# 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 Dirui CS- T180 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 | : | **DIRUI CS-T180 AUTO CHEMISTRY ANALYZER** |
| Model/Type | : | CS T180 |
| Serial No | : | 210T180CS0163K |
| Installation Date | : | 21.09.2021 |
| Calibration Done On | : | 21.09.2021 |
| Next Calibration Due On | : | 20.09.2022 |
| Laboratory/Hospital | : | House of Pathology Pvt. Ltd.<br>L-113, L-Block, Lajpat Nagar<br>New Delhi-24 |
| Supported By | : | Genworks Health Pvt Ltd,<br>New Delhi |

## CALIBRATION AND MAINTENANCE PROCEDURES

**MAINTENANCE:**

- Instrument was checked for cleanliness.
- Cuvettes were manually cleaned and also performed rinsing cuvette operation in maintenance.
- Wash unit working was checked whether it is dispensing and aspirating alkaline detergent and water in the perfect sequence manually
- Cleaned sample reagent and mixing probes manually with alcohol and then with distilled water also performed sample probe rinsing in the maintenance.
- Performed sample reagent and mixer probes horizontal and vertical checkup.
- Auto effluent pipeline rinsing was performed using magnetic valve detergent.
- Syringe exhaust was performed to remove any air bubbles present in the syringes.
- Instrument mechanism operation check was done by 20 times and found instrument satisfied operation conditions.

**CALIBRATION:**

- Input supply and lamp voltage for the machine was found adequate using the multimeter.
- Lamp intensity and cuvette check values are measured in the maintenance screen and reports are attached
- Incubation temperature are readings are indicated in the SW
- Reagent compartments cooling temperature is indicated in LED display behind the machine.
- Detectors performance were checked with and without water.

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 | 231V AC |
| *LAMP INTENSITY CHECK* | 9000- 18000 for all wavelengths | 9500 to 15,000 |
| *CUVETTE CHECK* | <+/- 1500 for all wavelengths | within +/- 150 |
| *INCUBATOR TEMP* | 37 degree +/- 0.3 | 37 degree |
| *REAGENT COMPARTMENT COOLING CHECK* | 4 to 10 degrees centigrade | 5.1 degree |
| *DETECTOR PERFOMANCE CHECK* | Voltage b/w 3.5 to 4.5V | 3.7 to 4.2V |
| *12V LAMP SUPPLY* | 12 +/- 0.3V | 12.10V |
| *5V SUPPLY* | 5 +/- 0.3V | 5.01V |
| *24V SUPPLY* | 24 +/- 0.3V | 23.97V |

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.

**Report Sign Off:**

Calibration Done By : Niladri Shankar Paul
Designation : Sr. Circle Manager- North India
Date & Sign :7.2.2022

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

# Calibration Curve

Calibration Method: 2 Point Linear

Calibration Time: 21-09-2021 13:10:37

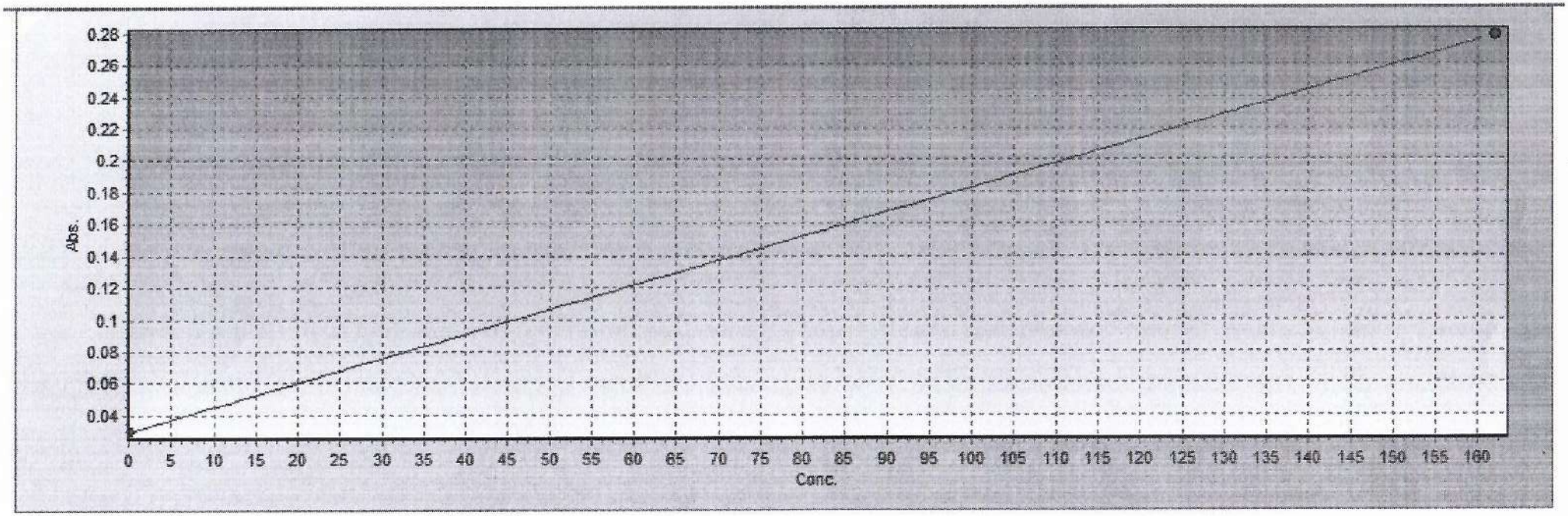
Test Item: TC

Absorbance: 0.02965

Calibrator: 1

| S1 Abs | K | A | B | C |
|---|---|---|---|---|
| 0.02965 | 652.568 | 0 | 0 | 0 |

| Calibration | Concentration | Abs. | Calibration | Concentration | Abs. |
|---|---|---|---|---|---|
| 1. | 0 | 0.0497 | 6. | 0 | 0 |
| 2. | 162 | 0.2905 | 7. | 0 | 0 |
| 3. | 0 | 0 | 8. | 0 | 0 |
| 4. | 0 | 0 | 9. | 0 | 0 |
| 5. | 0 | 0 | 10. | 0 | 0 |

