TULIP DIAGNOSTICS (P). LTD. (INSTRUMENT DIVISION)

BAMBOLIM, ST-INEZ & VERNA - GOA

Ref SOP No: SOP/ID/012
CC No: CC16/ID/003

Installation Report

Name & Address of Customer: GI pathology lab Services.	Instrument Model: rounreu penta. 2.0
	Instrument Sr. No. 0841230200217.
	Installation Date: 01/03/2021.
Contact Person: Mr. Gudappa Khodake.	Invoice No.:
Contact No.: 9673521051.	Invoice Date:
	AMC Due Date:

Power supply details:

Instrument connected to: Online UPS Yes/No ✓ Offline UPS Yes/No

Supply input to machine from UPS: LN: 241 NE: 3V LE: 244.

Supply input to UPS from mains: LN: — NE: — LE: —

Accessories Provided:
All Accessuries provided.

Person Trained: mr. Gudappa. Khodake

Demonstrated:
— yes —

Remarks If any:
— NO —

Note: The above machine is satisfactory installed at the site and staff adequately trained.
* Received all accessories as per packing list

Khodake

Name of Department Head:
Signature & Stamp
Date

Sachin Dange

Company's Sales & Service Engineer:
Signature
Date. 01/03/2021.

Gitaniali, Tulip Block ,Dr.Antonio Do Rego Bagh, Alto Santacruz,Bambolim P.O. Goa. Pin: 403 202.
Tel: 0832-2458546/51,Fax: 0832-2458544,E-mail:sales@tulipgroup.com,Website:www.tulipgroup.com

TULIP DIAGNOSTICS (P) LTD.

Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim P.O. Goa. Pin: 403 202. Tel: 0832-2458546/51, Fax: 0832-2458544.
Email ID:ccginstdiv@tulipgroup.org. Website: www.tulipgroup.com

Warranty Certificate

Customer Name:	G1 pathology lab services.		
Address:	Nyani Appt. Rajyog Society. Pune.		
Contact Person:	9099029851.	Contact No: —	Email ID:
Instrument Model:	Council penta 2.0	Instrument Sr. No:	08412302200217.
Invoice No. & Date:		Installation Date:	01/03/2021.

Warranty Condition

- To activate the warranty, the customer must fill the installation report & warranty certificate and return the slip to **Tulip Diagnostics (P) Ltd.**
- **Tulip Diagnostics (P) Ltd.**, guarantees that all its instruments are free from manufacturing defects or faults.
- **Tulip** undertakes repair or substitute free of charge replacement of spare part which may be found to have manufacturing defects.
- The warranty does not cover to defects of parts which are subject to wear & tear.
- Repair & interventions carried out during the period of the warranty do not extend or renew the period of warranty.
- The repairs of the instrument will be carried out by **Tulip**'s authorized engineer only.
- **Tulip** reserves the right to recall the instrument for repair at the head office if major/frequent problem has been observed in the instrument.

Termination Of Warranty

The warranty shall be terminated at the end of the warranty period & also in the following cases:

- Where attempts to make repairs or alterations have been made by unauthorized person &/or with spare parts which are not originals.
- Alteration have been made to the serial number of the product on the certificate or on the instrument.
- The instrument is transferred to a new locations without prior written approval from **Tulip Diagnostics (P) Ltd.**

Customer Signature & stamp

Name:

Date:

Validity & Duration

- This warranty shall be considered valid only on the condition that this certificate is accompanied by installation report and other purchase documents.
- The warranty is valid for a period of ____ months from the date of installation or____ months from the date of invoice whichever is earlier.

Elements Not Covered Under This Warranty

The following damage & faults are not covered under this warranty:

- Damage deriving &/or originating from an insufficient or inadequate electric circuit or from the area where the instrument is set up & used.
- Breakdowns caused by careless handling, imprudence, lack of expertise & in any case caused by lack of skill or any degree of negligence on the part of the operator.
- Damage, defects & faults deriving from unexpected events, accidents during transport by the purchaser, due to FORCE MAJORE & in any case, due to situation which can in no way be attributed to manufacturing &/or material defects.
- Replacement of the defective instrument is never foreseen.
- **Tulip** shall accept no responsibility whatsoever for damage either directly or indirectly to persons or materials from the use of the instrument.
- Consumable items such as fuses, lamps, all tubing's, etc. are not covered under this warranty condition.

Governing Law

In case of any disputes the Courts of Panaji, Goa will have the jurisdictions in all matters.

