REF 58663 ℞ IVD CE

Nova Allegro® Analyzer

nova® biomedical

Instructions for Use Manual

Allegro® Quick Start Guide: Lipids and HbA1c

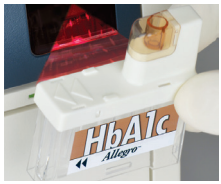
1 The 2 cartridges: Brown is for HbA1c, and Yellow is for Lipids.

NOTE: *For this Quick Start Guide, the HbA1c Cartridge will be used.*

2 Allegro with Home Screen. The 2 cartridge bays are at the bottom. The printer is on top of the analyzer.

LED indicators are below the Home screen
Solid green LED means ready to load a cartridge.
Blinking green means the sample is being analyzed.
Red means not available.

3 Verify the analyzer is ready to run a sample analysis (status LED is steady green).Scan the cartridge by pressing the barcode button on the home screen.

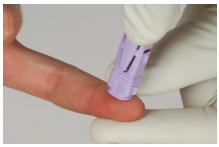


4 Use the on-screen keyboard and barcode scanner to enter any required pre-analysis information. Press √ when done.
The Insert Cartridge screen will display and the cartridge bay door will open.

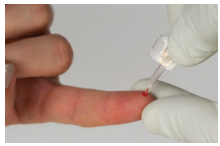
5 Open the HbA1c test cartridge and remove the Capillary.

6 Wash and dry hands thoroughly with a paper towel.
Select a finger stick site. Use an alcohol pad that **does not contain glycerol** to cleanse the site and allow to air dry.

7 Use a safety lancet to puncture the finger. Squeeze the finger to form a blood drop. Wipe away the first blood drop using a plain, clean, gauze pad containing **no glycerol**. Squeeze the finger again to form a second drop of blood.



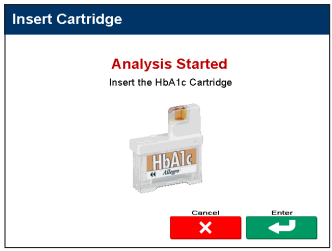
8 Insert the end of the Capillary into the center of the specimen. Draw specimen up into the Capillary until completely filled to the fill line. Verify that no air bubbles are observed.



9 Insert the Capillary back into the HbA1c Test Cartridge.

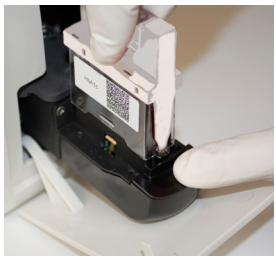
10 Place the test cartridge into the open bay within **2 minutes of sample collection**. Press down with finger as shown until the cartridge clicks into place.

11 Press the Enter icon ↵ on the Insert Cartridge screen. The Test Cartridge goes into the analyzer; the door closes; and analysis starts. The Status LED flashes green.



12 The Test Results screen is displayed with the time till completion shown in the header bar.
The status LED will blink green during sample analysis.
Sample results will be displayed on the Test Results screen as they become available. If the test result is questionable or if clinical signs and symptoms appear inconsistent with the test result, analyze control solutions and retest the specimen.

13 After the analysis is completed the cartridge bay will open and the used test cartridge may be removed for disposal into an appropriate biohazard container. Press the release button down and lift the cartridge up and out of the bay as shown.



14 Press Home to return to the Home screen.

Allegro® Quick Start Guide: UACR

1 The White cartridge is for Urine Albumin Creatine Ratio (UACR).

2 Allegro with Home Screen. The 2 cartridge bays are at the bottom. The printer is on top of the analyzer.

LED indicators are below the Home screen
Solid green LED means ready to load a cartridge.
Blinking green means the sample is being analyzed.
Red means not available.

3 Verify the analyzer is ready to run a sample analysis (status LED is steady green).Scan the cartridge by pressing the barcode button on the home screen.

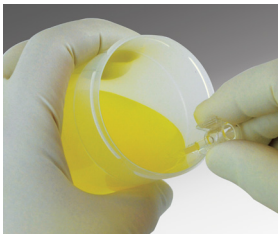
4 Use the on-screen keyboard and barcode scanner to enter any required pre-analysis information. Press √ when done.
The Insert Cartridge screen will display and the cartridge bay door will open.

5 Verify that the urine specimen is properly mixed in the collection container.

6 Remove the capillary adapter from the Cartridge.

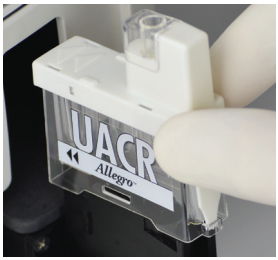
Allegro® Quick Start Guide: UACR

7 Insert the end of the Capillary into the urine specimen. Draw specimen up into the Capillary until completely filled to the fill line. Verify that no air bubbles are observed.

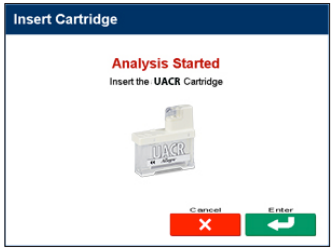


8 Insert capillary adaptor into the UACR Test Cartridge.

9 Place the test cartridge into the open bay within **5 minutes of sample collection**. Press down with finger as shown until the cartridge clicks into place.



10 Press the Enter icon  on the Insert Cartridge screen. The Test Cartridge goes into the analyzer; the door closes; and analysis starts. The Status LED flashes green.



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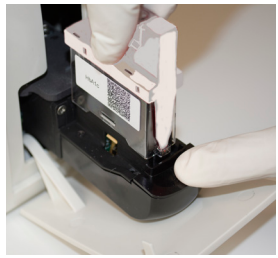
The status LED will blink green during sample analysis.
Sample results will be displayed on the Test Results screen as they become available. If the test result is questionable or if clinical signs and symptoms appear inconsistent with the test result, analyze control solutions and retest the specimen.

12 After the analysis is completed the cartridge bay will open and the used test cartridge may be removed for disposal into an appropriate biohazard container. Press the release button down and lift the cartridge up and out of the bay as shown.



13 Press Home to return to the Home screen.

NOVA BIOMEDICAL SYMBOL DIRECTORY

IVD — *In vitro* diagnostic medical device

CE — Product fulfills the requirements of Directive 98/79 EC (IVDD)

Caution, consult accompanying documents

Consult instructions for use

Biological risk

REF — Catalog number

Manufactured by

CONTROL — Control

LEVEL — Level

Hazard

LOT — Batch code

SN — Serial Number

Temperature limitation

Use by (last day of the month)

YYYY - MM

Electronic Waste

EC REP — Authorized Representative in the European Community

Laser Radiation - Do Not Stare Into Beam
Class II/IEC 825 Laser Product

Wavelength: 655 nm

℞ — Prescription Use Only

Corrosive

Nova *Allegro*® Instructions for Use Manual

Ordering Information

The *Nova Allegro® Instructions for Use Manual* can be ordered from Nova Biomedical Order Services. Write or call:

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Waltham, MA 02454-9141
U.S.A.

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FAX: 1-800-316-1178
(in the U.S.A.)
FAX: 1-781-891-9718
(outside the U.S.A.)
Web: www.novabiomedical.com

The Allegro is manufactured in the USA by Nova Biomedical Corporation.

EC REP Authorized Representative

Nova Biomedical UK
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Aston Lane South, Runcorn
Cheshire, WA7 3FY, UK

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For technical assistance inside the United States, call Nova Biomedical Technical Services at:

U.S.A.: 1-800-545-NOVA (Toll Free)
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For technical assistance outside the United States, call your local Nova subsidiary or authorized distributor.

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Contents

1 Introduction

This manual provides all necessary instructions for the routine operation and upkeep of the Nova Allegro Analyzer. Please read this manual carefully. It has been prepared to help you attain optimum performance from your Analyzer.

WARNING: Blood samples and body fluids are potential sources of infectious agents. Handle all blood products and body fluids with care. Gloves and protective clothing are recommended.

This section introduces the Allegro Analyzer and covers requirements, tests performed, procedural limitations, clinical utility, and sample handling.

1.1 About This Manual

This manual is for the Allegro Analyzer.

Throughout this manual, *NOTE:* indicates especially important information, ***CAUTION:*** indicates information that is critical to avoid instrument damage or incorrect results, and ***WARNING:*** indicates possible hazard to the operator.

1.2 Safety

Personnel operating this analyzer must be proficient in the operating and replacement procedures of the analyzer. The following safety procedures must be followed.

General Safety

1. Read the safety and operating instructions before operating the analyzer.
2. Retain the safety and operating instructions for future reference.
3. Observe all warnings on the analyzer and in the operating instructions.

4. Follow all operating and use instructions.
5. Do not use the analyzer near water, for example near a sink, etc.
6. Place the analyzer so that its location or position does not interfere with its proper ventilation.
7. Place the analyzer away from heat sources.
8. Connect the analyzer to a power supply only of the type described in the operating instructions or marked on the analyzer.
9. Do not defeat the safety purpose of the polarized or grounding type plug.
10. Route power cords so that they are not likely to be walked on or pinched by items placed upon or against them, paying particular attention to cords at plugs, power sockets, and at the point where they exit from the analyzer.
11. Take care not to let objects or liquids fall into the analyzer.
12. Do not attempt to service the analyzer beyond that described in the operating instructions. All other servicing should be referred to qualified service personnel.

Electrical Safety

1. To reduce the risk of electric shock, do not remove the cover.
2. To reduce the risk of fire or electric shock, do not expose the analyzer to water.
3. Use Nova Part Number 52894 external power supply to power up the analyzer.
4. Ensure that the wall outlet receptacle is properly wired and earth grounded.
5. DO NOT use a 3-to-2 wire plug adapter.
6. DO NOT use a 2-wire extension cord or a 2-wire multiple-outlet power strip.

Chemical and Biological Safety

1. Observe all precautionary information printed on the original solution containers.
2. Operate the analyzer in the appropriate environment.
3. Take all necessary precautions when using pathologic or toxic materials to prevent the generation of aerosols.
4. Wear appropriate laboratory attire, e.g., safety glasses, gloves, lab coat, and breathing apparatus, when working with hazardous materials.
5. Dispose of all waste solutions according to standard hospital procedures.

1.3 Installation and Use

Prior to installation and use of the analyzer, operators should be familiar with Chapter 2 Getting Started and Chapter 3 Sample Analysis.

1.4 Requirements

Working Area Requirements (Environmental):
Keep the working area around the system free of dirt, corrosive fumes, vibration, and excessive temperature changes.

Electrical Requirements:

- Operating Voltage Range: 90 - 264 VAC
- Operating Frequency: 50 - 60 Hz
- Power Consumption: Less than 100 Watts

Ambient Operating Temperature:

- 15°C to 32°C (59°F to 89.6°F)

Operate at Humidity:

- 20 to 85% without condensation

Operate at Altitude:

- up to 12,000 feet/3650 meters

Dimensions:

Height:	14.0 in (35.6 cm)
Width:	8.0 in (20.32 cm)
Depth:	15.0 in (38.1 cm)

Weight:

23.0 lb (10.43 kg)

Lifting the Analyzer:

1. One person is needed to lift the analyzer.
2. From the front of the analyzer, place your hands under each side of the analyzer.
3. Lift the analyzer. Remember to bend your knees and lift with your legs and not your back.
4. Place the analyzer onto a clean and flat surface.

