AGAPPE

ADL/DO/SER/IOP/0060/21-22

# INSTALLATION QUALIFICATION

| | |
|---|---|
| **Name of the instrument** | **MISPA VIVA** |
| **Instrument Model** | **Semi Automated Analyzer** |
| **Serial Number** | **212030355476** |
| **Date of installation** | **12/Sep/2020** |

Installation of Semi Automated Analyzer 'Mispa Viva' at **New Green Lab & Biopsy Centre, 1/786, Bharathi Nagar 7th Street, Ramanathapuram** involves the following checks done by the authorized Agappe Personnel as per the installation requirements given in Mispa Viva operation manual (OM), the respective sections and page numbers are given below

| S No | Service | Section & Ref. page of OM | Status | Checked by |
|---|---|---|---|---|
| 1 | Installation requirements | Section 2.2 to 2.5<br>Page 11 to 13 | OK | Senthilkumar R |

**For Agappe Diagnostics Ltd.**

**Name** : Senthilkumar R

**Date** :

**Signature** :

AGAPPE DIAGNOSTICS LTD. DELHI

**Customer: New Green Lab & Biopsy Centre, Ramanathapuram**

**Name** : N. MURUGAPRASATH

**Date** :

**Signature:**

New Green Lab
& Biopsy Centre
1/786,7th Street,
Bharathi Nagar,
Ramanathapuram.

CELEBRATING 25 YEARS
SURGING INNOVATION SERVING MANKIND

AGAPPE

ADL/DO/SER/IOP/0060/21-22

# OPERATIONAL QUALIFICATION

## SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all the criteria outlined in the Operational Qualification protocol.

| S No | Service | Section & Ref. page of OM | Status | Checked by |
|---|---|---|---|---|
| 1 | Operational requirements | Section 3 to 4<br>Page 14 to 38 | OK | Senthilkumar R |

| S No | Protocol | Status | Performed by |
|---|---|---|---|
| 1 | System Initialization | OK | Senthilkumar R |
| 2 | Temperature check | OK | Senthilkumar R |
| 3 | Filter check | OK | Senthilkumar R |
| 4 | Aspiration tube check | OK | Senthilkumar R |
| 5 | Reproducibility of Test | OK | Senthilkumar R |
| 6 | Printer Test | OK | Senthilkumar R |
| 7 | System menu check | OK | Senthilkumar R |
| 8 | QC validation | OK | Senthilkumar R |

Data Sheets attached

THE SYSTEM IS READY TO USE

**AGAPPE DIAGNOSTICS LTD.**

**Authorized Signatory**

AGAPPE DIAGNOSTICS LTD. AGAPPE DELHI

**New Green Lab & Biopsy Centre, Ramanathapuram**

**Authorized Signatory**

**Name** : Senthilkumar R

**Designation** : Manager - Customer Service

**Date** :

**Name** : N. MURUGA PRASAT

**Designation** : LAB INCHARGE

**Date** :

New Green Lab & Biopsy Centre
1/786,7th Street,
Bharathi Nagar,
Ramanathapuram.

CELEBRATING 25 YEARS
SURGING INNOVATION SERVING MANKIND

AGAPPE

ADL/DO/SER/IOP/0060/21-22

# PERFORMANCE QUALIFICATION

## SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all the criteria outlined in the Performance Qualification protocol.

| S No | Protocol | Status | Performed by |
|---|---|---|---|
| 1 | Touch screen response | OK | Senthilkumar R |
| 2 | Sample repeatability | OK | Senthilkumar R |
| 3 | QC response | OK | Senthilkumar R |

Data Sheets attached

THE SYSTEM IS READY TO USE

**AGAPPE DIAGNOSTICS LTD.**

**Authorized Signatory**

**Name** : Senthilkumar R

**Designation** : Manager - Customer Service

**Date** :

**New Green Lab & Biopsy Centre, Ramanathapuram**

**Authorized Signatory**

**Name** : N. MURUGA PRASAD

**Designation** : LAB INCHARGE

**Date** :

New Green Lab
& Biopsy Centre
1/786,7th Street,
Bharathi Nagar,
Ramanathapuram.

## 2) INSTALLATION

### 2.1) Unpacking and Installation

Place the shipper containing the analyser in upright position and remove the BOPP tape. Carefully lift the analyser with the supporting cushion packing and place on clean table top. Do not use any sharp objects or gadgets to unpack the shipper as they can cause damage to the analyser inside.

After unpacking the shipping package, please verify the product does not have any damage from shipment and make sure all listed components are included.

Power supply cable, RS 232 cable, Waste Bottle, Waste tube, Touch pen, Paper roll, User manual, Installation report, Warranty Card, Dust Cover, Pipette 100-1000 µL & 5-50 µL & micropipette tips.

### 2.2) Installation Environment

- Mispa Viva should be installed in a clean environment and it should be placed on a flat table surface.
- Keep 200mm distance between the analyser and wall for the proper ventilation. For the long life of the analyser these temperature conditions should be followed and the site should not have direct sunlight. The recommended room temperature and humidity are

  a) Temperature: 15-35°C (operating) and 5-50°C (non-operating).

  b) Relative humidity: 20-80% (operating) and 0-90% (non-operating), without condensation.

  c) Altitude: Less than 2000m (operating)

### 2.3) Printer and paper installation

- Pull up the printer cover on the left top of the analyser.
- Place the paper roll in the indented area.
- Close the printer cover.

## 2.4) Power supply connection

Follow the steps.

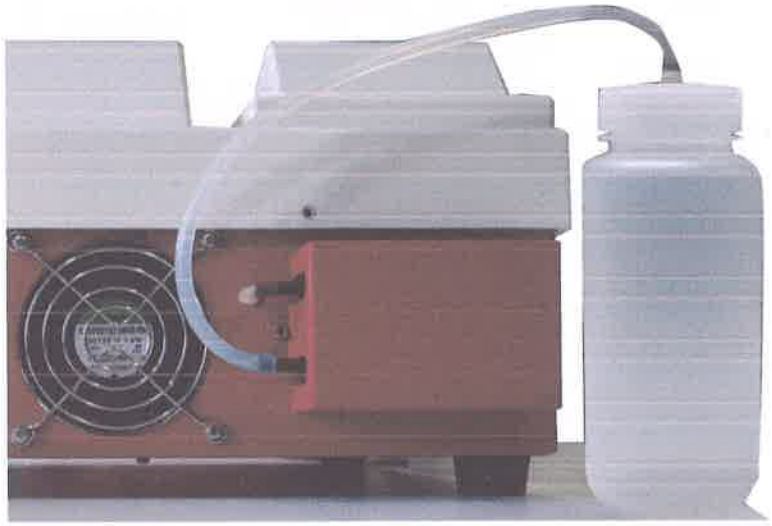
- **Before connecting the power cord, check the AC power supply corresponds to the value that is stated on the analyser label.**
- Make sure that your AC main line has an efficient ground line. Bad ground line connection may affect analysis result and damage the analyser.
- **Connect power cord to the port, at the rear panel of the analyser.**


**Caution**

- Connect the power plug to a good grounded AC wall outlet, preferably one that is not shared with other electric appliance and with low function of line voltage compared to the standard voltage specified (10-15%).
- Keep the analyser away from other appliances that generate high frequency electric noise (eg: radiological instrument).
- Before installing the analyser or connecting the power, make sure that the analyser is turned off.
- Make sure that your AC main line has an efficient ground line. Bad ground line connection may affect analysis result and damage the instrument.

## 2.5) Connecting waste bottle

- To avoid the spilling of waste water around the analyser, make sure that waste outlet tube is connected to waste bottle properly.



## 2.6) Test trial

⚠ **Do not operate the touch screen with sharp objects such as pin, pen tip, nails etc as they can cause scratches and damage on display screen**

- Turn "ON" the power switch, present at the back of the analyser.
- Analyser gets switched on. The analyser will perform the start-up function and display the main screen after successfully completing the start-up function.
- Perform wash function by selecting the wash function from main menu.
- Once the analyser stabilized, request to perform1-2 tests and evaluate the test results.
- Confirm that the analyser is working as per specifications.

