

INSTALLATION QUALIFICATION

The Installation for SYS200 Biochemistry Analyzer Instrument(S/N- SYS20180402) has been successfully Installed and Commissioned at PATHKIND LAB,Opp. Manchanda Petrol Pump,Sai Hotel,Main Civil Line,Bijnor-246701 U.P

Checked all the Mechanisms through the Software like Robotic Arm (Sample/Reagent Arm), Reagent Tray & Sample Tray Movement for different position.

Robotic Arm: Carried out the Adjustment for Robotic Arm for Wash station for Sample, Reagent, Cuvettes positions.

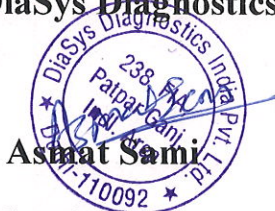
Lamp: The Photometer all channels are within range for all wavelengths.

Checked the system performance for different Parameters like End Point, Kinetic & Fixed-Time Kinetic.

Calibration & Control for all the Assays was satisfactory.

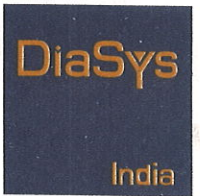
Carried out the Precision Check for above parameters which was also good.

For DiaSys Diagnostics India Pvt. Ltd.,



Area Service Manager (Delhi & NCR)

Date: 02/10/2018



OPERATIONAL QUALIFICATION

For Operational Qualifications carried out the following checks on the SYS200 (S/N- SYS20180402) in Pathkind Lab Opp. Manchanda Petrol Pump, Sai Hotel, Main Civil Line, Bijnor-246701 U.P

Checked the overall System Mechanism found the Robotic Arm (Sample/ Reagent Arm), Vertical and Horizontal Movement In/Out) Performance is ok.

Software Checks: Carried out the check for Calibration, Control, Assay, Results, Data & the performance is ok.

Checked all the Operational Qualifications & found the functioning is Satisfactory.

For DiaSys Diagnostics India Pvt. Ltd.,


Asmat Sami

Area Service Manager (Delhi & NCR)

Date: 02/010/2018

DiaSys Diagnostics India Private Limited

Plot No.238, F.I.A. , Patparganj Industrial area,

New Delhi - 110 092

Tel. No. : 011-22143142

DiaSys

India

PERFORMANCE QUALIFICATION

Carried out the following Checks for the Performance of the System SYS200 (S/N-SYS20180402) in Pathkind Lab Opp. Manchanda Petrol Pump, Sai Hotel, Main Civil Line, Bijnor-246701 U.P

Run the Calibration for End Point, Kinetic & Fixed-Time Kinetic Calibration was Successful.

Run the DIASYS CONTROL L1 & L2 control for Different Parameters.

Quality Checks for which the performance is OK & the Results are Satisfactory, within the Specified range.

Precision Checks: Carried out the Precision checks for different Parameters for which Precision was found to be satisfactory.

For Diasys Diagnostics India Pvt. Ltd.


Asmat Sami

Area Service Manager (Delhi & NCR)

Date: 02/10/2018

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Daily QC Report

Qc Test	Lot No.	QC Name	Target Mean	Target SD	Result	Unit	Status
ALB	28657	TRULAB N	3.57	0.274	3.75	g/dL	Normal
ALP	28657	TRULAB N	76	6.33	86.3	U/L	> +1SD
ALT	28657	TRULAB N	50.7	3.89	49	U/L	Normal
AST	28657	TRULAB N	39.9	3.06	35.7	U/L	< -1SD
Ca	28657	TRULAB N	8.65	0.317	8.68	mg/dL	Normal
cre erba	28657	TRULAB N	1.33	0.1	1.25	mg/dL	Normal
CRP	30682	CRP	59.3	5.9	64.6	mg/L	Normal
DBIL	28657	TRULAB N	0.721	0.062	0.71	mg/dL	Normal
GLUCOSE	28657	TRULAB N	85.6	4.56	82.5	mg/dL	Normal
HDL-C	28657	TRULAB N	45	2.1	44.1	mg/dL	Normal
TBIL	28657	TRULAB N	1.48	0.128	1.57	mg/dL	Normal
TG	28657	TRULAB N	87	5.22	86.8	mg/dL	Normal
TP	28657	TRULAB N	5.51	0.202	5.6	g/L	Normal
UA	28657	TRULAB N	5.07	0.236	4.61	mg/dL	< -1SD
UREA	28657	TRULAB N	36.2	2.65	37.7	mg/dL	Normal



