

**Dimension EXL200 Performance Evaluation, Annexure1**

Following Procedure was Carried out as part of the Performance Qualification:-

**1. Calibration of Assay**

Checked and found all calibrations within the acceptable CV limits and in range.  
See Print out Attached.

**2. Internal Quality Control Performance**

Two Level Biorad Lyphocheck Assayed Chemistry Control.  
Checked and found all level Controls to be within the acceptable limits.  
See print out Attached.

**3. Precision Study**

A Within Run Precision of replicates were carried out and CV % obtained are within the acceptable limit for the assay as stated in the IFU.

See print out attached.

**4. Linearity Study**

Linearity study done for AST, BUN, Creatinine, GGT, Glucose.

See Print out attached.

+++++  
 + IMPULSE DIAGNOSTICS +  
 + 01:04 Feb 12 2020 +  
 +++++

CALIBRATION REVIEW  
 Instrument Serial Number: 272658

METHOD: BUN LOT: FA0247  
 CALIB. PRODUCT/LOT: CHEM1 - 9CD036

Status: CALIBRATED  
 Set up by: J  
 Set up date: 02/12/20 12:39 AM  
 Accepted by:  
 Acceptance date: 02/12/20 01:04 AM  
 Acceptance mode: MANUAL  
 CAAP status:

Cal ID: 2002120104.BUN.FA0247

Units: mg/dL  
 Calculation: LINEAR

Calibration Coefficients  
 C0: -2.4932  
 C1: -2.8792  
 C2:  
 C3:  
 C4:

LEVEL	1	2	3	4	5
B TTL	0	180	354	***	***
MEAN	-1.7	183.8	352.6	***	***
SD	0.0	1.7	1.9	***	***
#1	-2	183	351	***	***
#2	-2	182	353	***	***
#3	-2	186	354	***	***
#4	***	***	***	***	***
#5	***	***	***	***	***

Statistics

m = 1.000  
 b = 0.000  
 r = 1.000

QC LEVEL	REF. INTERVAL	RESULT
#1	22.70-40.90	32.487
#2	79.40-113.2	100.89
#3	*** - ***	***
#4	*** - ***	***
#5	*** - ***	***

+++++  
 + IMPULSE DIAGNOSTICS +  
 + 01:03 Feb 12 2020 +  
 +++++

CALIBRATION REVIEW  
 Instrument Serial Number: 272658

METHOD: CRE2 LOT: GB0247  
 CALIB. PRODUCT/LOT: CHEM1 - 9CD036

Status: CALIBRATED  
 Set up by: J  
 Set up date: 02/12/20 12:38 AM  
 Accepted by:  
 Acceptance date: 02/12/20 01:03 AM  
 Acceptance mode: MANUAL  
 CAAP status:

Cal ID: 2002120103.CRE2.GB0247

Units: mg/dL  
 Calculation: LINEAR

Calibration Coefficients

C0: -0.2378  
 C1: 0.0840  
 C2:  
 C3:  
 C4:

Scalars: A: 0.000000 B: 0.000000  
 C: 1.000000 D: -0.050000

LEVEL	1	2	3	4	5
B TTL	0.00	10.56	21.14	***	***
MEAN	0.000	11.087	20.881	***	***
SD	0.037	0.067	0.106	***	***
#1	-0.04	11.02	20.89	***	***
#2	0.02	11.09	20.98	***	***
#3	0.02	11.15	20.77	***	***
#4	***	***	***	***	***
#5	***	***	***	***	***

Statistics

m = 0.988  
 b = 0.219  
 r = 0.999

QC LEVEL	REF. INTERVAL	RESULT
#1	1.820-3.050	2.738
#2	4.590-6.820	6.237
#3	*** - ***	***
#4	*** - ***	***
#5	*** - ***	***

+++++  
 + IMPULSE DIAGNOSTICS +  
 + 01:12 Feb 12 2020 +  
 +++++

CALIBRATION REVIEW  
 Instrument Serial Number: 272658

METHOD: GLUC LOT: GA0269  
 CALIB. PRODUCT/LOT: CHEM1 - 9CD036

Status: CALIBRATED  
 Set up by: J  
 Set up date: 02/12/20 01:06 AM  
 Accepted by:  
 Acceptance date: 02/12/20 01:12 AM  
 Acceptance mode: MANUAL  
 CAAP status:

Cal ID: 2002120112.GLUC.GA0269

Units: mg/dL  
 Calculation: LINEAR

Calibration Coefficients

C0: -3.6711  
 C1: 0.9612  
 C2:  
 C3:  
 C4:

LEVEL	1	2	3	4	5
B TTL	0	272	540	***	***
MEAN	-4.3	280.6	535.6	***	***
SD	0.0	3.1	5.1	***	***
#1	-4	283	541	***	***
#2	-4	277	531	***	***
#3	-4	282	535	***	***
#4	***	***	***	***	***
#5	***	***	***	***	***

Statistics

m = 1.000  
 b = 0.000  
 r = 1.000

QC LEVEL	REF. INTERVAL	RESULT
#1	68.00-102.0	81.226
#2	212.0-318.0	276.79
#3	*** - ***	***
#4	*** - ***	***
#5	*** - ***	***

IMPULSE DIAGNOSTICS  
 01:43 Feb 12 2020

CALIBRATION REVIEW  
 Instrument Serial Number: 272658

METHOD: GGT LOT: FD0177  
 CALIB. PRODUCT/LOT: ENZVER - 9DJ058

Status: CALIBRATED  
 Set up by: J  
 Set up date: 02/12/20 01:16 AM  
 Accepted by:  
 Acceptance date: 02/12/20 01:43 AM  
 Acceptance mode: MANUAL  
 CAAP status:

Cal ID: 2002120143.GGT.FD0177

Units: U/L  
 Calculation: VERIFY

Calibration Coefficients

C0: -1.0000  
 C1: 3.3600  
 C2:  
 C3:  
 C4:

LEVEL	1	2	3	4	5
B TTL	73	377	686	***	***
MEAN	68.7	358.4	650.3	***	***
SD	0.3	1.1	2.5	***	***
#1	68	359	653	***	***
#2	69	359	649	***	***
#3	69	357	649	***	***
#4	***	***	***	***	***
#5	***	***	***	***	***

Statistics

m = 0.949  
 b = -0.172  
 r = 1.000

QC LEVEL	REF. INTERVAL	RESULT
#1	63.30-87.20	71.682
#2	168.0-216.0	183.10
#3	*** - ***	***
#4	*** - ***	***
#5	*** - ***	***

IMPULSE DIAGNOSTICS  
 01:37 Feb 12 2020

CALIBRATION

METHOD: AST LOT ID: GB0249

Entered: 01:17 Feb 12 2020  
 Operator: J  
 Calibrator Name: ENZVER  
 Calibrator Lot: 9DJ058  
 Calibration status: NOT ACCEPTED