## 3) BASIC OPERATING INSTRUCTIONS

### a) How to aspirate liquid

Dip aspiration tip inside the cuvette. Ensure that aspiration tube is completely immersed into reagent to avoid any air to be aspirated. Press the aspiration switch, which present at the front of the analyzer. The analyzer will aspirate correct amount of liquid as per the pre-programmed volume. Aspiration automatically stops after aspirating the programmed volume. The recommended minimal aspiration volume is 300 µL (0.3mL). In order to reduce the carryover and interference, the analyzer is programmed to have air gap between two aspirations.

### b) Instructions for the correct aspiration

- Prepare the reagent and sample in the disposable cuvettes based on the selected test.
- Dip aspiration tip inside the cuvette. Make sure that the aspiration tip-laying corner of the cuvette, for the complete aspiration of the set volume.
- Press the aspiration switch, so that sample will aspirate automatically and make sure that aspiration completed before removing the cuvette.

### c) Manual reading mode (Cuvette Mode)

- In case of cuvette mode, user need not have to wash the tubing.
- Set the cuvette function 'ON' in the setup function.
- Start the test /QC run process.
- Remove the flow cell and keep it in flow cell resting slot. Place cuvette in the measuring slot of the instrument with reagent then close the lid, when the analyzer gives the instruction "insert cuvette".
- Make sure that at least 1000 µL (1.0 mL) reaction volume [reagent volume + sample volume] are taken in the cuvette and also ensure to position the cuvette correctly {the optical surface of the cuvette should be horizontal to light path}.

**If the cuvette function turned ON, make sure that cuvette inserted in the slot before starting the test.**

### d) Reset and Turn off

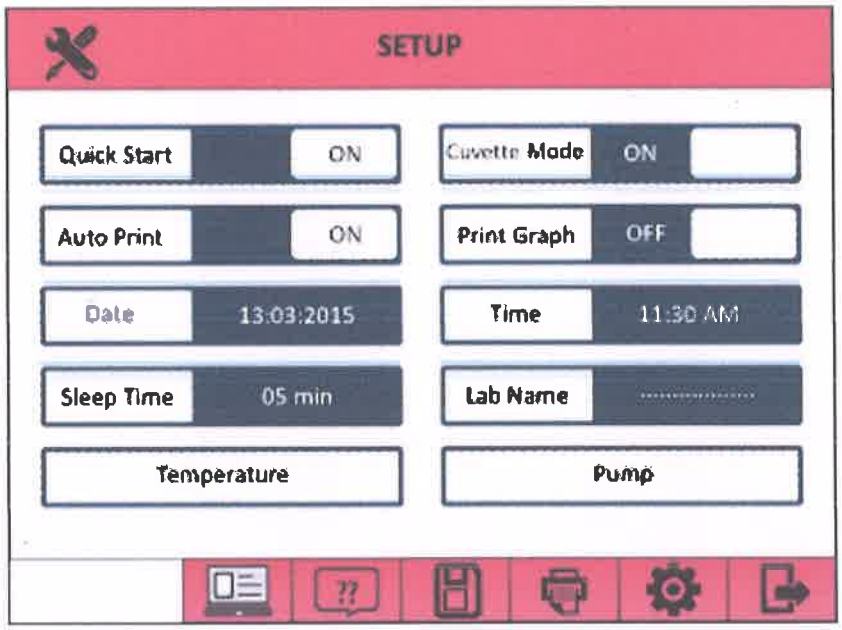
- To reset the analyzer by turning off the main power switch at the back of analyzer.
- Wait for 10 sec.
- Turn "ON" the power switch.

**e) Automatic lamp and display sleep function**

- Lamp and LCD sleeping function enabled to increase the life time of lamp and to save the power.
- User can set the sleeping time based on their needs, using setup function.

**f) Operation through PC**

- Turn on the analyzer .
- Connect serial port to com 1.
- Select PC connectivity icon in the setup menu of the analyzer.
- Press "connect" button in the PC software, connectivity will be established.
- Follow the procedure same as analyzer.




**g) Operation through External Keyboard**

- Turn on the analyzer.
- Connect external keyboard PS2 port of the analyzer.
- Make use of the mentioned keys for different functions.
- Use up, down, left and right keys for the navigation.

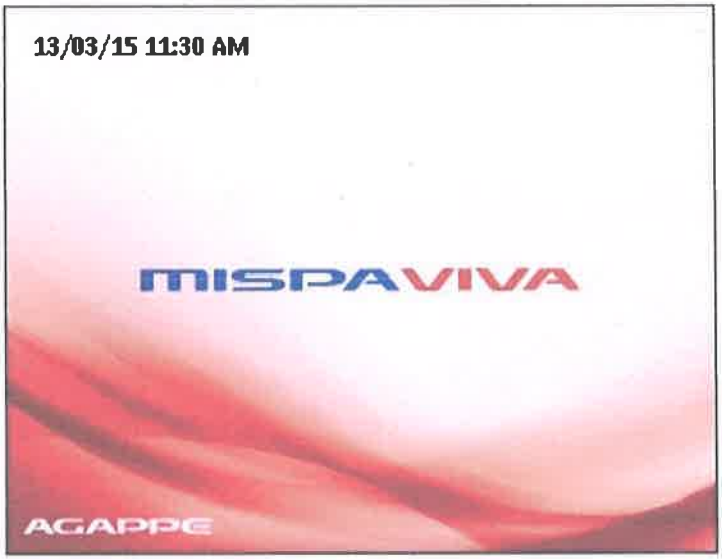
- Use  key to accept the functions.

- Use  key to exit the function.
- Make use of numeric, alpha numeric "+" " -" "/"and " ." keys for the data entry.

## 4) ANALYZER SETTINGS AND FUNCTIONS

### 4.1) Start-up

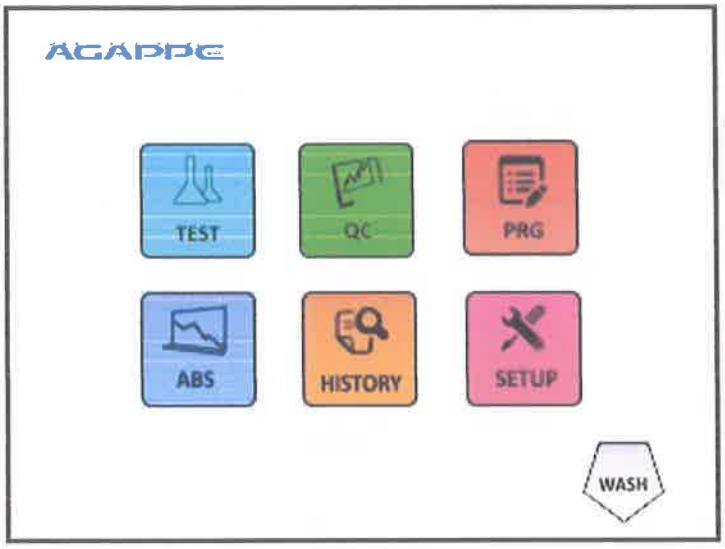
- Turn "ON" the power switch located behind the analyzer.
- Analyzer will start the initialization process and "welcome screen" gets displayed with analyzer name, Agappe Diagnostic's company logo along with date and time.




- Temperature stabilization will start after the power on. And it will displays the main menu.

### 4.2) Main menu

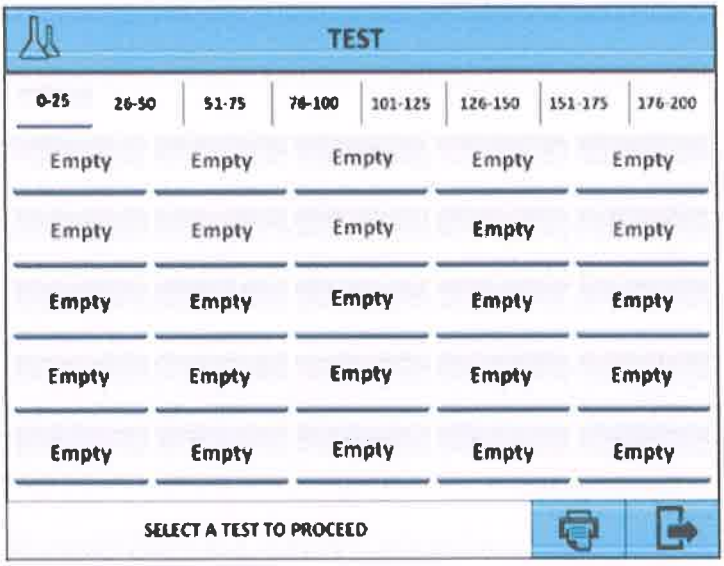
Mispa viva designed with seven functions -TEST, QC (Quality Control), PRG (Program), ABS (Absorbance), HISTORY, SETUP, and WASH. Every functional key is linked to the different functions of the analyzer.