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# Calibration Curve

Calibration Method: 2 Point Linear

Calibration Time: 21-11-2020 17:58:59

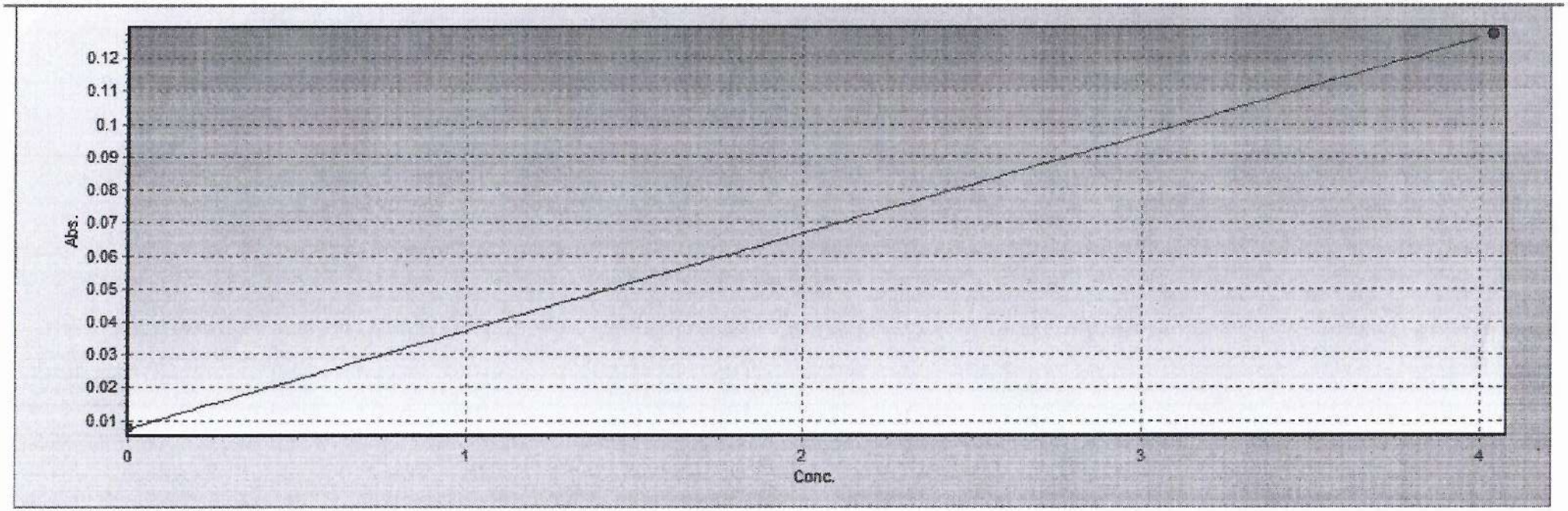
Test Item: TBIL

Absorbance: 0.0076

Calibrator: 1

| S1 Abs | K | A | B | C |
|---|---|---|---|---|
| 0.0076 | 36.9256 | 0 | 0 | 0 |

| Calibration | Concentration | Abs. | Calibration | Concentration | Abs. |
|---|---|---|---|---|---|
| 1. | 0 | 0.00555 | 6. | 0 | 0 |
| 2. | 4.04 | 0.1119 | 7. | 0 | 0 |
| 3. | 0 | 0 | 8. | 0 | 0 |
| 4. | 0 | 0 | 9. | 0 | 0 |
| 5. | 0 | 0 | 10. | 0 | 0 |