Company's Representative Signature & Stamp

Name: Sachin Dange

Date: 01/03/2021.

FM/ID/039-00

TULIP DIAGNOSTICS (P). LTD. (INSTRUMENT DIVISION)
BAMBOLIM, ST- INEZ & VERNA - GOA

Ref SOP no. : SOP/ID/010
CC. No. : CC16/ID/001

QUALITY CONTROL SHEET

Description	COUNCELL PENTA 2-0
Serial No.	0841230200217
QC Pass Date	22/02/2021

PART 1	**TEST APPARATUS**
REAGENTS	DILUENT = 20200106
	Differential Lyse = 20190909
	LH Lyse = 20190927
QC MATERIAL	CBC DH2101

PART 2	**QUALITATIVE TEST**				
	Circle which appropriate				
1. Chassis/ Housing – verify physical integrity cleanliness	(PASS)	FAIL	NA	14. HgB Lamp – Verify condition	(PASS) FAIL NA
2. AC Plug - Verify integrity	(PASS)	FAIL	NA	15. Fittings / Connectors – examine all cables and connectors	(PASS) FAIL NA
3. Mount/ Fastener – verify physical integrity	(PASS)	FAIL	NA	16. Audible Signals – Verify operation and level	(PASS) FAIL NA
4. Strain Relief – verify physical integrity at both ends of line cord	(PASS)	FAIL	NA	17. Indicators / Display – Verify proper illumination and operation	(PASS) FAIL NA
5. Line cord - verify proper insulation and integrity	(PASS)	FAIL	NA	18 Optics / Measuring Area- Inspect	(PASS) FAIL NA
6. Circuit Breakers/ Fuses – Verify correct rating	(PASS)	FAIL	NA	19. Alarms – Check all warning alarms	(PASS) FAIL NA
7. Cables – Verify physical integrity	(PASS)	FAIL	NA	20. Initialization Process – Verify	(PASS) FAIL NA
8. Control / Switches – Verify operation	(PASS)	FAIL	NA	21. User Settings – Verify	(PASS) FAIL NA
9. Hydraulics and Pneumatic System – Verify	(PASS)	FAIL	NA	22. Labeling – Verify caution and warning label	(PASS) FAIL NA
10. Tube / Hoses – Verify condition	(PASS)	FAIL	NA	23User Calibration – Verify	(PASS) FAIL NA
11. Electrodes and Transducers – Verify condition and operation	(PASS)	FAIL	NA	24. Accessories - Verify as appropriate	(PASS) FAIL NA
12. Probes - Verify Integrity	(PASS)	FAIL	NA	25. Others (Specify)	PASS FAIL (NA)
13. Fan / Motor / Compressor – Verify condition and operation	(PASS)	FAIL	NA		

PART 3	QUANTITATIVE TASKS	
A.	Gain Factor (%)	Remark
LAS	95	PASS FAIL
MAS	155	PASS FAIL
WAS	120	PASS FAIL
Width	120	PASS FAIL

B.	Set Value	Blank Voltage	Remark
RBC	39	-	PASS FAIL
HgB	85	4-52	PASS FAIL

C.	Calibration Coefficient	
Parameter	Coefficient	Remark
WBC	100	PASS FAIL
RBC	100	PASS FAIL
HgB	100	PASS FAIL
MCV	100	PASS FAIL
PLT	100	PASS FAIL

TULIP DIAGNOSTICS (P). LTD. (INSTRUMENT DIVISION)
BAMBOLIM, ST- INEZ & VERNA - GOA

Ref SOP no. : SOP/ID/010
CC. No. : CC16/ID/001

D.	Measured Values		
NORMAL CONTROL			
Parameter	Obtained Value	Range	Remark
WBC	8.27 10^9/L	(7.21 – 9.21) 10^9/L	PASS FAIL
Neu	4.64 10^9/L	(3.67 – 5.67) 10^9/L	PASS FAIL
Lym	2.36 10^9/L	(1.56 – 2.96) 10^9/L	PASS FAIL
Mono	0.46 10^9/L	(0.00 – 0.90) 10^9/L	PASS FAIL
Eoso	0.91 10^9/L	(0.00 – 1.66) 10^9/L	PASS FAIL
Baso	0.11 10^9/L	(0.00 – 0.20) 10^9/L	PASS FAIL
Neu %	0.561 %	(0.449 – 0.689) %	PASS FAIL
Lym %	0.285 %	(0.196 – 0.356) %	PASS FAIL
Mono %	0.056 %	(0.000 – 0.110) %	PASS FAIL
Eoso %	0.098 %	(0.000 – 0.202) %	PASS FAIL
Baso %	0.013 %	(0.000 – 0.024) %	PASS FAIL
RBC	4.56 10^{12}/L	(4.34 – 4.82) 10^{12}/L	PASS FAIL
HgB	13.2 g/dL	(12.7 – 13.9) g/dL	PASS FAIL
MCV	93.7 fL	(89.4 – 99.4) fL	PASS FAIL
PLT	236 10^9/L	(209 – 289) 10^9/L	PASS FAIL