Calibration Curve: VERIFY  
 Units: U/L

C0: 2.000 C1: -3.537

BOTTLE	RESULT	ERROR
38	37	
38	37	
38	36	
433	404	
433	408	
433	410	
851	806	
851	808	
851	797	

QC RANGE	RESULT	ERROR
37-53	43	
189-240	210	
*** - ***		
*** - ***		
*** - ***		



\*\*\*\*\*

IMPULSE DIAGNOSTICS, SILCHAR

16:10 FEB 12 2020

PRINT RESULTS

Patient: 2ND QC

Sample No: QC 2

Location:

Sample: SerumQC2

Priority: QC

Entered: 16:10 FEB 12 2020

Position: 2

Segment: A

TEST	RESULT	REF. INTERVAL	UNITS
GLUC	270	254-300	mg/dL.
BUN	102	89-117	mg/dL
CRE2	6.37	5.70-6.50	mg/dL
AST	218	182-234	U/L
ALTI	107	81-119	U/L
ALPI	407	363-459	U/L
TBI	4.48	3.70-4.78	mg/dL
DBI	0.99	0.72-1.12	mg/dL
TP	4.3	4.2-4.8	g/dL
ALB	2.4	2.2-2.7	g/dL
GGT	191	161-209	U/L
CHOL	102	81-108	mg/dL
TGL	96	82-110	mg/dL
AHDL	26.1	22.6-26.9	mg/dL.
CA	12.1	10.2-13.0	mg/dL
URCA	10.6	8.6-11.3	mg/dL
LIPL	303	244-323	U/L



PRINT RESULTS

*pre*

Patient: LIN  
 Sample No.: PRECI  
 Location:  
 Sample: SERUM  
 Priority: ROUTINE  
 Entered: 13:00 FEB 12 2020

Position:  
 Segment:

TESTRESULT REF. INTERVAL UNITS ---  
 - - - - -

GLUC	275 HI	74-106	mg/dL
GLUC	275 HI	74-106	mg/dL
GLUC	271 HI	74-106	mg/dL
GLUC	272 HI	74-106	mg/dL.
GLUC	273 HI	74-106	mg/dL
BUN	183 HI	assay range	mg/dL
BUN	184 HI	assay range	mg/dL
BUN	183 HI	assay range	mg/dL
BUN	185 HI	assay range	mg/dL
BUN	180 HI	assay range	mg/dL
CRE2	10.50 HI	0.55-1.30	mg/dL
CRE2	10.34 HI	0.55-1.30	mg/dL
CRE2	10.38 HI	0.55-1.30	mg/dL
CRE2	10.35 HT	0.55-1.30	mg/dL
CRE2	10.19 HI	0.55-1.30	mg/dL
URCA	11.8 HI	2.6-7.2	mg/dL
URCA	11.6 HI	2.6-7.2	mg/dL
URCA	11.6 HI	2.6-7.2	mg/dL
URCA	11.5 HI	2.6-7.2	mg/dL
URCA	11.6 HI	2.6-7.2	mg/dL
BUN	mean:182.89	sd:1.836	cv:1.00
URCA	mean:11.62	sd:0.116	cv:1.00
GLUC	mean:273.38	sd:1.786	cv:0.65



Dade Behring Dimension® Report for AST Method

Date:  
 Site:  
 Address:  
 Operator:  
 Inst. ID:  
 Flex LN: GB0249  
 Calib. LN: 9DJ058WED FEB 12 01:17:10 2020

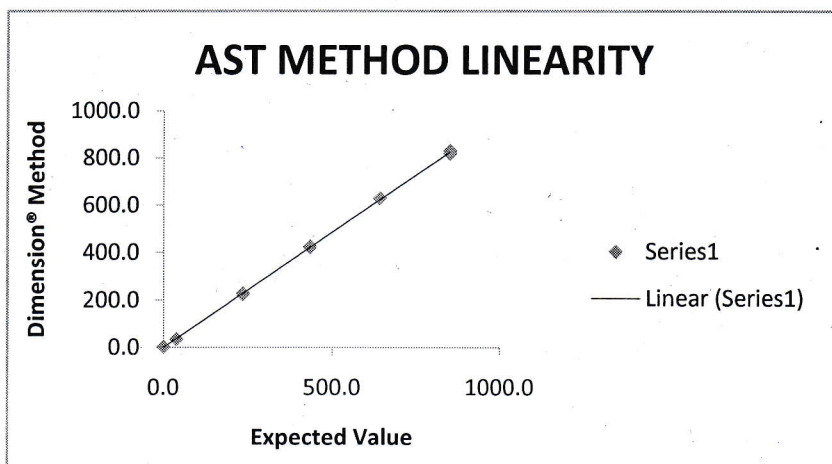
**Coefficients:**  


---

 C0: 2.000  
 C1: -3.537

Linearity Test Samples (Values are in U/L)

Sample	Expected	Dimension®
L0	0.0	3.9
L0	0.0	4.3
L1	38.0	35.9
L1	38.0	37.4
L1	38.0	36.0
L1	38.0	36.6
L1	38.0	35.8
L1.5	235.5	228.9
L1.5	235.5	223.9
L2	433.0	422.1
L2	433.0	426.6
L2.5	642.0	630.3
L2.5	642.0	627.7
L3	851.0	831.4
L3	851.0	830.4
L3	851.0	819.2
L3	851.0	817.2
L3	851.0	826.3



Linear Regression Statistics

No. of Samples	18
Slope	0.9702

Dade Behring Dimension® Report for AST Method

Date:  
 Site:  
 Address:  
 Operator:  
 Inst. ID:  
 Flex LN: GB0249  
 Calib. LN: 9DJ058WED FEB 12 01:17:10 2020