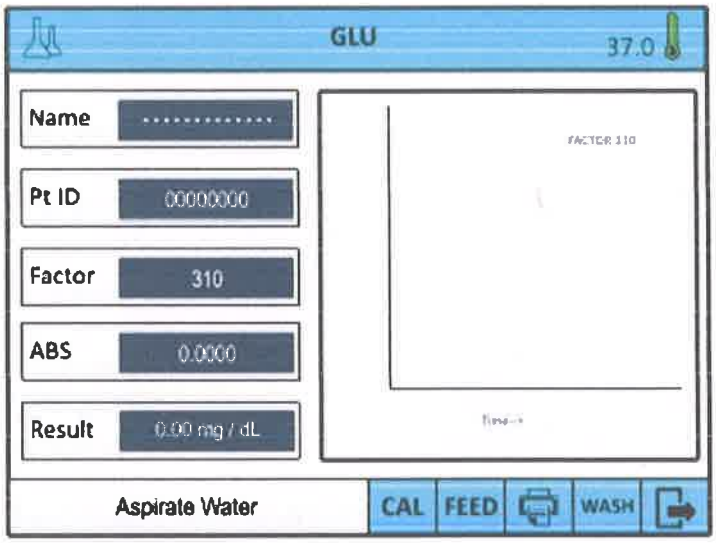

## 4.3) Test Function

Mispa Viva is a semi-automated analyzer, designed for the estimation of clinical chemistry and immunochemistry assay using kinetic, fixed time and end point methods.

- Select test function from the main menu.
- All 200-test names will be displayed in 8 screens of 25 tests per screen.
- Select print button to print the saved test names and its assigned number.
- Select particular test to run the process (The analyzer supplied with pre-programmed test names or the user can write their own test names using program menu [see 4.4])
- Select exit button to exit in to main menu.




- Select any test name from the list to proceed in to test run process.
- Analyser will load and display the selected test run screen. (as below)




- Selected test name will display on the information bar along with current temperature status.
- It has three different temperature conditions, Green color indicates the stable temperature condition, Red color indicates unstable temperature condition and orange color indicates analyser is obtaining stable temperature. Therefore, user can review the analyzer temperature before starting test run process.
- User need to enter Patient name (if required) and Pt ID (mandatory) before aspirating the sample. Otherwise, analyzer will increment the Pt ID based on the analyzer setup.
- Analyzer display's factor and reagent blank if any.
- Analyzer will prompt for the water aspiration, take a test tube containing minimum 1.0 mL or above DI Water, dip the aspiration probe into the tube. Then press aspiration switch to aspirate water.
- If analyzer temperature is not stable, then user will get the warning message along with selection "Wait for temperature stabilization", select "yes" for temperature stabilization or select "no "and continue.
- If there is no saved reagent blanks in the analyzer, message will pop up "No saved reagent blank", and it will prompt for the aspiration of reagent. Take a test tube containing minimum 1.0 mL test reagent, press the aspiration switch.
- If pre-set factor is not programmed, then "no saved factor" will be displayed on the graph and it will directly prompt for standard aspiration based on the program.

- Aspirate standard (tube containing reagent and standard) by dipping the aspiration probe into the standard tube and pressing aspiration switch.
- Analyzer will automatically perform the calibration and will display the message "do you want to save the factor/curve".
- Select "Yes" to save the factor/curve or select "No" then analyzer gives next selection message "Do you want to rerun" select "Yes" to rerun or select "No" and go with existing factor.
- Analyzer prompts for sample aspiration.
- Aspirate sample (tube containing reagent and clinical sample) analyzer will display the calibrated factor, absorbance result of the sample and real time graph will be plotted.
- Aspirate the next sample tube.
- Continue aspirating samples one after another until all the samples are measured.
- Select wash button to do the wash function.
- User can do the recalibration by selecting calibration function.
- Select "exit" to exit in to test name screen or select "home" go to the main screen.

**4. A) Kinetic**

- Perform the Kinetic assay for the sample using the reagent procedure as per instructions detailed in respective product insert supplied by reagent manufacturer.
- Analyzer will prompt for the water blank aspiration.
- Aspirate the water blank by taking minimum 1.0 mL of DI water in a test tube, dip the aspiration probe into the tube and pressing aspiration switch.
- If the ABS is out of range, analyzer will display the message "Low light" select "Ok" button. So analyzer will prompt for the same process.
- In case of kinetic with reagent blank, analyzer will display saved reagent blank value if any.

- If there is no saved reagent blank, it will show the message "no reagent blank" on the graph and it will prompt for the new reagent blank. In such instances, aspirate the reagent by pressing aspiration switch.
- Analyzer will display the ABS value.

**If Number of standard> or =1**

- Analyser prompts for the standard aspiration. Aspirate standard (tube containing reagent and standard) by dipping the aspiration probe into the standard tube and pressing Aspiration switch
- Analyser will measure the absorbance and display the STD ABS value along with the graph.

**If Number of standard=0**

- Analyzer will make use of the programmed factor.
- Analyzer will prompt for the sample aspiration.
- Aspirate sample (tube containing reagent and clinical sample) ensuring that aspiration probe is dipped into the sample tube and press aspiration switch for each aspiration.
- Aspirate sample tubes one after another.
- Analyzer will display and print the calculated result along with relevant flags for each sample.

**4. B) Fixed Time**

- Perform the fixed time assay for the sample using the reagent procedure as per instructions detailed in respective product insert supplied by reagent manufacturer.
- Select the Test function
- Analyzer will display the message "Aspirate water"
- Aspirate the water blank by taking minimum 1.0 mL of DI water in a test tube and pressing aspiration switch.

**In Case of reagent blank:**

After the aspiration, analyzer will display the saved reagent blank value if any along with selection box.

- Select "No" to use existing value or select "Yes" and aspirate the reagent.
- Analyzer displays old and new reagent blank value.
- Select "Yes" switch to save the new value
- If "No" switch selected, analyser will display the selection box, if user wants to rerun select "Yes" and do the process or Select "No" and go with old reagent blank value.

**If Number of standard >/= 1**

- Analyzer will prompt for standard aspiration. Aspirate standard (tube containing reagent and standard) by dipping the aspiration probe into the standard tube and pressing Aspiration switch
- Analyzer will measure absorbance of the sample and plot the real time graph of reaction.
- If the standard is more than one, continue the same procedure as detailed above.
- Analyzer will display the calculated factor along with selection box.
- Select "Yes" to save new factor.
- Or select "No" so analyzer will prompt for the STD rerun process
- Select "Yes" to rerun and do the same process.
- Or select "No" and go with existing factor.

**If Number of standard =0**

- Analyzer will make use of the saved factor.
- Analyzer will prompt for sample aspiration.
- Aspirate sample (tube containing reagent and clinical sample) ensuring that aspiration probe is dipped into the sample tube and press aspiration switch for each aspiration.

- Aspirate sample tubes one after another.
- Analyzer will display and print the calculated results with relevant flags for each sample.

**4. C) End Point**

- Perform the Endpoint assay for the sample using the reagent procedure as per instructions detailed in respective product insert supplied by reagent manufacturer.
- Select Test function
- Aspirate the water blank by taking minimum 1.0 mL of DI water in a test tube. Dip the aspiration probe into the tube and press aspiration switch.
- If the ABS is out of range, analyzer again prompts for the water aspiration.
- Continue the same process as above.

