GEN WORKS

A WIPRO GE HEALTHCARE INVESTED COMPANY

ANALYZER CALIBRATION CERTIFICATE

CALIBRATION PROTOCOL

The purpose of this calibration protocol is to define the qualifications and the acceptance standard in order to verify the normal operation and function of the AUTOChem Xpert auto chemistry analyzer in the laboratory. Trained knowledgeable personnel from GENWORKS Health Pvt. Ltd. along with the department personnel will perform and review analyzer calibration protocol as mentioned by the manufacturer. The satisfactorily outcome of this procedures assures that the system functions according to the parameters.

EQUIPMENT INFORMATION:-

Instrument Name	:	**AUTO CHEMISTRY ANALYZER**
Model/Type	:	AUTOChem XPert
Serial No	:	AE82K2KH01085YF
Installation Date	:	05-NOV-2023
Calibration Done On	:	07-NOV-2023
Next Calibration Due On	:	06-NOV-2024

Laboratory/Hospital Name	:	DIAGNOPATH LABS Plot no 4 & 41,Above Nobel pharmacy, 1st floor, beside HP petrol bunk,KR Nagar, New bowenpally .Secunderabad,TS-500011
Supported By	:	Genworks Health Pvt Ltd, Survey No 525/1 & 538/1, V.S Mani Nagar, Madhavaram, Chennai-600060

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CALIBRATION AND MAINTAINANCE PROCEDURES

MAINTAINANCE:

- Instrument was checked for cleanliness.
- Cuvettes were manually cleaned and performed wash cells (All) operation in maintenance.
- Wash unit working was checked whether it is dispensing and aspirating Xpert wash and water in the perfect sequence manually.
- Cleaned sample reagent and mixing probes manually with alcohol and then with distilled water also performed probe wash(Detergent) in the maintenance.
- Performed sample reagent and mixer probes horizontal and vertical movement.
- Air Purge was performed to remove any air bubbles present in the syringes.
- Instrument mechanism operation check was done and found instrument working in satisfied operation conditions.

CALIBRATION:

- Input supply and lamp voltage for the machine was found adequate using the multimeter.
- Cell blank values are measured in the maintenance screen and reports are attached.
- Cuvette temperature are readings are indicated in the Software
- Reagent compartments cooling temperature is indicated in LED display behind the machine.
- Detectors performance were checked by checking the temperature control voltage.
- All parameters Calibration and both level Quality control was done and results found satisfactory

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This is to certify that this Analyzer has been inspected and calibrated for following parameters

TEST PARAMETER	TARGET VALUE & RANGE	OBTAINED VALUE
INPUT VOLTAGE	230-240V AC	234V AC
CELL BLANK VAULE	20000- 60000 for all wavelengths	
Cuvette TEMP	37 degree +/- 0.3	37.1 degree
REAGENT COMPARTMENT COOLING CHECK	4 to 14 degrees centigrade	8.2 degree
TEMP CONTROL UNIT	24 +/- 0.2V	
6V LAMP SUPPLY	6 +/- 0.2V	
24V MAIN BOARD SUPPLY	24 +/- 0.3V	

The results are obtained as per specifications & tolerance ranges. Routine chemistry parameters precision study was carried out. The CV's obtained are in acceptable range (< 3.0% CV). Calibrations of routine tests were also done & the results of controls & samples found satisfactory.

Calibration Reports:-

The controls results are obtained as per specifications & tolerance ranges. Verified the calibration & controls results according to the specific limits and considered the satisfactory results herewith certificate that AUTOChem Xpert Analyzer operates correctly according to the instrument specifications.

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Calibration details of Standard used	: Multimeter
Make	: Fluke
Serial No	: **40640066WS**
Traceability Certificate	: HI Tech calibration Services
Certificate #	: HT\CC\201107-16\001 & CR\PCAL\51278
	Validity : 06-Nov-2024

Report Sign Off:

Calibration Done By: SHIVA

Designation: Application Specialist

Date & Sign:

GENWORKS HEALTH CARE PVT. LTD. CHENNAI

Note: Supportive date to be attached along with this certificate.

Traceability and Uncertainty Diacal Auto

Parameter	Traceability	Uncertainty
Albumin, BCG	ERM[1]-DA470	4.14 %
Alkaline Phosphatase, opt. DGKC	Molar extinction coefficient according to DGKC[3] recommendation	4.86 %
Alkaline Phosphatase, mod. IFCC	Molar extinction coefficient at 405 nm according to IFCC[2] recommendation	5.93 %
ALT (GPT), mod. IFCC with pyridoxal phosphate	Original formulation IFCC[2] (molar extinction coefficient 340 nm)	2.01 %
ALT (GPT), mod. IFCC without pyridoxal phosphate	Molar extinction coefficient 340 nm	1.74 %
AST (GOT), mod. IFCC with pyridoxal phosphate	Original formulation IFCC[2] (molar extinction coefficient 340 nm)	2.02 %
AST (GOT), mod. IFCC with pyridoxal phosphate	Molar extinction coefficient 340 nm	1.98 %
Alpha-Amylase, mod. IFCC (EPS-G7)	Original IFCC formulation IFCC[2] 2000 (Molar extinction coefficient 405 nm)	4.76 %
Alpha-Amylase, CNP-G3	Molar extinction coefficient 405 nm	4.83 %
Alpha-Amylase Pancreatic, ET-G7PNP	Molar extinction coefficient 405 nm	5.38 %
Bile Acids, enzymatic recycling	Primary Standard	1.29 %
Bilirubin Direct, DCA	Jendrassik-Grof (molar extinction coefficient 546 nm)	2.29 %
Bilirubin Direct, Jendrassik Grof	Molar extinction coefficient 546 nm	1.95 %
Bilirubin Total, DCA	SRM[4] 916	2.16 %
Bilirubin Total, Jendrassik Grof	Molar extinction coefficient 546 nm	1.87 %
Calcium, Arsenazo	Atomic Absorption Spectrometry (AAS)	1.21 %
Calcium, CPC	Atomic Absorption Spectrometry (AAS)	0.97 %
Cholinesterase, opt. DGKC	Original formulation DGKC[3] 1992 (molar extinction coefficient 405 nm)	6.62 %
Chloride, Mercuric Thiocyanate	Reference method Coulometry	1.28 %
Cholesterol, CHOD-PAP	GC-IDMS[5]	1.21 %
CK-NAC, opt. DGKC / IFCC	Original formulation IFCC[2] (molar extinction coefficient 340 nm)	3.53 %
CK-MB, opt. DGKC / IFCC	ERM[1]-AD455 / IFCC	6.55 %
Creatinine, enzymatic, PAP	GC-IDMS[5]	1.40 %
Creatinine, mod. Jaffé	GC-IDMS[5]	1.90 %
Creatinine, mod. Jaffé, with compensation	GC-IDMS[15]	2.12 %
Copper, 3,5-DiBrom-PAESA	Atomic Absorption Spectrometry (AAS)	3.03 %