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# Calibration Curve

Calibration Method: 2 Point Linear

Calibration Time: 21-09-2021 13:05:17

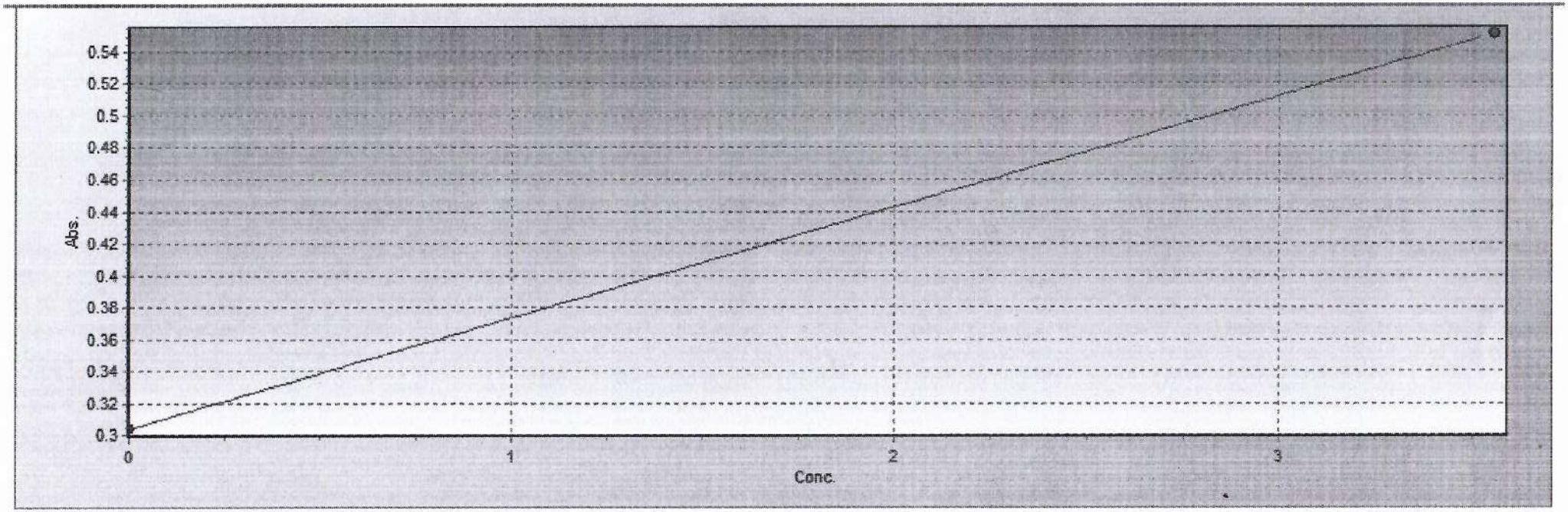
Test Item: ALB

Absorbance: 0.30405

Calibrator: 1

| S1 Abs | K | A | B | C |
|---|---|---|---|---|
| 0.30405 | 14.4188 | 0 | 0 | 0 |

| Calibration | Concentration | Abs. | Calibration | Concentration | Abs. |
|---|---|---|---|---|---|
| 1. | 0 | 0.29725 | 6. | 0 | 0 |
| 2. | 3.56 | 0.5447 | 7. | 0 | 0 |
| 3. | 0 | 0 | 8. | 0 | 0 |
| 4. | 0 | 0 | 9. | 0 | 0 |
| 5. | 0 | 0 | 10. | 0 | 0 |

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Print Time: 09-03-2022 13:48:57

# Calibration Curve

Calibration Method: 2 Point Linear

Calibration Time: 21-09-2021 13:06:37

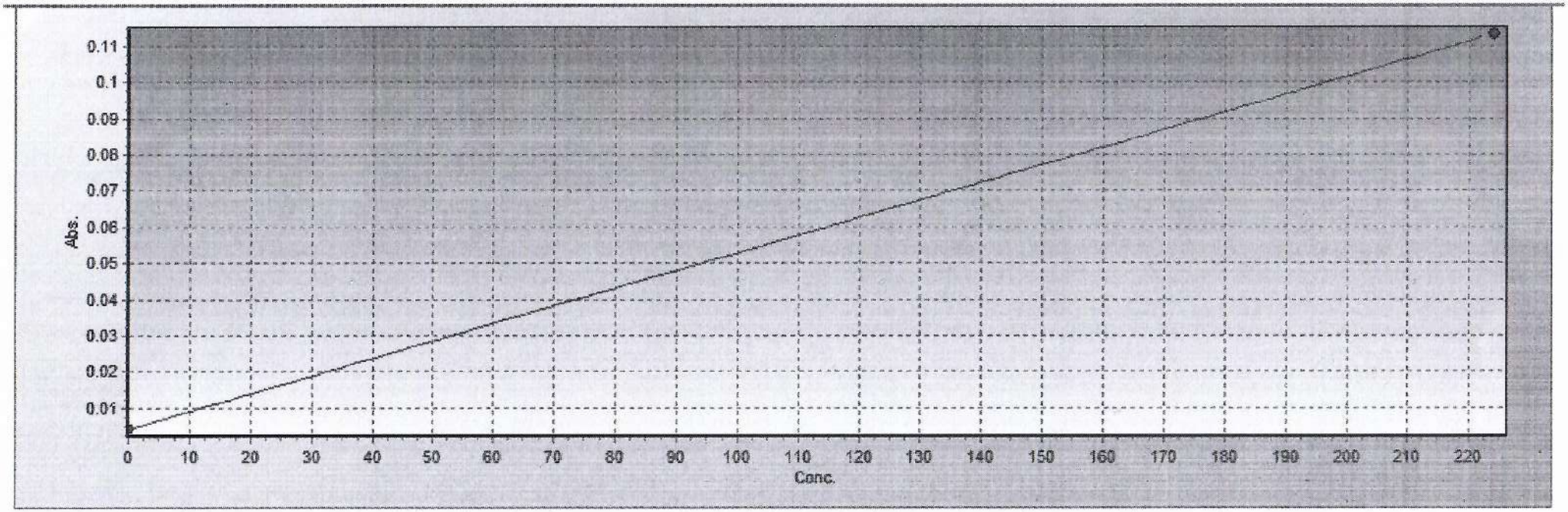
Test Item: ALP

Absorbance: 0.00405

Calibrator: 1

| S1 Abs | K | A | B | C |
|---|---|---|---|---|
| 0.00405 | 2049.4053 | 0 | 0 | 0 |

| Calibration | Concentration | Abs. | Calibration | Concentration | Abs. |
|---|---|---|---|---|---|
| 1. | 0 | 0.0037 | 6. | 0 | 0 |
| 2. | 224 | 0.0906 | 7. | 0 | 0 |
| 3. | 0 | 0 | 8. | 0 | 0 |
| 4. | 0 | 0 | 9. | 0 | 0 |
| 5. | 0 | 0 | 10. | 0 | 0 |

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Print Time: 09-03-2022 13:50:58