D.	Measured Values		
	LOW CONTROL		
Parameter	Obtained Value	Range	Remark
WBC	3-43 $10^9/L$	(2-93 - 3-93) $10^9/L$	PASS FAIL
Neu	1-71 $10^9/L$	(1-30 - 2-20) $10^9/L$	PASS FAIL
Lym	1-29 $10^9/L$	(0-91 - 1-61) $10^9/L$	PASS FAIL
Mono	0-23 $10^9/L$	(0-00 - 0-42) $10^9/L$	PASS FAIL
Eoso	0-20 $10^9/L$	(0-00 - 0-42) $10^9/L$	PASS FAIL
Baso	0-06 $10^9/L$	(0-00 - 0-14) $10^9/L$	PASS FAIL
Neu %	0-498 %	(0-388 - 0-628) %	PASS FAIL
Lym %	0-375 %	(0-278 - 0-458) %	PASS FAIL
Mono %	0-068 %	(0-000 - 0-126) %	PASS FAIL
Eoso %	0-059 %	(0-000 - 0-122) %	PASS FAIL
Baso %	0-017 %	(0-000 - 0-040) %	PASS FAIL
RBC	2-45 $10^{12}/L$	(2-26 - 2-62) $10^{12}/L$	PASS FAIL
HgB	5-8 g/dL	(5-4 - 6-2) g/dL	PASS FAIL
MCV	77-5 fL	(72-4 - 82-4) fL	PASS FAIL
PLT	49 $10^9/L$	(30 - 70) $10^9/L$	PASS FAIL

TULIP DIAGNOSTICS (P). LTD. (INSTRUMENT DIVISION)
BAMBOLIM, ST- INEZ & VERNA - GOA

Ref SOP no. : SOP/ID/010
CC. No. : CC16/ID/001

D.	Measured Values		
	HIGH CONTROL		
Parameter	Obtained Value	Range	Remark
WBC	18.31 10^9/L	(16.17 – 21.17) 10^9/L	PASS FAIL
Neu	11.82 10^9/L	(9.89 – 14.39) 10^9/L	PASS FAIL
Lym	3.53 10^9/L	(2.18 – 4.88) 10^9/L	PASS FAIL
Mono	1.04 10^9/L	(0.00 – 1.98) 10^9/L	PASS FAIL
Eoso	1.92 10^9/L	(0.00 – 4.00) 10^9/L	PASS FAIL
Baso	0.18 10^9/L	(0.00 – 0.40) 10^9/L	PASS FAIL
Neu %	0.645 %	(0.530 – 0.770) %	PASS FAIL
Lym %	0.193 %	(0.119 – 0.259) %	PASS FAIL
Mono %	0.057 %	(0.000 – 0.106) %	PASS FAIL
Eoso %	0.105 %	(0.000 – 0.214) %	PASS FAIL
Baso %	0.010 %	(0.000 – 0.022) %	PASS FAIL
RBC	5.18 10^{12}/L	(4.88 – 5.48) 10^{12}/L	PASS FAIL
HgB	16.4 g/dL	(15.8 – 17.4) g/dL	PASS FAIL
MCV	102.2 fL	(97.8 – 107.8) fL	PASS FAIL
PLT	469 10^9/L.	(409 – 529) 10^9/L	PASS FAIL