Light Quantity Checkup

Last Test Result		Current Test	
Test Date: 10/1/2018 7:27:11 AM		Test Date: 10/1/2018 7:31:33 AM	
340nm:	14500	340nm:	14500
380nm:	15340	380nm:	15341
405nm:	14308	405nm:	14308
450nm:	12925	450nm:	12924
480nm:	13281	480nm:	13281
505nm:	13036	505nm:	13037
546nm:	11832	546nm:	11832
570nm:	11302	570nm:	11300
600nm:	11907	600nm:	11906
660nm:	10586	660nm:	10586
700nm:	10267	700nm:	10265
800nm:	10480	800nm:	10480



Cuvette blank test

Cup No.	340	380	405	450	480	505	546	570	600	660	700	800
1	14503	15342	14310	12926	13282	13038	11833	11302	11908	10588	10268	10482
2	-39	-43	-32	-27	-21	-17	-11	-7	-7	-9	-11	-13
3	8	-11	-10	-3	1	3	8	11	12	11	12	7
4	22	8	7	6	10	11	14	17	18	18	16	7
5	41	21	17	18	19	19	21	24	25	26	25	12
6	45	34	32	33	34	34	34	36	35	35	30	17
7	54	27	22	18	16	13	12	13	13	11	8	-4
8	83	85	81	83	79	77	75	77	76	71	66	52
9	-60	-58	-54	-52	-45	-42	-35	-30	-27	-28	-27	-27
10	48	47	41	38	36	36	34	36	36	34	35	24
11	65	53	51	51	49	51	48	49	45	45	40	35
12	61	40	40	38	38	37	38	40	40	33	28	17
13	87	75	78	82	80	82	83	85	82	79	69	60
14	166	153	142	134	127	122	114	115	109	99	90	68
15	144	124	116	114	111	106	102	103	101	94	87	69
16	171	161	152	147	140	136	129	129	124	113	104	83
17	90	70	67	64	61	59	58	59	57	48	45	33
18	71	66	63	61	59	59	59	60	58	52	48	39
19	27	17	16	17	20	20	22	23	22	19	19	17
20	-1	-2	0	4	5	10	13	16	17	19	20	14
21	23	20	20	21	21	21	20	21	19	20	17	14
22	-68	-65	-59	-51	-44	-39	-31	-26	-25	-26	-29	-30
23	5	-12	-12	-10	-11	-9	-5	-2	-3	-6	-9	-17
24	-39	-62	-59	-53	-47	-46	-39	-35	-31	-30	-31	-35
25	-81	-96	-94	-86	-78	-76	-69	-64	-57	-50	-48	-53
26	-3	-17	-17	-10	-7	-5	0	4	5	6	4	-4
27	60	35	33	34	33	32	33	35	35	32	24	12
28	-4	-14	-16	-12	-9	-9	-5	-3	-1	-1	-2	-9
29	-100	-105	-102	-96	-88	-82	-73	-67	-62	-58	-54	-50
30	-81	-88	-85	-79	-73	-69	-60	-56	-50	-44	-37	-37
31	-162	-156	-151	-142	-130	-124	-113	-108	-101	-91	-86	-73
32	-108	-115	-110	-103	-94	-90	-80	-74	-68	-68	-65	-61
33	-136	-133	-124	-111	-98	-91	-79	-72	-65	-56	-55	-52