1.5 Intended Use, Tests Performed, and Clinical Utility

Intended Use

The **Nova Allegro System** is intended for *in vitro* diagnostic use by health care professionals for the quantitative determination of the percent of Hemoglobin A1c (HbA1c), Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol, and Triglycerides in capillary whole blood obtained from the fingertip and venous whole blood. It is also intended for quantitative determination of Albumin and Creatinine in urine.

Measured Parameters
Allegro Analyzer:

HbA1c Test Cartridge
- HbA1c

UACR Test Cartridge
- Albumin
- Creatinine

Lipids Test Cartridge
- Total Cholesterol
- HDL Cholesterol
- Triglycerides

Calculated Parameters

HbA1c Test Cartridge
- eAG (Estimated Average Glucose)

UACR Test Cartridge
- UACR (Urine Albumin/Creatinine Ratio)

Lipids Test Cartridge
- LDL Cholesterol
- non-HDL Cholesterol
- TC/HDL Ratio

Clinical Utility[1] The following list includes the clinical utility information for each of the analytes measured on the Allegro Analyzer.

Lipids Lipids[1,2,3] are a group of fats and fat-like substances that are important constituents of cells and sources of energy. A lipid profile measures the level of specific lipids in the blood.

Two important lipids, cholesterol and triglycerides, are transported in the blood by lipoprotein particles. Each particle contains a combination of protein, cholesterol, triglyceride, and phospholipid molecules. The particles measured with a lipid profile are classified by their density into high-density lipoproteins (HDL), low-density lipoproteins (LDL), and very low-density lipoproteins (VLDL).

Monitoring and maintaining healthy levels of these lipids is important in staying healthy. While the body produces the cholesterol needed to function properly, the source for some cholesterol is the diet. Eating too much of foods that are high in saturated fats and trans unsaturated fats (trans fats) or having an inherited predisposition can result in a high level of cholesterol in the blood. The extra cholesterol may be deposited in plaques on the walls of blood vessels. Plaques can narrow or eventually block the opening of blood vessels, leading to hardening of the arteries (atherosclerosis) and increasing the risk of numerous health problems, including heart disease and stroke. A high level of triglycerides in the blood is also associated with an increased risk of developing cardiovascular disease (CVD), although the reason for this is not well understood.

A lipid profile typically includes:

- Total cholesterol
- High-density lipoprotein cholesterol (HDL-C) — often called "good cholesterol" because it removes excess cholesterol and carries it to the liver for removal.
- Low-density lipoprotein cholesterol (LDL-C) — often called "bad cholesterol" because it deposits excess cholesterol in walls of blood vessels, which can contribute to atherosclerosis.
- Triglycerides

UACR The (UACR[4,5,6]) urine albumin test or albumin/creatinine ratio (ACR) is used to screen people with chronic conditions, such as diabetes and high blood pressure (hypertension) that put them at an increased risk of developing kidney disease. Studies have shown that identifying individuals in the very early stages of kidney disease helps people and healthcare providers adjust treatment. Controlling diabetes and hypertension by maintaining tight glycemic control and reducing blood pressure delay or prevent the progression of kidney disease.

Albumin is a protein that is present in high concentrations in the blood. Virtually no albumin is present in the urine when the kidneys are functioning properly. However, albumin may be detected in the urine even in the early stages of kidney disease.

Creatinine, a byproduct of muscle metabolism, is normally released into the urine at a constant rate and its level in the urine is an indication of the urine concentration. This property of creatinine allows its measurement to be used to correct for urine concentration in a random urine sample. The American Diabetes Association has stated a preference for the ACR for screening for albuminuria indicating early kidney disease.

HbA1c The HbA1c[7] level may be useful in differentiating between patients with and without diabetes, even in the presence of stress-induced hyperglycemia, and may be an ideal tool for case finding in the hospitalized patient. Similar to previously published studies on random hyperglycemia in hospitalized patients, it appears that a sizable proportion of patients with random hyperglycemia will turn out to have diabetes upon further testing, indicating a preexistent disease state rather than a stress response. Also, given the often unrecognized diagnosis of diabetes in patients with inpatient hyperglycemia and the increased mortality independently associated with inpatient hyperglycemia, the HbA1c level may provide a more specific cue to the provider.

Ref.

1. National Cholesterol Education Program (NCEP). Third report of the expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III). NIH Pub. No. 02-5215. National Heart, Lung, and Blood Institute; 2005. 284 p. Available from: http://www.nhlbi.nih. gov/guidelines/cholesterol/atp3full.pdf.
2. Reiner Z, Catapano A. L, et al. ESC/EAS Guidelines for the management of dyslipidaemias. European Heart Journal 2011 (32):1769-1818.
4. Ellis, D., et al.: Choice of Urine Sample Predictive of Microalbuminuria in Patients with Insulin-Dependent Diabetes Mellitus. Am. J. Kidney Diseases. 13:321 - 328; 1989.
5. Ginsberg, J.M., et al.: Use of Single Voided Urine Samples to Estimate Quantitative Proteinuria. N. Eng. J. Med. 309:1543-1546; 1983.
6. Watts, G.F., et al.L The Use of Random Urine Samples to Screen for Microalbumuria in the Diabetic Clinic. Practical Diabetes. 3:86-88; 1986.
7. Lenzi S et al., The Clinical Usefulness og Glycated Hemoglobin in Monitoring Diabetes Mellitus: A long-Term Study. Clin Chem 1987; 33:55-56.

1.6 The Sample

HbA1c, Lipids Test Cartridge

- Capillary whole blood (finger stick), venous whole blood
- Sample size: HbA1c - 1.5 µL,
- Sample size: Lipids - 5 µL

UACR Test Cartridge

- Urine (preservative free) - 25 µL

1.6.1 Handling Requirements

Capillary Whole Blood
Blood samples should be collected from a finger stick.
Venous Whole Blood
Blood samples should be collected with minimal stasis, without exercise of the arm. Collect blood for analysis in vacuum tubes containing either sodium or lithium heparin.

Urine
Careful attention to urine sample handling is critical to ensure that accurate results are obtained. Urine specimens should be collected in a clean, sterile container with a non-spill, anti-evaporation lid.
To ensure the accuracy of the urine measurements, it is essential that urine be analyzed within 2 hours of collection or refrigerated at temperatures between 2 and 8˚C for extended periods to prevent the growth and metabolism of micro-organisms.

1.6.2 Acceptable Anticoagulants

- **HbA1c Anticoagulants:** Venous whole blood samples containing EDTA, Sodium Heparin, or Lithium Heparin may be used.
- **Lipid Anticoagulants:** Venous whole blood samples containing Sodium Heparin or Lithium Heparin may be used. **EDTA cannot be used as an anticoagulant for lipids.**
- Citrate, oxalate, and sodium fluoride **ARE NOT** acceptable for use.

2 Getting Started

The Allegro Analyzer is pictured below.

Figure 2.1. Allegro Analyzer

1. Touch-screen Display
2. Printer
3. Left Cartridge Bay Door
4. Right Cartridge Bay Door
5. Left Cartridge Bay Status LED
6. Right Cartridge Bay Status LED
7. Barcode Scanner

2.1 Power Up Procedure

When the analyzer is powered on, it displays the Allegro boot screen. During this time, an internal Power On Self-Test (POST) is run. If an error should occur during the POST it is shown on the touch screen display. Once the POST has completed the analyzer goes through a brief Startup sequence then displays the Home screen.

Figure 2.2. Home Screen

2.2 Cartridge Bay Status LED

A Status LED is located above each of the 2 available test cartridge bays and indicates the status of each bay.

- A steady Green LED indicates the bay is empty and ready for use.
- A flashing Green LED indicates the bay is in use.
- A steady Red LED indicates the analysis is complete and the test cartridge can be removed from the bay.

2.3 Screen Header

The Screen Header at the top of the touch screen display shows the page name of the menu the analyzer currently is in when not running an analysis. During a sample analysis the header displays the next step to begin the analysis then the time to completion once the analysis has started.

2.4 Command Buttons

The Command Buttons are shown at the bottom of the display. The individual buttons displayed will vary with the screen being displayed. Buttons shown with a dark Blue background are active, those with a Grey background are inactive.

This is the Settings (Menu) Button. Press this button to bring up the main Menu screen. From this screen the Operator can set up QC/Linearity, Results Settings, Operators, Analyzer Settings, Sample Fields, and Service.

This is the Data button. Pressing this button displays the Recall Data screen. From this screen you can Search By Identifier, display QC/Linearity Data, display Data Management screen, Patient List screen, or Other Data screen.

This is the Door button. When grey it is not active.

This is the Barcode scan button. The Allegro uses a barcode to identify the test cartridge, QC material and patient.

This is the Home button to bring the analyzer back to the Home screen.

This is the Up/Down button to scroll from one data screen to the next if there are more than one screen.

This is the Print button to print the results.

This is the Back button to go back to the Previous screen.

This is the Cancel button to delete any input.

This is the Accept button to apply all inputs.

This is the Cancel Analysis button.

This is the Enter Start Analysis button to close door and start the analysis.

3 Sample Analysis

WARNING: The analyzer utilizes a barcode scanner containing a class 2 laser product. Do not stare into the beam.

The Allegro Analyzer is able to measure whole blood samples for HbA1c with the HbA1c test cartridge; Total Cholesterol, HDL Cholesterol ,and Triglycerides with the Lipids test cartridge; and Urine samples for Albumin and Creatinine with the UACR test cartridge. External Quality Control material is also analyzed with the test cartridges to verify the analyzer is performing to specifications.

- The left cartridge bay can be used for either Lipids or UACR test cartridges;
- The right cartridge bay can be used for either HbA1c or UACR test cartridges.

For improved system efficiency, when using a UACR test cartridge with either Lipids or HbA1c test cartridge always start the Lipids or HbA1c analysis first and the UACR analysis second.

3.1 HbA1c Patient Sample Analysis

HbA1c is measured from whole blood samples using the Allegro HbA1c test cartridge. A single-use, disposable safety lancet is needed to puncture the finger for capillary samples.