**Coefficients:**

C0:	2.000
C1:	-3.537

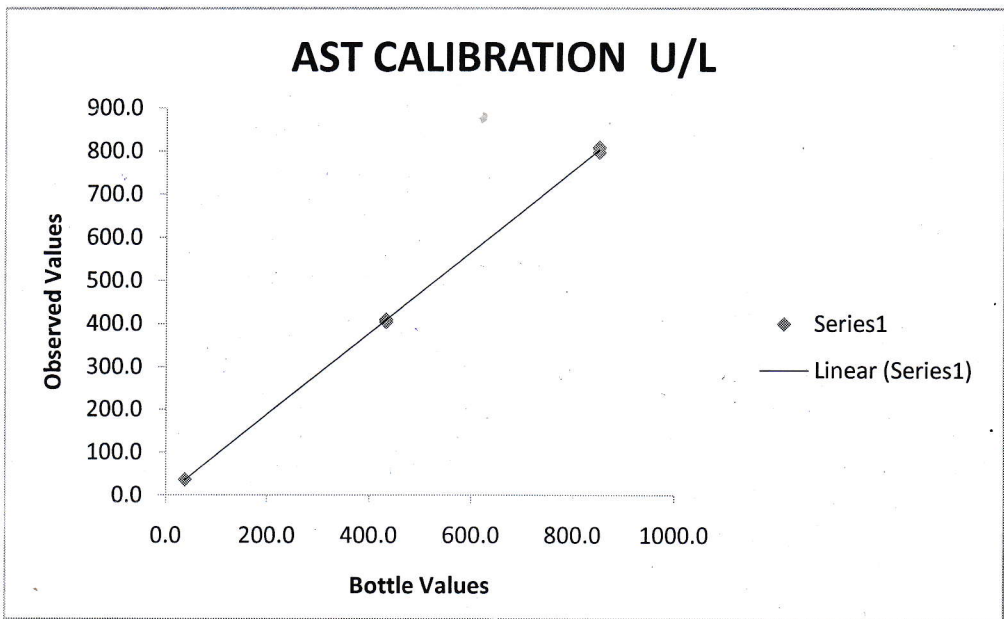
**Calibrations Samples**

Sample	Calib. BV	Obs. Value
Cal: Level 1	38.0	36.7
Cal: Level 1	38.0	36.9
Cal: Level 1	38.0	35.9
Cal: Level 2	433.0	403.5
Cal: Level 2	433.0	407.8
Cal: Level 2	433.0	409.7
Cal: Level 3	851.0	805.6
Cal: Level 3	851.0	808.2
Cal: Level 3	851.0	796.7

Slope (m) 0.943  
 Intercept (b) -0.093  
 Corr Coef (r) 1.000

**Acceptable calibration specifications:**

Slope 0.9 - 1.1  
 Intercept Close to zero  
 or clinically insignificant



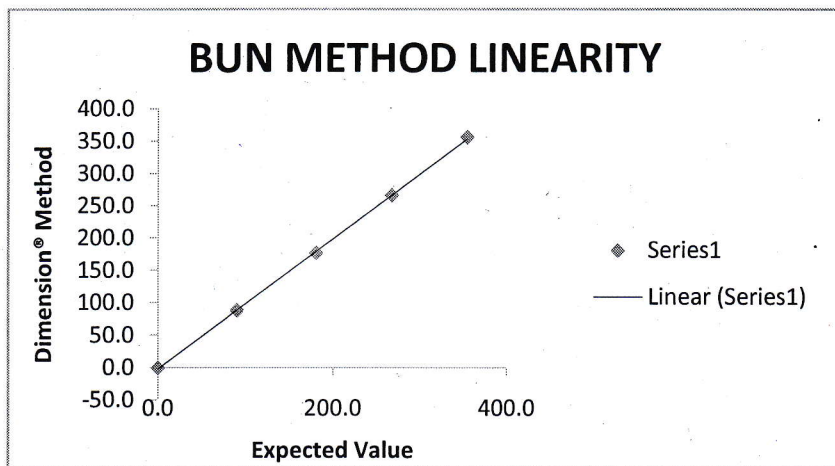
Dade Behring Dimension® Report for BUN Method

Date:  
 Site:  
 Address:  
 Operator:  
 Inst. ID:  
 Flex LN: FA0247  
 Calib. LN: 9CD036WED FEB 12 00:39:23 2020

Coefficients:  
 C0: -2.493  
 C1: -2.879

Linearity Test Samples (Values are in mg/dL)

Sample	Expected	Dimension®
L1	0.0	0.0
L1	0.0	0.0
L1.5	90.2	88.0
L1.5	90.2	89.0
L1.5	90.2	89.2
L1.5	90.2	87.4
L1.5	90.2	87.2
L2	180.4	177.6
L2	180.4	176.5
L2.5	267.4	265.9
L2.5	267.4	265.7
L2.5	267.4	265.5
L2.5	267.4	266.3
L2.5	267.4	267.7
L3	354.4	354.7
L3	354.4	356.7



Linear Regression Statistics

No. of Samples	16
Slope	1.0040



Dade Behring Dimension® Report for BUN Method

Date:  
 Site:  
 Address:  
 Operator:  
 Inst. ID:  
 Flex LN: FA0247  
 Calib. LN: 9CD036WED FEB 12 00:39:23 2020

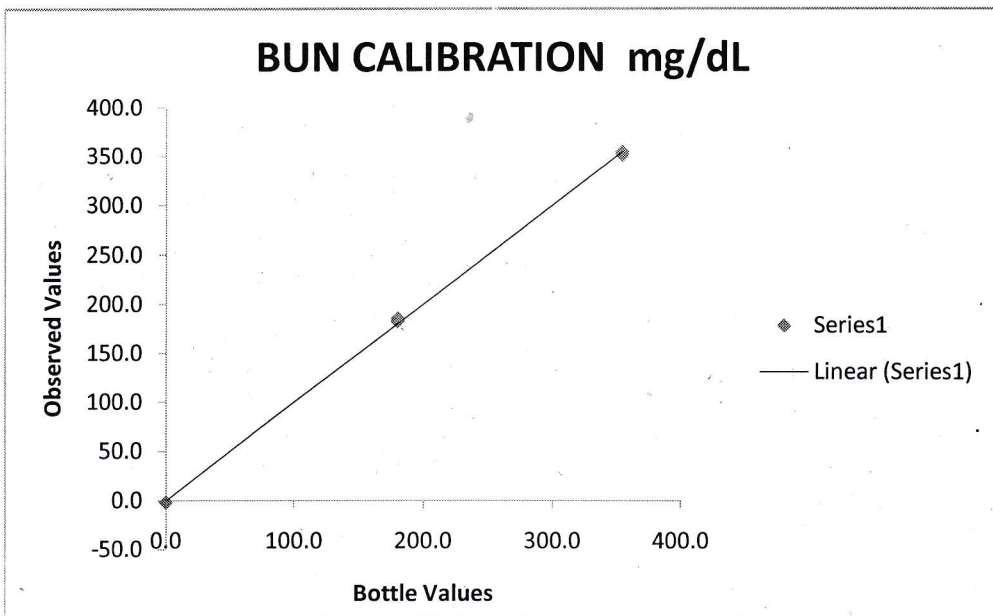
**Coefficients:**  
 C0: -2.493  
 C1: -2.879

Calibrations Samples		
Sample	Calib. BV	Obs. Value
Cal: Level 1	0.0	-1.7
Cal: Level 1	0.0	-1.6
Cal: Level 1	0.0	-1.7
Cal: Level 2	180.4	183.3
Cal: Level 2	180.4	182.4
Cal: Level 2	180.4	185.7
Cal: Level 3	354.4	350.7
Cal: Level 3	354.4	352.7
Cal: Level 3	354.4	354.5