# Calibration Curve

Calibration Method: 2 Point Linear

Calibration Time: 25-09-2021 13:15:27

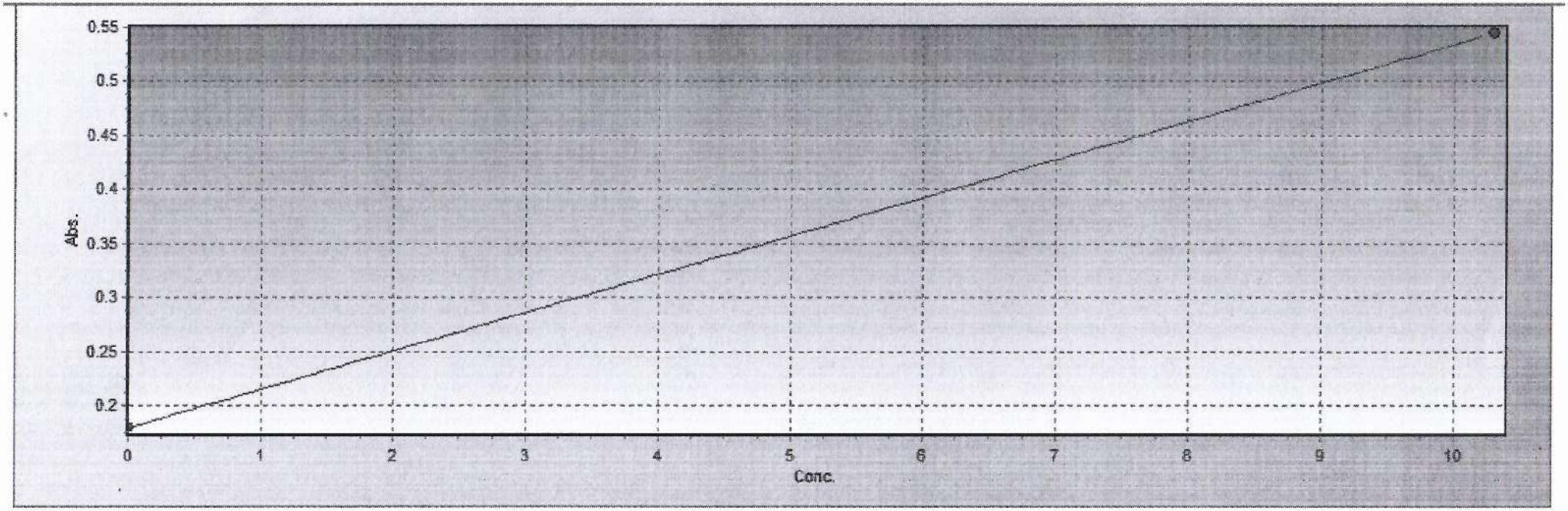
Test Item: Ca

Absorbance: 0.17995

Calibrator: 1

| S1 Abs | K | A | B | C |
|---|---|---|---|---|
| 0.17995 | 28.254 | 0 | 0 | 0 |

| Calibration | Concentration | Abs. | Calibration | Concentration | Abs. |
|---|---|---|---|---|---|
| 1. | 0 | 0.1679 | 6. | 0 | 0 |
| 2. | 10.3 | 0.5076 | 7. | 0 | 0 |
| 3. | 0 | 0 | 8. | 0 | 0 |
| 4. | 0 | 0 | 9. | 0 | 0 |
| 5. | 0 | 0 | 10. | 0 | 0 |

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Print Time: 09-03-2022 13:51:30

# Calibration Curve

Calibration Method: 2 Point Linear

Calibration Time: 20-09-2021 13:09:47

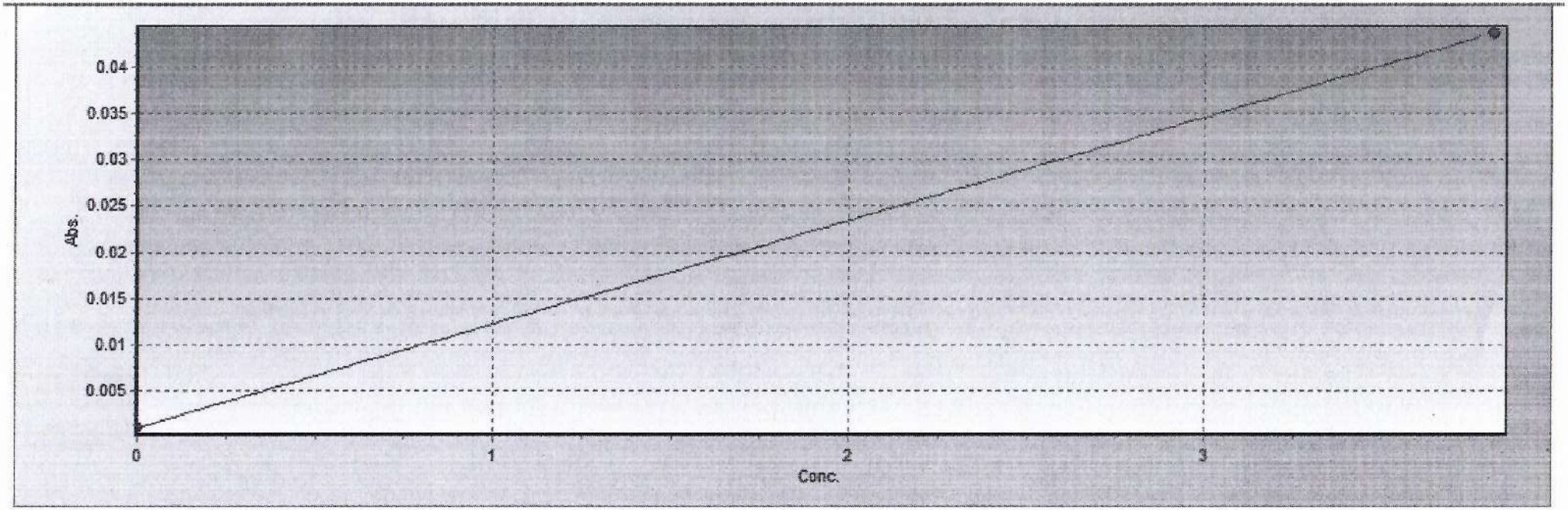
Test Item: CREA

Absorbance: 0.00105

Calibrator: 1

| S1 Abs | K | A | B | C |
|---|---|---|---|---|
| 0.00105 | 89.5417 | 0 | 0 | 0 |

| Calibration | Concentration | Abs. | Calibration | Concentration | Abs. |
|---|---|---|---|---|---|
| 1. | 0 | 0.00105 | 6. | 0 | 0 |
| 2. | 3.81 | 0.04405 | 7. | 0 | 0 |
| 3. | 0 | 0 | 8. | 0 | 0 |
| 4. | 0 | 0 | 9. | 0 | 0 |
| 5. | 0 | 0 | 10. | 0 | 0 |