CAUTION:

- ***Do not use the test cartridge if the pouch, test cartridge, desiccant pack or capillary are damaged.***
- ***Do not heat the cartridge.***
- ***Do not contaminate the optical window at the front of the test cartridge.***
- ***Sample analysis should be started no later than 2 minutes after the test cartridge capillary is filled.***
- ***Do not use a test cartridge that has been dropped after the capillary has been filled and inserted into the test cartridge.***
- ***Care should be used when entering patient ID's manually as incorrect entry could lead to improper treatment.***

1. Verify the analyzer is ready to run a sample analysis (status LED is steady green).

2.  Scan the HbA1c test cartridge by pressing the Scan button on the Home screen.

Figure 3.1. Scan the Cartridge Barcode

3. Use the on-screen keyboard and barcode scanner to enter any required pre-analysis information. Press √ when done.

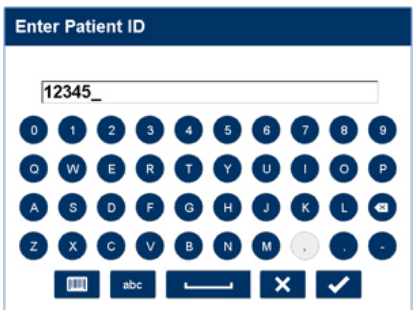


Figure 3.2. Enter Patient ID Screen

4. The Insert Cartridge screen will display and the cartridge bay door will open.

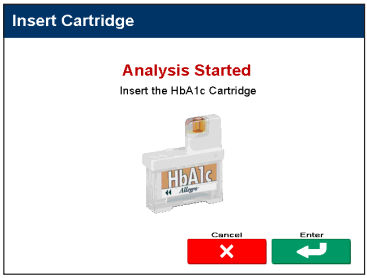


Figure 3.3. Insert Cartridge Screen for HbA1c

5. Open the HbA1c test cartridge and remove the Capillary.

Figure 3.4. Remove the Capillary from the HbA1c Cartridge

6. Wash and dry hands thoroughly with a paper towel.
7. Select a finger stick site.
8. Use an alcohol pad that **does not contain glycerol** to cleanse the site and allow to air dry.
9. Use a safety lancet to puncture the finger. Squeeze the finger to form a blood drop. Wipe away the first blood drop using a plain, clean, gauze pad containing **no glycerol**. Squeeze the finger again to form a second drop of blood.

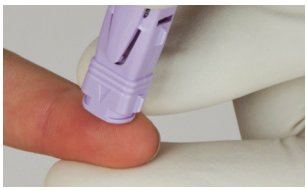


Figure 3.5. Safety Lancet to Puncture the Finger

10. Insert the end of the Capillary into the center of the specimen. Draw specimen up into the Capillary until completely filled to the fill line. Verify that no air bubbles are observed.

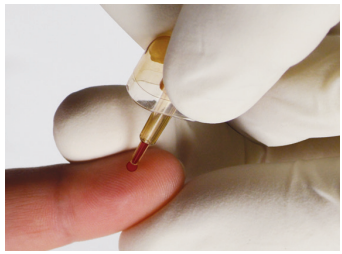


Figure 3.6. Wick Blood into Capillary to the Fill Line

11. Alternately, venous whole blood samples containing EDTA, Sodium Heparin or Lithium Heparin may be used. Samples must be well mixed by gentle inversion before analysis. Once mixed, wick the blood into the Capillary until completely filled to the fill line.

12. Insert the Capillary back into the HbA1c Test Cartridge.

Figure 3.7. Insert Capillary into the HbA1c Cartridge

13. Place the test cartridge into the open bay within **2 minutes of sample collection**. Press down with finger as shown until the cartridge clicks into place.

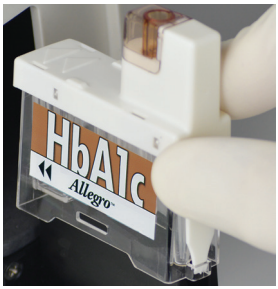


Figure 3.8. Place Cartridge into Sample Bay

14. Press the Enter icon on the Insert Cartridge screen. The Test Cartridge goes into the analyzer; the door closes; and analysis starts. The Status LED flashes green.

15. The Test Results screen is displayed with the time till completion shown in the header bar. The status LED will blink green during sample analysis.

16. Sample results will be displayed on the Test Results screen as they become available. If the test result is questionable or if clinical signs and symptoms appear inconsistent with the test result, analyze control solutions and retest the specimen.

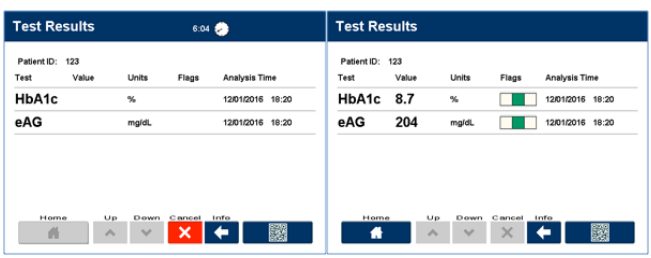


Figure 3.9. Test Results Screen for HbA1c

17. After the analysis is completed the cartridge bay will open and the used test cartridge may be removed for disposal into an appropriate biohazard container. Press the release button down and lift the cartridge up and out of the bay as shown.

Figure 3.10. Press the Release Button

18. Press Home to return to the Home screen.

3.1.1 HbA1c Test Result Reporting

The Nova Allegro HbA1c Test Cartridge measures the total glycated hemoglobin and the total hemoglobin concentration. The ratio between them is proportional to the % HbA1c of the sample. The Analyzer calculates the ratio.

- The test result is displayed as % HbA1c.
- The measurement range is 4.0-14.0% HbA1c.
- The HbA1c results are displayed in 0.1% intervals.

If a test result is below the Allegro's measurement range, 3 down arrows (↓↓↓) are displayed.
If a test result is above the Allegro's measurement range 3 up arrows (↑↑↑) are displayed.
If results outside the Allegro HbA1c measurement range are required, analyze the sample using another method.

Estimated Average Glucose: eAG
An average glucose value derived from and based upon the HbA1c value.
Like the HbA1c, the eAG provides an estimate of blood glucose levels during the 2 to 3 months preceding the test. It is used to help patients understand how their HbA1c levels would translate into daily capillary blood glucose values. An HbA1c of 7%, for example, translates into an eAG of 154 mg/dL; an HbA1c of 9% suggests that a patient's average blood glucose in the past few months was 212 mg/dL. Because

the eAG value matches the units that patients see when they test their own glycemic levels, it may be more readily understandable and a better tool for communicating to patients how to control their blood sugar levels than the HbA1c.

3.2 Analyzing Patient Samples for Lipids

Cholesterol, HDL Cholesterol and Triglyceride levels are measured from whole blood samples using the Allegro Lipids test cartridge. A single-use, disposable safety lancet is needed to puncture the finger for capillary samples.

CAUTION:

- ***Do not use the test cartridge if the pouch, test cartridge, desiccant pack or capillary are damaged.***
- ***Do not heat the cartridge.***
- ***Do not contaminate the optical window at the front of the test cartridge.***
- ***Sample analysis should be started no later than 2 minutes after the test cartridge capillary is filled.***
- ***Do not use a test cartridge that has been dropped after the capillary has been filled and inserted into the test cartridge.***
- ***Care should be used when entering patient ID's manually as incorrect entry could lead to improper treatment.***

1. Verify the analyzer is ready to run a sample analysis (status LED is steady green).
2.  Scan the Lipids test cartridge by pressing the Scan button on the Home screen.

Figure 3.11. Scan the Cartridge Barcode

3. Use the on-screen keyboard and barcode scanner to enter any required pre-analysis information. Press √ when done.

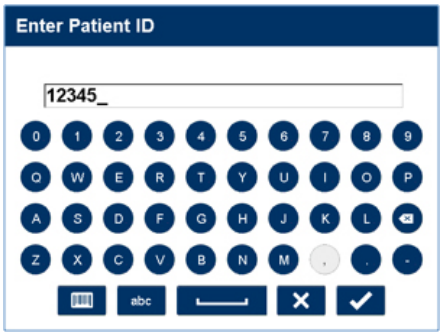


Figure 3.12. Enter Patient ID Screen

4. The Insert Cartridge screen will display and the cartridge bay door will open.

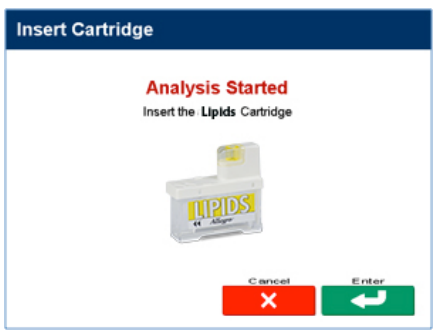


Figure 3.13. Insert Cartridge Screen for Lipids

5. Open the Lipids test cartridge and remove the Capillary.

Figure 3.14. Remove Capillary

6. Wash and then dry the patients' hands thoroughly with a paper towel.
7. Select a finger stick site. Use an alcohol pad that **does not contain glycerol** to cleanse the site and allow to air dry.
8. Use a single-use, disposable safety lancet to puncture the finger then squeeze the finger to form a blood drop. Wipe away the first blood drop using a plain, clean, gauze pad containing **no glycerol.** Squeeze the finger again to form a second blood drop.

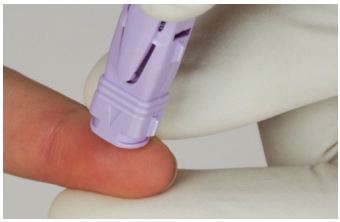


Figure 3.15. Safety Lancet to Puncture the Finger

9. Insert the end of the Capillary into the center of the specimen. Draw specimen up into the Capillary until completely filled to the fill line. Verify that no air bubbles are observed.

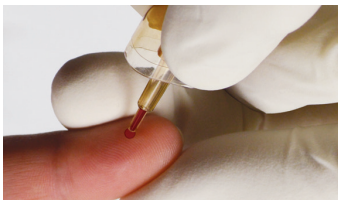


Figure 3.16 Wick Blood into Capillary to the Fill Line

10. Alternately, venous whole blood samples containing Sodium Heparin or Lithium Heparin may be used. Samples must be well mixed by gentle inversion

before analysis. Once mixed, wick the blood into the Capillary until completely filled to the fill line.

11. Insert the Capillary back into the Lipid Test Cartridge.

Figure 3.16. Figure 3.17 Insert Capillary into the Lipid Cartridge

12. Place the test cartridge into the open bay within **2 minutes of sample collection**. Press down with finger as shown until the cartridge clicks into place.

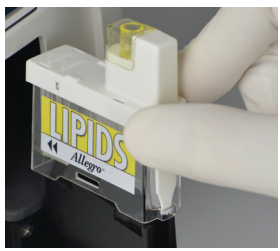


Figure 3.17. Place Lipid Cartridge into Sample Bay

13. Press the Enter icon on the Insert Cartridge screen. The Test Cartridge goes into the analyzer; the door closes; and analysis starts. The light flashes green.

14. The Test Results screen is displayed with the time till completion shown in the header bar. The status LED will blink green during sample analysis.

15. Sample results will be displayed on the Test Results screen as they become available. If the test result is questionable or if clinical signs and symptoms appear inconsistent with the test result, analyze control solutions and retest the specimen.

