

## Calibration Certificate

Following voltages have been checked & adjusted on DiaSys Resposn 910 (Sl. No. 170974) at Pathkind Lab, Kala aam chauraha, DM Road, Bulandshahr - 203001

### Calibration Report:

System voltages are in the specified range –Checked by Digital Multimeter are as below:

S.No.	Module	Observed Value	Acceptable Range
1	Power supply board o/p	+24.1 VDC	+24.0 +/- 0.5 VDC
		+05.1 VDC	+05.0 +/- 0.2 VDC
2	Lamp voltage	+12.2 VDC	12.0 +/- 0.5 VDC

System Temperature values are in the specified range –Checked by Digital Thermometer are as below:

S.No.	Module	Observed Value	Acceptable Range
1	Reaction Disk Temp	37.0 C	37.0 C +/- 0.2 C

Photometer Adjustment Values are within range as recommended:

S.No.	Module	Observed Value	Acceptable Range
1	ADC Count for all Wavelengths	19,700 to 20,200	19,500 to 20,500

- All other mechanisms have been checked through field service program & Software, found OK.
- Performed calibration for End Point, Kinetic & Fixed Time Kinetic. Run control & sample. Results were satisfactory.
- Next Calibration will be performed on 02/06/2022.

For DiaSys Diagnostics India Pvt. Ltd.



Asmat Sami  
RSM (North India)



Date: 03/06/2021

## PERFORMANCE QUALIFICATION

Carried out the following Checks for the Performance of the System  
**Respon 910 (S/N-170974) in PathKind Labs , Kothiyat ,IInd Floor, Kala Aam  
Choraha , D M Road, Bulandshahr-203001.**

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

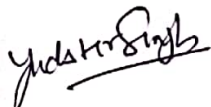
Run the TRULAB N & P control for Different Parameters.

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.

For



Asmat Sami

Area Service Manager

Date: 29/07/17

**DiaSys Diagnostics India Private Limited**

Plot No. A- 821, T.T.C, MIDC, Mahape, Navi Mumbai – 400710. Maharashtra, India.

For feedback/queries contact customer care at: Toll Free number: **1800 120 1447** (India), Email ID : [qmsupport.india@diasys.in](mailto:qmsupport.india@diasys.in),  
Website : [www.diasys.in](http://www.diasys.in)

## OPERATIONAL QUALIFICATION

For Operational Qualifications, carried out the following checks on the **Respons 910** (S/N-170974) in **PathKind Labs**, Kothiyat, IInd Floor, Kala Aam Choraha, D M Road, Bulandshahr-203001.

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.,

for

*Asmat Sami*

Asmat Sami

Area Service Manager

Date: 29/07/17

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## INSTALLATION QUALIFICATION

The Installation for **RESPONS 910** (S/N-170974) carried at **PathKind Labs** Kothiyat ,IInd Floor, Kala Aam Choraha , D M Road, Bulandshahr-203001.

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, Currettes positions.

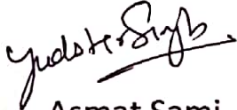
Lamp: The Photometer all channels are within range for all wavelengths.

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.,

For 

Asmat Sami

Area Service Manager

Date: 29/07/17

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Trulab N / 31891  
On Position 28

Test	Low Limit	High Limit	Drift%	Target/Concentration	Control Status
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
TP	4.91	6.12	10.00	5.51 5.37 g/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
TRIG	71	101	10.00	86 92 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
UA	4.28	5.68	10.00	4.98 4.68 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
UREA	28.5	44.6	10.00	36.6 38.5 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					

Trulab N / 31891  
On Position 28

Test	Low Limit	High Limit	Drift%	Target/Concentration	Control Status
ALB	2.76	4.41	10.00	3.58 3.41 g/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
ALT	39.4	62.9	10.00	51.2 53.0 U/L	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
AP	58.4	97.4	10.00	77.9 73.5 U/L	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
AST	29.9	47.8	10.00	38.9 40.9 U/L	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
CA	7.55	9.42	10.00	8.49 7.92 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
CHOL	123	163	10.00	143 141 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
CREA	1.10	1.73	10.00	1.41 1.35 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
DBIL	0.53	0.90	10.00	0.71 0.66 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
GLUC HK	66.90	92.40	10.00	79.70 83.94 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
HDL-C	36.00	47.70	10.00	41.80 43.61 mg/dL	OK
(1 aspirations, 1 Concentrations, Mean=(null), CV=(null)%)					
TBIL	1.10	1.87	10.00	1.48 1.63 mg/dL	OK