Slope (m) 1.000  
 Intercept (b) 0.000  
 Corr Coef (r) 1.000

**Acceptable calibration specifications:**

Slope 0.97 - 1.03  
 Intercept Close to zero  
 or clinically insignificant



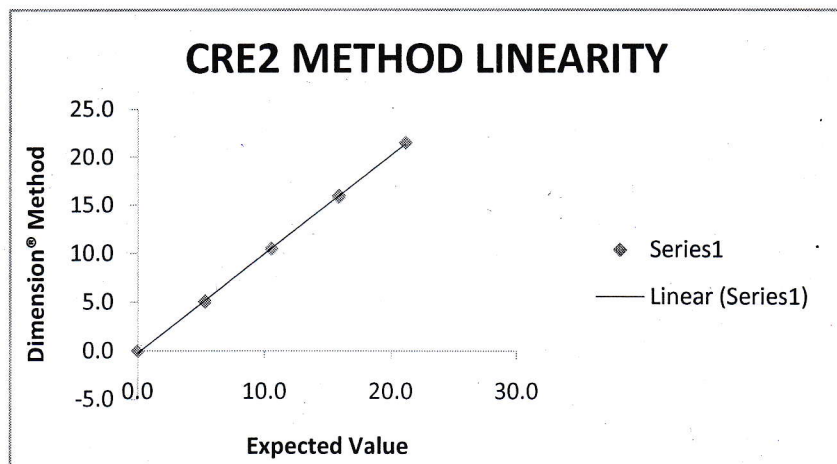
**Dade Behring Dimension® Report for CRE2 Method**

Date:  
 Site:  
 Address:  
 Operator:  
 Inst. ID:  
 Flex LN: GB0247  
 Calib. LN: 9CD036TUE FEB 18 01:55:41 2020

**Coefficients:**  
 C0: -0.464  
 C1: 0.084

**Linearity Test Samples (Values are in \*\*)**

Sample	Expected	Dimension®
L1	0.0	0.0
L1	0.0	0.0
L1.5	5.3	5.1
L1.5	5.3	5.2
L1.5	5.3	5.1
L1.5	5.3	5.1
L1.5	5.3	5.1
L2	10.6	10.6
L2	10.6	10.5
L2.5	15.8	16.0
L2.5	15.8	15.8
L2.5	15.8	16.0
L2.5	15.8	16.0
L2.5	15.8	16.0
L2.5	15.8	16.0
L3	21.1	21.5
L3	21.1	21.5



**Linear Regression Statistics**

No. of Samples	16
Slope	1.0220

Dade Behring Dimension® Report for CRE2 Method

Date:  
 Site:  
 Address:  
 Operator:  
 Inst. ID:  
 Flex LN: GB0247  
 Calib. LN: 9CD036TUE FEB 18 01:55:41 2020

**Coefficients:**  


---

 C0: -0.464  
 C1: 0.084

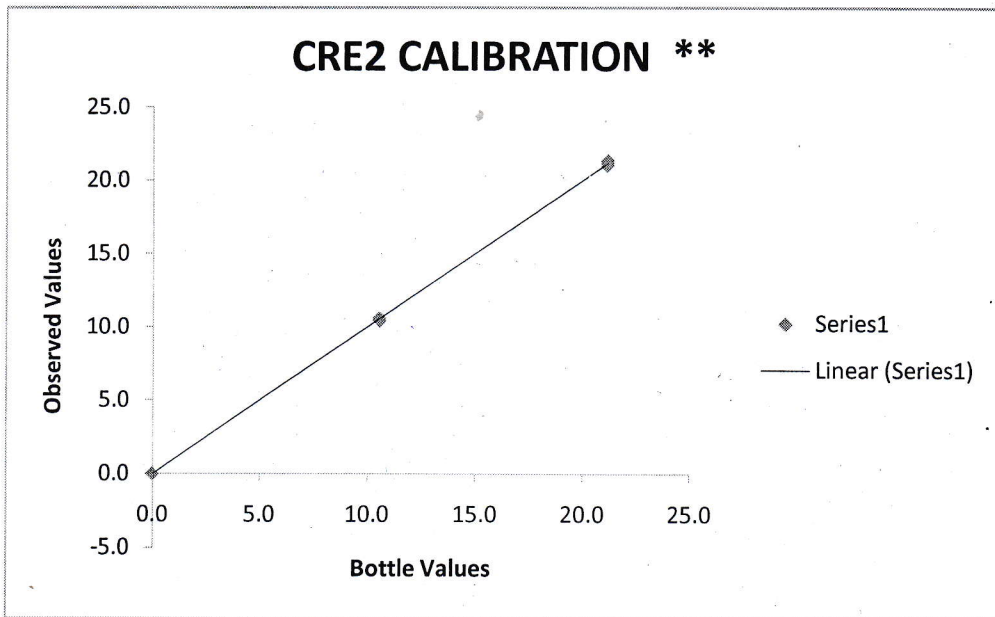
**Calibrations Samples**

Sample	Calib. BV	Obs. Value
Cal: Level 1	0.0	0.0
Cal: Level 1	0.0	0.0
Cal: Level 1	0.0	0.0
Cal: Level 2	10.6	10.6
Cal: Level 2	10.6	10.6
Cal: Level 2	10.6	10.4
Cal: Level 3	21.1	21.2
Cal: Level 3	21.1	21.3
Cal: Level 3	21.1	21.0

Slope (m) 1.001  
 Intercept (b) -0.014  
 Corr Coef (r) 1.000

**Acceptable calibration specifications:**

Slope \*\*\_\*\*  
 Intercept Close to zero  
 or clinically insignificant



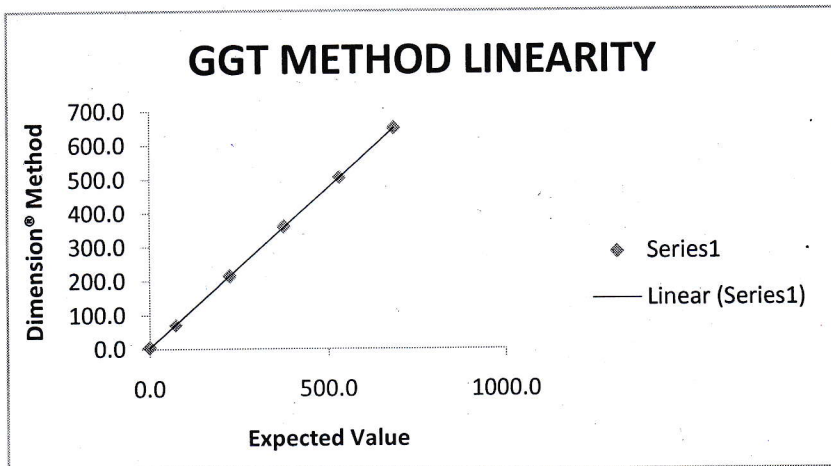
Dade Behring Dimension® Report for GGT Method