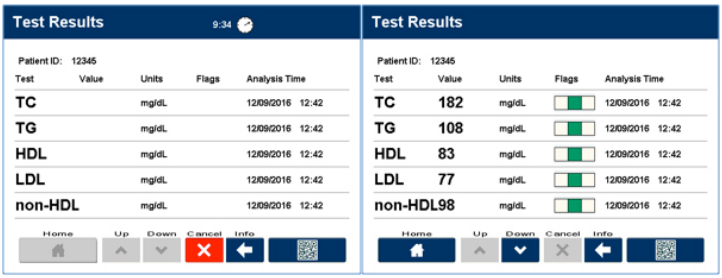


Figure 3.18. Test Results Screen for Lipids

16. After the analysis is completed the cartridge bay will open and the used test cartridge may be removed for disposal into an appropriate biohazard container. Press the release button down and lift the cartridge up and out of the bay as shown.

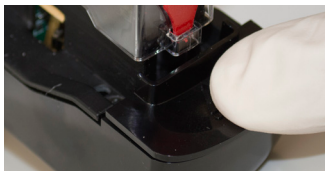


Figure 3.19. Press the Release Button

17. Press Home to return to the Home screen.

3.2.1 Lipid Test Result Reporting

The Nova Allegro Lipid Test Cartridge measures Total Cholesterol, HDL Cholesterol and Triglycerides.

The measurement range:

Total Cholesterol is 90-500 mg/dL (2.33-12.93 mmol/L).
HDL Cholesterol is 20-100 mg/dL (0.52-2.5 mmol/L).
Triglycerides is 50-600 mg/dL (0.57-6.78 mmol/L).

If a test result is below the Allegro's measurement range, 3 down arrows (↓↓↓) are displayed.
If a test result is above the Allegro's measurement range, 3 up arrows (↑↑↑) are displayed.
If results outside the Allegro Lipids measurement range are required, analyze the sample using another method.

Calculated Tests

- LDL Cholesterol
- Non-HDL Cholesterol
- Total Cholesterol/HDL Ratio

3.3 UACR Patient Sample Analysis

Albumin and Creatinine levels are measured from fresh urine samples using the Allegro UACR test cartridge.

CAUTION:

- ***Diluted samples cannot be analyzed with the Allegro UACR test cartridge.***
- ***Do not use the test cartridge if the pouch, cartridge or capillary are damaged.***
- ***Do not heat the cartridge.***
- ***Do not contaminate the optical window at the front of the test cartridge.***
- ***Sample analysis should be started no later than 5 minutes after the test cartridge capillary is filled.***
- ***Do not use a test cartridge that has been dropped after the capillary has been filled and inserted into the test cartridge.***
- ***Care should be used when entering patient ID's manually as incorrect entry could lead to improper treatment.***

1. Verify the analyzer is ready to run a sample analysis (status LED is steady green).
2.  Scan the UACR test cartridge by pressing the Scan button on the Home screen.

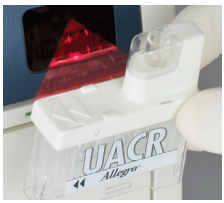


Figure 3.20. Scan the Cartridge Barcode

3. Use the on-screen keyboard and barcode scanner to enter any required pre-analysis information. Press √ when done.

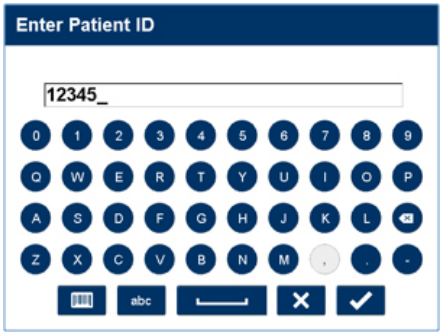


Figure 3.21. Enter Patient ID Screen

4. The Insert Cartridge screen will display and the cartridge bay door will open.

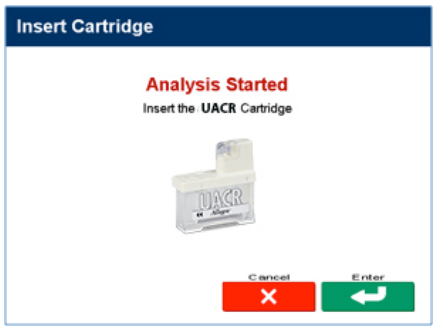


Figure 3.22. Insert Cartridge Screen for UACR

5. Open the UACR test cartridge and remove the Capillary.

Figure 3.23. Remove the Capillary from the UACR Cartridge

6. Verify that the urine specimen is properly mixed in the collection container.
7. Insert the end of the Capillary into the urine specimen. Draw specimen up into the Capillary until completely filled to the fill line. Verify that no air bubbles are observed.

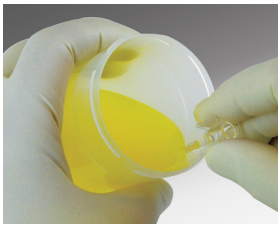


Figure 3.24. Draw Urine Sample into the Capillary

8. Insert Capillary back into the UACR Test Cartridge.

9. Place the test cartridge into the open bay within **5 minutes of sample collection**. Press down with finger as shown until the cartridge clicks into place.

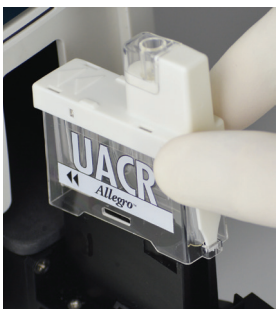


Figure 3.25. Place Cartridge into Sample Bay

10. Press the Enter icon on the Insert Cartridge screen. The Test Cartridge goes into the analyzer; the door closes; and the analysis starts. The light flashes green

11. The Test Results screen is displayed with the time till completion shown in the header bar. The status LED will blink green during sample analysis.

12. Sample results will be displayed on the Test Results screen as they become available. If the test result is questionable or if clinical signs and symptoms appear inconsistent with the test result, analyze control solutions and retest the specimen.

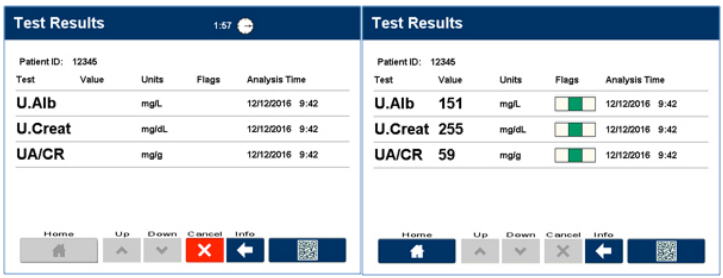


Figure 3.26. Test Results Screen for UACR

13. After the analysis is completed the cartridge bay will open and the used test cartridge may be removed for disposal into an appropriate biohazard container. Press the release button down and lift the cartridge up and out of the bay as shown.

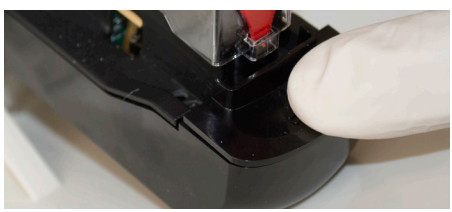


Figure 3.27. Press the Release Button

14. Press Home to return to the Home screen.

3.3.1 UACR Test Result Reporting

The Nova Allegro UACR Test Cartridge measures albumin and creatinine in urine samples. From these results the analyzer calculates the UACR ratio.

- The measurement range for albumin is 5-300 mg/L (0.5-30.0 mg/dL).
- The measurement range for creatinine 15-500 mg/dL (1.3- 44.2 mmol/L).

If a test result is below the Allegro's measurement range, 3 down arrows (↓↓↓) are displayed.
If a test result is above the Allegro's measurement range, 3 up arrows (↑↑↑) are displayed.
If results outside the Allegro UACR measurement range are required, analyze the sample using another method.

3.4 Analyzing a Second Test Cartridge

The Allegro analyzer contains 2 analysis bays and is able to analyze 2 different test cartridges for the same patient at the same time. The left bay is used for the Lipids test cartridge; the right bay is used for the HbA1c test cartridge. UACR test cartridges can be analyzed in either the left or the right bay. For improved analyzer efficiency when 2 test cartridges are to be analyzed, start the HbA1c or Lipids analysis first and the UACR analysis second.

To analyze

1. Follow the steps outlined in section 3.1 or 3.2 to initiate an HbA1c or Lipids test cartridge analysis.
2.  Once the first test cartridge analysis has begun press the scan button to scan the second test cartridge.
3. Verify the sample is from the same patient as the one identified for the first test cartridge and press Yes to continue. Press No to return to the test results page.

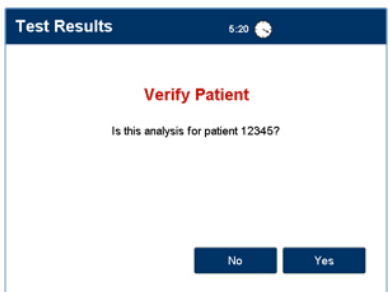


Figure 3.28. Verify Patient Screen

4. Follow the steps outlined in Section 3.3 to initiate a UACR Test Cartridge analysis.
5. Test results from both test cartridges are displayed on the Test Results page.
6. Press Home to return to the Home screen.

3.5 The Patient Test Results Display

Once the sample analysis is complete results for the measured and calculated tests are shown on the display. Each test is shown with its measured value, the unit of measure, a color bar graph for flags and the date and time of the analysis.

Normal Result

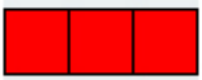
High Result

Low Result

Critical High

Critical Low

Outside Measurement Range



The colored bar graph provides a visual indication of the relative sample concentration. Green indicates the sample result is within the normal reference range for that test, Orange indicates the result is outside the normal reference range but does not exceed the critical alert range. Red indicates the result exceeds the critical alert range. All red indicates the result is outside of the assay's measurement range.

Test results above the assay's measurement range are printed as ↑↑↑.

Test results below the assay's measurement range are printed as ↓↓↓.

If an error occurred during the analysis and a result could not be displayed, the value is left blank and the Flags icon is replaced with  indicating an error occurred.

If the test results do not fit on one page use the buttons 

to scroll through the test results.

Press the 

button to access the Sample Information screen to enter additional information for the current sample analysis.

3.6 Quality Control

Quality Control (QC) solutions are used to monitor the performance of the analyzer and the test cartridges used with it. The expected range for the Nova Allegro Control Solutions was determined at Nova Biomedical by using multiple runs of each level of control on multiple instruments. The expected range indicates the maximum deviations from the mean value that may be expected under differing laboratory conditions for instruments operating within specifications. Refer to Expected Ranges Table. The ranges given are intended only as a guideline. Each laboratory should establish their own acceptable ranges and tolerance limits based on their Nova Allegro Analyzer.

Controls should be analyzed:

- With each new shipment of Nova Allegro Test Cartridges
- With each new lot of Nova Allegro Test Cartridges
- At least every 30 days
- When training new operators in the correct use of the Nova Allegro Test Cartridges
- Anytime an unexpected test result is obtained

If local and/or federal regulations require more frequent testing of control materials, then testing should be performed in compliance with these regulations.

