ON the Printer.
- Set report control and print the test page.

VII. Installation Report :

Activity	Observation	Remarks	Verified By / Date
Locating & unpacking the instrument.	Instrument was located and unpacked	**Ok**	**Mitesh Shah 05/12/2020**
Reaffix/verify the circuits boards & CPU	Reaffixed/verified the circuits boards & CPU	**Ok**	**Mitesh Shah 05/12/2020**
Nominal Line voltage frequency selection of transformer.	Nominal Line voltage frequency was sated.	**Ok**	**Mitesh Shah 05/12/2020**
Load Supply & Power ON the system.	Supply Loaded & Powered ON the system.	**Ok**	**Mitesh Shah 05/12/2020**
System Configuration.	System was configured as per the requirement.	**Ok**	**Mitesh Shah 05/12/2020**
System Tests and Adjustments	System Tested and Adjustments done.	**Ok**	**Mitesh Shah 05/12/2020**
Subsystems Performance Verification & calibration	Subsystems Performance Verified & calibrated	**Ok**	**Mitesh Shah**

	successfully.		**05/12/2020**
Setting and installing printer	Printer was installed and connected to the system.	**Ok**	**Mitesh Shah** **05/12/2020**

VIII. COMMENTS :

Deviation:

Nil

Impact On Operation:

Nil

Corrective Action:

Nil

IX. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outlined in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been / not been addressed. The system is ready for Operation Qualification.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	*Mitesh Shah*	Signature:
Designation	:	Sr. Zonal Manager	Date: 05/12/2020
Company	:	Ortho Clinical Diagnostics	

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name	:	Mr. K.N. Hotkar	Signature:
Designation	:	Asso. prof.	Date: 05/12/2020
Department	:	Biochemistry	
Name	:	Mr. Bhawar S.R.	Signature :
Designation	:	Sr. Lab. Tech.	Date : 05/12/2020
Department	:	Biochemistry	

Customer Authorizations:

Name : Dr. S.N. Jangle Sir

Designation : prof & Head Biochemistry.

Signature : S.N.Jangle

Date : 5/12/2020

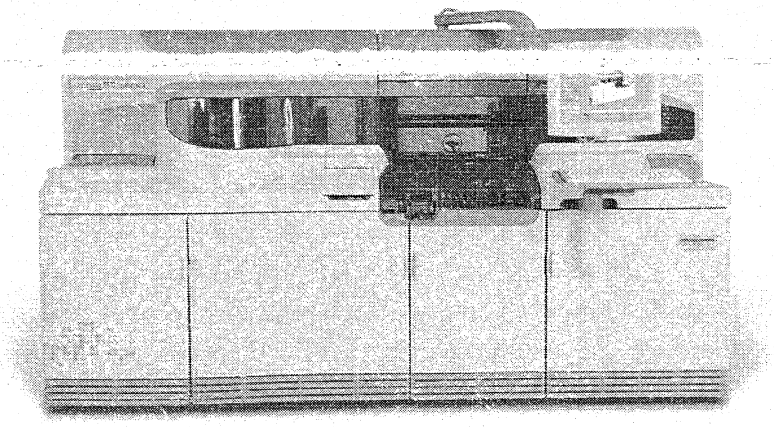
PROFESSOR & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736,(M.S.)INDIA

Ortho Clinical Diagnostics

OPERATIONAL QUALIFICATION

For

VITROS® 5600 INTEGRATED SYSTEM



Manufactured by:

Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. APPROVAL OF THE OQ PROCEDURE:

Both Central Clinical Laboratory Pravara Rural Hospital and Ortho Clinical Diagnostics are responsible for Operational check of VITROS® 5600 Integrated System bearing Sr. No. J56001041 installed in Central Clinical Laboratory Pravara Rural Hospital, Loni as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : Kailas Ghait Signature: Ghait

Designation : Territory Manager Date: 10/12/2020

Company : Ortho Clinical Diagnostics

Validation Team from Central Clinical Laboratory Pravara Rural Hospital:

Name : Mr. K. N. Hatkar Signature :

Designation : Asso. prof. Date: 10/12/2020

Department : Biochemistry

Name : Mr. Bhawar S. R. Signature : BSR

Designation : Sr. Lab Tech Date : 10/12/2020

Department : Biochemistry

Customer Authorizations:

Name : Dr. S. N. Jangle Sir

Designation: Prof. & Head Biochemistry.

Signature : S. N. Jangle

Date : 10/12/2020

PROFESSOP & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736,(M.S.)INDIA

II. INSTRUCTIONS:

1. This document is to be verified / completed at the time, the system is going for operational check of each purpose and set up for operation.
2. An authorized Ortho Clinical Diagnostics representative will check the system and enter the specific data as outlined in the appropriate Operational Qualification.
3. Employees of Central Clinical Laboratory, Pravara Rural Hospital will verify each result and sign in each page. The member of the validation team will carry out this procedure.
4. All deviations from expected specification during operation check will be noted under COMMENTS. All resolution to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this protocol for the same.

