

**CERTIFICATE OF CALIBRATION**

ADL/KO/SER/0468/22-23

Instrument : **Mispa Clinia Fully Automated Biochemistry Analyser**  
 Customer Name : **Shri Medscan Imaging Center, Chandrasekharpur, Bhubaneswar**  
 Date of Installation : **30/06/2023** S/N: **YM-67000743T**

**Alignment Check**

Motion Check	Checked	Remark
Sample Probe	<input type="checkbox"/>	OK
Reagent Probe	<input type="checkbox"/>	OK
Mixer Probes	<input type="checkbox"/>	OK
Reaction Disk	<input type="checkbox"/>	OK
Reagent Disk	<input type="checkbox"/>	OK
Sample Disk	<input type="checkbox"/>	OK
Wash Station	<input type="checkbox"/>	OK
Lamp	<input type="checkbox"/>	OK

System	Checked	Remark
Main unit	<input type="checkbox"/>	OK
Temp.unit	<input type="checkbox"/>	OK
Mixing unit	<input type="checkbox"/>	OK
Reaction unit	<input type="checkbox"/>	OK
Reagent unit	<input type="checkbox"/>	OK
Sample unit	<input type="checkbox"/>	OK

**AGAPPE DIAGNOSTICS LTD.** ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

**CORPORATE OFFICE / REAGENT PLANT**  
 Agappe Hills, Pattimattom (PO), Dist. Ernakulam, Kerala - 683 562, India.  
 Tel: +91 484 286 7000 | Email: agappe@agappe.in

**MUMBAI [REGISTERED OFFICE]**  
 401 & 402, 4<sup>th</sup> Floor, Jaisingh Business Centre, 119,  
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**EQUIPMENT PLANT**  
 X/588-CB, Block No. 32, KINFRA Small Industrial Park,  
 Nellikud, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

**DELHI OFFICE**  
 DSM 540, 5<sup>th</sup> Floor, DLF Tower, Shivaji Marg,  
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 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

**KOLKATA OFFICE**  
 406, Merlin Matrix, Plot No-30, Block-DN, Sector V,  
 Salt Lake City, Kolkata - 700 091.  
 Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in

**BANGALORE OFFICE**  
 5-6, 11<sup>th</sup> Floor, Red Cross Bhavan, No-26 Race Course Road,  
 Bangalore - 560 001. Tel: +91 80 2228 8288  
 Email: bangaloreoffice@agappe.in

**OPTICAL SECTION**

Photometer Unit Alignments	Status	Remarks
Lamp Brightness Adjustment	OK	
Signal Collecting Position Adjustment	OK	
Photoelectric Gain Adjustment	OK	

The equipment is calibrated for the different parameters by using Multi Calibrator  
Lot.No: \_Exp.: 32090010/ 31090275

This is to certify that the above mentioned product has been calibrated according to the standard operating procedure given by the MINDRAY Medical Systems.

Date of Calibration: 30/06/2023

Next Due : 29/06/2024

For Agappe Diagnostics Ltd,.