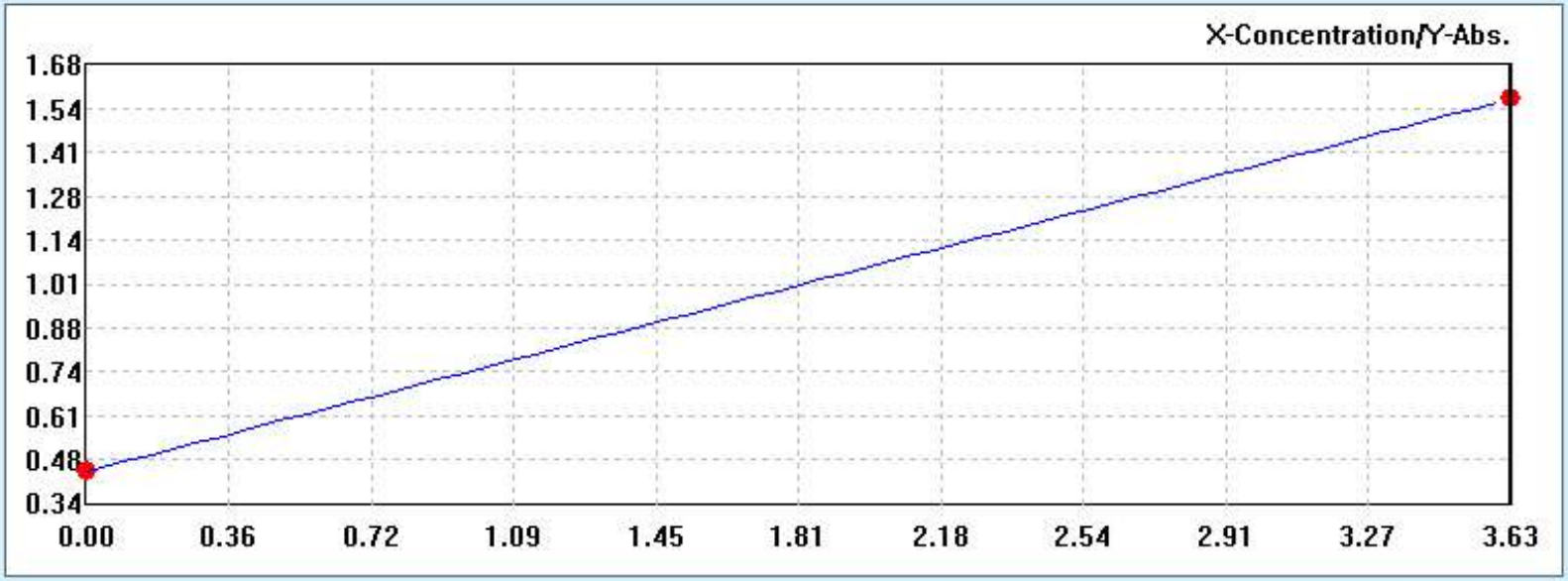
Gamma-GT, Szasz, stand. to IFCC	Original formulation IFCC[2] (molar extinction coefficient 405 nm)	1.56 %
GLDH, DGKC	Molar extinction coefficient according to DGKC[3] recommendation at 340 nm	10.80 %
Glucose, GOD-PAP	GC-IDMS[5]	0.95 %
Glucose, Hexokinase	GC-IDMS[5]	0.92 %
Alpha-HBDH, opt. DGKC	Molar extinction coefficient according to DGKC[3] recommendation at 340 nm	3.98 %
Beta-Hydroxybutyrate, enzymatic, NBT	Primary reference material R-(-)3-Hydroxybutyric acid > 99 %	3.03 %
Iron, Ferene	Titrisol $FeCl_3$ +/- 0.2 %; traceable to NIST[6]-SRM[4] 682[7] 3.74 %	3.74 %
Lactate, enzymatic, UV	Primary standard Lithium L-lactate, molar extinction coefficient 340 nm	5.24 %
LDH-L, mod. IFCC	Original formulation IFCC[2] (molar extinction coefficient 340 nm)	1.88 %
LDH-P, opt. DGKC	Molar extinction coefficient according to DGKC[3] recommendation at 340 nm	7.44 %
Lipase, enzymatic, colorimetric	Molar extinction coefficient according to Roche[8] procedure	2.93 %
Magnesium, Xylidyl blue	Atomic Absorption Spectrometry (AAS)	3.67 %
Phosphorus Inorganic, Molybdate	Phosphate standard solution Merck 1.19898.0500; traceable to NIST[6]-SRM[4] 723d	3.03 %
Total Protein, Biuret	Biuret method	1.00 %
Triglycerides, GPO-PAP	GC-IDMS[5]	1.60 %
Urea, Urease/GLDH	SRM[4] 909b Level 1	4.33 %
Urease, Urease/colorimetric	SRM[4] 909b Level 1	4.88 %
Uric Acid AOX, enzymatic, colorimetric	GC-IDMS[5]	1.06 %
Uric Acid TBHBA, enzymatic, colorimetric	GC-IDMS[5]	0.89 %
Zinc, 5-Br-PAPS	Mass spectroscopy	3.60 %

