



CUSTOMER SUPPORT CALL

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ACCOUNT PROTEUS LABORATORIES CC 18069 NGUNGYANE STR T/A JG KUBHEKA LABORATORIES CC SPRINGS GAUTENG 1576	MODEL Access 2	SERIAL NUMBER 502186	ID NUMBER 962400
CUSTOMER CONTACT JABU KUBHEKA 11-7372518 jabu@proteuslab.co.za	PURCHASE ORDER 0001	PROPERTY NUMBER	
AGREEMENT TYPE Warranty	AGREEMENT NUMBER 5329703	EFFECTIVE DATES 23-JUL-2014 To 22-JUL-2015	
SERVICE REQUEST NUMBER 22244931	REQUEST DATE 11-JUL-2014	CALL COMPLETE DATE 17-JUL-2014	
PERFORMED BY Netty Malatsi SENIOR ANALYST FIELD SYSTEMS SUPPORT			

DESCRIPTION OF WORK PERFORMED

PROBLEM: Installation Process

SOLUTION: 22-JUL-2014 - TRAINING INSTALLATION VERIFICATION TESTS WERE DELAYED DUE TO NON-AVAILABILITY OF SUBSTRATE AND WASH BUFFER. TWO ASSAYSS (FTSH AND TPSA) WERE CALIBRATED AND FAILED WITH HIGH CVS. PIPETTOR ALIGNMENTS AND VERIFICATIONS WERE PERFORMED BY ENGINEER. CALIBRATIONS PASSED. THEREAFTER, PATIENT AND QCS SAMPLES RAN. THREE PATIENT SAMPLES CORRELATED WELL WITH RESULTS FROM LANCET.

SYSTEM VALIDATION: For Medical Devices - Regulatory requirements call for a final validation of instrument repair and system readiness. The final validation of instrument repair and system readiness can only be obtained through a successful QC run using the laboratory's quality control system. This repair record and the laboratory's quality control records comprise the quality documents associated with this instrument repair. Copies of these records may be required by Beckman Coulter or regulatory authorities to complete technical investigations or quality audits. We appreciate your cooperation if requested to provide copies of your QC data related to this repair.

DATE	DESCRIPTION	TYPE	HOURS	RATE	EXTENDED AMOUNT	CUSTOMER CHARGE
22-JUL-2014	04-Training	TRAVEL	1.50	R 850.00	R 1,275.00	R 0.00
22-JUL-2014	04-Training	TRAVEL	1.50	R 850.00	R 1,275.00	R 0.00
22-JUL-2014	04-Training	LABOR	7.50	R 850.00	R 6,375.00	R 0.00
22-JUL-2014	04-Training	LABOR	8.50	R 850.00	R 7,225.00	R 0.00
22-JUL-2014	04-Training	TRAVEL	1.50	R 850.00	R 1,275.00	R 0.00
22-JUL-2014	04-Training	TRAVEL	1.50	R 850.00	R 1,275.00	R 0.00
LABOR/TRAVEL TOTAL					R 18,700.00	R 0.00
TOTAL CHARGE					R 18,700.00	R 0.00

CUSTOMER SIGNATURE

Total is an estimate only and does not include applicable sales tax and shipping charges.



CUSTOMER SUPPORT CALL
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ACCOUNT	MODEL	SERIAL NUMBER	ID NUMBER
PROTEUS LABORATORIES CC 18069 NGUNGUNYANE STR SPRINGS, GAUTENG 1576	Access 2	502186	962400
CUSTOMER CONTACT	PURCHASE ORDER	PROPERTY NUMBER	
AGREEMENT TYPE	AGREEMENT NUMBER	EFFECTIVE DATES	
XG 8x5	S2241ZA R02-OCT-19 10:00:17-1-XG ACCESS 2 Service Contract	2/1/2020 to 1/31/2021	
CASE NUMBER	CREATED DATE/TIME		
CA-01784580	2/2/2020 9:02 AM		
WORK ORDER NUMBER	COMPLETION DATE	PERFORMED BY	INSTRUMENT CONDITION
WO-01653855	12/17/2020 7:15 PM	BASEPEDI NKOANA	Operational

SUMMARY OF WORK PERFORMED

Reported Problem	PM C
Symptom Summary	Access2 PM C
Problem Summary	Access2 PM C to be carried out
Resolution Summary	I have performed the PM as per preventative maintenance procedure. I have cleaned, performed and verified mechanical alignments. Ran ultrasonic level sense. adjusted and verified luminometer read.
Verification of Activity	Ultrasonic level sense passed. System check passed. Customer ran Quality Control, passed. I handed over an operational instrument to the customer