**In case of reagent blank**

- Analyzer will display the saved reagent blank if any and will prompt for new reagent blank.
- Select "No" to go with saved reagent blank or select "Yes".
- Analyzer will prompt for the "aspirate reagent blank"
- Aspirate the reagent by dipping the aspiration probe into the tube containing only reagent by pressing aspiration switch.
- Analyzer will display old reagent blank and along with new reagent blank
- Analyzer will display "do you want to save the reagent"
- Select "Yes" to save the new reagent blank or select "No"
- Analyzer will prompt for the rerun, select "Yes" to rerun and proceed the same or select "No", and go with old reagent blank.

**If Number of standard>/ =1**

- Analyzer will prompt for the STD aspiration.

- Aspirate standard (tube containing reagent and standard) by dipping the aspiration probe into the standard tube and pressing aspiration switch
- If the STD repeat is more than one, Analyzer will prompt for STD aspiration.
- Aspirate the standard again by pressing the aspiration switch and do the same process with same STD.
- If there is, more than one standard analyzer will prompt for the next STD aspiration after finishing standard repeat.
- Aspirate each standard as above until all standards are aspirated.
- After finishing all STD and repeats, analyzer will display the calculated factor along with the message "Do you want to save new factor"
- Select "yes" to save new factor. Or select "No".
- Analyzer will prompt for rerun. Select "Yes" to rerun and do the same process or select "No" and go with saved factor.

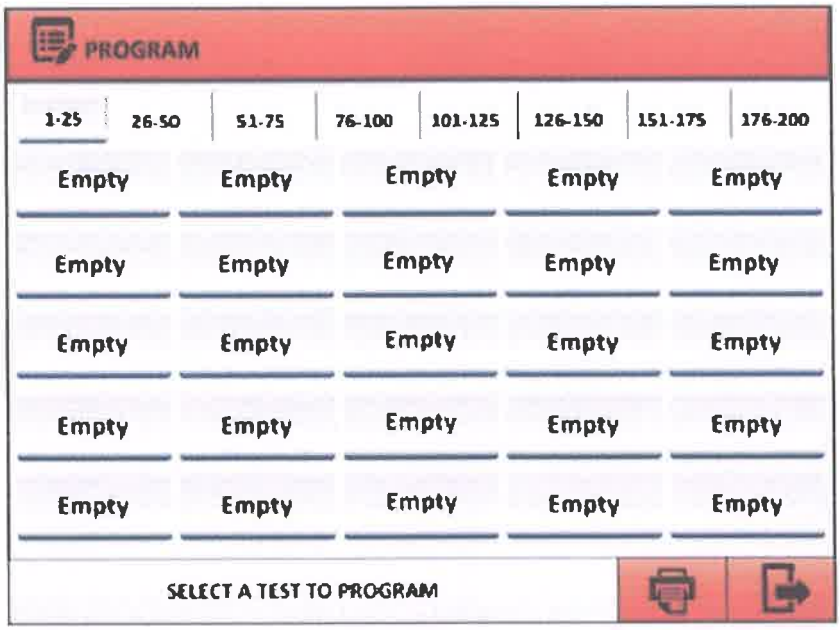
**If Number of standard=0**

- Analyzer will make use of the saved factor.
- If the sample blank is selected, analyzer will prompt for sample blank.
- Aspirate the sample blank.
- Analyzer displays the ABS of sample blank along with graph.
- Analyzer prompts for the sample aspiration.
- Aspirate sample (tube containing reagent and clinical sample) ensuring that aspiration probe is dipped into the sample tube and press aspiration switch for each aspiration.
- Aspirate sample tubes one after another.
- Analyzer will display and print the calculated result along with relevant flags for each sample.

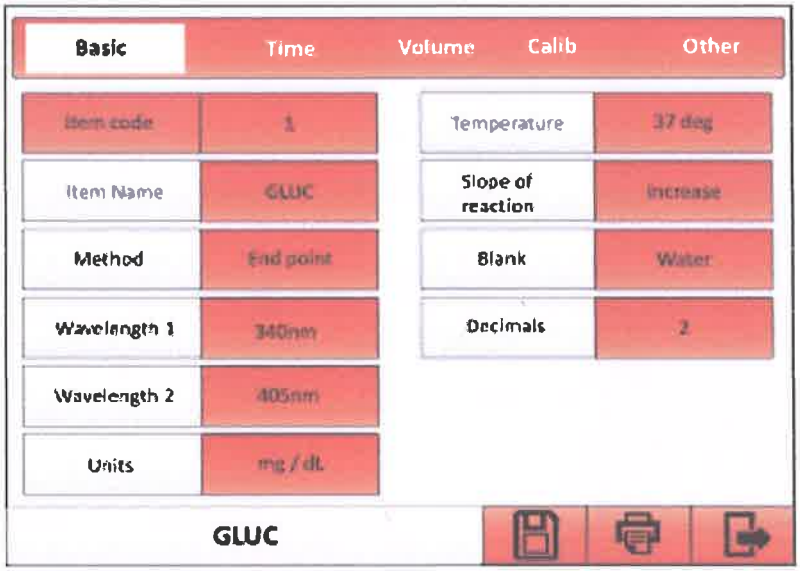
## 4.4) Program function

To run any test, operator needs to program the analyzer for different tests.

- Select program function from the main menu.
- All 200-test names will be displayed in different screens based on eight different categories.




- Select particular test key to program the test parameters.
- Analyzer will load and display program entry screen.
- Item code for each test is unique and the user does not have the authority to edit the item code.
- Selected test name will display in the status bar, user can edit the test name.
- Toggle in to different functions among Basic, Time, Volume, Calibration and others.
- Based on the selection, parameter that needs to be entered will be displayed on the screen.
- Make use of the toggle function and the keyboard to input all details.




**Description of each function**

**Basic**

- Analyzer display item code. Operator does not have the authority to edit the item code.
- Selected test name will be displayed on the status bar. User can edit and save the test name.
- User should use toggle key in each screen to select desired option.
- Select the wavelength1 from 340, 405, 505, 546, 578, and 630. And wavelength 2 from 340, 405, 505, 546, 578 and 630 from the pop up window.
- Set the unit from mg/dl, g/dl, mmol/L, mg/L, mEq/l, IU/L, ng/mL, IU/mL, ug/dL, %, u mol/L, ng/L, ng/mL, g/L, pg/mL, ng/dL, ug/L from pop up window.
- Set the temperature to 37, 25, or 30 degree.
- Set slope of reaction to increase or decrease.
- Set the blank to reagent, sample or water.
- Select decimal function to 0, 1, 2, or 3.

**Time**

- Input incubation time from the range 0-10 sec.
- Set delay and interval time from the range 3-999 sec.
- Set number of reading time from the range 3-10 sec.

**Volume**

- Set reagent 1 & 2 volume from the range 0-1000uL
- Set sample volume from the range 0-60000uL.
- Set aspiration volume from the range 300-1000uL.
- Set linearity limit from the range 0-60000uL.
- Set $D^{MAX}$ limit from the range 0.000-3.000uL.

**Calib**

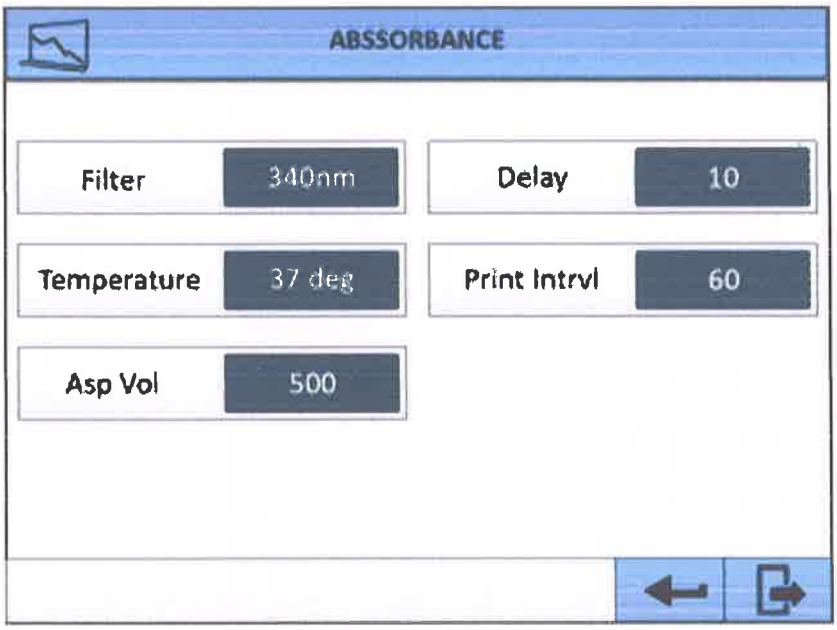
- Set number of standards from the range 0-9.
- Set factor value from the range 0.0000-20000.000.
- Select standard repeat to 1, 2 or 3.
- Set standards to 1, 2 or 3.
- Set absorbance from the range 0.000-3.000
- Set standard concentration from the range 0.000-10000.000.