III. SCOPE

This Operational Qualification protocol will be performed on the VITROS® 5600 Integrated System, bearing Sr. No. J56001041 located at Central Clinical Laboratory, Pravara Rural Hospital Loni.

This protocol will define the documentation that will be used to evaluate the instrument's operational check in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been operated in accordance with the intended usage.

Operational checks will also be performed to verify that the instrument has been operated with proper information / sequence and utilities.

Trained, knowledgeable personnel will perform operational Qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated, and the appropriate course of action determined. All documents will be initialed and dated.

IV. OPERATIONAL QUALIFICATION:

A. Instrument Identification — Verified Date

1. Model Name — VITROS® 5600 Integrated System
2. Serial Number — J56001041 — 08/12/2020

B. Following is a list of tests to be performed and verified:

Test No.	Test Name	Test purpose	Initial / Date
01	System centers Overview	To make the operator to identify the instrument subsystem.	Kailas Ghait 08/012/2020
02	Start up & Shutdown	To make the equipment ready for operation.	Kailas Ghait 08/012/2020
03	User Inter Face Overview	Different functionality of software utility available for the operator interaction.	Kailas Ghait 08/012/2020
04	Sample programming and Analysis	To process samples either by manual assigning or through LIS.	Kailas Ghait 08/012/2020
05	Performing Calibration	To calibrate the system for every new lot of assay or after calibration expiry.	Kailas Ghait 08/012/2020
06	Maintenance & System clean	To perform maintenance process to keep the system operating properly.	Kailas Ghait 08/012/2020
07	Reagent Management & supply	To update & monitor the status of reagents required for assay processing.	Kailas Ghait 08/012/2020
08	Performing Quality control	To confirm that systems, reagents and consumables are acceptable and working within specifications for each assay used	Kailas Ghait 08/012/2020
09	Result Review	To review the processed results in the system.	Kailas Ghait 08/012/2020
10	Result Intellicheck.	To check the Intellicheck function of the system.	Kailas Ghait 08/012/2020
11	Option & Configuration	To setup the system as per Laboratory requirement.	Kailas Ghait 08/012/2020

Test: 1 : **System Hardware Overview**

Purpose : To make the operator to identify the instrument subsystem.

Reference : Operator Reference Guide - Pages 4-1 to 4-5

Summary:

For better understanding purpose, Instrument has been divided into several parts according to its operation mode, so we call this partition as centers. And those centers are named as mention below.

Procedure:

This will list the available system centers in the instrument and its subsystem, contend to operator understanding. The operator has to overview the Service V-Docs to get an idea about the system centers overview.

- Sampling Centers
  - Sample Supply
  - Primary Tip sealer
  - Micro sensor subsystem
- Micro Immunoassay Center
  - Micro Immunoassay Metering & Reagent Metering
  - Micro Immunoassay Versa Tip Ring
  - Micro Well Incubator
  - Micro Well Wash Assembly
  - Signal Reagent Assembly
  - Luminometer
- Command Center
  - Master Computer & Monitor
  - Keyboard & Touch system
- System Frame and Cabinetry

Test: 2 : **Starting Up and Shutting Down**

Purpose : To make the instrument 'READY' for operation

Reference : Operator Reference Guide - Pages 3-0 to 3-25

Summary:

Instrument will check status of different parts of the instrument automatically after booting up to system status screen; if there is an error code posted, initialize the system and follow corrective action instructions provided for the error code.

Procedure:

Starting Up the System

- Check the room temperature and switch on the Air Conditioner.
- Check the UPS.
- Switch on the Printer & Load the paper.
- Switch on the VITROS® 5600 Integrated System by lift the main switch up and hold it for about 5 sec.
- Wait for the instrument to get ready after initialization.
- The machine is ready for next step if it displays "READY" on the status console.
- If not, initialize by pressing the initialize button on the error code screen.
- Follow the instructions provided for the error codes.

Shutting Down the system

- Touch **Shutdown** in the main menu.
- Press '**Y/N**' to continue the shutdown process.
- Desire normal shutdown or final shutdown and then select desired menu.
- If, you selected **Final Shutdown,** press the RESET button to restart the instrument, or press the Main power switch down to make it OFF.

Observation	System status console shows "Ready". Instrument is ready for operation	**Remarks**	**Initial/Date**
		Pass	Kailas Ghait 08/12/2020