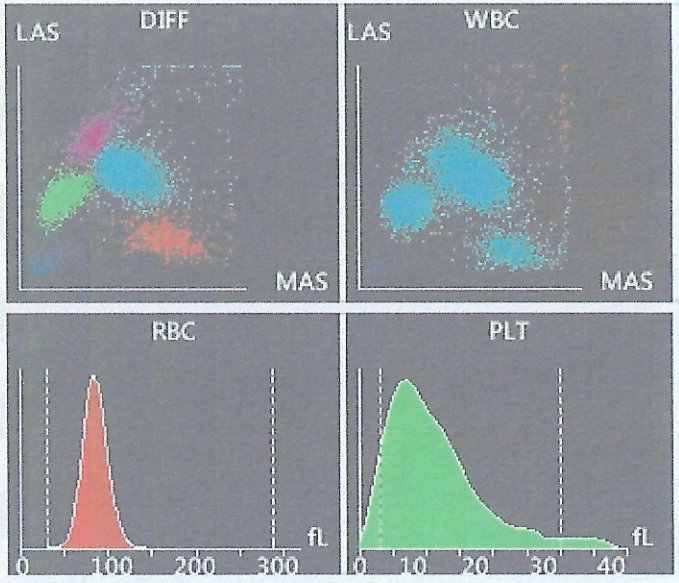
Checked By:

Approved By:

Sample Analysis | Review | QC | Reagent Setup | Diluent | Print

File No.	1	Lot No.	DH2101	Level	Normal	Exp.Date	05/03/2021
Mode	Whole Blood	QC Type	CBC 5D	QC Sample ID	1		

Para	Result	Unit	Para	Result	Unit
WBC	8.27	10^9/L	RBC	4.56	10^12/L
Neu#	4.64	10^9/L	HGB	13.2	g/dL
Lym#	2.36	10^9/L	HCT	0.427	
Mon#	0.46	10^9/L	MCV	93.7	fL
Eos#	0.81	10^9/L	MCH	29.0	pg
Bas#	0.11	10^9/L	MCHC	30.9	g/dL
Neu%	0.561		RDW-CV	0.154	
Lym%	0.285		RDW-SD	53.0	fL
Mon%	0.056		PLT	236	10^9/L
Eos%	0.098		MPV	9.4	fL
Bas%	0.013		PDW	16.0	
			PCT	2.20	mL/L
			P-LCC	62	10^9/L
			P-LCR	0.264	



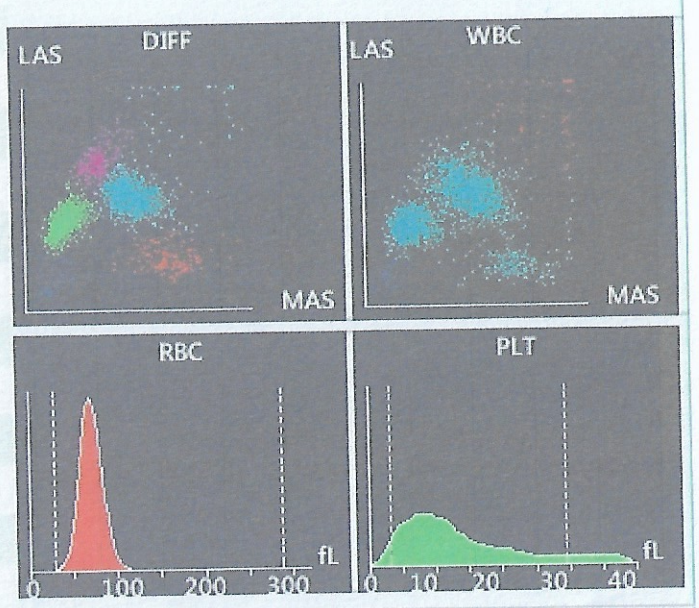
Setup | QC Table | QC Graph | Edit Result

Mode:Whole Blood-CBC+DIFF | Service | 11:26 22/02/2021

Sample Analysis | Review | QC | Reagent Setup | Diluent | Print

File No.	2	Lot No.	DH2101	Level	Low	Exp.Date	05/03/2021
Mode	Whole Blood	QC Type	CBC 5D	QC Sample ID	2		

Para	Result	Unit	Para	Result	Unit
WBC	3.43	10^9/L	RBC	2.45	10^12/L
Neu#	1.71	10^9/L	HGB	5.8	g/dL
Lym#	1.29	10^9/L	HCT	0.190	
Mon#	0.23	10^9/L	MCV	77.5	fL
Eos#	0.20	10^9/L	MCH	23.6	pg
Bas#	0.06	10^9/L	MCHC	30.4	g/dL
Neu%	0.498		RDW-CV	0.173	
Lym%	0.375		RDW-SD	49.0	fL
Mon%	0.068		PLT	49	10^9/L
Eos%	0.059		MPV	10.0	fL
Bas%	0.017		PDW	16.2	
			PCT	0.49	mL/L
			P-LCC	15	10^9/L
			P-LCR	0.304	