**Other**

- Set sample repeat from the range 1-3.
- Set normal low and normal high from the range 0.000-1000.000.
- Set absorbance low and high from the range 0.000-3.000
- Set slop intercepts value from the range 0.0000-1.000.
- Set slop value from the range 0.000-1000.000.
- Select $D^{MAX}$ ON or OFF by toggling.
- Select save key to save the set program.
- Select print key to print the data.
- Select exit key and exit into program name list.

## 4.5) Absorbance Function

In order to check the performances of the analyzer along with reagent, perform absorbance check function. After doing absorbance check, user can analyzer the obtained result.




- Select "Absorbance" from the main menu.
- Input and save the different parameters like Filter, Temperature, Aspiration Volume, Delay and Print interval.
- Select "enter" key to proceed.
- When temperature is not stable, a message will be displayed "temperature not stable need to wait?" Select "Yes" for the temperature stabilization. Or select 'No' and proceed.
- Analyzer will adjust to pre-set filter and displays messages "moving to filter".
- On successful completion of Set Up activity, "aspirate blank" is prompted on display screen. Aspirate blank by pressing aspiration switch.
- "Aspirate sample" is prompted on screen. After aspiration, analyzer will plot a graph and displays the ABS value.
- Based on the programmed print interval limit the ABS will be printed.
- When user wants to perform the process again, select "Set 0" so ABS will be set to 0.00. Follow the same process.
- When auto print is "OFF", analyzer will not print the details automatically and user needs to select print key for printing.
- Select "Reset" key to reset the enter function.

- Select "Exit" key to exit the function.


## 4.6) Setup Function

In order to setup the analyzer function, select 'Setup' key from the main menu.

### Temperature

- Select temperature function from the setup menu.
- Current temperature of the analyzer will be displayed in the screen.
- Select "Cool" function to down the temperature from 37°C
- Select "Heat" function to increase the temperature from 25°C.

### Pump

- Select pump function to do the pump calibration.
- Input the pump delay. It should be within the 50-500.
- Select calibration key.
- Aspirate 3000 uL DI water by pressing aspiration switch.
- Pump factor will be displayed.
- Select save function to save the pump calibration. Otherwise select exit and abort the function.

**Date**

- Select date function to edit the date.
- Enter the date in dd/mm/yyyy format and save the date. Analyzer updates the new date.

**Time**

- Select time function to edit the time.
- Enter the time in hh:mm specified format and save. Analyzer updates with the new time.

**Sleep time**

- User can set the sleep time, if the analyzer is not active within pre-set sleep time, it will shift to sleep mode. By touching on the LCD screen, it is possible to shift change in to normal mode of operation.
- Select the sleep time function from the main menu in hh:mm format
- Input and save the sleep time. And it should be within the 60-60000 sec.

**Quick Start**

- This function can be turned 'ON' or 'OFF', if the quick start is turned 'ON' the analyser directly displays the test selection screen without going into main menu. When quick start is turned 'OFF' the analyser displays main menu. Select "save" key to save the function.

**Auto Txn**

- It can be turn 'ON' or 'OFF', When it is turned 'ON' the data is transferred automatically from analyser to system. Select "save" key to save the function.

**Cuvette**

- It can be turn 'ON' or 'OFF'. When user required to perform the measurements in cuvette mode, then turn 'ON' the cuvette function. Select "save" key to save the function.

**Auto Print**

- It can be turned 'ON' or 'OFF', when it is turned 'ON 'analyser automatically print data. Otherwise, user needs to select print key to print the details. Select "save" key to save the function.

**Graph Print**

- It can be turned 'ON' or 'OFF', when it is turned 'ON ' analyser automatically print the graphs, otherwise user needs to select print key to print the graphs. Select "save" key to save the function.

**Lab Name**

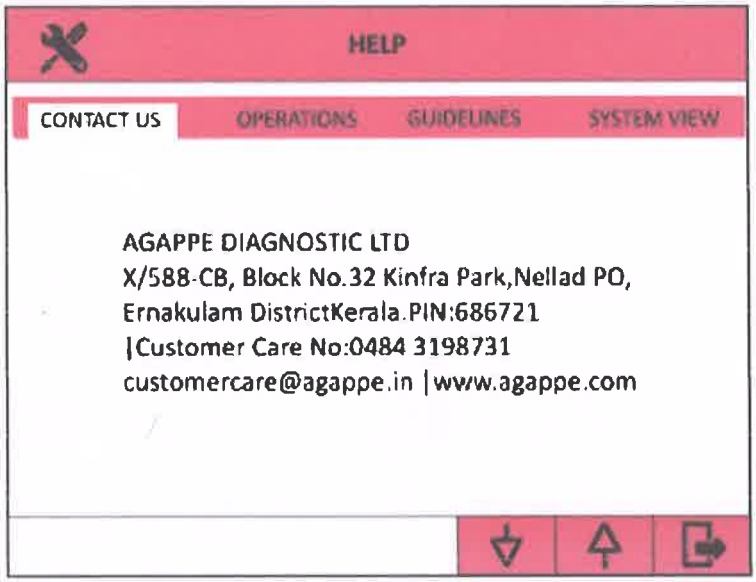
- User can enter the lab name.
- Select "save" key to save the analyzer setup or select exit and abort the he function.

**PC connectivity**

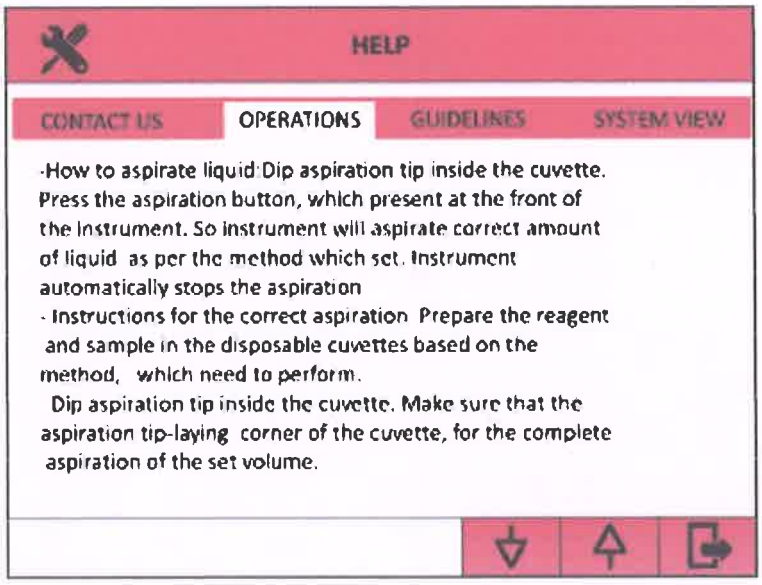
- Connect the analyzer with PC through the Interfacing software via RS 232 by selecting "PC connect icon" from the setup function of the analyser.
- User can do all the functions, which displayed in the main menu through PC.