Date:  
 Site:  
 Address:  
 Operator:  
 Inst. ID:  
 Flex LN: FD0177  
 Calib. LN: 9DJ058WED FEB 12 01:16:21 2020

**Coefficients:**  
 C0: -1.000  
 C1: 3.360

Linearity Test Samples (Values are in U/L)

Sample	Expected	Dimension®
L0	0.0	6.0
L0	0.0	5.9
L1	73.0	71.1
L1	73.0	70.7
L1	73.0	70.8
L1	73.0	70.9
L1	73.0	71.5
L1.5	225.0	213.8
L1.5	225.0	216.3
L2	377.0	361.5
L2	377.0	360.2
L2	377.0	359.5
L2	377.0	361.6
L2	377.0	359.4
L2.5	531.5	505.0
L2.5	531.5	505.5
L3	686.0	650.8
L3	686.0	649.3



Linear Regression Statistics

No. of Samples	18
Slope	0.9439

Dade Behring Dimension® Report for GGT Method

Date:  
 Site:  
 Address:  
 Operator:  
 Inst. ID:  
 Flex LN: FD0177  
 Calib. LN: 9DJ058WED FEB 12 01:16:21 2020

**Coefficients:**

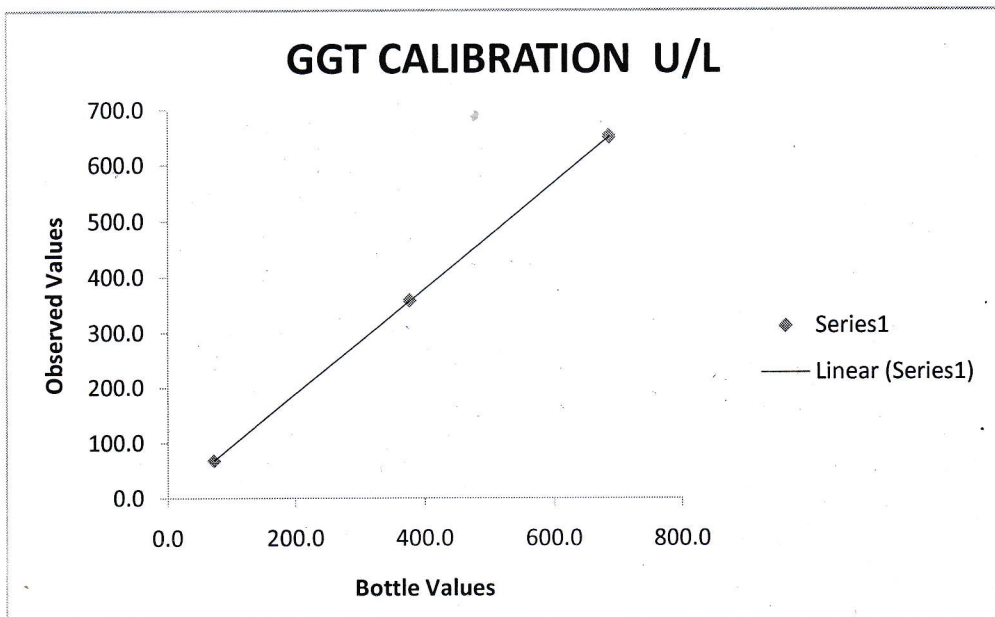
C0:	-1.000
C1:	3.360

Calibrations Samples		
Sample	Calib. BV	Obs. Value
Cal: Level 1	73.0	68.3
Cal: Level 1	73.0	69.0
Cal: Level 1	73.0	68.7
Cal: Level 2	377.0	359.5
Cal: Level 2	377.0	358.5
Cal: Level 2	377.0	357.2
Cal: Level 3	686.0	653.2
Cal: Level 3	686.0	648.7
Cal: Level 3	686.0	649.1

Slope (m) 0.949  
 Intercept (b) -0.172  
 Corr Coef (r) 1.000

**Acceptable calibration specifications:**

Slope 0.9 - 1.1  
 Intercept Close to zero  
 or clinically insignificant





**Dade Behring Dimension® Report for GLUC Method**

Date:  
 Site:  
 Address:  
 Operator:  
 Inst. ID:  
 Flex LN:  
 Calib. LN:

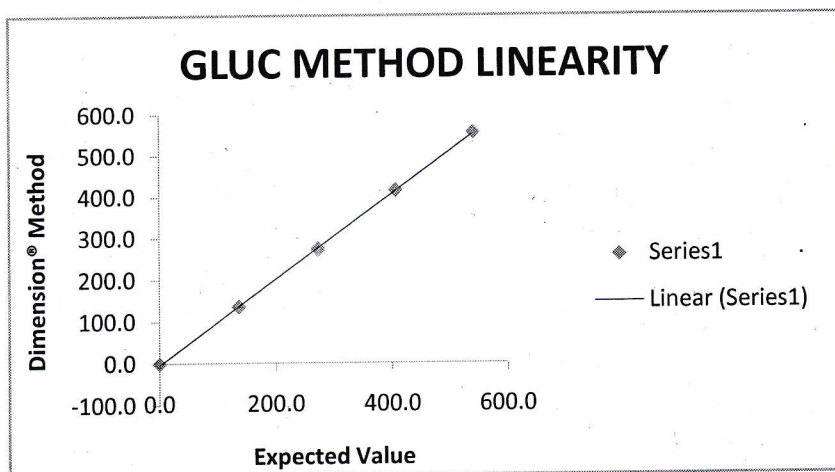
GA0269  
 9CD036WED FEB 12 01:06:05 2020

**Coefficients:**

C0: -3.671  
 C1: 0.961

**Linearity Test Samples (Values are in mg/dL)**

Sample	Expected	Dimension®
L1	0.0	0.0
L1	0.0	0.0
L1.5	136.0	136.3
L1.5	136.0	135.6
L1.5	136.0	135.9
L1.5	136.0	135.8
L1.5	136.0	136.3
L2	272.0	273.5
L2	272.0	271.1
L2	272.0	275.0
L2	272.0	274.5
L2	272.0	275.1
L2.5	406.0	414.7
L2.5	406.0	416.0
L3	540.0	555.4
L3	540.0	555.1



**Linear Regression Statistics**

No. of Samples 16  
 Slope 1.0299

Dade Behring Dimension® Report for GLUC Method

Date:  
 Site:  
 Address:  
 Operator:  
 Inst. ID:  
 Flex LN: GA0269  
 Calib. LN: 9CD036WED FEB 12 01:06:05 2020