Test: 3 : **User Interface Overview**

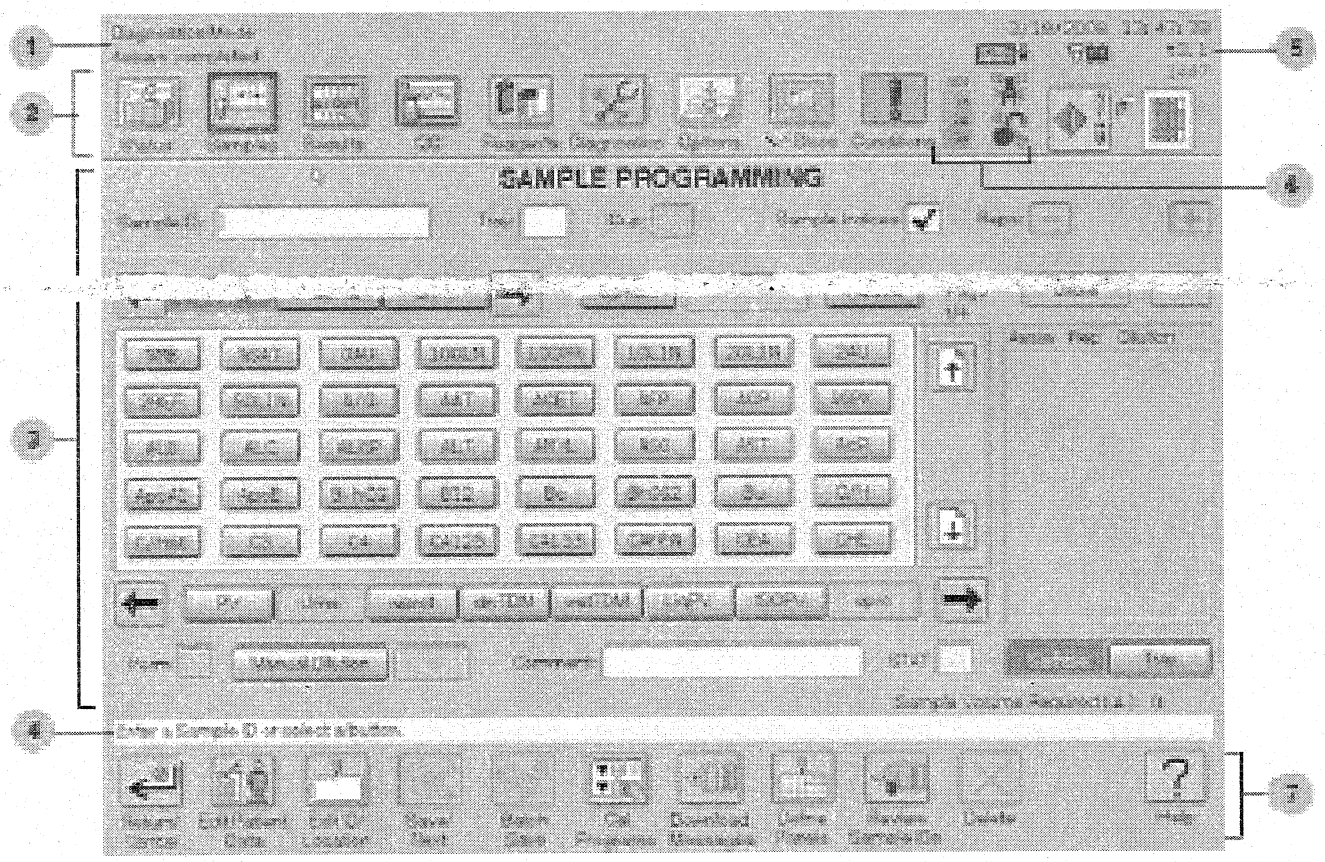
Purpose : To make the operator to understand the system screens.

Reference : Operator Reference Guide - Pages 6-0 to 6-12

Summary:

The System status screen will make the operator to understand of different functionality of software utility available for the operator. This will helps operator to check system status as well as to instruct any commands to the system for required operation.

Procedure:



The above (as shown in the Previous Page) picture is actual system software screen and the number in the blue circle is to identify the several functionality of the software icons designed for the operator to interact with the system. We call these software icon as mentioned below.,

1. Status Line
2. Status Console
3. Function Screen
4. Prompt Line

5. Time, Date and Version Display
6. Status Indicators
7. Process Buttons

Test: 4 : **Sample programming and Analysis**

Purpose : To program and process the samples

Reference : Operator Reference Guide (pages 9-1 to 9-13)

Summary: The operator can process assay by assigning program manually in the Universal Sample tray in **'Sample Program'** menu or they can download sample program through **'LIS'**. Sample programming is the process of selecting assays and programming characteristics for samples. The system uses the sample program to meter appropriate sample and select the right reagent for the assay, process and then report results with the correct identification.

Procedure:

Sr. No.	Activity	**Observation**	Remarks Pass / Fail	Done By Date
01	Sample Programming methods & Overview	Desire the sample Programming method.	Pass	Kailas Ghait 09/12/2020
02	Loading and Processing of samples	Tray cover opened and samples loaded in sample tray placed in sample supply.	Pass	Kailas Ghait 09/12/2020
03	Programming samples	Sample program assigned for selected tray.	Pass	Kailas Ghait 09/12/2020
04	Processing samples	Samples are processed automatically by the system.	Pass	Kailas Ghait 09/12/2020
05	Unloading the samples	Tray cover opened and processed sample tray unloaded.	Pass	Kailas Ghait 09/12/2020
06	Viewing samples in process	Sample under process are displayed on the 'View Sample Status' Screen.	Pass	Kailas Ghait 09/12/2020

Test: 5 : **Performing Calibration**

Purpose : To calibrate the system for every new lot of assay

Reference : Operator Reference Guide (pages 10-1 to 10-9)

Summary: The system requires its own calibration for every individual assay to measure the analytic concentration as well as to accept reagent pack status ready for processing. Assay calibration is a process that relates the response of the system to analyte concentration or activities. Calibration is performed periodically to adjust for changes in the system, assay protocols, or assay reagent lots.