3.6.1 Analyzing a Quality Control Solution

Before analyzing Quality Control Solution, read the Instructions for Use for the control solution.
To analyze a Quality Control solution:

1. First, scan the barcode on the quality control solution's label.

2. Next, scan the test cartridge barcode label. The door opens to accept the cartridge.

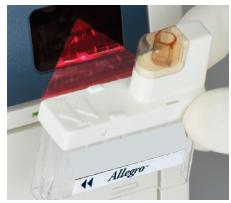


Figure 3.29. Scan the Cartridge Barcode

2. Remove capillary adapter from the Test Cartridge.

Figure 3.30. Remove Capillary Adaptor

3. Remove the control vial from the refrigerator package and mix by gentle inversion. Do not shake. Do not mix mechanically.
4. Use the control solution immediately or return to 2-8°C (36 to 46°F).
5. Place a droplet of control solution onto the supplied Control Solution Prep Sheet.
6. Touch the end of the Capillary to the droplet on the Prep Sheet, ensuring it is drawn up into the Capillary and completely filled.

7. The control vial should remain stored at 2-8°C at all times. If additional sampling is necessary, the time outside of 2-8°C storage should be minimized.
8. Insert the Capillary adaptor back into the Test Cartridge.

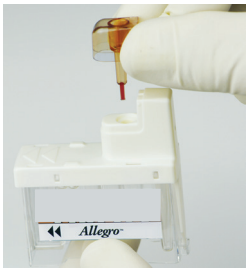


Figure 3.31. Capillary Adaptor into Cartridge

9. Place the Test Cartridge into the cartridge carrier **within 2 minutes for HbA1c and Lipids and within 5 minutes for UACR.** Press down with finger as shown until clicks into place.

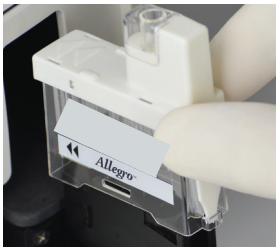


Figure 3.32. Place Cartridge into Sample Bay

10. Press the Enter icon  on the analysis. The cartridge goes into the analyzer; the door closes; and analysis starts.

11. The Test Results screen is displayed with the time till completion shown in the header bar. The status LED will blink green during sample analysis.

12. Control Solution results will be displayed on the Test Results screen as they become available.

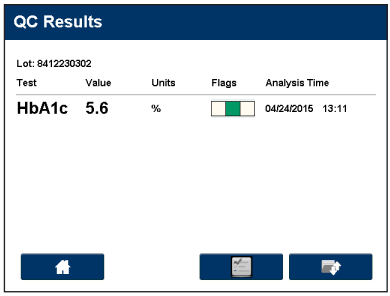


Figure 3.33. QC Results Screen for HbA1c Shown

13. To remove the used test cartridge after the analysis has completed, press the open door icon.  Then press the button down and pull out the cartridge as shown and dispose it in an appropriate biohazard container.

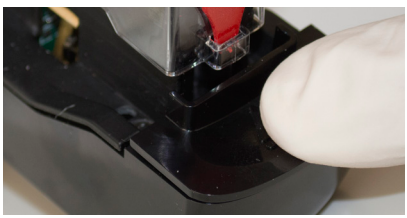


Figure 3.34. Press down as Shown Above To Release the Cartridge

14. Press Home to return to the Home screen.

4 Reviewing Patient and QC Data

Patient and Quality Control data are stored on the analyzer and can be recalled to review at any time. If needed, recalled results can be viewed, reprinted, or retransmitted. To access stored data, press the Data button.

4.1 Recalling Patient Data

Patient data can be recalled by entering the patient identifier (Patient ID, MRN Number, or Patient Name) used by the analyzer or by choosing the patient from the Patient List.

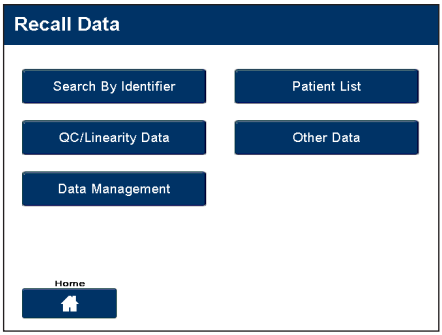


Figure 4.1. Recall Data Menu Screen

To recall patient data using Search By Identifier:

1. Press the Search By Identifier button.
2. Enter the Patient ID, MRN Number, or Patient Name. Then press the √ button.

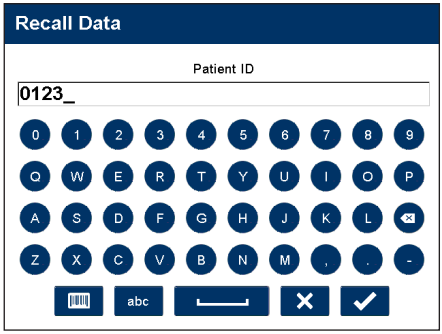


Figure 4.2. Search Patient ID Screen

To recall patient data using the Patient List button:

1. Press the Patient List button.
2. Use the Up/Down buttons to scroll through all entered patient identifiers.
3. Select the Patient to view.

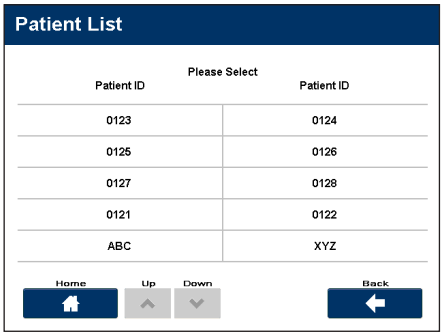


Figure 4.3. Patient List Screen

All test results for the selected patient are displayed on the Patient Data screen.

- Press Home to return to the Home Screen.
- Press Up or Down to scroll through all of the patient's test results. The most recent result is at the top of the list.
- Press Trend to display a graph of all the patient's test results.
- Press Data to return to the Recall Data screen.

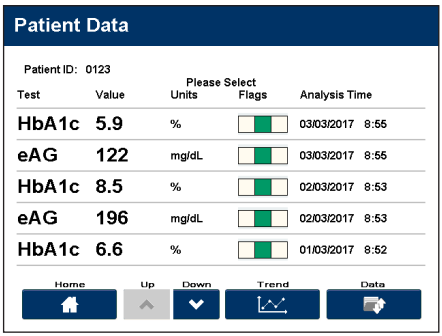


Figure 4.4. Patient Data Screen

4.1.1 Patient Trends

The Patient Trend screen displays a graphical representation of the patient's historical test results.

- Press Home to return to the Home Screen.
- Press In to zoom in on the results if more detail is needed. Press Out to zoom out if less detail is needed.

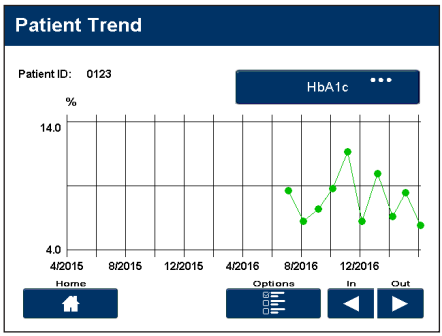


Figure 4.5. Patient Trend HbA1c Screen

Press Options to modify the graph.

- Press Plot Low to enter the value for the low range displayed on the graph.
- Press Plot High to enter the value for the high range displayed on the graph.
- Press Print to print the graph on the thermal printer.
- Press Print All to print a graph of each test that has results for the patient.
- Press X to cancel any changes and return to the Patient Trend screen
- Press √ to save any changes and return to the Patient Trend screen.

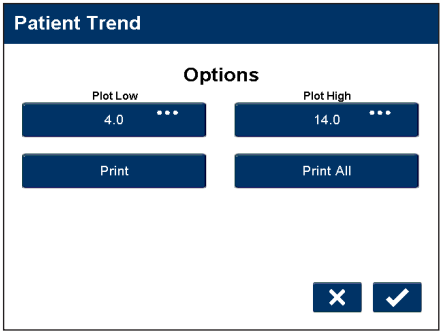


Figure 4.6. Patient Trend Options Screen

To display the Patient Trend for a different test

- Press the test name button.
- Press the test name of the desired test to display the trend for that test.

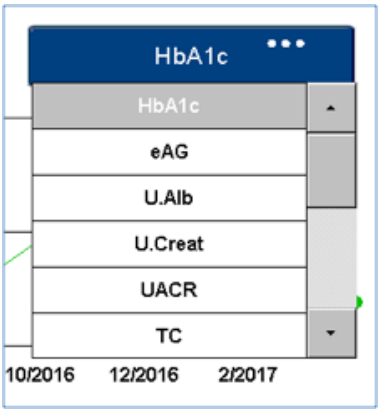


Figure 4.7. Test Name Selection

4.2 Recalling QC Data

To recall QC data press the QC/Linearity Data button.

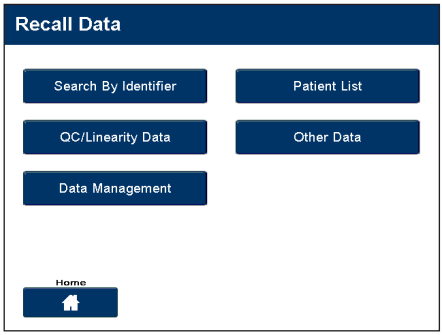


Figure 4.8. Recall Data Screen

Select the QC lot number from the displayed list.

- Use the Up / Down buttons if active to scroll through additional QC lots.

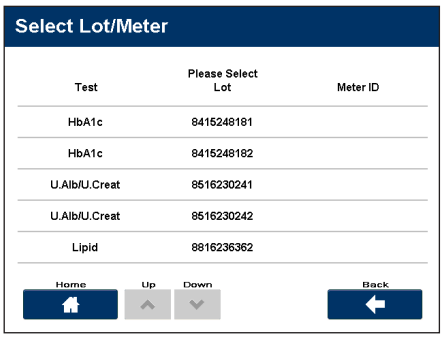


Figure 4.9. Select Lot/Meter Screen

QC Data for the selected lot is displayed with the most recent result on top.

- If active, use the Up / Down buttons to scroll through additional results.
- Press Options for QC Data Options.

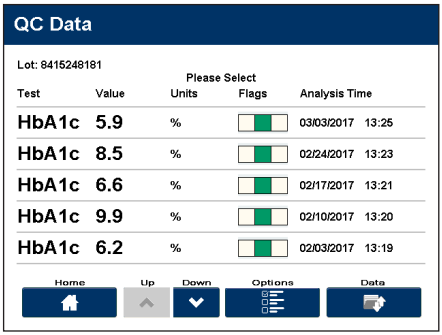


Figure 4.10. QC Data Result Screen

To view a specific QC result, select that result from the QC Data list.

- Press Options to display the QC Result options screen.

