


## Ortho Clinical Diagnostics

### 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

  
Signature:

Date: 07/07/2018


Name : Rathod Vijaykumar

Designation : Territory Manager

Company : Ortho Clinical Diagnostics

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K. N. Hotkga-

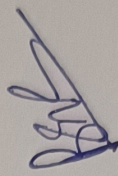
  
Signature:

Designation : Asso. Prof.

Date: 07/07/2018

Department : Biochemistry

Name : Mr. Shaware S.R.

  
Signature:

Designation : Sr. Lab. Technician

Date: 07/07/2018

Department :

Customer Authorizations:

Name : Dr. S. H. Jangale, Sr

Designation : Prof. & Head Biochemistry

Signature : 

Date : 07/07/2018

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



# Ortho Clinical Diagnostics

## I. APPROVAL OF THE IQ PROCEDURE:

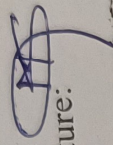
Both Central Clinical Laboratory Pravara Rural Hospital and Ortho Clinical Diagnostics are responsible for installation of VITROS® 5600 Immundiagnostic System bearing Sr. No J5600-0703 in Central Clinical Laboratory, Pravara Rural Hospital as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : Mitesh Shah

Designation : Sr. Zonal Manager

Company : Ortho Clinical Diagnostics

Signature: 

Date: 23/06/2018

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K. N. Hotkar.

Designation : Asso. Professor.

Department : Biochemistry

Name : Mr. Bhaware S.R.

Designation : SE, Lab. Tech.

Department : Biochemistry


Customer Authorizations:

Name : Dr. S.N. Jangale, Sr.

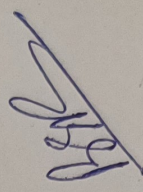
Designation : Prof. & Head, Dept. of Biochemistry.

Signature : S.N. Jangale

Date : 23/06/2018

Signature: 

Date: 23/06/2018

Signature: 

Date: 23/06/2018

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

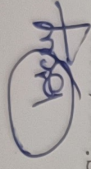


Ortho Clinical Diagnostics

**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



Signature:

Name : Rathod Vijaykumar

Date: 07/07/2018

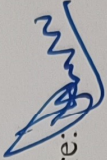
Designation : Territory Manager

Company : Ortho Clinical Diagnostics

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name

: Mr. K. N. Hotekar

Signature: 

Designation

: Asso. Prof.

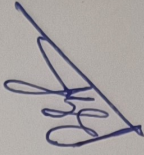
Date: 07/07/2018

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, Sr.

Designation

: Prof. & Head, Biochemistry

Signature

: S. N. Jangle

Date

: 07/07/2018

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



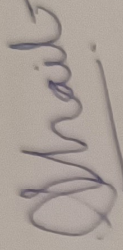
## I. APPROVAL OF THE PQ PROCEDURE:

### Ortho Clinical Diagnostics

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  
Designation : Sr. Territory Manager  
Company : Ortho Clinical Diagnostics

Signature: 

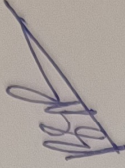
Date: 10/12/2020

Validation Team from Central Clinical Laboratory, Pravara Rural Hospital:

Name : Mr. K. N. Hattke  
Designation : ASSO. prof.  
Department : Biochemistry  
Name : Mr. Bhawar S. R.  
Designation : ~~Asst.~~ Lab Tech.  
Department : Biochemistry


Signature: 

Date: 10/12/2020

Signature: 

Date: 10/12/2020

Customer Authorizations:

Name : Dr. S. H. Jangle Sir  
Designation: Prof. f Head Biochemistry  
Signature :   
Date : 10/12/2020

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



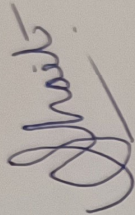
## Ortho Clinical Diagnostics

### 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: 

Designation : Territory Manager  
Company : Ortho Clinical Diagnostics

Date: 10/12/2020

Validation Team from Central Clinical Laboratory Pravara Rural Hospital:

Name : Mr. K. N. Hote

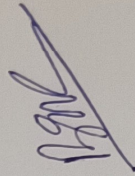
Signature: 

Designation : Asst. 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. H. 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**




## Ortho Clinical Diagnostics

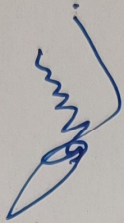
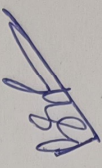
### I. APPROVAL OF THE IQ PROCEDURE:

Both Central Clinical Laboratory Pravara Rural Hospital and Ortho Clinical Diagnostics are responsible for installation of VITROS® 5600 Immundiagnostic 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. Hattar Signature:   
Designation : Asso. prof. Date: 05/12/2020  
Department : Biochemistry  
Name : Mr. Bhawar S. P. Signature:   
Designation : So. 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**



CALIBRATION REPORT

SYSTEM NAME: 5601041

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

KIT LOT: 0110

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

SUPPLY HUMIDITY: 34

PARAMETERS

INTERCEPT: 0.0384845  
SLOPE: 95.6149  
CURVATURE/SLOPE2: 0.000000000000

LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
1	3	1.7	0.683448
2	2	9.0	1.12001
3	1	13.9	1.33930

End of Report

PAGE 1

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CCL- Biochemistry  
PMT, RMC, Loni



22  
20.1  
97.6  
7.7  
8  
46.8  
0.9  
0.11

SYSTEM NAME: S601041

LIBRATION REPORT

CAL DATE/TIME: 30/11/2021 14:33:12  
REAGENT GEN/LOT: 32060412

KIT LOT: 0110

ASSAY: Mg  
FLUID: Serum  
Status: Passed  
OP ID:  
SITE TEMP: 27.5C

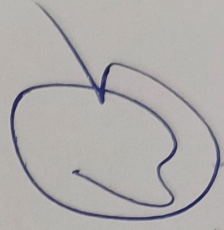
SUPPLY HUMIDITY: 34

LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
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2	2	3.8	1.39952
3	3	9.6	1.99517

PARAMETERS  
INTERCEPT: -0.0162041  
SLOPE: 110.985  
CURVATURE/SLOPE2: 38.1848

PAGE 1 PRINT DATE/TIME: 17/3/2022 16:30:19

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OPERATION REPORT

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

KIT LOT: 6110

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

SUPPLY HUMIDITY: 35

LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
1	1	1.2	0.217389
2	2	5.6	0.473451
3	3	12.9	0.680923

PARAMETERS  
INTERCEPT: 0.546283  
SLOPE: 86.2334  
CURVATURE/SLOPE2: 213.892

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2.47  
2.35  
2.23  
5.4  
5.2  
5.1  
17.5  
0.14  
16.0  
0.9  
0.30  
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0.4  
0.19  
1.6

CALIBRATION REPORT

SYSTEM NAME: 5600703

CAL DATE/TIME: 5/6/2021 12:40:46  
REAGENT GEN/LOT: 03484850

KIT LOT: 0110

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

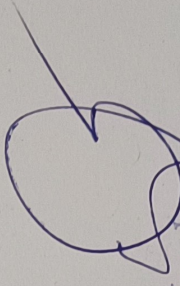
SUPPLY HUMIDITY: 35

PARAMETERS	LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
INTERCEPT: 0.0144503	1	3	1.8	0.646544
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CURVATURE/SLOPE2: 0.000000000000	3	1	13.9	1.34932

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End of Report

  
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CALIBRATION REPORT

SYSTEM NAME: 5600703

KIT LOT: 0110

CAL DATE/TIME: 30/11/2021 14:21:24  
REAGENT GEN/LOT: 32060412

ASSAY: Mg  
FLUID: Serum  
Status: Passed  
OP ID:  
SITE TEMP: 26.4C

SUPPLY HUMIDITY: 34

PARAMETERS

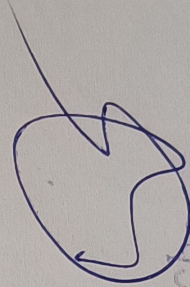
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SLOPE: 99.4943  
CURVATURE/SLOPE2: 211.650

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2	2	3.8	1.41230
3	3	9.6	1.97214

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PAGE 1

End of Report



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MT, RMC, Loni



LABORATION REPORT

SYSTEM NAME: 5600703

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

KIT LOT: 0110

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

SUPPLY HUMIDITY: 35

PARAMETERS

INTERCEPT: 0.597449  
SLOPE: 88.2428  
CURVATURE/SLOPE2: 226.099

LEVEL	BOTTLE	CALIB VALUE mg/dL	RESPONSE
1	1	1.2	0.212526
2	2	5.6	0.466079
3	3	12.9	0.672439

PRINT DATE/TIME: 17/3/2022 16:24:43

PAGE 1

End of Report

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PMT,RMC,Loni