The system requires calibration for individual assays when:

- A new assay is uploaded to the system
- The calibration expires (up to 28 days after it is processed, depending on the assay; refer to the package insert for expiration information)
- An assay reagent lot number changes
- Government regulations specified
- An assay's protocol changes

You also may need to perform calibration when:

- Certain service procedures are performed
- Quality control performance is out of range

Procedure:

Sr. No.	Activity	**Observation**	Remarks	Done By
			Pass / Fail	Date
01	Load New ADD via CD or Downloaded file (New Gen Lot, Protocol , reagent lot calibration , Diluents lot information).	Calibrator identified and updated for protocol & master calibration data.	Pass	Kailas Ghait 09/12/2020
02	Preparing calibrators.	Calibrators are ready for processing.	Pass	Kailas Ghait 09/12/2020
03	Performing Calibration with Bar code label.	System recognizes the barcode and processing the calibration automatically.	Pass	Kailas Ghait 09/12/2020
04	Performing Calibration with Sample processing screen.	In the sample programming, the calibration program is assigned and processed the calibration assigned for each assay.	Pass	Kailas Ghait 09/12/2020

05	Calibration report.	Calibration completed successfully. Report printed.	Pass	Kailas Ghait 09/12/2020

Test: 6 : **Maintenance & System Clean**

Purpose : Clean appropriate modules to maintain Accuracy and precision.

Reference : Operator Reference Guide 16-13 to 16-17

Summary:

Maintenance procedures are tasks that are performed to keep the system operating properly. Maintenance protocols to be performed according to the recommended schedule (daily, weekly, monthly, or as required). Ensure that we need to use 70% Isopropyl alcohol to disinfect the appropriate module to keep cleanliness and maintain the accuracy & precision.

The Maintenance is classified into four-category ie.,

1. Daily Maintenance
2. Weekly Maintenance
3. Monthly Maintenance
4. As required Maintenance

Daily Maintenance: Pages from 16-14 to 16-15

Sr. No.	Activity	Observation	Remarks Pass/Fail	Done By Date
01	Perform Metering Maintenance	Metering Maintenance Performed	Pass	Kailas Ghait 09/12/2020
02	Empty Solid and Liquid waste container	Solid & Liquid waste containers are emptied.	Pass	Kailas Ghait 09/12/2020
03	Remove outdated or empty reagent packs, Signal Reagent packs and Universal Wash Buffer	Outdated empty Reagent packs, SR packs and UWR bottles are removed & discarded.	Pass	Kailas Ghait 09/12/2020
04	Inspect sample trays and adaptors	Sample Trays are cleaned.	Pass	Kailas Ghait 09/12/2020
05	Clean the SR Probe assembly	SR Probes are cleaned.	Pass	Kailas Ghait

				09/12/2020
06	Load required reagent packs, Signal Reagent pack and Universal Wash Buffer.	All the required reagent packs are loaded and updated in the system as required.	Pass	Kailas Ghait 09/12/2020
07	Run Q.C fluids	Q.C samples are processed successfully.	Pass	Kailas Ghait 09/12/2020

Weekly Maintenance: Pages from 16-15 to 16-16

Sr. No.	Activity	Observation	Remarks Pass/Fail	Done By Date
01	Clean the Micro well Incubator.	Micro well incubator – Inner ring, outer ring, middle ring, shuttle weight, drop holes, Luminometer FOB, Wash reagent and signal reagent probes are cleaned.	Pass	Kailas Ghait 09/12/2020
02	Clean the Primary tip sealer.	Primary Tip Sealer cleaned.	Pass.	Kailas Ghait 09/12/2020
03	Clean the Secondary Tip Sealer.	Secondary Tip Sealer cleaned.	Pass	Kailas Ghait 09/12/2020
04	Clean the Sample Supply and Cap Retainer.	Cap Retainer & Sample Supply cleaned.	Pass	Kailas Ghait 09/12/2020
05	Clean the Touch Screen Monitor & Keyboard.	Touch Screen Monitor & Key board Clean Done.	Pass	Kailas Ghait 09/12/2020
06	Run the maintenance Pack for Subsystem cleaning.	Maintenance pack is loaded; subsystem cleaning done automatically by the system.	Pass	Kailas Ghait 09/12/2020
07	Run QC Fluids	Q.C Processed successfully.	Pass	Kailas Ghait 09/12/2020