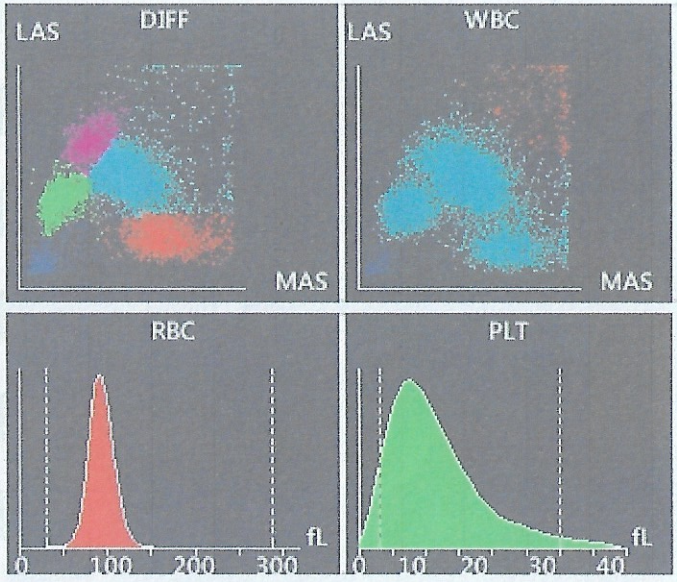
Setup | QC Table | QC Graph | Edit Result

Mode:Whole Blood-CBC+DIFF | Service | 11:54 22/02/2021

Sample Analysis | Review | QC | Reagent Setup | Diluent | Print

File No.	3	Lot No.	DH2101	Level	High	Exp.Date	05/03/2021
Mode	Whole Blood	QC Type	CBC 5D	QC Sample ID	3		

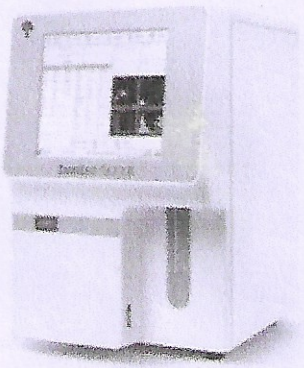
Para	Result	Unit	Para	Result	Unit
WBC	18.31	10^9/L	RBC	5.18	10^12/L
Neu#	11.82	10^9/L	HGB	16.4	g/dL
Lym#	3.53	10^9/L	HCT	0.529	
Mon#	1.04	10^9/L	MCV	102.2	fL
Eos#	1.92	10^9/L	MCH	31.6	pg
Bas#	0.18	10^9/L	MCHC	30.9	g/dL
Neu%	0.645		RDW-CV	0.141	
Lym%	0.193		RDW-SD	53.4	fL
Mon%	0.057		PLT	469	10^9/L
Eos%	0.105		MPV	9.6	fL
Bas%	0.010		PDW	15.9	
			PCT	4.52	mL/L
			P-LCC	132	10^9/L
			P-LCR	0.281	



Setup | QC Table | QC Graph | Edit Result

Mode:Whole Blood-CBC+DIFF | Service | 12:03 22/02/2021

Installation Qualification
For
Councell Penta 2.0
Auto hematology Analyzer



Tulip Diagnostics (P) Ltd.

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Instrument Identification

Auto hematology analyzer (Councell penta 2.o)

Sr. No.	Specification	As per design qualification	Specification received	Match (Yes/No)
1	General Feature	The measurement methods used in this analyzer are: the electrical Impedance method for determining the RBC and PLT data; the colorimetric method for determining the HGB; laser-based flow cytometry for determining the WBC data.	Electrical. Impedence method. for RBC and PLT. colorimetric. method for HGB laser. based flow. Cytometry for. WBC data.	YES.
2	Sample aspiration volume.	Whole Blood mode_20µL,pri-diluted mode_20µL of whole blood/capillary blood sample and 480µL of diluent	whole blood 20µl pridiluted 20µl. capillary/whole blood = 20µl Diluent - 480µl	YES.
3	LED lamp	530nm LED	530nm LED	YES.
4	Communication port	LAN Port	LAN Port.	YES.
5	Printer	External ink tank and leaser printer	External ink. tank & laser printer.	YES
6	Power requirement	AC100V~240V, Input Power ≤200VA, 50/60HZ.	AC100V~240V. Input Power ≤200VA 50/60HZ.	YES
7	Grounding	Good grounding <5V	Good grounding.. <5V.	YES.