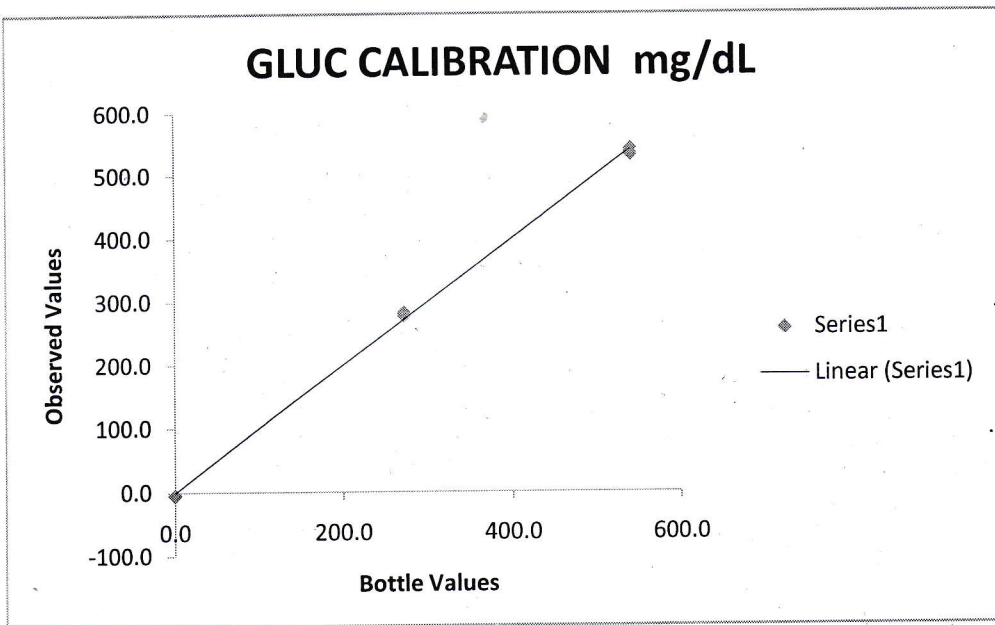
**Coefficients:**  
 C0: -3.671  
 C1: 0.961

Calibrations Samples		
Sample	Calib. BV	Obs. Value
Cal: Level 1	0.0	-4.3
Cal: Level 1	0.0	-4.3
Cal: Level 1	0.0	-4.3
Cal: Level 2	272.0	282.8
Cal: Level 2	272.0	277.1
Cal: Level 2	272.0	282.0
Cal: Level 3	540.0	541.0
Cal: Level 3	540.0	530.9
Cal: Level 3	540.0	535.0

Slope (m) 1.000  
 Intercept (b) 0.000  
 Corr Coef (r) 1.000

**Acceptable calibration specifications:**

Slope 0.97 - 1.03  
 Intercept Close to zero  
 or clinically insignificant





## 5.11 System Check

Serial Number: DE 27 26 58

Attach System Check printout



OFFSET                    ALIGNMENT POINT

- 0 R2 reagent; arm
- 0 R2 reagent; arm 0 offset
- 1 R2 reagent; arm 34 offset
- 11 R2 reagent; probe to plate
- 7 F2 reagent; probe to cartridge
- 38 F2 reagent; carriage to cartridge
- 4 F2 reagent; carriage
- 1 F2 reagent; arm to drain
- 3 R2 reagent; carriage to drain
- 10 Ri reagent; probe to plate
- 7 R1 reagent; probe to cartridge
- 20 R1 reagent; carriage to cartridge
- 1 R1 reagent; carriage to drain
- 2 R1 reagent; carriage
- 2sample arm
- 40 sample probe
- 111 sample arm to cup
- 21 sample probe to cup
- 17 sample drain
- rotate wheel to outer sample arm
- 1 sample arm to inner cup
- 6 rotate wheel to inner sample arm
- 74 F1 Flex tray
- 20 P2 Flex tray
- 0 photometer arm
- 21 inner scanner to wheel
- 1 cuter scanner to wheel
- 1c0 sample wheel target
- 1:20 sample probe max depth
- cartridge insert offset
- 746 reagent loader to solenoid
- 242.1 reagent loader to tray
- 0 pod sample max probe depth
- 0 ssc sample max probe depth
- 220 photometer 203 offset
- 246 photometer 340 offset
- photometer 383 offset
- 241 photometer 405 offset
- 241 photometer 402 offset
- 225 photometer 510 offset
- 223 photometer 540 offset
- 227 photometer 577 offset
- 226 photometer 600 offset 24,
- photometer 700 offset --I incubate
- wheel to sample probe
- incubate wheel to reagent probe
- 1 incubate wheel to transfer open
- 20 sample arm to vessel -,
- sample probe to- vessel 1- reagent
- probe to vessel -1.1 reagent
- carriage to vessel --7wash probe
- to vessel -I wash wheel to
- incubate wheel
- vessel transfer to incubate whl
- vessel transfer to wash wheel



Alignment: print out attached

**Voltages:**

	Power OFF	Power ON	Power ON
G-H	_____ V (0-1V)	_____ ( 90-110V)	_____ (198-264V)
	_____ V (0-1V)	_____ (110-125V)	
H-N	_____ V (0-1V)	_____ ( 90-110V)	_____ (198-264V)
	_____ V (0-1V)	_____ (110-125V)	
G-N	_____ V (0-1V)	_____ (Max 0.5)	_____ (< 2V)
	_____ V (0-1V)	_____ (< 2 V)	

**Gaps:**

Syringe

<u>(Glass to plunger)</u>	<u>Observed</u>	<u>Adjusted</u>	<u>Specification</u>
Sample Metering	_____	_____	(.005" - .010")
Sample Flush	_____	_____	(.005" - .010")
Reagent 1 Metering	_____	_____	(.005" - .010")
Reagent 1 Flush	_____	_____	(.005" - .010")
Reagent 1 Metering	_____	_____	(.005" - .010")
Reagent 1 Flush	_____	_____	(.005" - .010")
Reagent 1 Flush	_____	_____	(.005" - .010")
IF HM Instrument Chemistry Wash	_____	_____	(.005" - .010")

Cuvette Manufacture Solenoids

	<u>Observed</u>	<u>Adjusted</u>	<u>Specification</u>
Top Seal	_____	_____	(.010" *)
Cuvette Form	_____	_____	(0.020" - 0.045"**)
U-Sea 1	_____	_____	(0.020" ± 0.010"*)
	_____	_____	

++++  
IMPULSE DIAGNOSTICS, SILCHAR +  
10:00 FEB 12 2020  
++++

REAGENT CARTRIDGE INVENTORY

LOT	SEQUENCE TEST		
METHOD	LOT NUMBER	SEQUENCE NO.	TESTS LEFT
ALB	GA9337	16107	50
ALPI	FA9302	04213	25
ALTI	FB0042	15050	30
AMY	BA9261	78100	23
AST	FA9337	21604	28
BUN	FB9297	06054	19
CA	EC0058	20129	44
CHK	BA0024	16091	5
CHOL	BC004	48711	30
CRE2	BB0049	35016	19
DBI	FC0028	40853	33
GGT	FA9303	19955	41
GLUC	GB9351	09355	219
TBI	GC9330	09547	39
TP	BA9330	06995	10
URCA	EB9361	06995	58

++++

ATTACH INVENTORY PRINTOUT

THIS INVENTORY SUMMARY CONSISTS OF ALL METHODS CALIBRATED AND INTENDED FOR USE  
AT TIME OF INSTALL.