Monthly Maintenance: Pages from 16-15 to 16-16

Sr. No.	Activity	Observation	Remarks Pass/Fail	Done By Date
01	Clean Micro sensor Cover & Ring Area.	Micro Sensor Cover & Ring Surface cleaned.	Pass	Kailas Ghait 09/12/2020
02	Inspect/Clean Micro Immuno Assay reagent Supply top Cover.	Micro Immuno Assay Reagent Supply top Cover Inspected and Cleaned.	Pass	Kailas Ghait 09/12/2020
03	Clean VITROS Versa Tip supply Registration Rail.	Versa tip Supply Registration Rail cleaned.	Pass	Kailas Ghait 09/12/2020
04	Inspect Reagent cooler filter for cleanliness.	Reagent cooler filter removed & cleaned.	Pass	Kailas Ghait 09/12/2020
05	Replace Vapors adsorption cartridge for every two months.	Every two months once, VAC replaced.	Pass	Kailas Ghait 09/12/2020
06	Make a backup of Q.C, Calibration and Configuration.	Backup of QC, Calibration and Configuration made successfully.	Pass	Kailas Ghait 09/12/2020
07	Inspect / Clean Master Computer Filter.	Inspected and Cleaned Master computer Air Filter.	Pass	Kailas Ghait 09/12/2020

Test: 7 : **Managing reagents Inventory and Supply**

Purpose : To Maintain & monitor the status of reagents or supply required for assay processing.

Reference : Operator Reference Guide (pages 15-1 to 15-7)

Summary: The Reagent Management feature enables you to review current inventory Information for the reagents loaded on the system. Using this function, you can load and unload reagents as necessary. To maintain the required reagents in the system for processing, the operator should review the Reagent management screen.

Procedure:

Sr. No.	Activity	**Observation**	Remarks Pass/Fail	Done By Date
01	Review the reagent inventory to plan for the day.	The reagent inventory for the day planned.	Pass	Kailas Ghait 09/12/2020
02	Loading of Reagent Pack automatically	Required Reagent Packs loaded automatically by software request.	Pass	Kailas Ghait 09/12/2020
03	Loading of Reagent Pack with help of Manual Lot Entry button.	Requested Lot Information fed and the reagent pack loaded.	Pass	Kailas Ghait 09/12/2020
04	Loading of Signal Reagent automatically.	SR Pack loaded in position 1 & 2 and accepted by barcode reading.	Pass	Kailas Ghait 09/12/2020
05	Loading of Signal Reagent with Manual Load Button.	SR packs information fed and loading done.	Pass	Kailas Ghait 09/12/2020
06	Loading of Universal Wash Buffer	UWR buffer loading done through Load supply Software icons.	Pass	Kailas Ghait 09/12/2020
07	Unloading of Reagents	The entire Empty & expired reagents packs are unloaded by Load/Unload software icons.	Pass	Kailas Ghait 09/12/2020

Test: 8 : Performing Quality control

Purpose : Quality Control (QC) is important in determining the performance and accuracy of the system. To perform Quality Control, QC materials are run with either known, or unknown values along with patient samples to determine whether the system is functioning within the established ranges for your lab.

Reference : Operator Reference Guide (Pages 9-6 to 9-8)

Summary: Performing quality control procedures is an important part of using or maintaining the system. This section explains:

- When you should perform quality control
- How to choose a control fluid

The recommended frequency for processing quality control fluids is once in every 24 hours. However, the frequency with which you perform quality control procedures may vary, depending on the requirements and regulations for processing control fluids by your national, state, provincial, and local governments. Quality control procedures within your own Laboratory may also require a different frequency. You should also perform quality control procedures when:

- Assays have been calibrated
- Certain service procedures are performed, other than routine maintenance

Procedure:

Sr. No.	Activity	**Observation**	Remarks Pass / Fail	Done By Date
01	Choosing the Control fluid	Required control fluid identified.	Pass	Kailas Ghait 09/12/2020
02	Preparing Liquid or Lyophilized control fluids	Control fluid prepared and ready for processing.	Pass	Kailas Ghait 09/12/2020
03	Creating QC file.	Q.C file created for assay in the system according to control fluid.	Pass	Kailas Ghait 09/12/2020
04	Process QC samples	QC samples are programmed in the sample programming window and the QC samples are loaded and processed automatically	Pass	Kailas Ghait 09/12/2020
05	Review Q.C result.	Processed Q.C results are reviewed and found satisfactory.	Pass	Kailas Ghait 09/12/2020
06	Display & printing graph.	Q.C graph reviewed and printed.	Pass	Kailas Ghait 09/12/2020

07	Managing Quality control Reports	Required reports printed and filed.	Pass	Kailas Ghait 09/12/2020

Test: 9 : **Result Review.**

Purpose : To review the processed results in the system.

Reference : Operator Reference Guide (Pages 11-1 to 11-6)

Summary: The Results Review function helps to evaluate result records for patient and quality control samples. The results will be displayed along with the Reagents Lot information, Dilution information & if there is any error codes or Flags.

Result records contain the data generated by the system when assays are processed. The system can store up to 25,000 result records. When this limit is reached, new result records overwrite the oldest records. The system permanently deletes the overwritten records from computer memory.