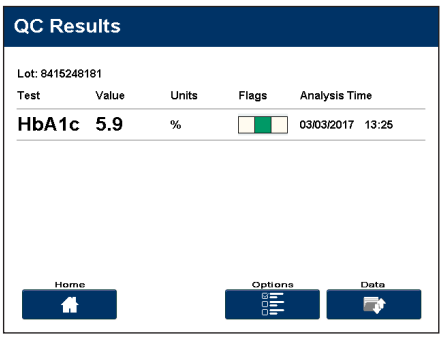


Figure 4.11. QC Result Screen

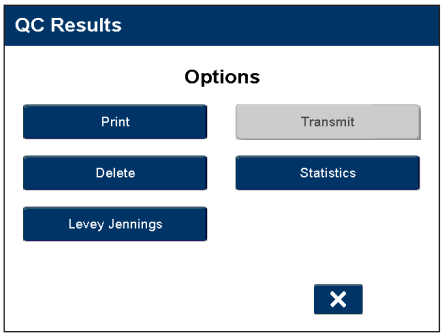


Figure 4.12. QC Results Options Screen

- Press Print to print the QC result
- Press Delete to delete the QC result
- Press Transmit to transmit the QC result to your lab manager software.
- Press Statistics to display the statistics for the selected QC lot.
- Press Levey Jennings to display the Levey Jennings graph for the selected QC lot.

4.2.1 QC Data Options

The QC Data Options screen provides 2 ways to view QC data.

- Press Statistics to view QC Statistics for the selected lot of QC
- Press Levey Jennings to view a Levey Jennings graph for the selected lot of QC.

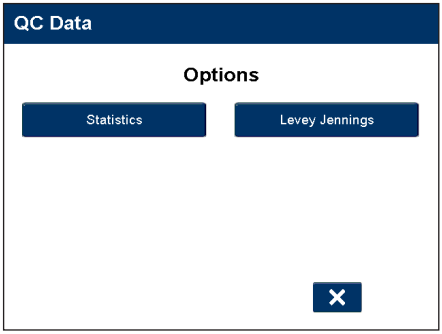


Figure 4.13. QC Data Options Screen

QC Statistics are displayed showing the QC test name, the Mean, the Standard Deviation (SD), the Coefficient of Variation (CV%), and the Number (n) of results.

- Statistics are calculated using all QC results from the selected lot.
- Press Print to print the statistics.

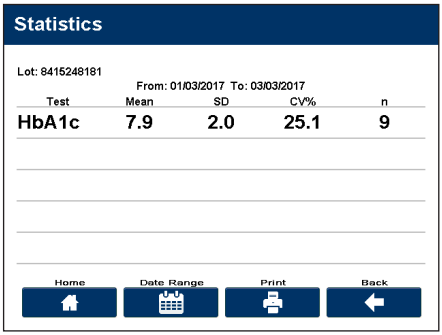


Figure 4.14. QC Statistics Screen

- To display statistics for a specific date range, select the Date Range button then enter the date range of interest.

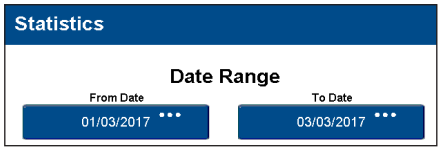


Figure 4.15. Statistics Date Range Screen

The Levey Jennings graph is a pictorial representation of QC recovery over the last 30 days with the most recent result on the right-hand side.

- Use the Left / Right buttons if active to scroll through additional results.

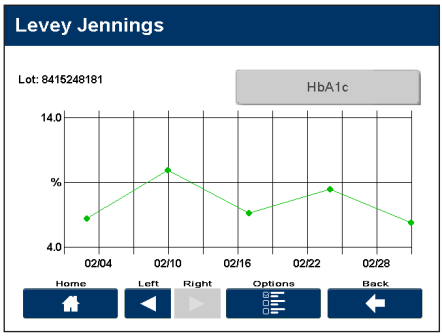


Figure 4.16. Levey Jennigs Graph (Screen)

- Press the Options button to display the Levey Jennings Options screen.
- Press Plot Low to change the lowest value displayed on the chart.
- Press Plot High to change the highest value displayed on the chart.
- Press Print to print a copy of the displayed Levy Jennings chart.

4.3 Other Data

Other Data contains Patient result data with no sample identifier.

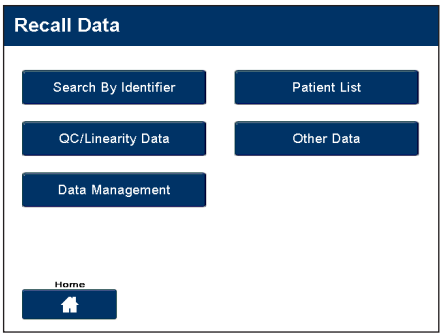


Figure 4.17. Recall Data Screen

4.4 Data Management

The Data Management screen has multiple functions: all require a compatible USB drive be connected to the back of the analyzer. If no USB drive is connected or cannot be recognized, the buttons will be inactive (grey). If an existing Setup or Operators list is not found on a connected USB drive the Import button will be remain inactive.

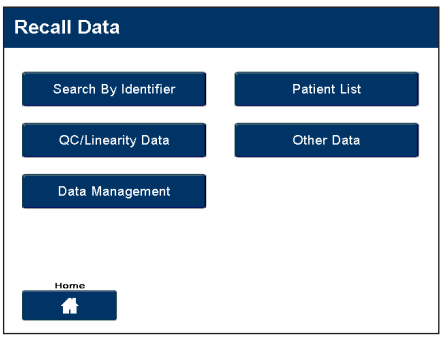


Figure 4.18. Recall Data Screen

Figure 4.19. Data Management Screen

The analyzers setup configuration, all the choices that were made in the Settings menu, can be exported to a USB drive connected to the analyzer for backup purposes. If needed, these settings can be imported back into the analyzer or into another analyzer.

If the analyzer is configured to use Operators to identify individual users, the list of operators can be exported to a USB drive connected to the analyzer for backup purposes. If needed, the list can be imported back into the analyzer or into another analyzer.

4.4.1 Exporting Samples

Patient samples can be exported to a compatible USB drive as a comma separated values (.csv) file that can be opened with any spreadsheet application.

NOTE: *Exported samples are not deleted from the analyzer.*

To export patient samples

- Press Export Samples.
- From the Patient List, select the Patient to export.
- The analyzer automatically uses a date range that includes all data for the selected patient. If a specific date range is required, use the From Date / To Date buttons to specify the date range.

- Press Export to copy the selected data to a USB drive.

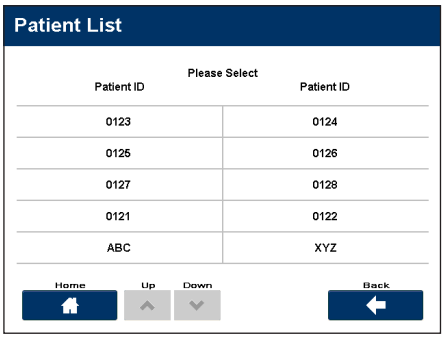


Figure 4.20. Patient List Screen

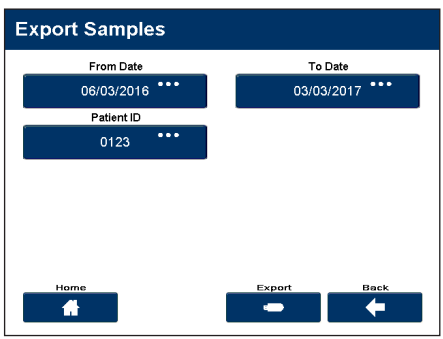


Figure 4.21. Export Samples Screen

4.4.2 Archive Samples

Patient samples can be archived to a compatible USB drive as a comma separated values (.csv) file that can be opened with any spreadsheet application.

NOTE: *Archived samples are deleted from the analyzer and cannot be restored.*

To Archive patient samples

- Press Archive Samples.
- From the Patient List, select the Patient to archive.
- The analyzer automatically uses a date range that includes all data for the selected patient.
- Press Archive to copy the selected data to a USB drive and permanently delete it from the analyzer.

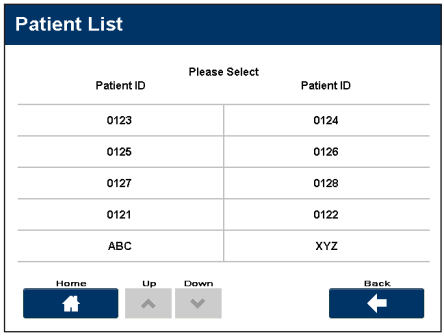


Figure 4.22. Patient List Screen

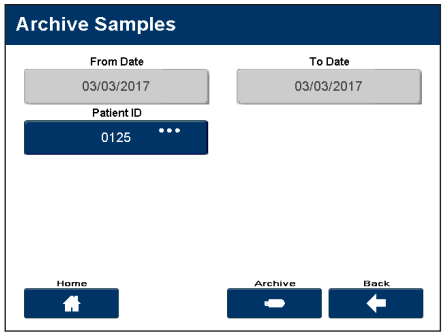


Figure 4.23. Archive Samples Screen

4.4.3 Export QC

QC data can be exported to a compatible USB drive as a comma separated values (.csv) file that can be opened with any spreadsheet application.

NOTE: *Exported QC samples are not deleted from the analyzer.*

To export QC data,

- Press Export QC.
- From the QC Lot List, select the QC Lot to export.
- The analyzer automatically uses a date range that includes all data for the selected lot. If a specific date range is required, use the From Date / To Date buttons to specify the date range.
- Press Export to copy the selected data to a USB drive.

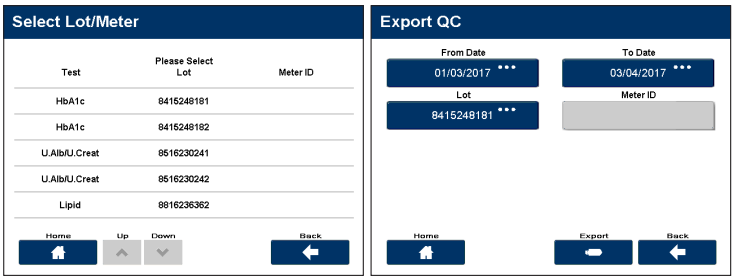


Figure 4.24. Select Lot/Meter Screen and Export QC Screen

4.4.4 Archive QC

QC data can be archived to a compatible USB drive as a comma separated values (.csv) file that can be opened with any spreadsheet application.

NOTE: *Archived QC data is deleted from the analyzer and cannot be restored.*

To Archive QC data

- Press Archive QC.
- From the QC Lot List, select the QC lot to archive.
- The analyzer automatically uses a date range that includes all data for the selected lot.
- Press Archive to copy the selected data to a USB drive and permanently delete it from the analyzer.

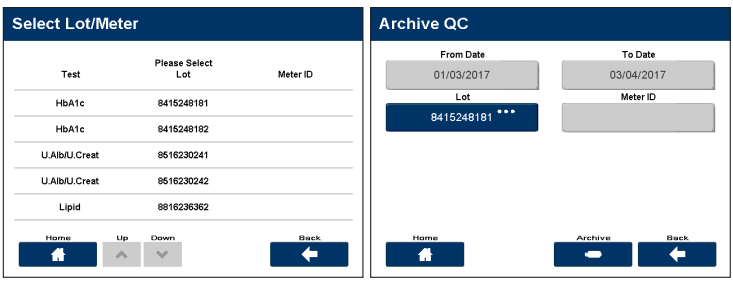


Figure 4.25. Select Lot/Meter Screen and Archive QC Screen

5 Settings

The Settings Menu provides a means of configuring the analyzer to meet the requirements of each location where it is used. From the Settings Menu, Quality Control settings, Test Result settings, Analyzer settings, and user defined Sample Field settings can be configured. An Operators list can be created and maintained and the Service menu accessed.