**Help**

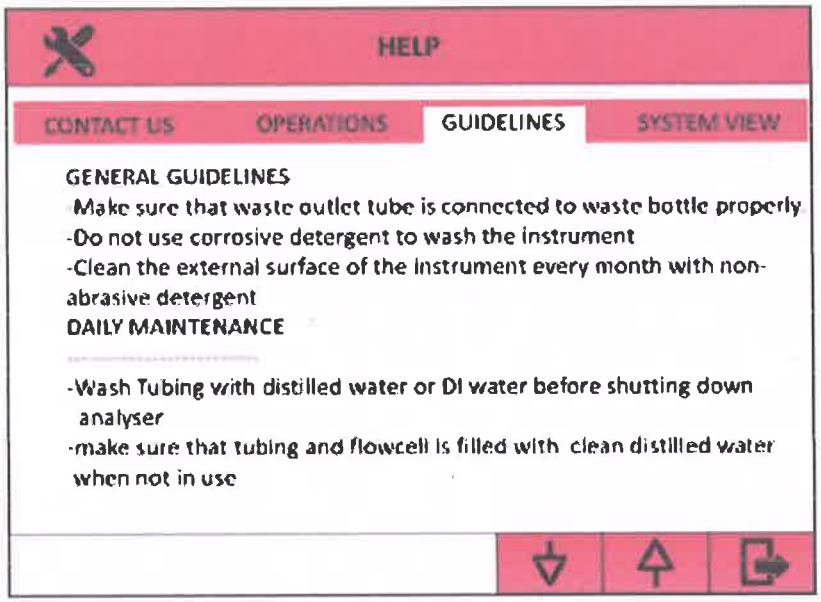
- When 'Help' function selected, by default analyzer displays company contact details in "contact us" function.



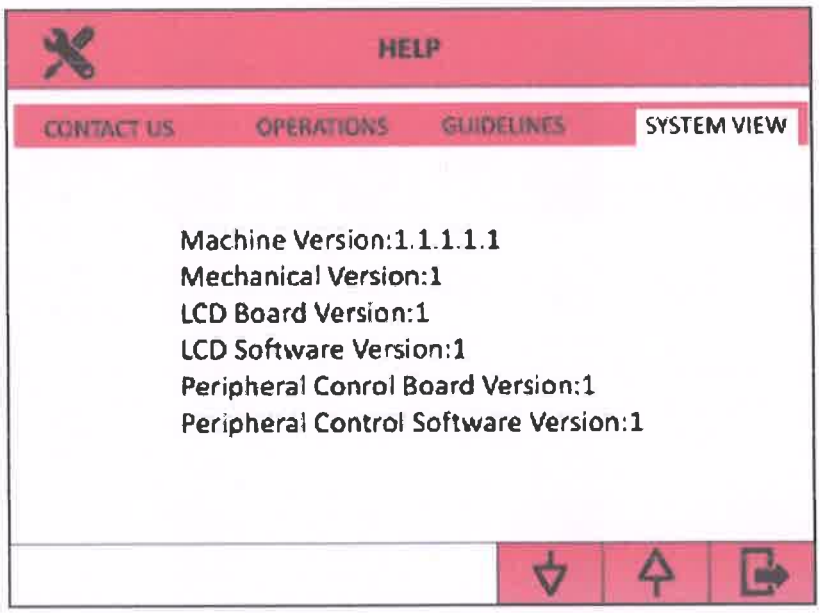

- When "operations" key is selected, analyzer displays basic operational guidelines. Select Up/Down key to scroll the details up and down.



- When "Guidelines" key selected, analyzer displays instructions which user need to follow for the efficient performance of the analyzer.

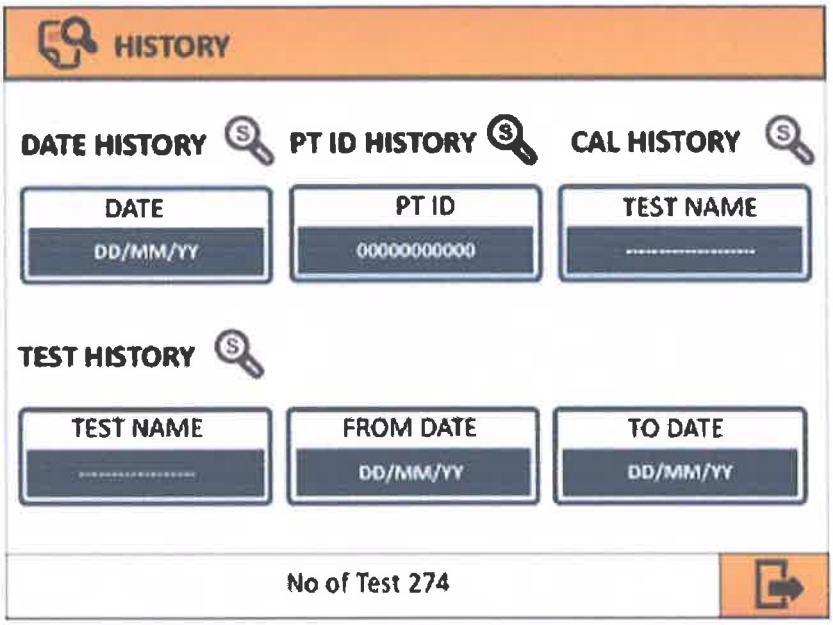



- When "system view" function selected, analyzer will displays all system view details




## 4.7) History Function

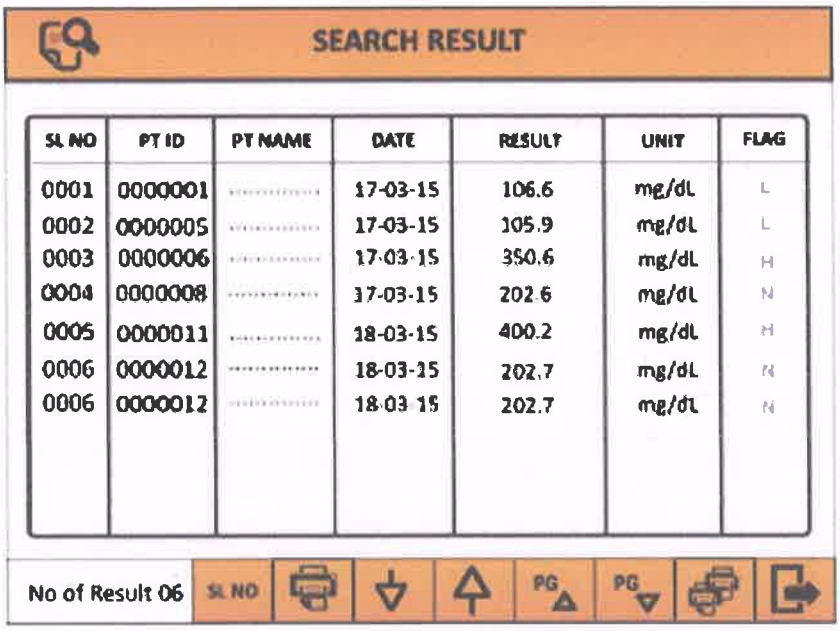
The analyzer is made with inbuilt storage capacity up to 5000 test results. The user can review and retrieve these saved data by accessing "history" function. In the 'history' menu, user will get three options Test history, Date history, Patient ID history and CAL history.




### 4.7. a) TEST HISTORY

To view the results based on the test, proceed with "test history".

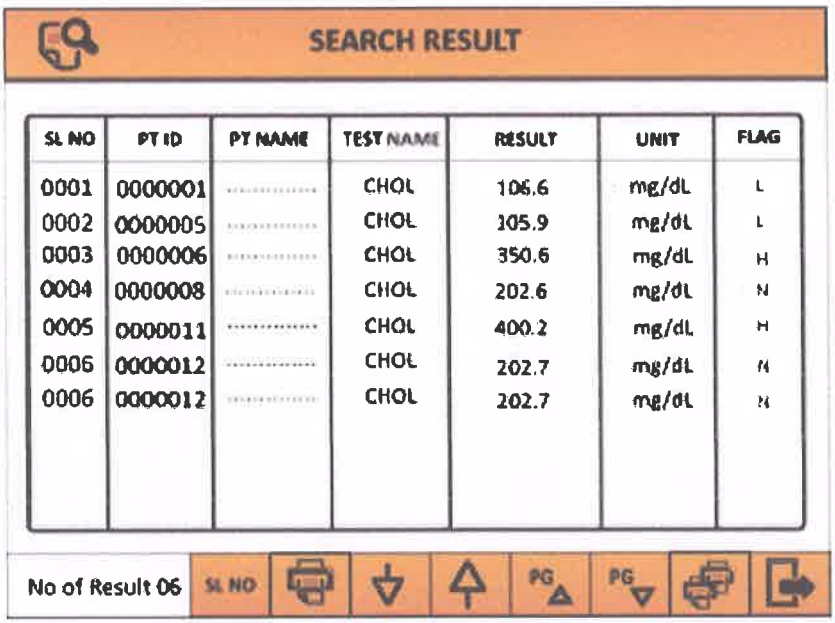
- Enter test name and date, then select search key.
- Analyzer will displays the Serial No, Patient Identification number, Patient Name, Date, Result, Unit and Flag.
- Make use of line-up/down and page-up/down keys to scroll the data.
- Select 'print' key to print the displayed results.
- Input serial number and select 'single print' key to print the single result.
- Select exit key to abort the function.