Procedure:

Sr. No.	Activity	**Observation**	Remarks Pass / Fail	Done By Date
01	Update List.	Sample under process status displayed with all information.	Pass	Kailas Ghait 09/12/2020
02	Monitoring Results.	Completed Recent Assay Results displayed on the screen.	Pass	Kailas Ghait 09/12/2020
03	Filter Results.	Processed Assay Results displayed as per the selected criteria.	Pass	Kailas Ghait 09/12/2020
04	Edit Patient Data	User can Edit/Add Patient Demography information, but the Patient ID will remain same.	Pass	Kailas Ghait 09/12/2020
05	Retrieving and Reviewing Archive Results by Set Report Status.	Archived Results are updated successfully in the CD/Pen Drive. The same Retrieved from the CD/Pen Drive.	Pass	Kailas Ghait 09/12/2020
06	Managing Reports by Set Report Status.	Required Reports got printed and filed.	Pass	Kailas Ghait 09/12/2020
07	Integrated Codes and Flags	Reported Codes and Flags are referred in Flags and Code chart. Necessary corrective action taken.	Pass	Kailas Ghait 09/12/2020

Test: 10 : **Result Intellicheck.**

Purpose : To check the Integrity of Performed assays.

Reference : Operator Reference Guide (Pages 11-8 to 11-9).

Summary: The Result Intellicheck screen to view Intellicheck Technology Verifications performed for each sample and assay processed. For the selected result record, you can view verification data and detected exceptions for each analyte.

Example:

- On Review results screen, touch the 'Result Intellicheck' Icon.
- Result Intellicheck report comes on the screen.
- Check the parameters of Sample Metering, Sample + Reagent volume, Signal reagent volume and well wash verification for their acceptance.
- Take print of the Result Intellicheck report.

Acceptance criteria:

Sr. No.	Parameter	Acceptance limit	Remarks Pass / Fail	Done By Date
01	**Sample Metering** • Clot • Bubble • Short sample • Viscosity • Thin layer of fluid	Against all the parameters, "No" should be displayed on screen	Pass	Kailas Ghait 09/12/2020
02	**Reagent Metering** Sample + Reagent volume	No Exception. Range: 12700 – 19000	Pass	Kailas Ghait 09/12/2020
03	Signal Reagent	No Exception Range: 17500 – 22800	Pass	Kailas Ghait 09/12/2020
04	Well wash verification	No Exception Range: 21300 – 25000	Pass	Kailas Ghait 09/12/2020
05	Luminometer – Self calibration	No Exception	Pass	Kailas Ghait 09/12/2020

Test: 9 : **Option & Configuration**

Purpose : To setup the system as per laboratory requirement

Reference : Operator Guide (Pages 11-8 to 11-14)

Summary: The Options & Configuration function provides many features for customizing your VITROS® 5600 Integrated System. It is organized into three main groups:

- Configure Analyte Data & Review/Edit Calibration Data
- System Setup
- System Services

Selections within these groups allow you to customize analyte parameters, review calibration data, perform user calibrations, configure and set system parameters, review usage inventory, configure e-Connectivity® and network device parameters, configure printer, laboratory computer and auxiliary ports, perform backup for quality control, calibration and configuration files and perform an archive procedure for result records.

Procedure:

Sr. No.	Activity	Observation	Remarks Pass / Fail	Done By Date
01	Configure Assays	Analyte parameters are configured as desired by laboratory.	Pass	Kailas Ghait 09/12/2020
02	Review / Edit Calibration Data	Calibration data updated.	Pass	Kailas Ghait 09/12/2020
03	Configure System Setup	Required subsystem configuration is done successfully.	Pass	Kailas Ghait 09/12/2020
04	Configure Subsystem Setup	The required subsystem can be disabled / deactivated as per needs.	Pass	Kailas Ghait 09/12/2020
05	Configure Report Control	System report parameter has set for printer & LIS.	Pass	Kailas Ghait 09/12/2020
06	Configure Communication	System interface protocol set for Laboratory Information System (LIS), Ethernet and e-Connectivity® communications,	Pass	Kailas Ghait 09/12/2020
07	Configure Demography	Global demographic attributes to be used when configuring age, sex, and normal ranges for specific	Pass	Kailas Ghait 09/12/2020

		assay/body fluids is defined.		
08	System Services 1.Datalogger 2.Perform Backup 3.Usage Counters 4.Option Summary 5.Load System Data	Shall be performed and reviewed as & when required.	Pass	Kailas Ghait 09/12/2020

V. Operational procedure:

Certificate of Training

1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

Mr. Kailas Ghait, Sr. Territory Manager from Ortho Clinical Diagnostics has conducted the training.

Sr. No.	Training program	Initials	Date
1.	Instrument Setup	Kailas Ghait	
2.	System Operation	Kailas Ghait	
3.	Basic trouble shooting and Maintenance	Kailas Ghait	

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

Sr. No.	Operators	Department	Initials	Date
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

b. Customer SOP / Manuals:

Title	Number	Version	Verified by	Date
Vitros 5600 Integrated System Reference Guide				
Microslide Instruction for use Manual				
Microtip Chemistry Instruction For Use Manual				
Micro Well Instruction For Use Manual				

VI. COMMENTS :

Deviation:

Nil

Impact On Operation:

Nil

Corrective Action:

Nil

VII. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outlined in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been / not been addressed. The system is ready for Performance Qualification.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	Kailas Ghait	Signature: Ghait
Designation	:	Sr. Territory Manager	Date: 10/12/2020
Company	:	Ortho Clinical Diagnostics	