Print By: 1

Print Time: 09-03-2022 13:52:17

# Calibration Curve

Calibration Method: 2 Point Linear

Calibration Time: 21-09-2021 13:07:57

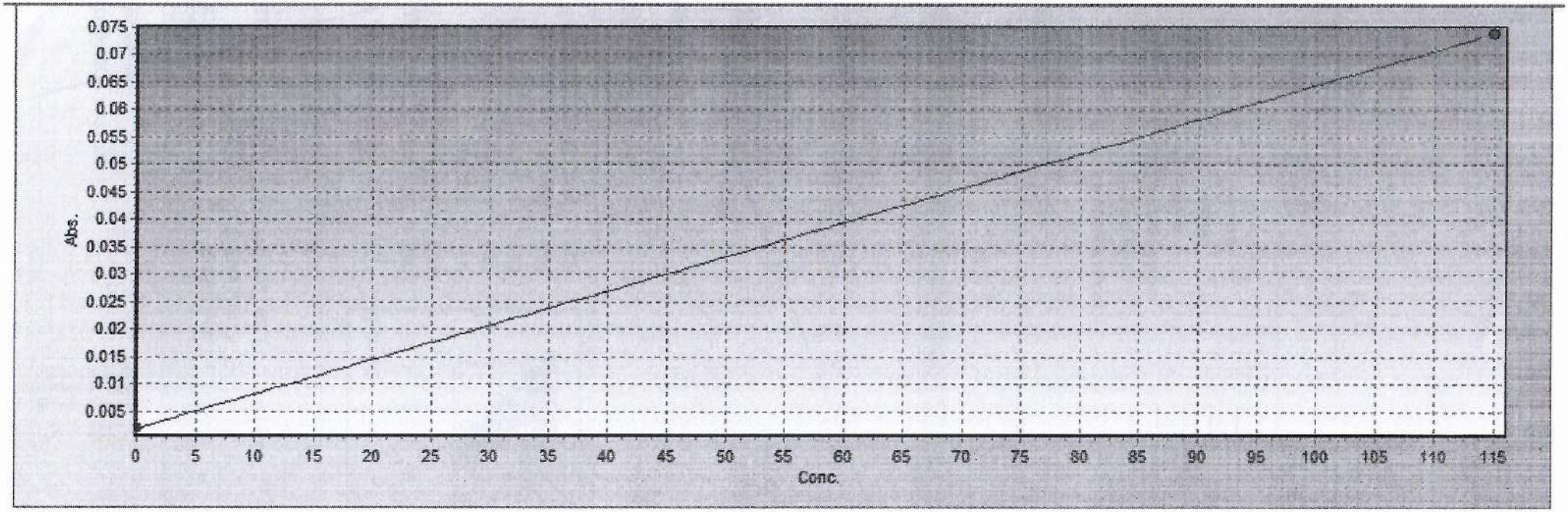
Test Item: GGT

Absorbance: 0.0019

Calibrator: 1

| S1 Abs | K | A | B | C |
|---|---|---|---|---|
| 0.0019 | 1598.3322 | 0 | 0 | 0 |

| Calibration | Concentration | Abs. | Calibration | Concentration | Abs. |
|---|---|---|---|---|---|
| 1. | 0 | 0.00175 | 6. | 0 | 0 |
| 2. | 115 | 0.0704 | 7. | 0 | 0 |
| 3. | 0 | 0 | 8. | 0 | 0 |
| 4. | 0 | 0 | 9. | 0 | 0 |
| 5. | 0 | 0 | 10. | 0 | 0 |

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Print Time: 09-03-2022 13:54:30