Glossary:

1 European Reference Material
2 International Federation of Clinical Chemistry
3 Deutsche Gesellschaft für Klinische Chemie (German Society for Clinical Chemistry and Laboratory Medicine)
4 Standard Reference Material
5 Gas-Chromatography-Isotope Dilution Spectrometry
6 National Institute of Standards and Technology; www.nist.gov/srm
7 The concentration of the reference material Titrisol $FeCl_2$ is verified by complexometric titration with Titriplex III. The molarity of the used Titriplex III solution is verified by complexometric titration with an Zinc solution. The Zinc solution is traceable on a Zinc primary titer substance. The primary titer substance is directly traceable to SRM 682 (High-Purity Zinc).
8 Roche Diagnosstics GmbH, Sandhofer Straße 116, D-68305 Mannheim/Germany; www.roche.com

Calibration Trace

No.	Test Name	Calibration Type	S1Abs.	K	A	B	C	Test Date	Calibration
7	ALB1	2 point linear	0.4701	3.2897	0.0000	0.0000	0.0000	12-02-2024 14:49:35	Diacal Au
8	ALB1	2 point linear	0.4612	3.2332	0.0000	0.0000	0.0000	28-01-2024 13:01:00	Diacal Au
9	ALB1	2 point linear	0.4596	3.0785	0.0000	0.0000	0.0000	23-01-2024 12:36:10	Diacal Au
10	ALB1	2 point linear	0.4500	3.1191	0.0000	0.0000	0.0000	02-01-2024 13:50:39	Diacal Au
11	ALB1	2 point linear	0.4483	3.3171	0.0000	0.0000	0.0000	07-12-2023 13:11:06	Diacal Au
12	ALB1	2 point linear	0.4322	3.1473	0.0000	0.0000	0.0000	17-11-2023 13:00:27	Diacal Au
13	ALB1	2 point linear	0.4444	3.2133	0.0000	0.0000	0.0000	07-11-2023 12:39:24	Diacal Au
14	ALB1	2 point linear	0.4507	3.3000	0.0000	0.0000	0.0000	04-11-2023 11:34:40	Diacal Au



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Concentration	0.0	3.6						
Abs.	0.4444	1.5772						