---

CAS

---

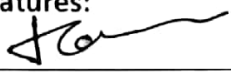
CUSTOMER

The DIMENSION EXL 200 s/n DE 2726 58  
has been successfully installed as of 18<sup>th</sup> Feb 2020.  
(Date)

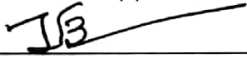
Customer Accepted: Impulse Diagnostix  
Date: 18 Feb 2020  
Title: IO OS PR

- EM Checklist attached (Obtain FSR signature)
- Calibration and QC Summary Sheets attached
- Inventory Summary Sheet attached
- Method Calibration / Verification / IMT Reports attached
- Rating Form completed and attached
- Training Checklists completed and attached
- Installation Completion Statement
- Software Revision Level 10.3.1.

Signatures:

  
\_\_\_\_\_

Clinical Applications Specialist

  
\_\_\_\_\_

Field Service Representative

Feb 18 2020

date

Feb 18 2020

date

#### NOTICE TO INSTALLERS

This package contains new revisions

PLEASE READ PRIOR TO INSTALLATION



### Instrument Installation Acceptance Statement

Account Name: Impulse Diagnostic

City: Silchar State: Assam

Instrument Installed: 13/02/2020 S/N: DE272658

S/N: \_\_\_\_\_

S/N: \_\_\_\_\_

S/N: \_\_\_\_\_

Install Completion Date: 13/02/2020

**Customer:**

I understand and state that the installation of the Siemens Instrument(s) has/have been completed to my satisfaction, including training of laboratory personnel on the operation and maintenance of this Instrument(s).

I also state that the Instrument(s) is/are (1) operating in accordance with manufacturing specification and (2) the Instrument(s) and consumable(s) performance has/have been validated according to Siemens protocol.

Customer's Name: Impulse Diagnostics  
Print Name

Customer Signature: [Signature] Date: 18/2/20

Siemens CAS

CAS's Name: Da I monmi lakai  
Print Name Date: 18/2/20

CAS Signature: \_\_\_\_\_

**Installation Procedure and Checklist – Dimension EXL200.**

Models @ Serial No : Dimension EXL200  
Instrument Sr # : DE272658  
Customer Name : Impulse Diagnostic  
Doctor / In-Charge : Dr. Dipayan Saha  
Address : Hailakandi, Meherpur  
  
City : Silchar  
Phone : 3482224542

1. Inspect Shipper for physical damage, then Uncrate.

- a. Physical Damage to shipper :  Yes  No  
b. Accessories as per packing List :  Yes  No

2. Environmental Conditions.

- a. Air Conditioned Environment Available :  Yes  No  
b. Room free of Rodents/ Insects/ Pests :  Yes  No  
c. Humidity is less than 80 % :  Yes  No



**8. System Calibration and Inspection.**

- a. Verified All Mechanical Configuration Adjustment of the Site  
and Back up in Disc   
(Instrument Calibration Diskette provided to the User Department)
- b. Checked the Thermal Operations of Reagent compartment and Thermal Chamber.
- c. Checked the Reagent area and Automatic Flex Loader
- d. Checked Sample area.
- e. Checked the Barcode reader.
- f. Checked the Lamp Calibration
- g. Checked the Photometer alignment and mAU Offset calibration.
- h. Calibrated the Cuvette and reagent temperature

**9. System Preparation: System Check**

Run the System check with CHK Reagent to check the performance of Sample Probe assembly, Reagent Probe 1 and 2 assembly, Photometer alignment.

Attached System check Printout attached

Alignment: print out attached

**Voltages:**

	Power OFF	Power ON	Power ON
G-H	_____ V (0-1V)	_____ ( 90-110V)	_____ (198-264V)
	_____ V (0-1V)	_____ (110-125V)	
H-N	_____ V (0-1V)	_____ ( 90-110V)	_____ (198-264V)
	_____ V (0-1V)	_____ (110-125V)	
G-N	_____ V (0-1V)	_____ (Max 0.5)	_____ (< 2V)
	_____ V (0-1V)	_____ (< 2 V)	

**Gaps:**

**Syringe**

<u>(Glass to plunger)</u>	<u>Observed</u>	<u>Adjusted</u>	<u>Specification</u>
Sample Metering	_____	_____	(.005" - .010")
Sample Flush	_____	_____	(.005" - .010")
Reagent 1 Metering	_____	_____	(.005" - .010")
Reagent 1 Flush	_____	_____	(.005" - .010")
Reagent 1 Metering	_____	_____	(.005" - .010")
Reagent 1 Flush	_____	_____	(.005" - .010")
Reagent 1 Flush	_____	_____	(.005" - .010")
IF HM Instrument Chemistry Wash	_____	_____	(.005" - .010")

Cuvette Manufacture Solenoids

	<u>Observed</u>	<u>Adjusted</u>	<u>Specification</u>
Top Seal	_____	_____	(.010" *)
Cuvette Form	_____	_____	(0.020" - 0.045"**)
U-Seal	_____	_____	(0.020" ± 0.010"**)
	_____	_____	



**Installation Qualifications for Dimension EXL200.**

Carried out all the Installation Steps as well as the Necessary Checks and Alignments of all Robotics were done for Dimension EXL200 located in Impulse Diagnostic, Silchar bearing serial No. DE272658 as per Installation Procedure and Checklist.

Checked the System check report and the obtained values acceptable. (Printout attached)

Performed all due maintenance activities such as Daily, Weekly Maintenance, Automated System Prime.

Handed over the Instrument for Operations Training & Qualifications.

For Siemens Ltd.

Name : Mr. Kamal Kumar Baishya

Designation : Field Service Engineer

Signature : *K Baishya*

Date : 19/02/20

**Installation Certificate**

This is to certify that the Dimension EXL200 Clinical Chemistry **System**, Instrument Serial DE272658 has been successfully Installed and Commissioned in Impulse Diagnostic, Meherpur, Silchar, Assam as per the Installation Procedure & Checklist.