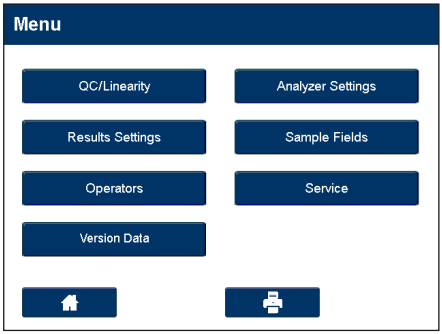


Figure 5.1. Menu Screen

5.1 QC/Linearity

Quality Control (QC) solutions are used to monitor the performance of the analyzer and the test cartridges used with it. Each QC solution that will be used with the analyzer must first be set up for use.

To setup a new QC lot, the operator must first scan the 2-D barcode located on the package insert sheet. This barcode contains the lot number, expiration date, and expected range of each test in the solution. When the barcode is scanned this information is read into the analyzer's memory and the lot is enabled for use. If the lot has already been setup, the operator will be notified the lot already exists and will be asked if they want to overwrite the existing settings.

With each new lot of QC:

1. Locate the 2-D barcode on the upper left corner of the QC package insert sheet.
2. From the analyzer's Home screen, press Scan to scan the barcode and download the QC lot number, expiration date, and expected ranges to the analyzer memory.

5.1.1 Change Lot

Once a lot of QC has been scanned into the analyzer, the manufacturer expected ranges can be adjusted if necessary.

1. From the Settings Menu, press the QC/Linearity button.
2. Press the Change Lot button.
3. Select the Lot number of the control to be edited.

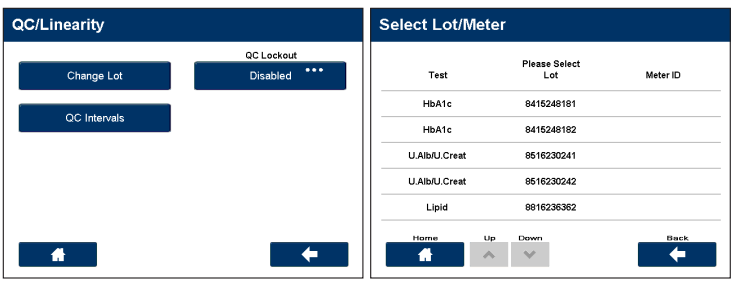


Figure 5.2. QC/Linearity Screen to Select Lot/Meter Screen

4. Select the Test to be edited then enter the High Limit and Low Limit for that control.

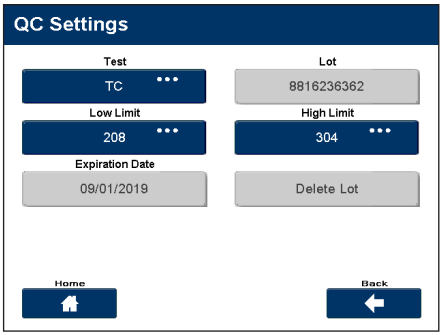


Figure 5.3. QC Settings

5.1.2 QC Lockout

QC Lockout prevents the analyzer from using a test cartridge (HbA1c, Lipids, or UACR) if QC results for that cartridge fall outside their expected ranges or, if a scheduled QC has not been run.

To enable QC Lockout, toggle the QC Lockout button to Enabled.

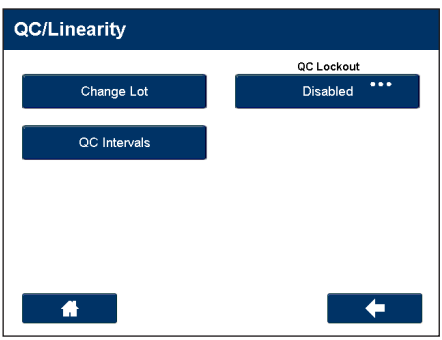


Figure 5.4. QC Linearity Screen

5.1.3 QC Intervals

QC Intervals can be set up to ensure QC is run as scheduled up to 3 times per day. If a scheduled QC is not run before the designated time, the test cartridge will become locked out until the QC is run.

To configure QC Intervals

1. From the QC/Linearity screen, press the QC Intervals button.

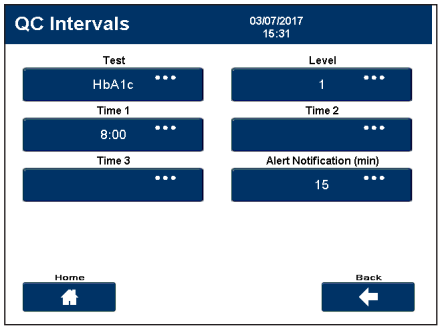


Figure 5.5. QC Intervals Screen

2. Select the Test cartridge name from the drop down list.
3. Select the QC Level from the drop down list.
4. Select Time 1 and enter the first time QC should be run that day.
5. Time 2 and Time 3 can be utilized if the QC solution is expected to be run more than once per day.
6. The analyzer will display an Alert Notification to remind the operator that QC is required. An Alert Notification can be set to display 15, 30, 45, or 60 minutes before the scheduled time to help insure the analyzer is always ready to use.

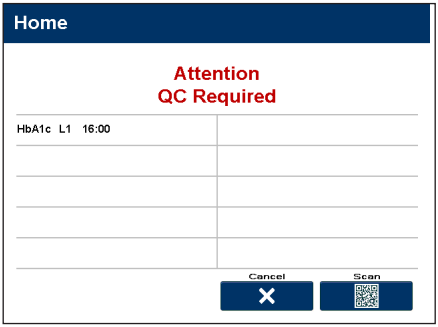


Figure 5.6. Home Screen: Attention QC Required

7. If a test cartridge for a QC Locked test is scanned on the analyzer, a QC Locked pop-up window is displayed. Depending on the analyzer's configuration, an authorized operator may bypass the lockout and continue with testing. Otherwise, the cartridge type will remain unavailable until the QC has been run and passed.

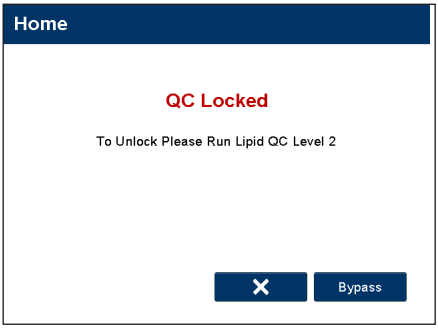


Figure 5.7. Home Screen: QC Locked

5.2 Analyzer Settings

The Analyzer Settings provides a means of configuring many of the analyzer's general settings including Date and Time, display language, and computer interface.

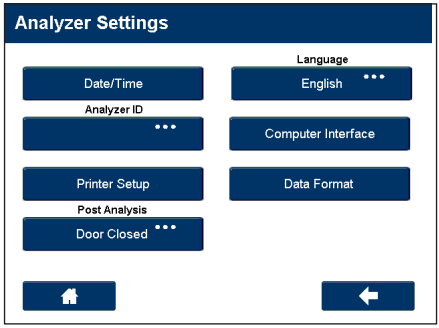


Figure 5.8. Analyzer Settings Screen

5.2.1 Date and Time

To update the analyzer's date and time

1. Press Set Date/Time.

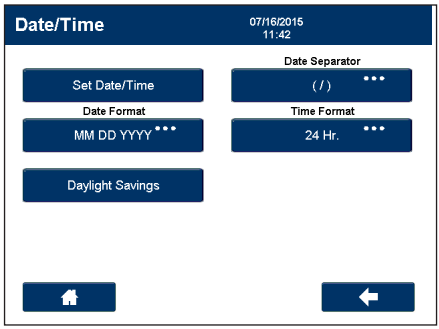


Figure 5.9. Date/time Screen

2. Select the desired Date Format from the drop down list: MM DD YYYY, DD MM YYYY, or YYYY MM DD.
3. Select the Date Separator to use from the drop down list.
4. Select the Time Format: 12 Hr. or 24 Hr.
5. Press the Date/Time button on the Analyzer Settings screen.
6. Use the Year, Month, Day, Hour, and Minute buttons to enter the correct date and time. Select AM/PM if the 12 Hour time format is selected.

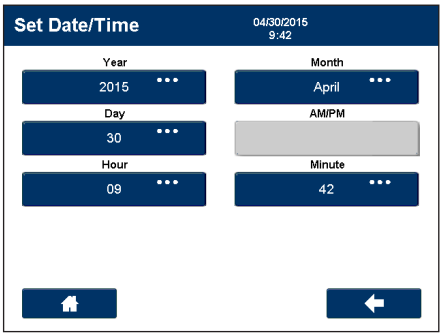


Figure 5.10. Set Date/Time Screen

7. Press Back to return to the Date/Time screen.
8. To set Daylight Savings, press the Daylight Savings button.
9. Enter the start and end dates then set Daylight Savings to Enabled.

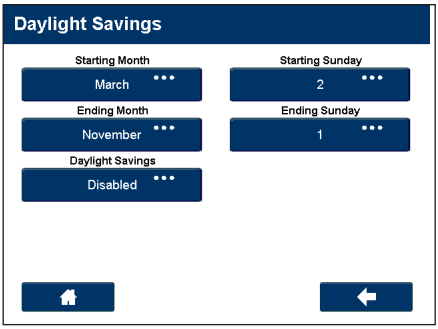


Figure 5.11. Daylight Savings Screen

5.2.2 Analyzer ID

The Analyzer ID button identifies the analyzer being used on all patient and QC samples and reports. The analyzer ID may consist of an alphanumeric name of no more than 12 characters. To enter an Analyzer ID, first press the Analyzer ID button then use the on-screen keyboard to enter an ID.

5.2.3 Printer Setup

The Printer Settings provide a means of setting the printing mode to 1 of 3 settings.

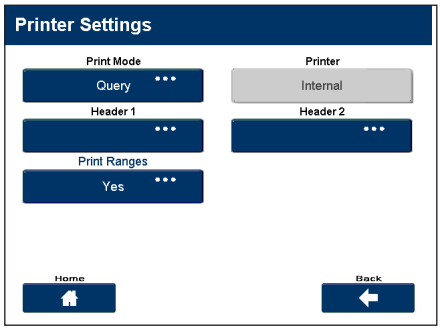


Figure 5.12. Printer Settings Screen

- Manual – the user must recall test results, select the Options button, then press Print to print a result.
- Automatic – test results are printed automatically at the conclusion of each sample analysis.
- Query – At the conclusion of the sample analysis, the operator is asked if they would like to print a report.
- The printout can be customized with 2 alphanumeric print headers.
  Select Header 1 or Header 2 and use the on-screen keyboard to enter the desired text: up to 25 characters.