### 4.7. b) DATE HISTORY

To view the results in date wise, proceed with 'date history'.

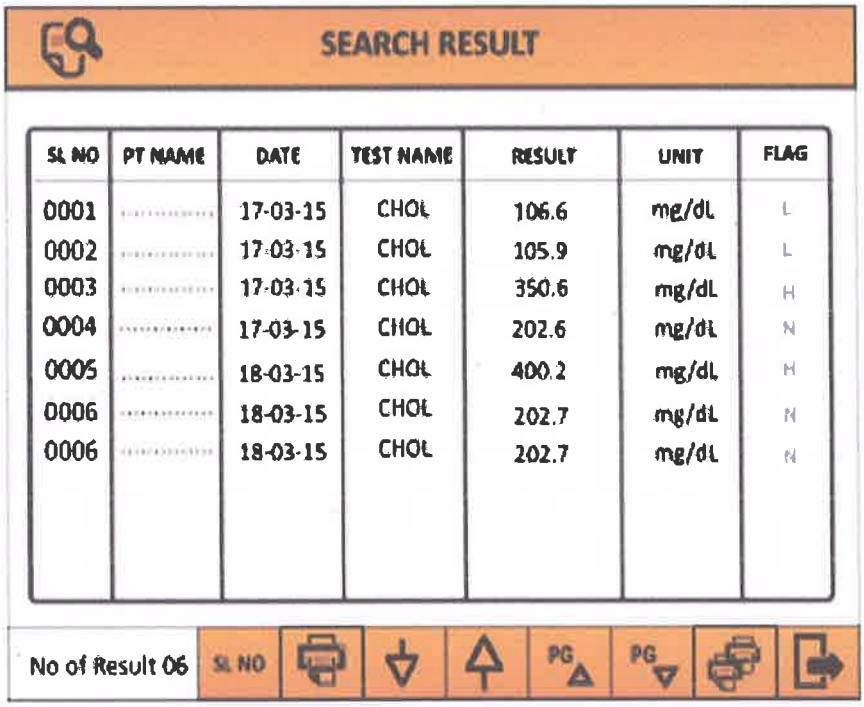
- Enter the date in the specified format and select search key.
- So analyser will load and display the Serial No, Patient Identification number, Patient Name, Test Name, Result, Unit & flag.
- Make use of line-up/down and page-up/down keys to scroll the data.
- Select "print" key to print the displayed results.
- Input serial number and 'select single print' key to print the single result.
- Select exit key to abort the function.




### 4.7. c) PT ID HISTORY

To view the result in PT ID wise, select 'PT ID function' from the main menu.

- Enter the PT ID and select search key.
- Analyser will load and display the Serial No, Date, Patient Name, Test Name, Result , Unit and Flag.
- Make use of line-up/down and page-up/down keys to scroll the data.
- Select 'print' key to print the all displayed results.
- Input serial number and select 'single print' key to print the single result.
- Select exit key to abort the function.



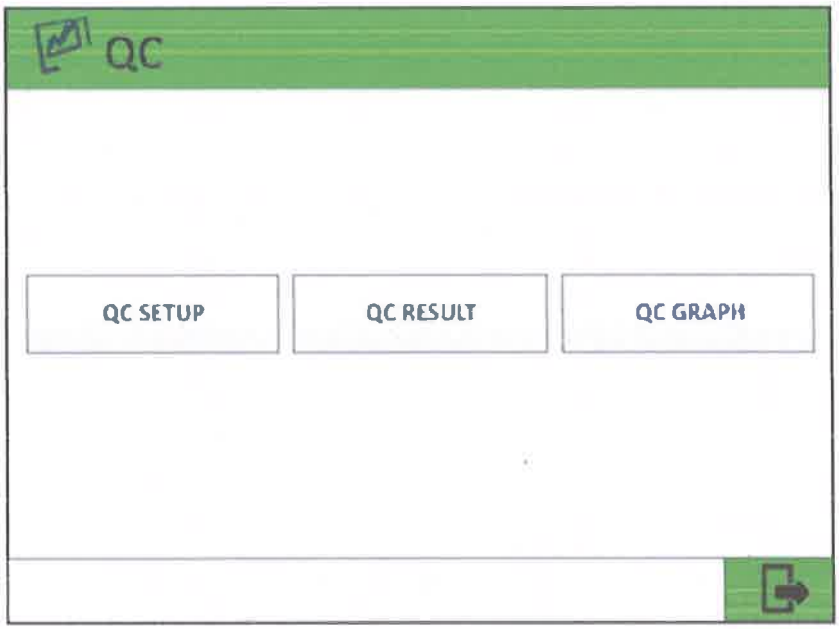

### 4.7.d) CAL History

In order to view the date on which the test has been calibrated, proceed with "CAL history" function.

- Select test name key of the CAL function.
- Analyzer will displays all the test name.
- Select any test name and the test calibrated date will be displayed.
- If any test is not calibrated, analyser will display "No calibration".

### 4.8) QC Function

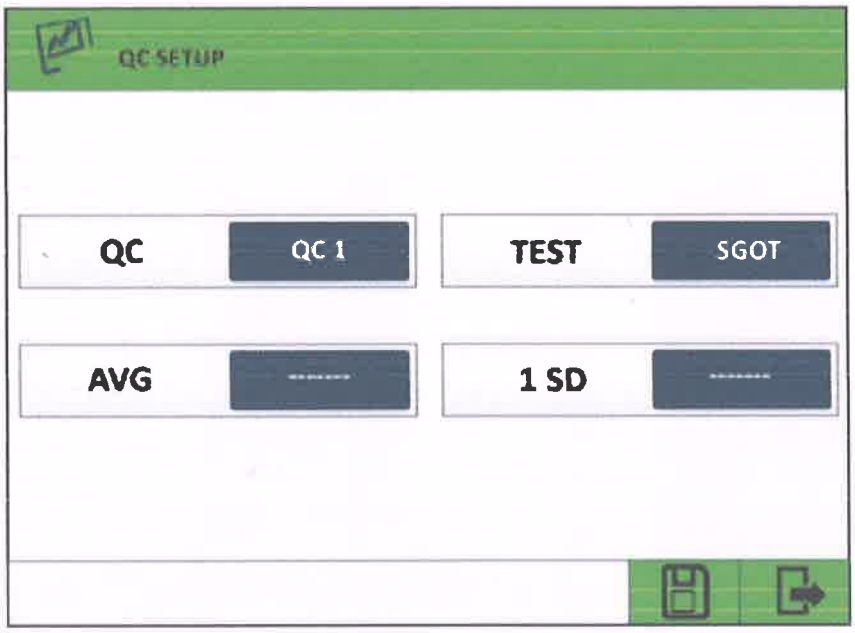
The analyzer designed with three levels of 'QC function'. Select 'QC SETUP' function to setup the quality control reference for each parameter. In order to run the QC, edit the PTID to required QC level. Select 'QC RESULTS' function to review the result of performed QC. By selecting 'QC GRAPH' function, user can see the graphs of performed QC.




### 4.8. a) QC SETUP

To setup the QC reference select 'QC SETUP' function from the QC menu.