Validation Team From Central Clinical Laboratory Pravara Rural Hospital:

Name	:	Mr. K. N. Hotkar	Signature:
Designation	:	Asso. prof.	Date: 10/12/2020
Department	:	Biochemistry	
Name	:	Mr. Bhawar S. R	Signature :
Designation	:	Sr. Lab Tech.	Date : 10/12/2020
Department	:	Biochemistry	

Customer Authorizations:

Name	:	Dr S. N. Tangle Sir
Designation	:	prof. & Head Biochemistry
Signature	:	S. N. Tangle
Date	:	10/12/2020

PROFESSOP & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736,(M.S.)INDIA

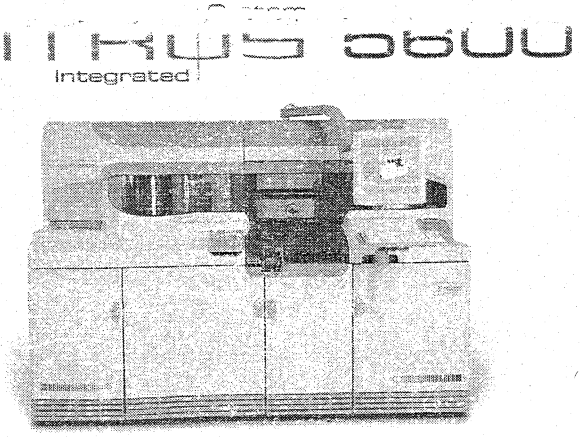
1041

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS® 5600 INTEGRATED SYSTEM



Manufactured by:

Ortho Clinical Diagnostics, Inc., US

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I. APPROVAL OF THE PQ PROCEDURE:

Both Central Clinical Laboratory, Pravara Rural Hospital and Ortho Clinical Diagnostics are responsible for Performance check of VITROS® 5600 Integrated System bearing Sr. No J56001041 in Central Clinical Laboratory, Pravara Rural Hospital, Loni as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics representative

Name : Kailas Ghait Signature: Ghait

Designation : Sr. Territory Manager Date: 10/12/2020

Company : Ortho Clinical Diagnostics

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K.N. Hotkar Signature:

Designation : Asso. prof. Date: 10/12/2020

Department : Biochemistry

Name : Mr. Bhawar S.R. Signature:

Designation : Sr. Lab Tech. Date: 10/12/2020

Department : Biochemistry

Customer Authorizations:

Name : Dr. S.N. Jangle Sir

Designation: Prof & Head Biochemistry

Signature : S.N. Jangle

Date : 10/12/2020

PROFESSOR & HEAD
DEPARTMENT OF BIOCHEMISTRY
RURAL MEDICAL COLLEGE
LONI-413736,(M.S.)INDIA

II. INSTRUCTIONS:

1. An authorized Ortho Clinical Diagnostics representative will check for the performance of the instrument and enter the specific data as outlined in the Performance Qualification.

2. The concerned lab personnel are responsible for performance checks described in the Performance testing.

3. The concerned employees of Central Clinical Laboratory Pravara Rural Hospital will verify each result and sign in each page. The member of the validation team will carry this out.

4. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of each PQ protocol. All conclusions to such problems will also be noted in the **COMMENTS** section and must be resolved prior to issuance of a SYSTEM CERTIFICATION.

III. SCOPE

This Performance Qualification protocol will be performed on the VITROS® 5600 Integrated System, and the Sr. No. J56001041 located at Central Clinical Laboratory Pravara Rural Hospital, Loni.

This protocol will define the documentation that will be used to evaluate the instrument's performance check in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been performed in accordance with the intended usage.

Performance checks will also be performed to verify that the instrument has been operated with proper information/sequence and utilities.

Trained, knowledgeable personnel will perform Performance Qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated, and the appropriate course of action determined. All documents will be initialed and dated.

IV. PERFORMANCE QUALIFICATION

A. Instrument Identification

		Verified Date
1. Model Name	VITROS 5600	05/12/2020
2. Serial Number	J56001041	05/12/2020

B. Following is a list of tests to be performed and verified:

Sr.No.	Test Name	Test Purpose	Initial / Date
01	QC Run	To see the performance of quality control material on the equipment on selected assay parameters as per the specifications given	Kailas Ghait 05/12/2020
02	Accuracy Study	To compare the obtained value with true values of processed control.	Kailas Ghait 05/12/2020
03	Precision Study	To check the precision performance of the equipment	Kailas Ghait 05/12/2020

C. Performance Testing:

Test I

Test Name	:	**QC Run**
Purpose	:	To see the performance of quality control material on the equipment as per the specifications given
Method	:	Microslide – Rate Chemistry & Endpoint Chemistry Microslide – Potentiometric Chemistry; Microslide – Immunorate Chemsitry; Microtip Chemistry Microsensor Chemistry Microwell - Chemiluminescence Immunoassay

Analysis of controls:

Note: Analyze controls for ALT (Microslide Rate Chemistry);
Sodium (Potentiometric Chemistry);
BuBc (Microslide End point Chemistry)
Phenytoin (Microslide – Immunorate Chemistry)
dLDL (Microtip Chemistry)
Gentamycin (Microtip Chemistry)
IgM (Microtip Chemistry)
HIT (Microsensor Chemistry)
TSH (Microwell - Immunometric assay) &
TT4 (Microwell - Competitive assay).