*Sr Sahoo*



**Authorised signatory**

Name: Saroj Kr. Sahoo

Designation: Asst. Manager- Customer Service

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Sr. No.	Product Name	Method	TBA 120FR	TMS 30I	BS 390	BS 480(Clinia)	BS 200(Nano)	Nano plus	CCXL	Clinia Plus	Unit
12	Gamma GT	Szasz method	117	117	117	117	117	117	117	117	U/L
			1.95	1.95	1.95	1.95	1.95	1.95	1.95	1.95	μkat/L
13	Glucose	GOD-PAP/Hexokinase	200	200	200	200	200	200	200	200	mg/dL
		Hexokinase	198	197	197	197	197	197	197	197	mg/dL
14	LDH	SCE Kinetic	540	540	540	540	540	540	540	540	U/L
			9	9	9	9	9	9	9	9	μkat/L
15	Lipase	Methyl Resorufin	101	101	101	101	101	101	101	101	U/L
			1.68	1.68	1.68	1.68	1.68	1.68	1.68	1.68	μkat/L
16	Magnesium	Xylidyl Blue with ATCS	2.65	2.65	2.65	2.7	2.75	2.65	2.7	2.7	mg/dL
			1.67	1.67	1.67	1.7	1.73	1.67	1.7	1.7	mmol/L
17	Phosphorus	Phospho-Molybdate UV	5.22	5.15	5.22	5.22	5.22	5.15	5.15	5.22	mg/dL
			1.68	1.66	1.68	1.68	1.68	1.66	1.66	1.68	mmol/L
18	Trilycerides	GPO-TOPS	129	130	130	130	130	132	130	130	mg/dL
			1.46	1.47	1.47	1.47	1.47	1.49	1.47	1.47	mmol/L
19	Total Protein	Biuret	4.95	4.95	4.95	4.95	4.95	4.95	4.95	4.95	g/dL
			49.5	49.5	49.5	49.5	49.5	49.5	49.5	49.5	g/L
20	Uric Acid	Uricase - PAP	5.05	5.05	5.05	5.05	5.05	5.05	5.05	5.05	mg/dL
			300.4	300.4	300.4	300.4	300.4	300.4	300.4	300.4	μmol/L
		Uricase - TOPS	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	mg/dL
21	Urea	Urease/GLDH	101	101	101	101	101	101	101	101	mg/dL
			16.8	16.8	16.8	16.8	16.8	16.8	16.8	16.8	mmol/L
22	Chloride	Thiocyanate	98	98	98	98	98	98	98	98	mEq/L
23	HDL Cholesterol	Selective inhibition method	63	63	63	63	63	63	63	63	mg/dL
			1.63	1.63	1.63	1.63	1.63	1.63	1.63	1.63	mmol/L
24	LDL Cholesterol	Selective solubilization method	76	76	76	76	76	76	76	76	mg/dL
			1.96	1.96	1.96	1.96	1.96	1.96	1.96	1.96	mmol/L

# QC Summary

Summary Date: 01/07/2023-04/07/2023

Control	Lot No.	Chemistry	Mean	SD	Summary			
					Mean	SD	CV%	N
QC NORM	33030426	ALB	4	0.3	4.10	0.005	0.12	2
QC NORM	33030426	ALP	240	20	243.19	20.20	8.30	2
QC NORM	33030426	ALPIFCC	150	23				0
QC NORM	33030426	AMY	85	7				0
QC NORM	33030426	BILT	1.5	0.2	1.574	0.020	1.26	2
QC NORM	33030426	BILD	0.6	0.1	0.465	0.010	2.26	2
QC NORM	33030426	CALCIUM	8.9	0.45	8.432	0.0233	0.28	2
QC NORM	33030426	CHO	140	10	148.05	0.17	0.11	2
QC NORM	33030426	E-CRT	1.4	0.16	1.272	0.0016	0.13	2
QC NORM	33030426	GGT	55	4	51.98	0.57	1.09	2
QC NORM	33030426	GLUCOSE	75	8.7				0
QC NORM	33030426	HDL	52.3	4.05	50.775	0.3740	0.74	2
QC NORM	33030426	IRON	107.78	9.5				0
QC NORM	33030426	LDH P	292	27				0
QC NORM	33030426	LDL	84.5	7				0
QC NORM	33030426	LIPASE	39	3.5	41.54			1
QC NORM	33030426	MAG	2.4	0.2				0
QC NORM	33030426	PHO	4.5	0.3				0
QC NORM	33030426	SGOT	32.8	3	31.183	0.46	1.47	2
QC NORM	33030426	SGPT	38	4	35.66	0.41	1.15	2
QC NORM	33030426	TGL	95	7.9	90.80	1.668	1.84	2
QC NORM	33030426	TIBC	216.6	24	199.430			1
QC NORM	33030426	TPR	5.77	0.58	6.2684	0.0102	0.16	2
QC NORM	33030426	UAC	5.9	0.38	5.938	0.0998	1.68	2
QC NORM	33030426	UREA	43	3.4	42.33	0.259	0.61	2
QC NORM	33030426	Ca	2.22	0.11				0
QC NORM	33030426	Glu-H	80.8	6.25				0
QC NORM	33030426	GLU-HE	112	8.7	95.38	4.498	4.72	3
QC NORM	33030426	IRON M	107.78	9.4	105.9865			1
QC NORM	33030426	CK NAC	205	19				0
QC PATH	33030426	ALB	3	0.22	3.14	0.0218	0.69	2
QC PATH	33030426	ALP	430	38.5	409.14	16.345	3.99	2
QC PATH	33030426	ALPIFCC	370.29	70				0
QC PATH	33030426	AMY	275	21	251.38			1
QC PATH	33030426	BILT	5	0.55	5.23	0.0127	0.24	2
QC PATH	33030426	BILD	0.82	0.15	0.6648	0.0157	2.36	2
QC PATH	33030426	CALCIUM	12.5	0.45	11.910	0.0439	0.37	2