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START DATE	END DATE	DESCRIPTION	HOURS	RATE	TOTAL LINE PRICE	CUSTOMER CHARGE
12/17/2020 6:30 AM	12/17/2020 11:15 AM	SERVICE TRAVEL	4.75	1,024.00 ZAR	4,864.00 ZAR	0.00 ZAR
12/17/2020 11:15 AM	12/17/2020 8:15 PM	SERVICE LABOR	9	985.00 ZAR	8,865.00 ZAR	0.00 ZAR
12/17/2020 8:15 PM	12/18/2020 12:45 AM	SERVICE TRAVEL	4.5	1,024.00 ZAR	4,608.00 ZAR	0.00 ZAR
LABOR/TRAVEL TOTAL					18,337.00 ZAR	0.00 ZAR
PART NUMBER	PART DESCRIPTION	QTY	PRICE	TOTAL LINE PRICE	CUSTOMER CHARGE	
B21390	Kit Access 2 Minor PM with Probe Tip	1	16,804.00 ZAR	16,804.00 ZAR	0.00 ZAR	

PART NUMBER	PART DESCRIPTION	QTY	PRICE	TOTAL LINE PRICE	CUSTOMER CHARGE
PARTS/EXPENSES TOTAL				16,804.00 ZAR	0.00 ZAR
TOTAL CHARGE				35,141.00 ZAR	0.00 ZAR

<p>Customer Call Originator: Name of Person Signing Service Report: Percy</p>  <p style="text-align: center;">Customer Signature</p>	<p>Technician Name: BASEPEDI NKOANA</p>  <p style="text-align: center;">Technician Signature</p>
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Proteus Laboratory

Equipment/IQC Action Log

Name: Access

SIN: 502186

Date	Problem	Action Taken	Resolved (Y/N)	Sign
17/12/2020	No records kept available for PM service			
	Calibration & QI records			
	Patient samples appeared on Access	see attached evidence - QI was done	17/12/20	

PROTEUS LABORATORY

QC Data Report
 Access 2 Immunoassay System
 S/N 502186

Test:	Ferritin	Start Date:	01.11.20
Control:	Immuno1	End Date:	07.02.21
Control Lot:	85211	Points:	18
Expiration:	30.06.21	Mean:	21.80
Stated Mean:	20.5000	SD:	1.11
Stated SD:	1.9500	%CV:	5.09
Des. Pipettor:	N/A	Units:	ng/mL

<u>Value</u>	<u>SDI</u>	<u>Completion</u>	<u>QC Rules</u>	<u>Comment</u>	<u>Omit</u>	<u>Reagent Lot</u>	<u>Pipettor</u>
No Value	No Value	09.12.20 21:34			X	971224	N/A
20.4 ng/mL	0.0	10.12.20 13:50				971224	N/A
19.3 ng/mL	-0.6	14.12.20 22:11				971224	N/A
22.6 ng/mL	1.1	17.12.20 19:40				971224	N/A
2.6 ng/mL	1.1	21.12.20 21:29				971224	N/A
21.5 ng/mL	0.5	23.12.20 21:13				971224	N/A
21.4 ng/mL	0.5	28.12.20 20:00				971224	N/A
22.3 ng/mL	0.9	04.01.21 09:50				971224	N/A
22.7 ng/mL	1.1	07.01.21 16:12				971224	N/A
23.6 ng/mL	1.6	10.01.21 17:59				971224	N/A
21.3 ng/mL	0.4	13.01.21 12:12				971224	N/A
23.4 ng/mL	1.5	15.01.21 21:41				971224	N/A
No Value	No Value	17.01.21 19:50			X	971224	N/A
22.8 ng/mL	1.2	20.01.21 13:27				971224	N/A
21.0 ng/mL	0.3	22.01.21 21:35				971224	N/A
21.8 ng/mL	0.7	26.01.21 00:47				971224	N/A
20.3 ng/mL	-0.1	27.01.21 19:45				971224	N/A
1.7 ng/mL	0.6	02.02.21 00:01				971224	N/A
22.0 ng/mL	0.8	03.02.21 21:35				971224	N/A
21.6 ng/mL	0.5	05.02.21 20:36				971224	N/A

QC Rules: 1=1-2s; 2=2-2s; 3=1-3s; 4=4-1s; X=10x

Technologist _____

PROTEUS LABORATORY

ata Report
 ess 2 Immunoassay System
 N 502186

Test:	Ferritin	Start Date:	01.11.20
Control:	Immuno2	End Date:	07.02.21
Control Lot:	85212	Points:	18
Expiration:	30.06.21	Mean:	131.28
Stated Mean:	126.0000	SD:	5.21
Stated SD:	12.2500	%CV:	3.97
Des. Pipettor:	N/A	Units:	ng/mL