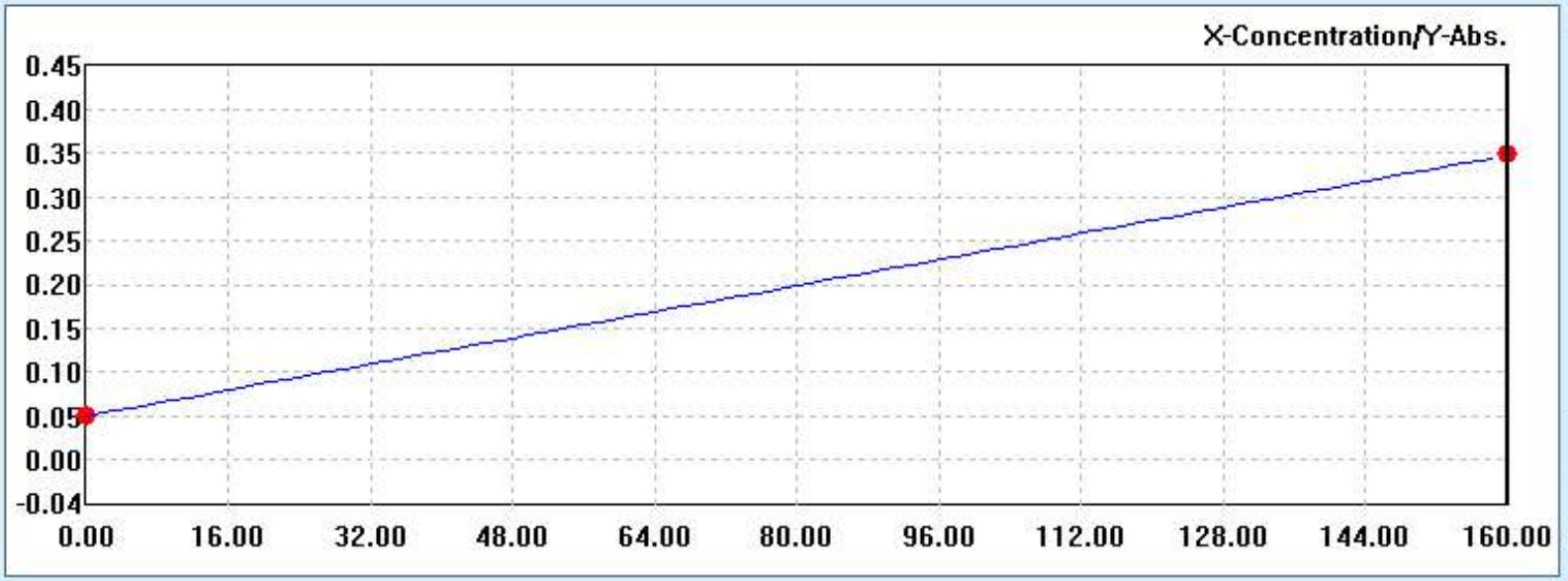
Apply Trace
Reaction Curve
Return

Max Delay :77.082 ms

Search

Calibration Trace

No.	Test Name	Calibration Type	S1Abs.	K	A	B	C	Test Date	Calibration
9	CHO1	2 point linear	0.0570	560.6363	0.0000	0.0000	0.0000	24-02-2024 12:24:47	Diacal Au
10	CHO1	2 point linear	0.0756	584.4740	0.0000	0.0000	0.0000	12-02-2024 14:49:59	Diacal Au
11	CHO1	2 point linear	0.0687	540.8431	0.0000	0.0000	0.0000	28-01-2024 13:01:24	Diacal Au
12	CHO1	2 point linear	0.0659	543.9789	0.0000	0.0000	0.0000	23-01-2024 12:36:34	Diacal Au
13	CHO1	2 point linear	0.0604	540.8433	0.0000	0.0000	0.0000	02-01-2024 13:51:03	Diacal Au
14	CHO1	2 point linear	0.0479	575.8240	0.0000	0.0000	0.0000	07-12-2023 13:11:30	Diacal Au
15	CHO1	2 point linear	0.0585	574.9199	0.0000	0.0000	0.0000	23-11-2023 12:15:00	Diacal Au
16	CHO1	2 point linear	0.0528	542.6299	0.0000	0.0000	0.0000	07-11-2023 12:39:48	Diacal Au



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0	160						
Abs.	0.0528	0.3476						

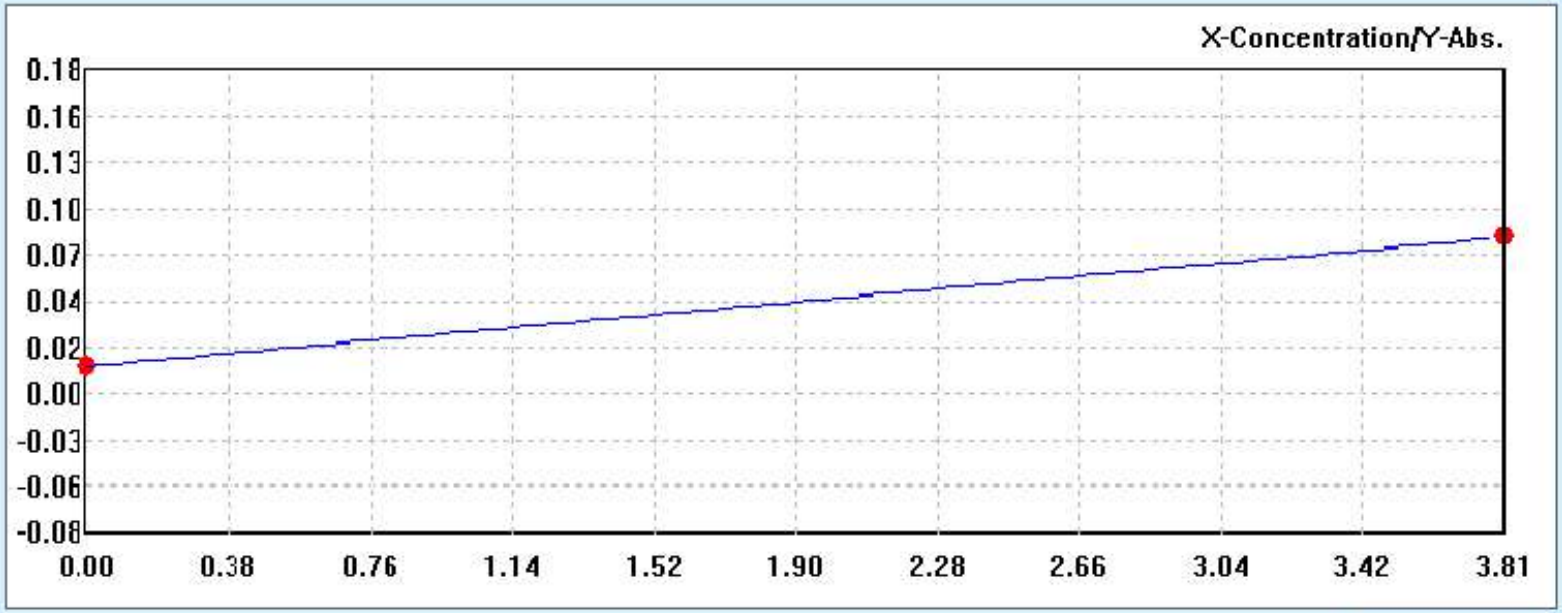
Apply Trace
Reaction Curve
Return

Max Delay :77.082 ms

Search

Calibration Trace

No.	Test Name	Calibration Type	S1Abs.	K	A	B	C	Test Date	Calibration
8	CREA-E2	2 point linear	0.0047	48.4062	0.0000	0.0000	0.0000	02-01-2024 13:52:39	
9	CREA-E2	2 point linear	0.0062	62.7024	0.0000	0.0000	0.0000	27-12-2023 12:18:46	
10	CREA-E2	2 point linear	0.0043	51.7598	0.0000	0.0000	0.0000	07-12-2023 13:13:06	
11	CREA-E2	2 point linear	0.0053	52.6184	0.0000	0.0000	0.0000	19-11-2023 13:36:51	
12	CREA-E2	2 point linear	0.0050	47.7532	0.0000	0.0000	0.0000	14-11-2023 12:30:22	
13	CREA-E2	2 point linear	0.0050	52.7379	0.0000	0.0000	0.0000	13-11-2023 17:07:58	
14	CREA-E2	2 point linear	0.0052	48.5554	0.0000	0.0000	0.0000	11-11-2023 13:06:46	
15	CREA-E2	2 point linear	0.0058	49.2961	0.0000	0.0000	0.0000	07-11-2023 12:41:48	



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.0	3.8						
Abs.	0.0058	0.0831						