# QC Summary

Summary Date: 01/07/2023-04/07/2023

Control	Lot No.	Chemistry	Mean	SD	Summary			
					Mean	SD	CV%	N
QC PATH	33030426	CHO	260	18	266.61	0.53	0.20	2
QC PATH	33030426	E-CRT	4.5	0.45	4.125	0.0092	0.22	2
QC PATH	33030426	GGT	173	13	166.28	2.80	1.68	2
QC PATH	33030426	GLUCOSE	188.5	15				0
QC PATH	33030426	HDL	107	8	101.69	0.85	0.83	2
QC PATH	33030426	LDH P	694	45				0
QC PATH	33030426	LDL	148	16	150.69			1
QC PATH	33030426	LIPASE	70	9	77.54			1
QC PATH	33030426	MAG	4.1	0.25	4.146			1
QC PATH	33030426	PHO	7.2	0.54	6.981			1
QC PATH	33030426	SGOT	136	13.5	123.97	0.147	0.12	2
QC PATH	33030426	SGPT	140	16	143.82	0.04	0.03	2
QC PATH	33030426	TGL	248	21	236.55	0.18	0.08	2
QC PATH	33030426	TIBC	245	28	212.17	0.57	0.27	2
QC PATH	33030426	TPR	4.8	0.45	4.926	1.2852	26.09	3
QC PATH	33030426	UAC	9.4	0.6	9.301	0.019	0.21	2
QC PATH	33030426	UREA	117	8.5	112.89	0.858	0.76	2
QC PATH	33030426	Mg	3.5	0.41				0
QC PATH	33030426	Glu-H	178	15				0
QC PATH	33030426	GLU-HE	283	21.5	249.62	0.690	0.28	2
QC PATH	33030426	IRON M	233.4	21.2	232.840	1.738	0.75	2
QC PATH	33030426	CK NAC	520	47	443.33			1
HBA1C QCL1		HBA1C	5.9	1	5.581	0.11	1.99	4
CRP L1	32010258	CRP	13.4	2.2	13.884			1

# Calibration Result List

Chemistry	Cal Status	R0	K	A	B	C	D	Cal Date/Time
LIPASE	Calibrated	1073.9140						03/07/2023 08:38:43 AM
			0.0565					
MAG	Calibrated	-88.4832						19/06/2023 08:57:13 AM
			0.0036					
PHO	Calibrated	-27.5333						12/06/2023 08:46:57 AM
			0.0010					
SGOT	Calibrated	8.8044						30/06/2023 10:05:33 AM
			0.4322					
SGPT	Calibrated	6.9992						30/06/2023 08:56:09 AM
			0.4855					
TGL	Calibrated	1.6768						30/06/2023 08:51:49 AM
			0.0757					
TIBC	Calibrated	42.9562						20/05/2023 10:16:17 AM
			0.0691					
TPR	Calibrated	18.2995						02/07/2023 09:56:29 AM
			0.0018					
UAC	Calibrated	-8.6011						30/06/2023 08:52:25 AM
			0.0063					
UREA	Calibrated	67.8577						30/06/2023 08:54:57 AM
			0.0282					
JS	Calibrated	4609.1328		18.0000		0.0381		
					-0.6326			
		4908.2929		28.5135		-0.0360		
					1.2652			
		5566.9630		40.7553		0.0209		
					-0.5290			
		7104.1728		74.7757		-0.0283		
					1.5522			
		10267.4475		84.2457		0.0191		04/03/2021 10:35:23 PM
					-1.2674			
GLU-HE	Calibrated	26.9954						04/07/2023 08:55:54 AM
			0.0419					
IRON M	Calibrated	163.8107						20/05/2023 10:16:26 AM
			0.2374					
MALB	Calibrated	7212.4319		12.9633		0.0047		
					-0.1168			
		7536.5139		15.8834		-0.0027		
					0.2336			
		8037.5611		22.5188		-0.0004		
					0.0318			
		9195.8813		22.8710		0.0000		
					-0.0248			
		11268.9425		18.9267		0.0000		15/03/2023 05:01:14 PM
					-0.0147			