Cuvette blank test

Cup No.	340	380	405	450	480	505	546	570	600	660	700	800
34	-126	-134	-130	-120	-108	-105	-95	-90	-81	-73	-69	-69
35	-73	-83	-84	-78	-68	-66	-60	-54	-46	-42	-38	-43
36	-130	-135	-132	-121	-110	-107	-97	-91	-82	-76	-72	-72
37	-165	-168	-162	-154	-143	-139	-125	-121	-110	-103	-95	-87
38	-137	-132	-125	-118	-108	-104	-92	-87	-78	-70	-65	-59
39	-213	-201	-194	-181	-166	-159	-145	-137	-128	-117	-108	-95
40	-193	-175	-169	-157	-146	-138	-125	-117	-107	-96	-87	-81
41	-46	-43	-43	-42	-36	-33	-31	-27	-25	-20	-19	-16
42	-52	-48	-39	-32	-27	-21	-16	-8	-8	-9	-13	-16
43	-23	-40	-44	-39	-37	-33	-29	-23	-21	-20	-23	-28
44	-44	-43	-44	-40	-37	-34	-32	-27	-25	-25	-27	-34
45	-49	-67	-67	-61	-54	-49	-46	-40	-36	-32	-31	-38
46	-53	-53	-54	-45	-38	-35	-31	-26	-23	-18	-20	-25
47	-17	-42	-43	-35	-30	-28	-25	-20	-17	-14	-15	-20
48	-79	-69	-67	-59	-50	-46	-41	-36	-30	-27	-27	-29
49	-104	-102	-95	-88	-80	-76	-67	-59	-55	-51	-46	-41
50	-137	-130	-126	-117	-110	-104	-96	-90	-81	-73	-64	-60
51	-160	-144	-139	-125	-115	-108	-99	-93	-88	-80	-76	-64
52	-96	-86	-80	-67	-58	-52	-44	-35	-30	-29	-27	-24
53	-78	-75	-69	-55	-44	-38	-30	-23	-22	-14	-16	-17
54	-119	-110	-106	-93	-81	-75	-67	-59	-53	-44	-42	-42
55	20	-2	-5	0	7	8	13	17	23	28	28	18
56	-54	-49	-48	-39	-32	-25	-18	-11	-6	1	3	0
57	-126	-119	-113	-105	-95	-90	-80	-73	-64	-58	-50	-45
58	-63	-61	-56	-44	-37	-32	-23	-15	-10	-3	3	6
59	-123	-109	-103	-92	-81	-75	-65	-58	-52	-46	-38	-31
60	117	114	117	128	130	137	143	148	150	155	156	148
61	-112	-109	-105	-92	-84	-79	-71	-67	-63	-53	-49	-43
62	-141	-151	-140	-125	-113	-106	-92	-83	-77	-70	-70	-65
63	-69	-89	-88	-77	-71	-68	-60	-53	-48	-44	-46	-49
64	-28	-45	-45	-34	-28	-26	-22	-17	-15	-12	-14	-21
65	-40	-49	-49	-41	-35	-31	-28	-22	-18	-14	-14	-21
66	29	6	3	12	15	16	18	20	20	21	16	7