# Calibration Curve

Calibration Method: 2 Point Linear

Calibration Time: 14-01-2022 12:31:34

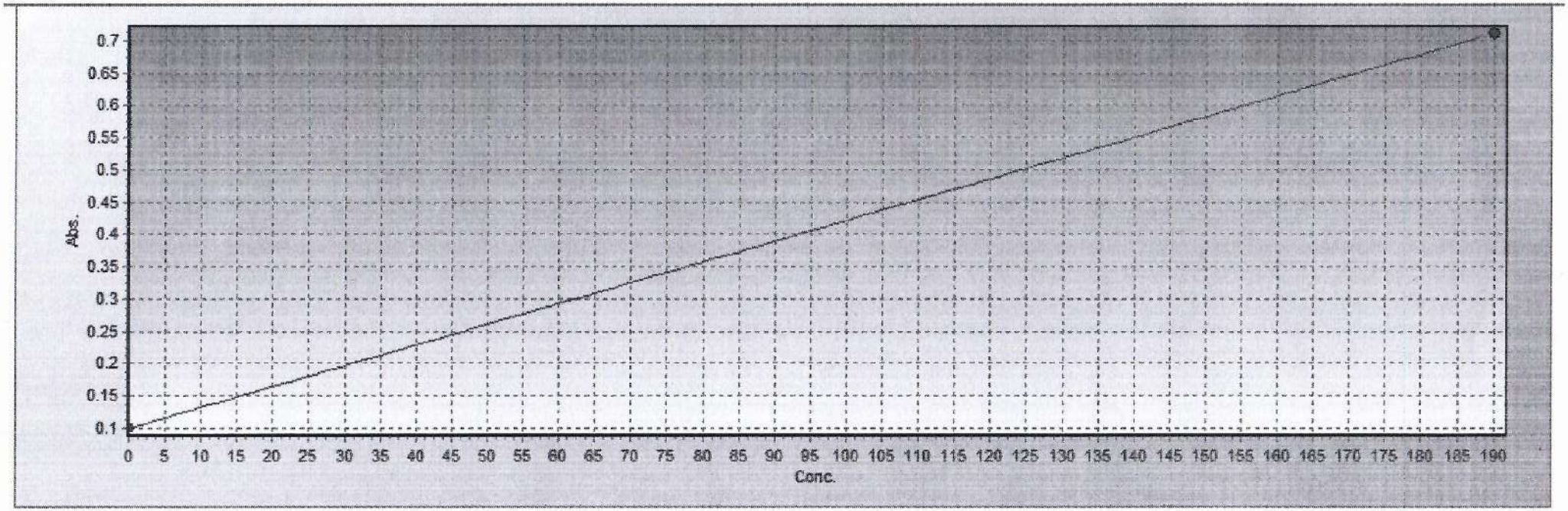
Test Item: GLU

Absorbance: 0.09975

Calibrator: 1

| S1 Abs | K | A | B | C |
|---|---|---|---|---|
| 0.09975 | 310.813 | 0 | 0 | 0 |

| Calibration | Concentration | Abs. | Calibration | Concentration | Abs. |
|---|---|---|---|---|---|
| 1. | 0 | 0.09975 | 6. | 0 | 0 |
| 2. | 190 | 0.71105 | 7. | 0 | 0 |
| 3. | 0 | 0 | 8. | 0 | 0 |
| 4. | 0 | 0 | 9. | 0 | 0 |
| 5. | 0 | 0 | 10. | 0 | 0 |

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Print Time: 09-03-2022 13:54:48

# Calibration Curve

Calibration Method: 2 Point Linear

Calibration Time: 20-09-2021 13:14:27

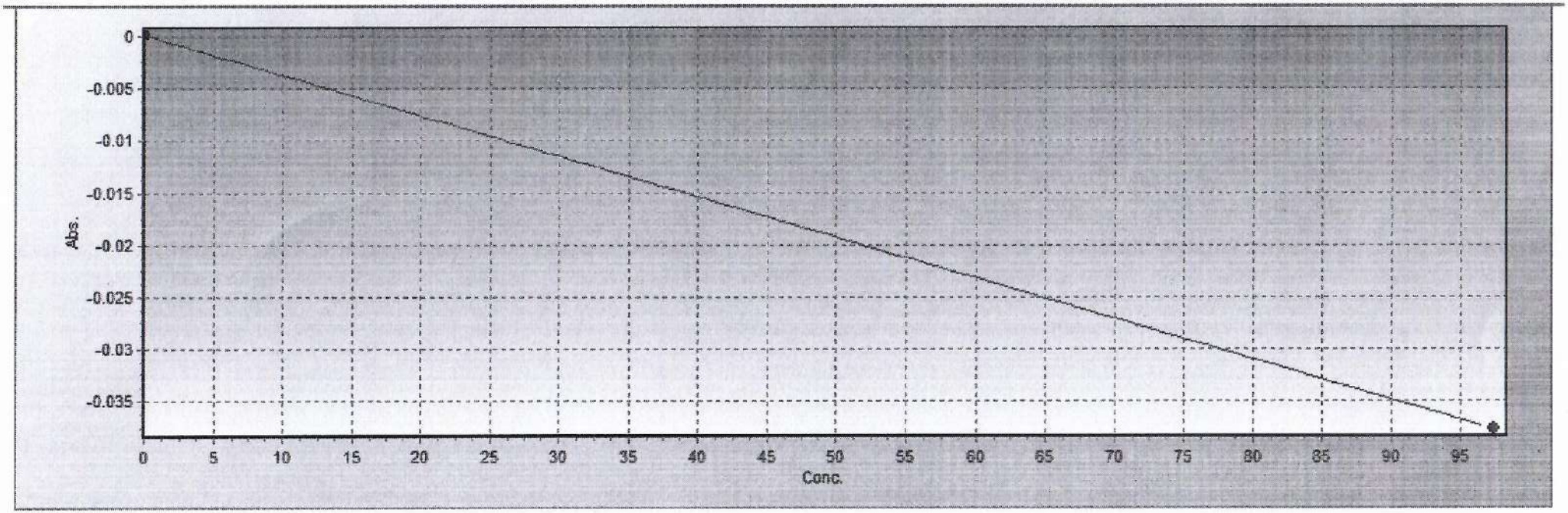
Test Item: SGPT

Absorbance: 0.00015

Calibrator: 1

| S1 Abs | K | A | B | C |
|---|---|---|---|---|
| 0.00015 | -2574.0741 | 0 | 0 | 0 |

| Calibration | Concentration | Abs. | Calibration | Concentration | Abs. |
|---|---|---|---|---|---|
| 1. | 0 | -0.0003 | 6. | 0 | 0 |
| 2. | 97.3 | -0.05435 | 7. | 0 | 0 |
| 3. | 0 | 0 | 8. | 0 | 0 |
| 4. | 0 | 0 | 9. | 0 | 0 |
| 5. | 0 | 0 | 10. | 0 | 0 |

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# DIRUI CS-T180 AUTO CHEMISTRY ANALYZER

## INSTALLATION QUALIFICATION PROTOCOL DOCUMENT

The purpose of this installation qualification protocol is to define the qualifications and the acceptance standard in order to verify that instrument installation, normal operation and function of the Dirui CS-180 auto chemistry analyzer in the laboratory. The satisfactorily outcome of this procedures assures that the system functions according to the parameters.

The results of these installation activities are the base for the subsequent Operational & Performance Qualification Protocol.

The customer has to check that all the controls are correct and will subscribe the validity and the acceptance date.