Apply Trace
Reaction Curve
Return

Max Delay :77.082 ms

Search

Calibration Trace

No.	Test Name	Calibration Type	S1Abs.	K	A	B	C	Test Date	Calibration
16	GLU3	2 point linear	0.0280	363.3485	0.0000	0.0000	0.0000	27-12-2023 12:17:10	Diacal Au
17	GLU3	2 point linear	0.0186	327.2319	0.0000	0.0000	0.0000	14-12-2023 13:17:59	Diacal Au
18	GLU3	2 point linear	0.0189	225.9565	0.0000	0.0000	0.0000	12-12-2023 18:19:01	Diacal Au
19	GLU3	2 point linear	0.0293	300.0700	0.0000	0.0000	0.0000	07-12-2023 13:09:54	Diacal Au
20	GLU3	2 point linear	0.0310	294.9324	0.0000	0.0000	0.0000	28-11-2023 12:47:27	Diacal Au
21	GLU3	2 point linear	0.0222	282.4083	0.0000	0.0000	0.0000	26-11-2023 15:51:11	Diacal Au
22	GLU3	2 point linear	0.0210	274.1497	0.0000	0.0000	0.0000	07-11-2023 12:38:12	Diacal Au
23	GLU3	2 point linear	0.0134	292.5071	0.0000	0.0000	0.0000	06-11-2023 11:38:40	Diacal Au

Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0	189						
Abs.	0.0210	0.7104						

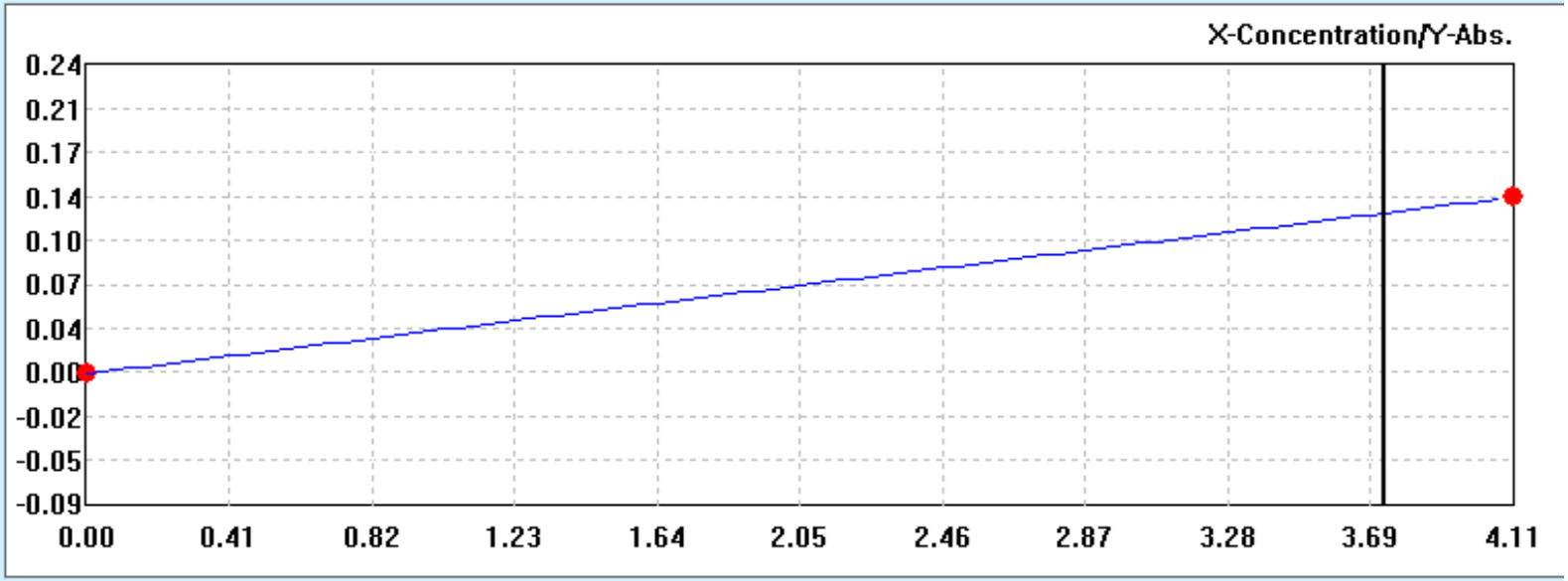
Apply Trace
Reaction Curve
Return

Max Delay :77.082 ms

Search

Calibration Trace

No.	Test Name	Calibration Type	S1Abs.	K	A	B	C	Test Date	Calibration
14	TBIL2	2 point linear	0.0059	31.3198	0.0000	0.0000	0.0000	12-02-2024 14:48:23	Diacal Au
15	TBIL2	2 point linear	0.0046	33.0022	0.0000	0.0000	0.0000	28-01-2024 12:59:25	Diacal Au
16	TBIL2	2 point linear	0.0048	30.0512	0.0000	0.0000	0.0000	23-01-2024 12:34:34	Diacal Au
17	TBIL2	2 point linear	0.0034	29.9332	0.0000	0.0000	0.0000	02-01-2024 13:49:27	Diacal Au
18	TBIL2	2 point linear	0.0037	31.3439	0.0000	0.0000	0.0000	30-12-2023 12:37:26	Diacal Au
19	TBIL2	2 point linear	0.0029	43.3926	0.0000	0.0000	0.0000	27-12-2023 12:16:46	Diacal Au
20	TBIL2	2 point linear	0.0042	31.2893	0.0000	0.0000	0.0000	07-12-2023 13:09:30	Diacal Au
21	TBIL2	2 point linear	0.0044	30.6128	0.0000	0.0000	0.0000	07-11-2023 12:37:48	Diacal Au