Cuvette blank test

Cup No.	340	380	405	450	480	505	546	570	600	660	700	800
67	75	50	44	46	46	45	42	43	42	40	33	19
68	27	17	16	21	24	26	26	27	27	27	22	12
69	29	17	17	21	22	26	29	35	34	34	31	27
70	87	65	60	59	57	56	55	58	58	55	55	43
71	189	161	155	154	148	149	141	141	132	127	116	107
72	156	128	122	123	119	119	116	118	113	102	95	81
73	159	131	129	139	141	147	148	155	150	155	144	135
74	62	57	54	62	66	69	68	73	72	72	66	54
75	168	134	124	124	122	120	116	118	116	114	107	89
76	182	158	153	160	160	162	157	162	158	153	146	131
77	115	93	91	97	99	102	103	108	107	103	102	94
78	127	107	106	115	117	121	123	129	129	128	128	124
79	84	80	79	86	89	93	93	99	97	92	91	87
80	235	216	201	193	182	181	173	175	169	164	159	145
81	-124	-126	-124	-114	-104	-100	-91	-85	-80	-71	-67	-57
82	-168	-168	-158	-144	-130	-124	-109	-99	-93	-85	-86	-80
83	-32	-52	-53	-45	-39	-38	-33	-26	-23	-18	-22	-26
84	-126	-135	-131	-119	-108	-105	-94	-87	-79	-69	-69	-69
85	-56	-66	-70	-62	-54	-51	-46	-39	-34	-26	-26	-31
86	-50	-65	-66	-56	-48	-46	-41	-36	-32	-25	-27	-31
87	-122	-128	-131	-119	-107	-105	-94	-88	-79	-68	-68	-66
88	-140	-141	-141	-128	-115	-111	-101	-94	-87	-77	-76	-73
89	-179	-172	-169	-156	-143	-138	-122	-114	-106	-98	-94	-84
90	-138	-137	-138	-128	-120	-115	-105	-98	-89	-79	-71	-66
91	-108	-109	-108	-99	-90	-85	-79	-74	-71	-65	-62	-54
92	-88	-107	-109	-99	-90	-88	-79	-72	-66	-64	-64	-62
93	-107	-116	-113	-100	-89	-85	-74	-66	-61	-51	-52	-50
94	-151	-158	-158	-149	-134	-132	-121	-115	-106	-96	-92	-89
95	58	31	18	15	17	13	15	19	22	25	24	12
96	-108	-117	-119	-107	-95	-93	-84	-79	-72	-63	-62	-61
97	-77	-91	-90	-79	-70	-67	-58	-49	-43	-38	-34	-31
98	-59	-74	-72	-62	-54	-51	-42	-35	-30	-24	-22	-18
99	-77	-87	-87	-78	-68	-65	-56	-51	-48	-45	-43	-38

Cuvette blank test

Cup No.	340	380	405	450	480	505	546	570	600	660	700	800
100	-80	-91	-93	-81	-73	-69	-59	-52	-47	-39	-35	-33
101	157	147	136	132	125	122	115	116	110	105	98	89
102	58	35	36	44	46	48	53	59	54	50	42	36
103	63	18	7	9	10	8	10	15	14	12	7	-3
104	31	2	-5	-3	0	-1	2	7	7	8	4	-6
105	89	46	33	33	33	30	30	33	32	34	28	15
106	130	131	128	131	128	127	124	129	124	121	111	92
107	317	276	257	253	242	235	226	227	219	212	197	171
108	121	127	121	120	117	114	111	115	112	105	94	77
109	214	206	195	190	183	181	174	178	171	160	150	136
110	166	186	183	182	175	176	168	174	170	163	156	137
111	86	84	80	81	79	78	74	78	73	73	67	63
112	176	173	164	158	151	148	141	145	138	127	117	98
113	180	180	173	176	172	175	171	179	172	170	161	146
114	192	191	180	175	168	164	155	157	151	145	136	113
115	461	426	398	383	366	358	337	339	326	313	299	260
116	301	335	330	329	318	317	303	310	297	289	277	247
117	152	157	153	154	152	153	151	159	154	148	144	132
118	133	152	149	148	144	144	141	146	140	135	130	119
119	101	104	101	107	107	111	110	117	113	109	105	99
120	146	169	164	166	160	164	159	166	161	159	156	141