Comments:

Environment Condition

Has the Instrument been adequately acclimatized since transport or storage?

YES: NO:

Operating Parameters	Specified Range	Conditions Met
Ambient Temperature	10 to 30 degrees	27°C.
Relative Humidity	<=85%	YES
Supply Voltage & Frequency	100 to 240V, 50/60 Hz AC	~~LN2 41LE~~ 244, NE 3V.

Comments:

Instrument is in good condition -

Instrument Delivery and Documentation

Unpack the Instrument carefully. Are any items missing against the Packing List? YES: NO: ✓ If yes, state the missing Items:_____
Is there any damage to the Instrument or Accessories? YES: NO: ✓ If yes: Description of Damage:_____ Corrective Action:_____ Manufacturing informed: YES: NO:
Is all Standard Documentation Included? Operating Manual: Present: ✓ Missing: Warranty Card: Present: ✓ Missing:
Is all additional documentation Included: Present: ✓ Missing: Installation Qualification: Operational Qualification: Performance Qualification:

Comments:

All document are present with instrument.

Instrument Safety

Manufacturer Safety Recommendations:

Allow enough space for the Instrument	YES: ✓	NO:
Position on level, non-combustible surface Indoors	YES: ✓	NO:
Area free from aggressive/ explosive chemical mixtures	YES: ✓	NO:
Ensure correct power supply and all power switches Easily accessible	YES: ✓	NO:
Keep the analyzer away from electromagnetic waves	YES: ✓	NO:
Read Operator Manual before use	YES: ✓	NO:

Comments:

followed all the safety instructions.

TULIP DIAGNOSTICS PVT. LTD. PUNE

Assembly and Installation

Assembled and installed By:	User:	Specialized Engineer:
Installation Procedure: N/A Unpack and retain Packaging Verifying the site before connecting to UPS power supply Checking the instrument before performing the Test		OK

Comments:

All check completed.

Summary Report

Instrument Name: Councell Penta. 2.0.

Sr. No.: 08412302 00217.

Manufacturer: Tulip Diagnostics Pvt Ltd [Colad clinical system]

Assessment of complete Installation Qualification:

No Deviations: ✓ Deviations:

Deviation	Impact on Operation	Justification for Acceptance

Successful completion of the preceding activities and checks indicates that this Instrument is installed successfully as per the set protocol. The instrument has passed the Installation Qualification procedure and may now be released for use.

IQ Completed By:	Mr. Sachin. Dangle.	**Date:** 01/03/2021	
Deviations Approved By:		**Date:**	
IQ Approved By:		**Date:**	

Comments:

Installation completed.

TULIP DIAGNOSTICS PVT. LTD. PUNE

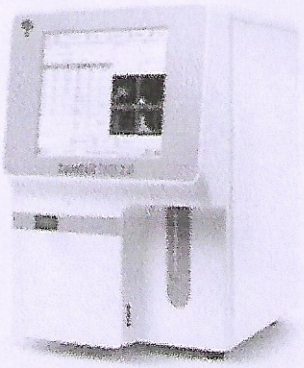
Tulip Diagnostics (P) Ltd.

Operation Qualification

For

Councell penta 2.0

Auto Hematology Analyzer.



Tulip Diagnostics (P) Ltd.

Contents

Safety Tests

This instrument confirms to the following standards and is supplied fully tested by the Manufacturer.

Electrical equipment for measurement, control and laboratory use.
Instrument requirement for laboratory for Whole Blood testing.

The following electrical safety tests should be carried out by a competent person after Installation.

Safety Tests	Pass	Fail	Date	Signed
Earthling voltage	Pass.		01/03/2021	Saclin. Wangle
Input Supply voltage	Pass		01/03/2021	Saclin Wangle.

Comments:
Safety test pass.

Pre-Run Checks

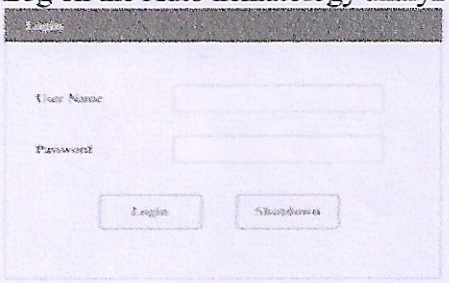
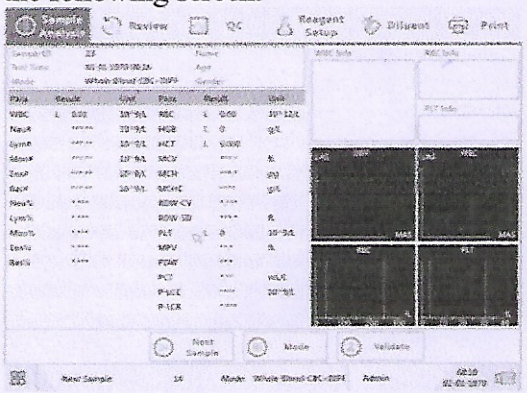
Auto Hematology Analyzer (Councell Penta 2.0)