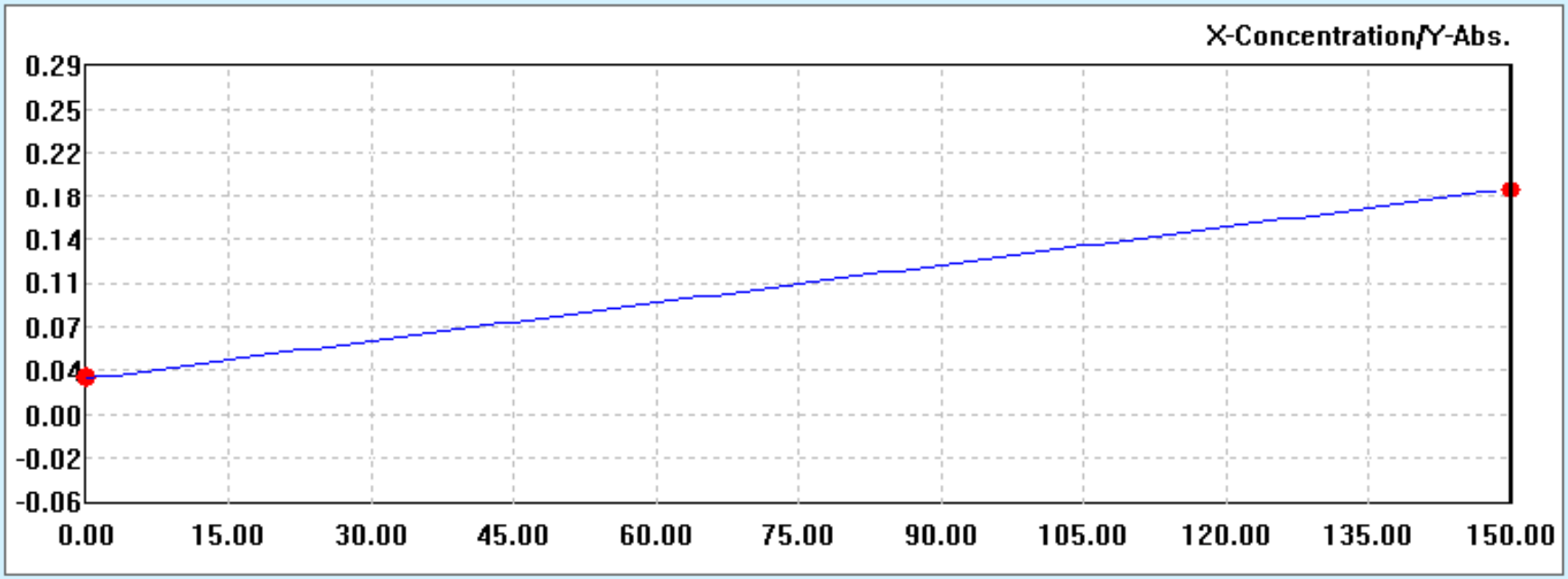


Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.0	4.1						
Abs.	0.0044	0.1386						

Apply Trace
Reaction Curve
Return

Calibration Trace

No.	Test Name	Calibration Type	S1Abs.	K	A	B	C	Test Date	Calibration
7	TGL-V	2 point linear	0.0416	962.1607	0.0000	0.0000	0.0000	02-01-2024 13:52:15	
8	TGL-V	2 point linear	0.0453	1349.10...	0.0000	0.0000	0.0000	29-12-2023 11:50:49	
9	TGL-V	2 point linear	0.0462	1374.27...	0.0000	0.0000	0.0000	27-12-2023 12:18:22	
10	TGL-V	2 point linear	0.0394	1095.07...	0.0000	0.0000	0.0000	07-12-2023 13:12:42	
11	TGL-V	2 point linear	0.0364	976.4202	0.0000	0.0000	0.0000	27-11-2023 12:52:33	
12	TGL-V	2 point linear	0.0375	954.5485	0.0000	0.0000	0.0000	14-11-2023 12:29:58	
13	TGL-V	2 point linear	0.0331	979.9978	0.0000	0.0000	0.0000	07-11-2023 12:41:24	
14	TGL-V	2 point linear	0.0276	990.1079	0.0000	0.0000	0.0000	29-10-2023 13:19:20	



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.00	150.00						
Abs.	0.0331	0.1862						