Calibration Result

Test Item	S1 Abs.	K	A	B	C	Unit	Calibration Time	Status
AST	-0.0005	-2642.0079				U/L	10/1/2018 07:41:52 AM	Success
P	0.30665	10.6202				mg/dL	10/1/2018 07:42:12 AM	Success
ALT	-0.00065	-2890.1734				U/L	10/1/2018 07:43:20 AM	Success
TP	-0.1441	22.5537				g/L	10/1/2018 07:45:32 AM	Success
ALB	0.13365	4.7518				g/dL	10/1/2018 07:46:52 AM	Success
TBIL	0.00775	68.363				mg/dL	10/1/2018 07:47:30 AM	Success
DBIL	0.0001	35.1573				mg/dL	10/1/2018 07:48:50 AM	Success
LDH	0.0067	13663.366				U/L	10/1/2018 07:48:59 AM	Success
ALP	0.0058	3308.9312				U/L	10/1/2018 07:49:52 AM	Success
CRE	0.004	78.4195				mg/dL	10/1/2018 07:50:32 AM	Success
UREA	-0.0111	-763.6888				mg/dL	10/1/2018 07:51:52 AM	Success
GGT	0.00305	4524.181				U/L	10/1/2018 07:52:22 AM	Success
UA	0.00255	89.6664				mg/dL	10/1/2018 07:53:42 AM	Success
TC	0.02485	433.8701				mg/dL	10/1/2018 07:54:22 AM	Success
TG	0.142	556.4648				mg/dL	10/1/2018 07:55:42 AM	Success
HDL-C	0.0047	329.836				mg/dL	10/1/2018 07:56:12 AM	Success
LDL-C	0.0348	3455.83				mg/dL	10/1/2018 07:56:49 AM	Success
GLUCOSE	0.0837	216.0459				mg/dL	10/1/2018 07:57:32 AM	Success
CREA PAP	0.0033	76.0603				mg/dL	10/1/2018 07:58:02 AM	Success
Ca	0.83775	28.8314	0	0	0	mg/dL	10/1/2018 07:58:29 AM	Success
CRP	-4.06600635 80695E-5	0				mg/L	10/1/2018 07:58:42 AM	Success

Control Run, 2018-10-01T08:19:56

TRULAB P / 22804
On Position 29

System validations : OFF

Test	Low Limit	High Limit	Drift%	Target/Concentration	Control Status
ALB	4.03	6.44	10.00	5.23 5.27 g/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
ALT	100.0	160.0	10.00	130.0 100.6 U/L	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
AP	143.0	238.0	10.00	190.0 224.0 U/L	OK FAIL M+d:Conc>Mean+drift%
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
AST	126.0	201.0	10.00	163.0 144.7 U/L	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
CA	10.50	13.10	10.00	11.80 11.35 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
CHOL	175	232	10.00	204 202 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
CREA	3.76	5.88	10.00	4.82 4.55 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
CREA PAP	3.76	5.88	10.00	4.82 4.76 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
DBIL	1.25	2.12	10.00	1.69 1.61 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
GGT	65.8	103.0	10.00	84.4 83.0 U/L	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
GLUC HK	214.00	295.00	10.00	254.00 255.08 mg/dL	OK

OK 



Control Run, 2018-10-01T08:19:56

TRULAB P / 22804
On Position 29

System validations : OFF

Test	Low Limit	High Limit	Drift%	Target/Concentration	Control Status
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
HDL-C	50.30	66.70	10.00	58.50 57.36 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
LDH	250.0	359.0	10.00	304.0 291.5 U/L	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
LDL-C	95.20	126.00	10.00	111.00 117.87 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
TBIL	3.57	6.08	10.00	4.82 3.92 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
TP	8.23	10.30	10.00	9.25 8.60 g/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
TRIG	165	238	10.00	201 197 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
UA	7.23	9.58	10.00	8.40 8.80 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
UREA	117.0	184.0	10.00	150.0 149.5 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					

Control Run, 2018-10-01T08:19:56

TRULAB PROT L1 / 22564
On Position 30

System validations : OFF

Test	Low Limit	High Limit	Drift%	Target/Concentration	Control Status
CRP	11.80	20.40	10.00	16.10 17.07 mg/L	OK

(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)