Pre run check	OK	N/A
Mechanics initialization	OK	
Fluidic initialization	OK	
Ambient temperature	OK	
HGB AD value	OK	
Background test	OK.	

Comments:

Functional Tests

Auto Hematology Analyzer (Councell Penta 2.0)

Functional Test	Acceptance Criteria	Pass	Fail
Instrument power ON	Log on the Auto hematology analyzer  After self test the instrument will display the following screen. 	Pass	
Self Test	The instrument will also prompt the error status on the screen if any.	Pass.	
Background Test	WBC ≤0.2×109 /L ,RBC ≤0.02×1012/L ,HGB ≤1g/L ,PLT ≤10×109 /L ,HCT ≤0.5%	Pass.	

Comments:

Training

Trained Operators	Read Operator Manual	Read SOP	Practical Training	Authorizing Signature
Suraj Rathod	YES.	YES.	YES.	Sachin Dongre.

Shalendkamble	YES.	YES	YES	Sachin Danghe
Gundappakhadke	YES.	YES.	YES.	Sachin Danghe.
MonikaVeer.	YES.	YES	YES	Sachin Danghe.
Ms. Kajal.	YES	YES.	YES.	Sachin. Danghe.
Mr. Omkal.	YES.	YES	YES	Sachin Danghe.
Omkarhalihal	YES	YES.	YES	Sachin Danghe
Prajwalphalthade	YES	YES	YES	sachin. Danghe
AkshayRathod.	YES.	YES.	YES.	Sachin Danghe.

Comments:

Training completed.

Summary Report

Instrument Name: Councell Penta. 2.0

Sr. No.: 08412302 00217

Manufacturer: Tulip Diagnostic Pvt Ltd.

Assessment of complete Operational Qualification:

No Deviations: ✓ Deviations:

Deviation	Impact on Operation	Justification for Acceptance

Successful completion of the preceding activities and checks indicates that this Instrument is operating satisfactorily following delivery and installation. The instrument has passed the Operational Qualification procedure and may now be released for use.

OQ Completed By:	Sachin Dinghe	**Date:** 01/03/2021.	
Deviations Approved By:		**Date:**	
OQ Approved By:		**Date:**	

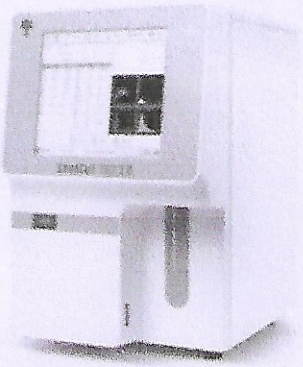
Comments:

Operation Qualification completed.

TULIP DIAGNOSTICS PVT. LTD. PUNE

PERFORMANCE QUALIFICATION
FOR
COUNCELL PENTA 2.0

AUTO HEMATOLOGY ANALYZER



Tulip Diagnostics (P) Ltd.

Contents

1) Performance Check

Auto Hematology Analyzer (Councell penta 2.0)

Test 1

Test Name: Sample Processing

Purpose: Ability to Process Samples

Method:

Run the control samples five times consecutively

Acceptance Criteria: Each of the results obtained above should be within the range as specified in the control chart.

Parameters Values for Verification:
Level 1 (Low Control)

RBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	(2.26 – 2.62) 10^{12}/L	2.45 10^{12}/L	Pass	
2.				
3.				

WBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	(2.93–3.93) 10^{9}/L	3.43 10^{9}/L	Pass.	
2.				
3.				

Hemoglobin:

Test	Control Values	Results Obtained	Pass	Fail
1.	(5.4 – 6.2) g/dL	5.8 g/dL	Pass	
2.				
3.				

MCV:

Test	Control Values	Results Obtained	Pass	Fail
1.	(72.4 - 82.4) fL	77.5 fL	Pass	
2.				
3.				

Platelet Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	(30-70) 10^9/L	49 10^9/L	Pass	
2.				
3.				