<u>Value</u>	<u>SDI</u>	<u>Completion</u>	<u>QC Rules</u>	<u>Comment</u>	<u>Omit</u>	<u>Reagent Lot</u>	<u>Pipettor</u>
No Value	No Value	09.12.20 21:35			X	971224	N/A
134.0 ng/mL	0.7	10.12.20 13:50				971224	N/A
121.6 ng/mL	-0.4	14.12.20 22:12				971224	N/A
131.6 ng/mL	0.5	17.12.20 19:41				971224	N/A
36.2 ng/mL	0.8	21.12.20 21:33				971224	N/A
128.5 ng/mL	0.2	23.12.20 21:14				971224	N/A
126.8 ng/mL	0.1	28.12.20 20:01				971224	N/A
133.0 ng/mL	0.6	04.01.21 09:56				971224	N/A
137.1 ng/mL	0.9	07.01.21 16:13				971224	N/A
141.4 ng/mL	1.3	10.01.21 18:00				971224	N/A
131.7 ng/mL	0.5	13.01.21 12:13				971224	N/A
137.4 ng/mL	0.9	15.01.21 21:45				971224	N/A
No Value	No Value	17.01.21 19:52			X	971224	N/A
126.3 ng/mL	0.0	20.01.21 13:28				971224	N/A
129.3 ng/mL	0.3	22.01.21 21:36				971224	N/A
128.4 ng/mL	0.2	26.01.21 00:48				971224	N/A
124.9 ng/mL	-0.1	27.01.21 19:46				971224	N/A
37.2 ng/mL	0.9	02.02.21 00:02				971224	N/A
130.5 ng/mL	0.4	03.02.21 21:40				971224	N/A
127.0 ng/mL	0.1	05.02.21 20:40				971224	N/A

QC Rules: 1=1-2s; 2=2-2s; 3=1-3s; 4=4-1s; X=10x

Technologist _____

PROTEUS LABORATORY

ata Report
 ess 2 Immunoassay System
 N 502186

Test: **Ferritin**
 Control: **Immuno3**
 Control Lot: 85213
 Expiration: 30.06.21
 Stated Mean: 294.0000
 Stated SD: 28.2500
 Des. Pipettor: N/A

Start Date: 01.11.20
 End Date: 07.02.21
 Points: 18
 Mean: 296.89
 SD: 18.39
 %CV: 6.19
 Units: ng/mL

<u>Value</u>	<u>SDI</u>	<u>Completion</u>	<u>QC Rules</u>	<u>Comment</u>	<u>Omit</u>	<u>Reagent Lot</u>	<u>Pipettor</u>
No Value	No Value	09.12.20 21:39			X	971224	N/A
291.6 ng/mL	-0.1	10.12.20 13:51				971224	N/A
263.9 ng/mL	-1.1	14.12.20 22:13				971224	N/A
298.7 ng/mL	0.2	17.12.20 19:42				971224	N/A
233.4 ng/mL	0.3	21.12.20 21:34				971224	N/A
290.0 ng/mL	-0.1	23.12.20 21:14				971224	N/A
293.0 ng/mL	0.0	28.12.20 20:01				971224	N/A
316.1 ng/mL	0.8	04.01.21 09:56				971224	N/A
310.6 ng/mL	0.6	07.01.21 16:13				971224	N/A
337.0 ng/mL	1.5	10.01.21 18:01				971224	N/A
305.1 ng/mL	0.4	13.01.21 12:18				971224	N/A
332.3 ng/mL	1.4	15.01.21 21:47				971224	N/A
No Value	No Value	17.01.21 19:56			X	971224	N/A
291.6 ng/mL	-0.1	20.01.21 13:33				971224	N/A
279.4 ng/mL	-0.5	22.01.21 21:37				971224	N/A
290.1 ng/mL	-0.1	26.01.21 00:52				971224	N/A
289.4 ng/mL	-0.2	27.01.21 19:50				971224	N/A
1,34.4 ng/mL	-0.3	02.02.21 00:03				971224	N/A
290.8 ng/mL	-0.1	03.02.21 21:42				971224	N/A
276.6 ng/mL	-0.6	05.02.21 20:42				971224	N/A

QC Rules: 1=1-2s; 2=2-2s; 3=1-3s; 4=4-1s; X=10x

Technologist _____