# Calibration Result List

Chemistry	Cal Status	R0	K	A	B	C	D	Cal Date/Time
ALB	Calibrated	2.8914						30/06/2023 08:44:18 AM
ALP	Calibrated	16.0954	0.0006					03/07/2023 08:37:31 AM
ALPIFCC	Calibrated	4.3256	0.4064					28/09/2022 09:17:36 AM
AMY	Calibrated	0.8648	0.6233					30/06/2023 08:47:37 AM
BILT	Calibrated	1.8547	0.3218					30/06/2023 08:54:30 AM
BILD	Calibrated	0.4960	0.0037					30/06/2023 08:54:48 AM
CALCIUM	Calibrated	9.8526	0.0031					30/06/2023 08:45:48 AM
CHO	Calibrated	3.9627	0.0025					30/06/2023 10:00:18 AM
CRP	Calibrated	-9.9959	0.0877	105.2428		-0.2702		
					2.7017			
		1042.4320		78.2263		0.1995		
					-5.4033			
		1483.8980		30.0204		-0.0158		
					0.5827			
		2191.0695		34.3806		0.0017		
					-0.3647			
		3093.3743		13.4999		0.0010		26/06/2023 08:48:06 AM
					-0.1573			
CRT	Calibrated	-3.5167						04/02/2022 03:04:03 PM
E-CRT	Calibrated	27.2524	0.0051					30/06/2023 08:55:42 AM
GGT	Calibrated	7.7453	0.0039					30/06/2023 10:05:15 AM
HBA1C	Calibrated	2381.7185	0.2115	114.3968		2.3327		
					-13.5296			
		3045.2202		192.8683		-2.7158		
					27.0591			
		3935.2919		282.4752		1.5693		
					-1.4572			
		5247.7640		356.9937		-3.7574		07/04/2023 09:41:59 PM
					18.7870			
HDL	Calibrated	7.9647						30/06/2023 08:56:18 AM
			0.0664					
LDL	Calibrated	15.1570						30/06/2023 08:56:27 AM
			0.0724					



# Calibration Result List

Chemistry	Cal Status	R0	K	A	B	C	D	Cal Date/Time
CK NAC	Calibrated	6.6835	8.0557					19/06/2023 09:38:27 AM

# Smart Module Status

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Name	Status
Reagent Probe Unit	OK
Sample Probe Unit	OK
Reagent Mixer Unit	OK
Sample Mixer Unit	OK
Probe Interior Wash Unit	OK
Rgt Carousel	OK
Sample Carousel	OK
Reaction Carousel Unit	OK
Temperature Unit	OK
Cuvette Wash Station	OK
Reagent Refrigeration Unit	OK
Sample/Reagent Mixer Unit	OK

# Hydropneumatic Status

Name	Status	Name	Actual	Valid Range
Water Tank	OK	Primary Vacuum Pressure	0.55 kPa	< -20 kPa
Diluted Wash Solution Tank	OK	Resistivity of Cleaning Water	18.00 MΩ.CM	≥ 1 MΩ.CM
Concentrated Wash Solution Tank	OK			
High-concentration Waste Collector	OK			
Low-concentration Waste Collector	OK			
Primary Vacuum Container	OK			
High Concentration Waste Tank	OK			
External Drain Canister	OK			

# Fan Status

Name	Measured Value	Valid Range
Reagent Refrigeration Fan 1	OK	OK / Error
Reagent Refrigeration Fan 2	OK	OK / Error
Lamp Housing Fan	OK	OK / Error
Vacuum Pump Cooling Fan	OK	OK / Error

# Temperature Status

Name	Measured Value	Valid Range
Reaction Carousel Temperature	37.0 °C	36.7 °C - 37.3 °C
Cuvette Cleaning Fluid Temperature	44.1 °C	39.0 °C - 49.0 °C
Cuvette Wash Solution Temperature	44.0 °C	39.0 °C - 49.0 °C
Reagent Refrigeration Temperature	4.8 °C	2.0 °C - 10.0 °C
Internal Temperature of Whole Unit	28.9 °C	15.0 °C - 40.0 °C