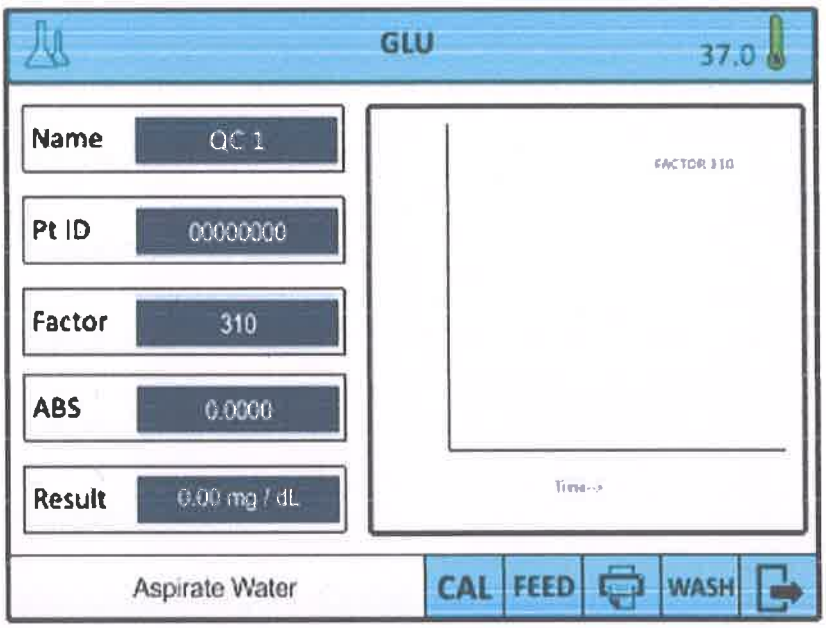
- Select the test name from the list.
- Select QC level.
- Enter the Mean and SD of the selected item from control value sheet.
- Select 'save' key to save entered data, or select 'exit' key and abort the function.



### 4.8. b) QC RUN

To run QC, follow the procedure as below.

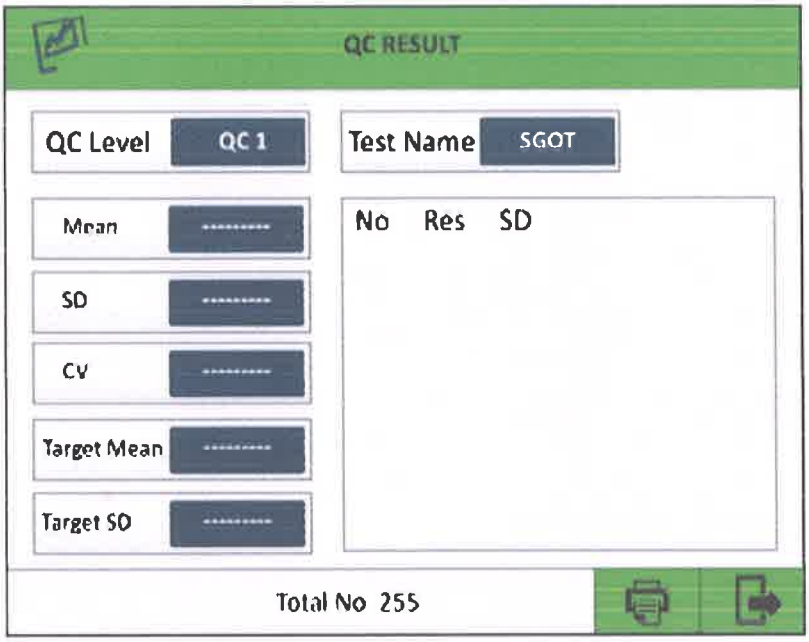
- Select the required test from Test menu.
- In PT name entry, select QC level which need to run.
- Select 'Yes' key to save the result to QC file. Or select 'No' key and abort the function.




### 4.8. c) QC RESULT

To retrieve the results of performed QC select 'QC HISTORY' function from the QC menu.

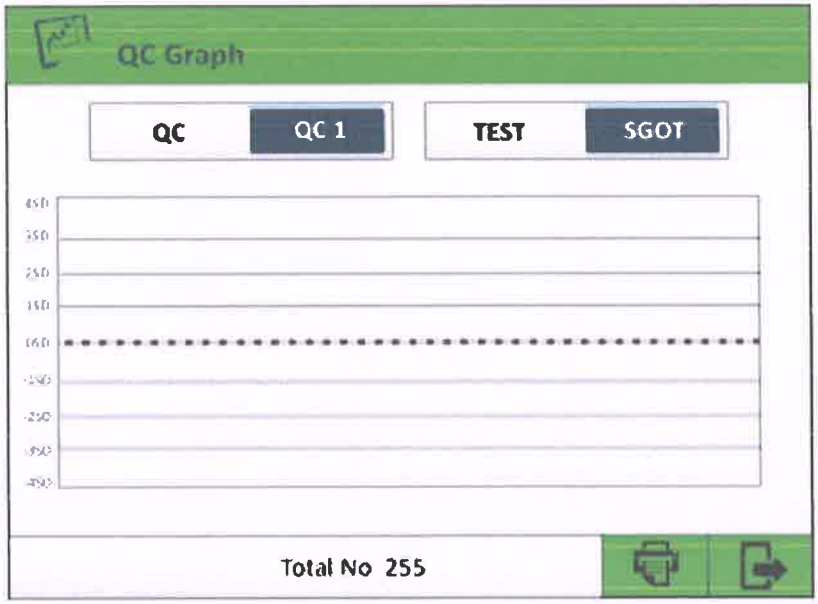
- Select test name and QC level.
- Analyzer will display Target Mean, Target SD, observed Mean, SD and CV and it will list out the result and SD of all the performed QC.
- Select 'print' key to print the details.
- Select "exit "key to exit.




### 4.8. d) QC GRAPH

To see the graph of performed QC, select 'QC Graph' function

- Select the test name and the QC level.
- Select 'Show' key to plot the graph.
- Mean, SD and CV will be displayed along with the graph.
- Select 'Print' key to print the details along with graph.
- Select exit key to abort the function.



### 4.9) Wash

After the completion of each test/QC run, it is recommended that the flow cell should be washed with deionised water. This is possible every time even when analyzer is in RUN mode.

- Select the "Wash" button from the main menu. The pump will drain out the water at high speed from the flow cell.
- It is necessary to repeat the operation without water so that the water remaining inside the analyzer can be expelled completely.

## 5) MAINTENANCE

### 5.1) Daily Maintenance

a) Flow cell cleaning using distilled water or any recommended cleaning solution through wash function.

- Select "Wash" key from the main menu for the flow cell washing
- The peristaltic pump will aspirate the distilled water/cleaning solution.
- Use wet cloth to remove the spillage if any on the instrument.

### 5.2) Periodical Maintenance

- Every week perform at least two complete washing cycle using DI Water.
- Wipe the external surface of the analyzer every month with non-abrasive detergent using soft sponge.
- Wash the waste bottle interior with clean water or disinfectant if necessary.

**Do not use corrosive detergent to wash analyzer**

## 1.4) Specifications

| Heads | Specifications |
|---|---|
| Dimension | 362x364x195(LxWxH) |
| Weight | 6 Kg |
| Graphic display | 5.7 inch |
| Patient name length | 16 Characters |
| Maximum test result storage capacity | 5000 test results |
| Light source | Halogen lamp 12V /20W |
| Photo detector | Silicon photodiode (range 300-1000nm) |
| Absorbance Range | 0 - 2.5 OD |
| External Interface | RS 232 |
| Wave length | 340-630nm |
| Wave length selection | Automatic via 8-position filter wheel, 6 standard interference filter, 340nm, 405nm, 505nm, 546nm, 578nm, 630nm. Two free position for optional filters. |
| Photometric range | 0-2.5OD |
| Flow cell system | 30 µL flow cell with 10 mm light path, inter changeable with disposable macro, semi-micro or special optical glass cuvettes. |
| Temperature control | 25°C, 30°C, 37°C |
| Reading time | 1-999 sec |
| Incubation time | 30-999 sec |
| Printer | Graphic, Thermal printer |
| Input Power | AC 85-265V, 50-60Hz, 90WA |