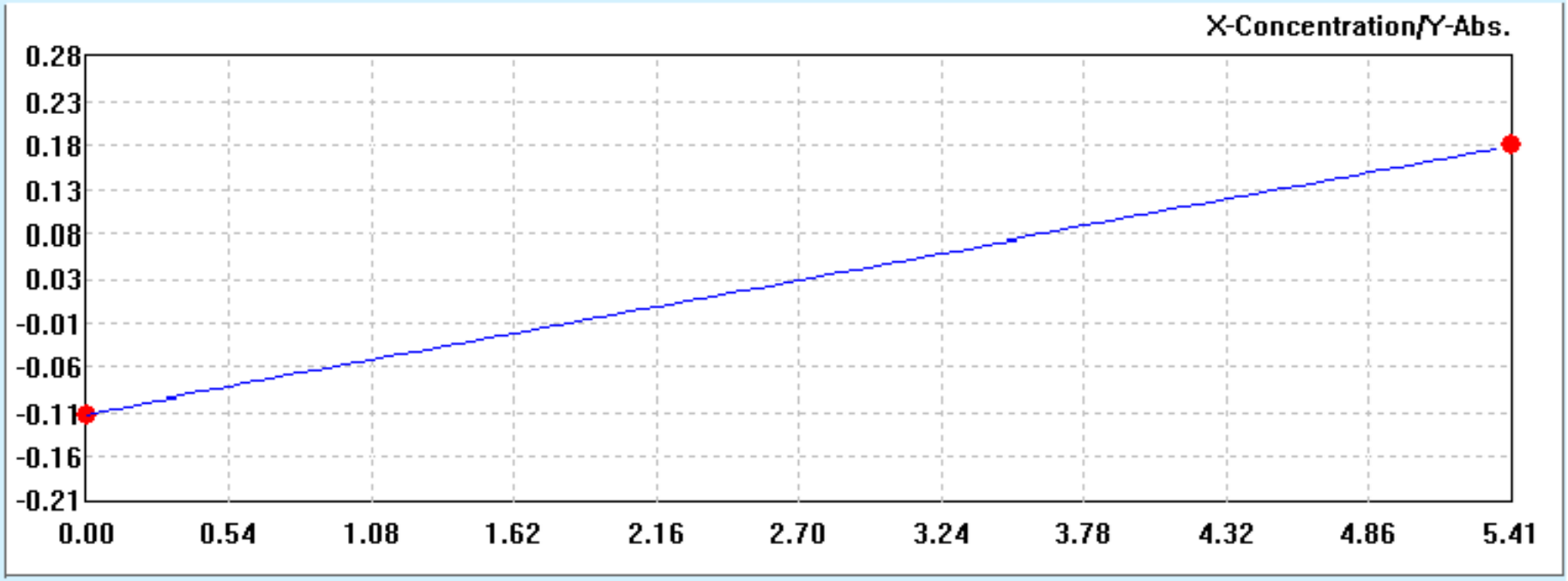
Apply Trace

Reaction Curve

Return

Calibration Trace

No.	Test Name	Calibration Type	S1Abs.	K	A	B	C	Test Date	Calibration
28	TPM1	2 point linear	-0.1258	19.2781	0.0000	0.0000	0.0000	23-11-2023 12:13:48	Diacal Au
29	TPM1	2 point linear	-0.1246	18.7253	0.0000	0.0000	0.0000	19-11-2023 13:35:15	Diacal Au
30	TPM1	2 point linear	-0.1220	16.1298	0.0000	0.0000	0.0000	17-11-2023 13:00:03	Diacal Au
31	TPM1	2 point linear	-0.1315	18.9479	0.0000	0.0000	0.0000	14-11-2023 13:26:26	Diacal Au
32	TPM1	2 point linear	-0.1276	17.8949	0.0000	0.0000	0.0000	11-11-2023 13:05:58	Diacal Au
33	TPM1	2 point linear	-0.1238	17.5503	0.0000	0.0000	0.0000	08-11-2023 11:55:30	Diacal Au
34	TPM1	2 point linear	-0.1249	17.8107	0.0000	0.0000	0.0000	07-11-2023 12:37:24	Diacal Au
35	TPM1	2 point linear	-0.1249	18.7007	0.0000	0.0000	0.0000	06-11-2023 11:38:16	Diacal Au



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.0	5.4						
Abs.	-0.1249	0.1788						