Siemens Ltd.

Impulse Diagnostic

Name: Kamal Kumar Baishya

Name: Jantu Das

Designation: Field Service Engineer

Designation: Technician In-charge

Signature : *K Baishya*

Signature: *Jantu Das,*

Date: *18/02/20*

Date: *18/02/20*

**Operational Qualification for Dimension EXL200**

Operator Qualification: Conducted the operator Training on the following Topic

- 1, Component Overview 
  - a, System Components
  - b, Keyboard, Touchscreen and Alert Keys
- 2, Calibration: 
  - a, Calibrated Linear Method and verify Enzyme Method
- 3, Maintenance: 
  - a, Daily, Weekly, Monthly Maintenance and Periodic Maintenance
  - b, Replace Cuvette Nozzle Diaphragm
  - c, Replace Cuvette film cartridge
  - d, Replace Reagent and Sample Probe tip.
- 4, Sample Processing 
  - a, Running sample using Sample cup, primary tube.
  - b, Manual dilution and respond to system needs.
  - c, Determine Segment status and delete Segment.
  - d, Review use of System status key
  - e, Edit samples including adding and deleting tests, rerunning test and deleting Samples.
  - f, Review use of these keys:  
Pause, Exit, Shift, Reset, Backspace, Backslash, Run and Arrow keys.
  - g, Review Interpreting test report messages.
- 5, Customization 
  - a, Set Password
  - b, Enable automatic cartridge removal, and automatic repeat for panic
  - c, Enable Automatic Flex reagent cartridge testing.



- d, Select Plumbing configuration
- e, Define panel
- f, Define QC Status and QC ranges
- g, Review method QC results from method review screen.
- h, Enter Panic values
- i, Configure barcode choice
- j, Touchscreen and alert features
- k, Configure QC Alerts, QC ranges and QC Panels.
- l, Define calibration products and calibration alert.
- m, Setting calibration.

## 6, Problem Resolution

ACTIVITY	Reference
Review response to alarm ON/OFF	Operator's Guide, <i>Introducing</i> ,
Review response to error messages using ALT M	Operator's Guide, <i>Introducing</i>
Review using Reset key to clear error messages	Operator's Guide, <i>Introducing</i>
Review active and resident error logs; including More Info and See Minor functions	Operator's Guide, <i>Troubleshooting</i>
Review troubleshooting, emphasizing system check troubleshooting guidelines	Operator's Guide, <i>Troubleshooting</i>
Review icons and using CTL Help to respond to icons	Operator's Guide, <i>Appendix</i>

REAGENT INVENTORY SUMMARY

Attached printout

**THIS INVENTORY SUMMARY CONSISTS OF ALL METHODS  
CALIBRATED AND INTENDED FOR USE AT TIME OF INSTALL.**

Moumi Lakari

CAS

[Signature]

CUSTOMER

**Dimension EXL200 Performance Evaluation, Annexure1**

Following Procedure was Carried out as part of the Performance Qualification:-

**1. Calibration of Assay**

Checked and found all calibrations within the acceptable CV limits and in range.

See Print out Attached.

**2. Internal Quality Control Performance**

Two Level Biorad Lyphocheck Assayed Chemistry Control.

Checked and found all level Controls to be within the acceptable limits.

See print out Attached.

**3. Precision Study**

A Within Run Precision of replicates were carried out and CV % obtained are within the acceptable limit for the assay as stated in the IFU.

See print out attached.

**4. Linearity Study**

Linearity study done for AST, BUN, Creatinine, GGT, Glucose.

See Print out attached.



**Performance Qualification for Dimension EXL200**

With reference to the Annexure 1 and studies carried out in the Laboratory have determined that the analyzer meets all performance criteria and has passed Performance Qualification.

**The System is ready for specific usage.**

Protocol performed by : Siemens Ltd.

Signature : *Monmi Lakai*

Name : Da I Monmi lakai

Designation : Application Service

Customer Authorization : Impulse Diagnostic

Signature : *Jantu Das*

Name : Jantu Das

Designation : Technician In-charge

Date: *18/02/20*

## CALIBRATION CERTIFICATE

Dimension Exl 200, bearing serial number: DE272658 Installed at IMPULSE DIAGNOSTIC, Silchar, Assam has been duly calibrated on 10<sup>th</sup> March 2022.

**Final calibration results are as follows:**

### PHOTOMETER DARK CALIBRATION:

Reference : 9015.67 Hz  
 Sample (outer on) : 8793.78 Hz  
 Sample (outer off) : 8795.38 Hz

### LAMP CALIBRATION:

Low Calib level : 47.6%  
 High Calib level : 60.6%

### PHOTOMETER

<u>Filters</u>	<u>System Check Wavelength</u>	<u>Acceptable Range</u>
293nm ----	0.53	$\pm 2.5$
340nm ----	0.31	$\pm 1.5$
383nm ----	0.40	$\pm 1.5$
405nm ----	0.37	$\pm 1.5$
452nm ----	0.46	$\pm 1.5$
510nm ----	0.55	$\pm 1.5$
540nm ----	0.47	$\pm 1.5$
577nm ----	0.50	$\pm 1.5$
600nm ----	0.56	$\pm 1.5$
700nm ----	0.64	$\pm 1.5$

### PHOTOMETER LAMP VOLTAGE:

Set at 24.00V calibrated by DVM

### PHOTOMETER ALINGMENT:

Range: -3 to -9

Unrestricted

**ABS SYSTEM CHECK RESULTS:**

**RESULTS FROM INSTRUMENT**

	<u>OBSERVED</u>	<u>ACCEPTABLE RANGE</u>
Reagent 1:	Mean: 399.31 SD : 1.39	Mean: 392±12 SD : 3.80
Reagent 2 :	Mean: 393.31 SD : 2.53	Mean: 392±12 SD : 3.80
Sampler :	Mean: 40.66 SD : 0.13	Mean: 39.2±2 SD : 1.6

**TEMPERATURE CALIBRATION:**

Reagent : 6.8°C	Range: 2°C to 8°C
Cuvette : 37°C	Range : 37.1 +/- 0.2°C

The instrument is working satisfactorily, subsequent to Calibrations of the above parameters, and the Next Calibration is due on 09<sup>th</sup> September 2022.

**Note:** CHK kit is an USFDA approved kit used in performing the system check in all Dimension systems. The carton value is a predetermined values for which the limits are defined in system check screen and operator guide of Dimension.

**Siemens Healthineers**

*Chinmoy Hazarika*

**Chinmoy Hazarika**  
Field Service Engineer  
10.03.2022