**Protocol Prepared By**

| | | |
|---|---|---|
| Designated Company Person Name | : | **Mohd Zafrullah** |
| Designation | : | **Application Manager** |
| Date | : | **21.09.2021** |

**Protocol Prepared For**

| | | |
|---|---|---|
| Customer / Contact Person Name | : | **Mr. Manzar Alam** |
| Hospital / Institution | : | **HOUSE OF PATHOLOGY LABS PVT. LTD.** |
| Address | : | **L-113 LAJPAT NAGAR PART-2,** |
| | | **NEW DELHI 110024** |

# INSTRUMENT INSTALLATION QUALIFICATION PROTOCOL

Dirui CS-T180 Auto-Chemistry Analyzer found to be the satisfactory installation condition at biochemistry department with comply the installation requirement based on the below described items.

| S. No | Installation Requirement Item | Description | Requirement Qualification | Remark |
|---|---|---|---|---|
| 1. | Power Supply | AC220V, 50Hz<br>Power: 2000VA<br>Circuit Breaker: 250V, 20A | Satisfactory | The department fully equipped with online UPS power supply |
| 2. | Grounding Condition | A good grounding condition | Satisfactory | Nil |
| 3. | Discharge Equipment | 5m within mainframe<br>Height: below 100mm,<br>Inner diameter: above 50mm | Satisfactory | Nil |
| 4. | Ground | The ground should be level up | Satisfactory | Nil |
| 5. | Temperature and Humidity | Temperature: 15 - 32°C<br>Humidity: 32 - 85%RH | Satisfactory | Nil |
| 6. | Air condition | Air condition | Satisfactory | AC |
| 7. | Dehumidifier | Dehumidifier | Satisfactory | Nil |
| 8. | Water Supply Equipment | Water supply: 2.5L/hour<br>Conductivity: below 1us/cm | Satisfactory | Nil |
| 9. | Water Supply Mode | DI water | Satisfactory | Purified water |
| 10. | Communication Interface | RJ-45 | Yes | Nil |

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**Equipment Information:-**

| | | |
|---|---|---|
| Equipment Name | : | **DiruiCS-T180 Auto Chemistry Analyzer** |
| Model/Type | : | **CS-T180** |
| Serial No | : | **210T180CS0163K** |
| Equipment Installed Location : | | **L-113 LAJAPAT NAGAR PART-2, NEW DELHI- 110024** |
| Installation date | : | **21.09.2021** |

**Installation Information:-**

Name of the Instrument :**Dirui CS-T180 Auto Chemistry Analyzer**

Physical Verification of the instrument before installation : Satisfactory

Description of the equipment along with the components : Computer, Keyboard& accessories.

Date of Installation :**21.09.2021**

Name of Engineer (S) :**Mr. Saurabh Kumar**

Installation conclusion:

Overall instrument installation requirements found to be satisfied, handed over the instrument for operation & performance qualification.

Installation Certificate: Enclosed

Engineer (S) Sign :

Date : **21.09.2021**

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Installation Protocol Remarks:

Action to be taken (if any) :

Designated Person Name: **Mohd Zafrullah** Laboratory Personal Name: **Mr. Manzar Alam**

Designation:**Application Manager** Designation: **Quality Manager**

Signature: Mzafrullah Signature: Manzar

Date: 21-09-2021 Date: 21/9/2021

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# DIRUI CS-T180 AUTO CHEMISTRY ANALYZER

## OPERATIONQUALIFICATION PROTOCOL DOCUMENT

The purpose of this operation qualification protocol is to define the qualifications and the acceptance standard in order to verify the normal operation and function of the Dirui CS-T180 auto chemistry analyzer in the laboratory. The satisfactorily outcome of this procedures assures that the system functions according to the parameters.

The results of that installation activity are the base for the subsequent of Operational Qualification Protocol.

The operational qualification protocol will verify the review of the start-up procedure, Operation processes, instrument routine maintenance, instrument safety handling in the laboratory.

The customer has to check that all the controls are correct and will subscribe the validity and the acceptance date.

**Protocol Prepared By**

| | | |
|---|---|---|
| Designated Company Person Name | : | **MOHD. ZAFRULLAH** |
| Designation | : | **APPLICATION MANAGER** |
| Date | : | **21.09.2021** |

**Protocol Prepared For**

| | | |
|---|---|---|
| Customer / Contact Person Name | : | **Mr. MANZAR ALAM** |
| Hospital / Institution | : | **HOUSE OF PATHOLOGY LABS PVT. LTD.** |
| Address | : | **L-113 LAJPAT NAGAR PART-2,** |
| | | **NEW DELHI- 110024** |

**Equipment Information:-**

| | | |
|---|---|---|
| Equipment Name | : | **Dirui CS-T180 Auto Chemistry Analyzer** |
| Model/Type | : | **CS-T180** |
| Serial No | : | **210T180CS0163K** |
| Equipment Installed Location | : | **Dept. of Biochemistry** |
| Installation date | : | **21.09.2021** |

# INSTRUMENT OPERATIONAL QUALIFICATION PROTOCOL

## 1. OPERATION QUALIFICATION PROCEDURES

Instrument Turn On and Turn off Procedures – To check the instrument normal start up processes while login & switch on the instrument. After turning on the analyzer it ensure the instrument startup "Rinsing Incubation Bath" processes & reaction disk temperature optimization.

Verified system "On-line" and "Off-line" communication link.

Verified software logon & logoff options between management to operation and vice versa.

Verified instrument "sleep" mode condition & complete "shutdown" and "startup" processes.

Place onboard "Alkaline Detergent" & "Antibacterial Phosphorous Free Detergent".