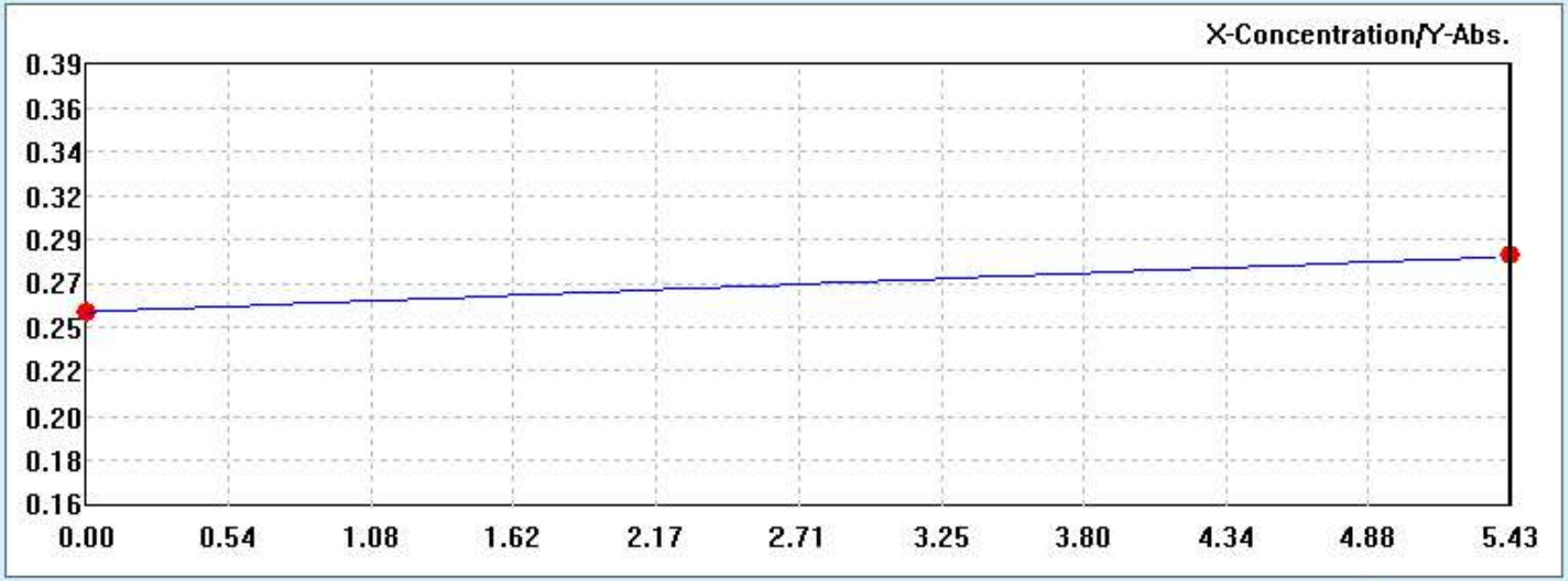
Apply Trace

Reaction Curve

Return

Calibration Trace

No.	Test Name	Calibration Type	S1Abs.	K	A	B	C	Test Date	Calibration
1	UA1	2 point linear	0.2884	4696.09...	0.0000	0.0000	0.0000	23-11-2023 12:15:24	
2	UA1	2 point linear	0.2627	427.9844	0.0000	0.0000	0.0000	19-11-2023 13:37:15	
3	UA1	2 point linear	0.2764	166.2171	0.0000	0.0000	0.0000	17-11-2023 13:00:51	
4	UA1	2 point linear	0.2778	240.5549	0.0000	0.0000	0.0000	14-11-2023 12:30:46	
5	UA1	2 point linear	0.2946	-725.2929	0.0000	0.0000	0.0000	08-11-2023 11:56:42	
6	UA1	2 point linear	0.2563	186.9438	0.0000	0.0000	0.0000	07-11-2023 12:42:36	
7	UA1	2 point linear	0.2536	181.6800	0.0000	0.0000	0.0000	06-11-2023 12:56:42	
8	UA1	2 point linear	0.2505	502.9033	0.0000	0.0000	0.0000	06-11-2023 11:40:40	



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.00	5.43						
Abs.	0.2563	0.2853						

Apply Trace

Reaction Curve

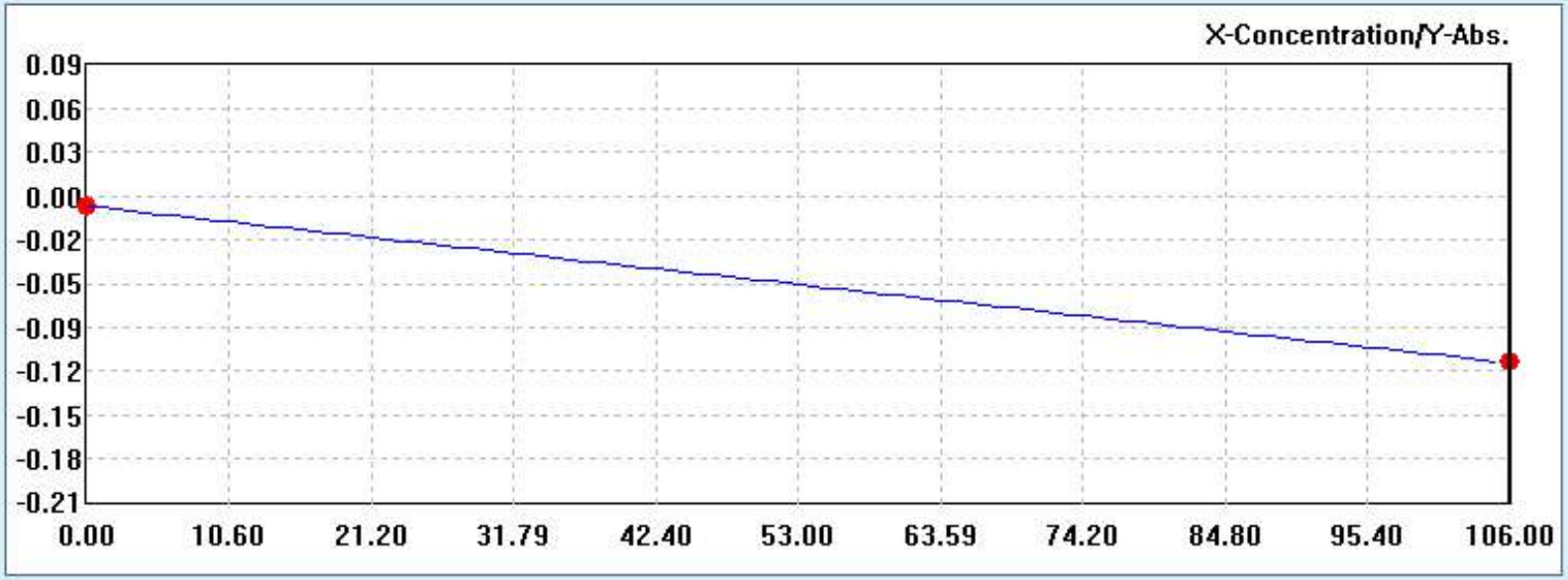
Return

Max Delay :77.082 ms

Search

Calibration Trace

No.	Test Name	Calibration Type	S1Abs.	K	A	B	C	Test Date	Calibration
19	UREA1	2 point linear	-0.0066	-1029.9...	0.0000	0.0000	0.0000	07-12-2023 13:12:18	Diacal Au
20	UREA1	2 point linear	-0.0072	-999.0457	0.0000	0.0000	0.0000	30-11-2023 16:18:36	Diacal Au
21	UREA1	2 point linear	-0.0083	-1477.6...	0.0000	0.0000	0.0000	23-11-2023 12:38:53	Diacal Au
22	UREA1	2 point linear	-0.0047	-2524.2...	0.0000	0.0000	0.0000	19-11-2023 13:36:27	Diacal Au
23	UREA1	2 point linear	-0.0031	-2485.6...	0.0000	0.0000	0.0000	14-11-2023 13:47:27	Diacal Au
24	UREA1	2 point linear	-0.0094	-1036.4...	0.0000	0.0000	0.0000	13-11-2023 17:07:34	Diacal Au
25	UREA1	2 point linear	-0.0096	-995.6788	0.0000	0.0000	0.0000	11-11-2023 13:06:22	Diacal Au
26	UREA1	2 point linear	-0.0089	-950.2328	0.0000	0.0000	0.0000	07-11-2023 12:41:00	Diacal Au



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0	106						
Abs.	-0.0089	-0.1205						

Apply Trace
Reaction Curve
Return

Max Delay :77.082 ms

Search