Level 2 (Normal Control)

RBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	(4.34 - 4.82) 10^{12}/L	4.56 x 10^{12}/L	Pass	
2.				
3.				

WBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	(7.21 - 9.21) 10^9/L	8.27 10^9/L	Pass.	
2.				
3.				

Hemoglobin:

Test	Control Values	Results Obtained	Pass	Fail
1.	(12.7 - 13.9) g/dL	13.2 g/dL.	Pass.	
2.				
3.				

MCV:

Test	Control Values	Results Obtained	Pass	Fail
1.	(89.4 - 99.4) fL	93.7 fL	Pass.	
2.				
3.				

Platelet Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	(209-289) 10^9/L	236 10^9/L	Pass	
2.				
3.				

Level 3 (High Control)

RBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	(4.88 - 5.48) 10^{12}/L	5.18 10^{12}/L	Pass	
2.				
3.				

WBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	(16.17 - 21.17) 10^9/L	18.31 10^9/L.	Pass.	
2.				
3.				

Hemoglobin:

Test	Control Values	Results Obtained	Pass	Fail
1.	(15.8 - 17.4) g/dL	16.4 g/dL	Pass.	
2.				
3.				

MCV:

Test	Control Values	Results Obtained	Pass	Fail
1.	(97.8 - 107.8) fL	102.2 fL	Pass.	
2.				
3.				

Platelet Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	(409 - 529.) 10^9/L.	469 10^9/L.	Pass	
2.				
3.				

Validation Team: Instrument division.

Name: Sachin Danghe

Designation: Senior sales & service Engineer.

Signature Sachin Danghe.

Date 05/03/2021.

TULIP DIAGNOSTICS PVT. LTD. GOA

Tulip Diagnostics (P) Ltd.

Test 2

Test Name:

Tests for checking the performance of the instruments during analysis
Tests for checking long term performance of the instrument

Purpose:

The purpose of the above checks is to ensure the reliability of the results being obtained.

Method:

1. During Sample analysis:

To run control samples each time the instrument is used for sample analysis and verification of the results of the controls to be within the reference range to be established by performance of the precision experiments.

2. Long term Performance

This is to be checked by Levy Jennings plots to be updated once in six months

Validation Team: Instrument division.

Name Sachin Dongke

Designation Senior Sales & Service Engineer.

Signature Sachin Dangle.

Date 05/03/2021.

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Routine Maintenance

Using probe cleaner daily

The cleanser soak should be performed:
1 During the installation and shut down of the machine
2 When the background results' abnormal , bad differential of scattergram or clogging.
3 Analyzer has been running for more than 24 hours.
4 More than 1000 samples were run within 24 hours.

2)Swab Cleaning and Maintenance

Repeatedly scrub the bottom end of the swab and the inside of its lower aperture with a Q-tip dampened with the diluted probe cleanser

Washing.

1.High background of WBC or HGB, clean WBC chamber
2. High background of RBC or PLT, clean RBC chamber
3. High background of scatter gram, clean Flowcell.
4. Clean Sampling probe when it's dirty

.Maintenance for other parts

Clean the dirty area with soft cloth with alcohol

Validation Team : Instrument division.

Name: Ravi Annigeri

Designation: Sales Offices.

Signature

TULIP DIAGNOSTICS PVT. LTD. PUNE

Date:

3) Safety Tests

This instrument confirms to the following standards and is supplied fully tested by the Manufacturer.
Electrical equipment for measurement, control and laboratory use.
Instrument requirement for laboratory for Blood testing.

The following electrical safety tests should be carried out by a competent person after Installation.

Safety Tests	Pass	Fail	Date	Signed
Earthing	Pass		01/03/2021.	Sachin Donghe.
UPS Supply	Pass.		01/03/2021	Sachin Donghe.

Comments:

4) Summary Report

Instrument Name: Coucell Penta 2.0.

Sr. No.: 08412302000217

Manufacturer: Tulip Diagnostic Pvt Ltd.

Assessment of complete Performance Qualification:

No Deviations: ✓ Deviations:

Deviation	Impact on Operation	Justification for Acceptance

Successful completion of the preceding activities and checks indicates that this Instrument is operating satisfactorily following delivery and installation. The instrument has passed the Operational Qualification procedure and may now be released for use.

PQ Completed By:	Sachin Dangle	**Date:** 01/03/2021	
Deviations Approved By:		**Date:**	
PQ Approved By:		**Date:**	

Comments:

Control & Safety test pass.

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