### 1.1 Preliminary Operation

| | |
|---|---|
| Carry out the maintenance procedures | : yes |
| Check the reaction disk temperature | : yes |
| Check the reagent disk temperature | : yes |
| Carry out light quantity checkup | : yes |

| | |
|---|---|
| Carry out cuvette blank test | : yes |
| If necessary, check the probes vertical & horizontal checkup | : yes |

**1.2 Parameter Setup**

| | |
|---|---|
| Routine parameter setting according to the reagent's instruction | : yes |
| Reagent inventory set up | : yes |
| Calibration parameter set up | : yes |
| QC parameter set up | : yes |

**1.3 Reagent Preparation and place reagent disk**

| | |
|---|---|
| Reagent preparation | : Done |
| Place the small (S), large (L) & medium (M) reagents bottle | : Use all the bottles |
| Check the inner & outer disk reagent positions | : yes |
| Scan the remaining reagent volume level check | : yes |

**1.4 Calibration & QC Materials Preparation**

| | |
|---|---|
| Calibration materials preparation according to the instruction | : yes |
| QC materials preparation according to the instruction | : yes |

**1.5 Calibration & QC Request**

| | |
|---|---|
| Place the normal saline, calibrator & controls solution with appropriate position | : yes |
| Run the calibration test for relevant parameters | : yes |
| Run the QC test for relevant the parameters | : yes |
| Repeat the calibration & QC if get any alert or alarm message | : Nil |

| | |
|---|---|
| Carry out cuvette blank test | : yes |
| If necessary, check the probes vertical & horizontal checkup | : yes |

**1.2 Parameter Setup**

| | |
|---|---|
| Routine parameter setting according to the reagent's instruction | : yes |
| Reagent inventory set up | : yes |
| Calibration parameter set up | : yes |
| QC parameter set up | : yes |

**1.3 Reagent Preparation and place reagent disk**

| | |
|---|---|
| Reagent preparation | : Done |
| Place the small (S), large (L) & medium (M) reagents bottle | : Use all the bottles |
| Check the inner & outer disk reagent positions | : yes |
| Scan the remaining reagent volume level check | : yes |

**1.4 Calibration & QC Materials Preparation**

| | |
|---|---|
| Calibration materials preparation according to the instruction | : yes |
| QC materials preparation according to the instruction | : yes |

**1.5 Calibration & QC Request**

| | |
|---|---|
| Place the normal saline, calibrator & controls solution with appropriate position | : yes |
| Run the calibration test for relevant parameters | : yes |
| Run the QC test for relevant the parameters | : yes |
| Repeat the calibration & QC if get any alert or alarm message | : Nil |

**1.6 Calibration & QC verification**

Check the calibration & control results : Done

**Conclusion:**

With the reference to the instrument operation procedures and studies carried out in the laboratory, the Dirui CS-T180 Auto Chemistry Analyzer meets all criteria outlined for respective protocol.

Operation Protocol Remarks:

Action to be taken (if any):

Designated Person Name: **MOHD. ZAFRULLAH** Laboratory Personal Name: **MANZAR ALAM**

Designation: **APPLICATION MANAGER** Designation: **QUALITY MANAGER**

Signature: Mzafrullah. Signature: Alam

Date: 21-09-2021 Date: 21/9/2021

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# DIRUI CS-T180 AUTO CHEMISTRY ANALYZER

## PERFORMANCE QUALIFICATION PROTOCOL DOCUMENT

The purpose of thisperformance qualificationprotocol is to define the qualifications and the acceptance standard in order to verify the normal operation and function of the DiruiCS-T180auto chemistry analyzer in the laboratory. The satisfactorily outcome of this procedures assures that the system functions according to the parameters.

The results of that installation qualification protocol and operation qualification protocol are the base for the subsequent Performance Qualification Protocol.

The performance qualification protocol will verify the instrument test results accuracy and precision by reviewing the calibration & controls results within the acceptance limits.

The customer has to check that all the controls are correct and will subscribe the validity and the acceptance date.

**Protocol Prepared By**

| | | |
|---|---|---|
| Designated Company Person Name | : | **MOHD. ZAFRULLAH** |
| Designation | : | **APPLICATION MANAGER** |
| Date | : | **21.09.2021** |

**Protocol Prepared For**

| | | |
|---|---|---|
| Customer / Contact Person Name | : | **Mr. MANZAR ALAM** |
| Hospital / Institution | : | **HOUSE OF PATHOLOGY LABS PVT. LTD.** |
| Address | : | **L-113 LAJPAT NAGAR PART-2,** |

**NEW DELHI-110024**

**Equipment Information:-**

| | | |
|---|---|---|
| Equipment Name | : | **Dirui CS-T180 Auto Chemistry Analyzer** |
| Model/Type | : | **CS-T180** |
| Serial No | : | **210T180CS0163K** |
| Equipment Installed Location | : | **Dept. of Biochemistry** |
| Installation date | : | **21.09.2021** |

## INSTRUMENT PERFORMANCE QUALIFICATION PROTOCOL

### 1. Performance Qualification Procedures

- Run Two controls (Lyphocheck L-1 and Lyphocheck L-2) material with appropriate normal level and high level at known concentration to check the test items accuracy.
- Comparison correlation with appropriate patient test result.

**Conclusion:**

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 Dirui CS-T180 Auto Chemistry Analyzer operates correctly according to the instrument specifications.

With the reference to the installation, operation& performance procedures and studies carried out in the laboratory, Dirui CS-T180 Auto Chemistry Analyzer meets all criteria outlined for respective protocol.

User operation & maintenance hands-on training was given to those respective technical personal in the laboratory according to the protocol.

Performance Protocol Remarks :

Action to be taken (if any) :

Designated Person Name: **MOHD. ZAFRULLAH** Laboratory Personal Name: **MANZAR ALAM**

Designation: **APPLICATION MANAGER** Designation: **QUALITY MANAGER**

Signature: _____ Signature: _____

Date: 21-09-2021 Date: 21/9/2021