Sr. No.	Activity	Procedure done as per the protocol defined in Vitros 5600 V Docs – System Operation – Quality Control	Remarks Pass/Fail	Done By Date
01	Preparing Liquid or Lyophilized control fluids	"Instructions for use" of QC material	Pass	Kailas Ghait 05/12/2020
02	Creating QC file	V Docs – System Operation – Quality Control – Define control fluids	Pass	Kailas Ghait 05/12/2020
03	QC sample programming and analysis	V Docs – System Operation – Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	Kailas Ghait 05/12/2020

Test II

Test Name : **Accuracy**

Purpose : To see the accuracy of obtained quality control value in comparison with the expected mean values.

Method : Microslide; Microtip; Microsensor and Microwell method as mentioned above

Analysis of controls:

Note: Analyze controls as mentioned above.

Sr. No.	Activity	Procedure done as per the protocol defined in Vitros 5600 V Docs – System Operation – Quality Control	Remarks Pass/Fail	Done By Date
01	Preparing Liquid or Lyophilized control fluids	'Instructions for use' of QC material	Pass	Kailas Ghait 05/12/2020
02	QC sample programming and analysis	V Docs – System Operation – Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	Kailas Ghait 05/12/2020
03	Accuracy Analysis	Compare the obtained Q.C value with mean of expected value as mentioned in the QC Value chart.	Pass	Kailas Ghait 05/12/2020

Test III

Test Name	:	**Precision Study**
Purpose	:	To see the precision performance of the equipment
Method	:	Microslide – Rate Chemistry & Endpoint Chemistry Microslide – Potentiometric Chemistry; Microslide – Immunorate Chemsitry; Microtip Chemistry Microsensor Chemistry Microwell - Chemiluminescence Immunoassay

- Analyze Vitros Performance Verifier Level 1 control for the following tests : ALT (5 x 7 times), Na+ (5 x 8 times), dLDL (6 x 6 times), BuBc (5 x 7 times)
- Analyze TDM Performance Verifier Level 3 for Phenytoin (5 x 7 times).
- Analyze TDM Performance Verifier Level 1 for Gentamycin (6 x 6 times).
- Analyze Protein Peformance Verifier Level 1 for IgM (6 x 6 times).
- Analyze Microsensor Check Fluid Level I for Hemolysis, Icterus and Turbidity (20 times each).
- Analyze all the three levels of Vitros Total Thyroid controls for Microwell – Chemiluminescence Immunoassay TT4 and TSH (10 times each).
- Calculate the Mean, SD and CV%.

Acceptance Criteria :

Sr. No.	Analyte	Control Level	Precision Limit
01	ALT	PV I	≤ 2.2 SD
02	Sodium	PV I	≤ 0.69% CV
03	dLDL	PV I	SD < 1.1
04	Bu	PV I	≤ 0.3 SD
05	Bc	PV I	≤ 0.6 SD

06	Phenytoin	TDM PV III	≤ 0.75 SD
07	Gentamycin	TDM PV I	SD < 0.11
08	IgM	Protein PV I	SD < 2.1
09	Hemolysis	MS Check Fluid Level I	SD < 4.4
10	Icterus	MS Check Fluid Level I	SD < 0.4
11	Turbidity	MS Check Fluid Level I	SD < 14.8
12	TT4	Total Thyroid Control Level 1	CV% ≤ 4.9
		Level 2	CV% ≤ 4.6
		Level 3	CV% ≤ 6.0
13	TSH	Total Thyroid Control Level 1	CV% ≤ 10.9
		Level 2	CV% ≤ 4.9
		Level 3	CV% ≤ 4.7

* Reference: The acceptance SD & CV% has been taken from Manufacturer's recommended limits.

Table for Record the Obtained Q.C Values :

Test Name: **Control Level:**

Control Lot: **Expiry Date:**

Sr. No	Obtained Q.C Value	Range of the Comparator	Mean of the Comparator	Remarks	Done By
				Pass / Fail	Date
01					
02					
03					
04					
05					
06					
07					
08					
09					
10					

V. COMMENTS:

Deviation:

Nil

Impact On Operation:

Nil

Corrective Action:

Nil

VI. System Certification

Study data has determined that the system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : *Kailas Ghait* Signature: Ghait

Designation : Sr. Territory Manager Date: 05/12/2020

Company : Ortho Clinical Diagnostics

Validation Team Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K. N. Hatkar Signature:

Designation : Asso. Prof. Date: 05/12/2020

Department : Biochemistry

Name : Mr. Bhawar S. R Signature:

Designation : & Lab Technician Date: 05/12/2020

Department : Biochemistry

Customer Authorizations:

Name : Dr. S. N. Jagle Sir

Designation : Prof. & Head Biochemistry

Signature : S.N.Jagle

Date : 05/12/2020

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