- If Reference and Alert ranges are not required on the results printout, toggle the Print Ranges button to No. If ranges are required, toggle to Yes.

5.3 Results Settings

The Results Settings provide a way to select the unit of measure for each test result and to define the normal and critical range of that test. If the analyzer will be utilizing slope and offset corrections, the slope and offset values are entered here.

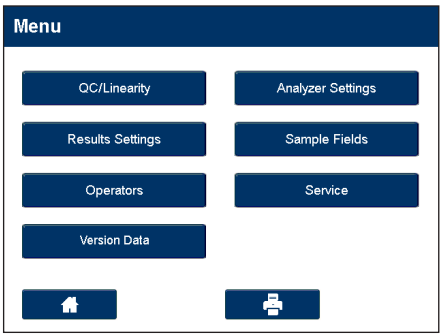


Figure 5.13. Menu Screen

From the Menu screen, press Results Settings to display the Results Settings screen.

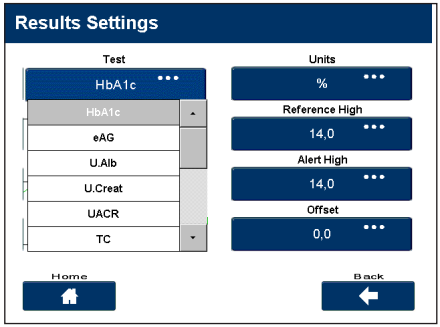


Figure 5.14. Results Settings Screen With Test Pulldown

1. Select the Test button then select the test name from the displayed list you wish to configure.
2. Select the Units button then select the desired Unit of Measure from the list.

Reference ranges are the normal low and normal high values for the selected test. Test results that fall within these ranges are displayed on the test results screen with a green icon. Test results that fall outside this range will be displayed on the test results screen with an Orange icon to indicate the result is abnormal.
The Alert range is the critical range for the selected test. Test results that fall outside the Alert range are displayed on the test results screen with a red icon to indicate the result is in a critical range.

To set the Reference and Alert Ranges

1. Select the button for the value to be entered: Reference Low, Reference High, Alert Low, and/or Alert High.
2. Once selected, use the on screen keyboard to enter your laboratory's Reference and Alert ranges.

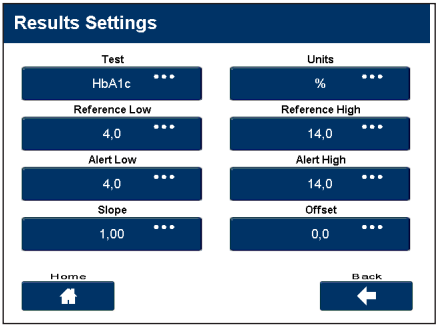


Figure 5.15. Results Settings Screen

Slope and Offset may be used to correlate the analyzer's results to those from a reference analyzer if there is a significant difference between them. If you are unfamiliar with the use of slope and offset corrections, please contact Nova Biomedical Technical Support or your local Nova distributor for assistance.

5.4 Sample Fields

If needed, the Sample Fields provide a way to identify each patient and allow the creation of up to 7 additional information fields.

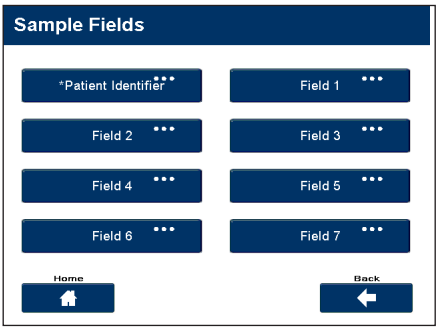


Figure 5.16. Sample Fields Screen

1. Press the Patient Identifier button and select the patient identifier to be used on the analyzer (Patient ID, MRN, or Name) from the list.
2. Choose if the selected Patient Identifier must be entered after the test cartridge is scanned (After Scan), before the analysis is complete (Before Complete), or not required (No).

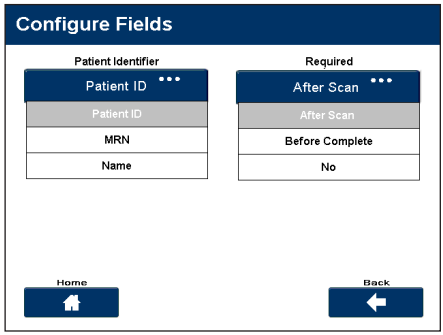


Figure 5.17. Configure Fields Screen

Up to 7 user defined fields can be enabled. To configure an additional field:

1. Select the Field to configure: Field 1 through Field 7 button.
2. From the Configure Fields screen, select Title and use the on-screen keyboard to enter an alphanumeric field name: up to 25 characters long.
3. Select Type and choose the Type of field: Alphanumeric, Date, or Time from the drop down list.
4. To enable the field, press the Enabled button and toggle to Yes.
5. To make the field required before a result can be printed or transmitted, press the Required button and toggle to Yes.

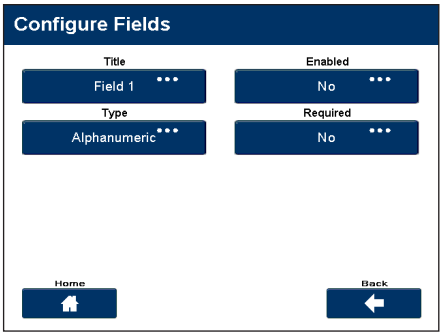


Figure 5.18. Configure Fields: Title, Type, Enabled, Required

5.5 Operators

The analyzer can be configured to allow only users that have been set up as an Operator to use the analyzer. This prevents unauthorized staff from using the analyzer and identifies which operator is using the analyzer.

When Operators are enabled, the analyzer cannot be used for a sample analysis until an operator logs in. A closed lock icon is displayed on the Home screen to indicate the analyzer state.

Figure 5.19. Home Screens: Locked and Unlocked

To log into the analyzer

1. Press the Lock icon.

2. If prompted, enter your Operator ID.
3. If prompted, enter your Password.

Once an operator is logged into the analyzer the Lock icon is shown as open, and the Operator ID of the logged in operator is displayed.

To log out of the analyzer

1. Press the open Lock icon.

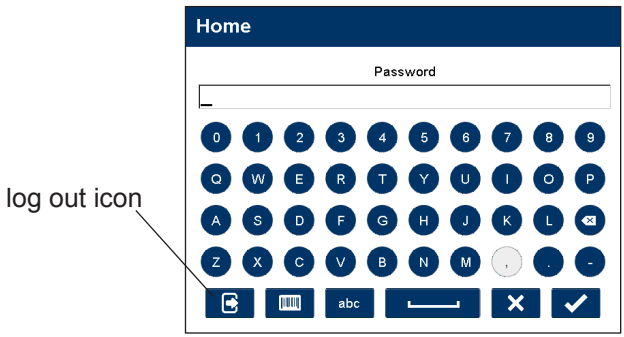


Figure 5.20. Enter Password

2. Press the log out icon in the lower left corner of the screen.

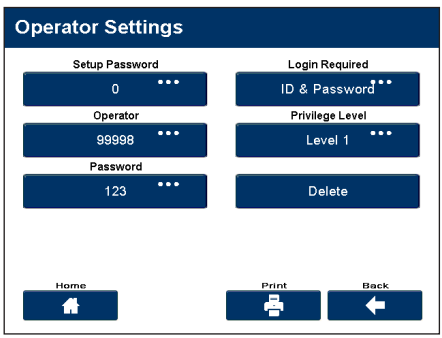


Figure 5.21. Operator Settings Screen

To configure Operators

1. From the Settings Menu, press the Operators button.
2. Press Setup Password and enter a new password if needed. All users are required to enter this password in order to access the Settings menu.
3. Press the Login Required button and select what the operator must enter when logging into the analyzer: ID and Password or Password Only.

NOTE: If None is selected, operator passwords are disabled and any existing operators will be deleted.

4. Press the Operator button and use the onscreen keyboard to enter an alphanumeric operator identifier of up to 18 characters
5. Press the Password button and use the onscreen keyboard to enter an alphanumeric password of up to 15 characters.
6. Press the Privilege Level button to select a privilege level for that Operator.
   - Level 1 operators are able to bypass QC lockout if needed.
   - Level 2 operators are not able to bypass QC lockout.
7. Press Add to add a new operator.
8. Existing operators can be deleted from the operator list if no longer applicable. Enter the Operator ID to be deleted then Press Delete to remove that operator from the list.

5.6 Service

The Service Menu provides the operator with useful tools and information about the analyzer. Some functions are protected by a daily password and are for use by Technical Support or Service personnel.

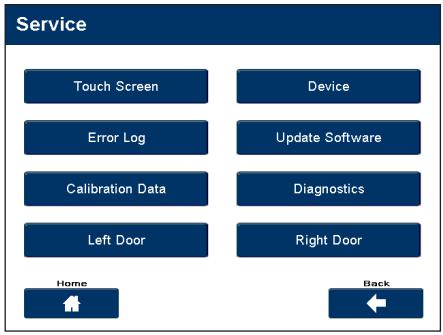


Figure 5.22. Service Menu Screen

5.6.1 Touch Screen

The analyzer utilizes a touch screen for most data entry purposes and if it is not calibrated correctly the user may have difficulty selecting the desired input. To calibrate the touch screen:

1. Press the Touch Screen button to display the calibration screen.
2. Follow the instructions on the screen and press √ when done.

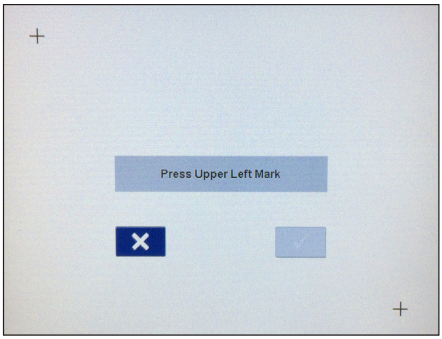


Figure 5.23. Calibration Screen

5.6.2 Error Log

The Error Log displays a list of errors that have occurred on the analyzer and may be useful if there is a need to troubleshoot a problem. Errors are displayed showing the Date and Time of the event, a description of the error and if the error occurred in the left or right analytical bay. For additional detail on an error refer to the troubleshooting section of this manual.

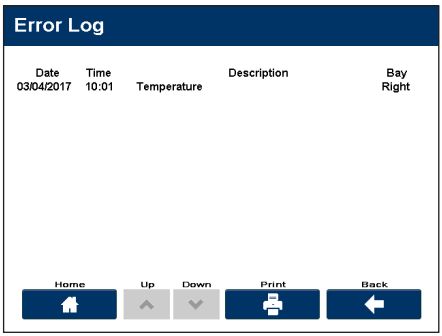


Figure 5.24. Error log Screen

5.6.3 Update Software

Software updates are installed using the Update Software button. The new software must first be copied to a compatible USB drive and the drive installed in the analyzer's USB connector located on the back of the analyzer.

If the USB drive or the software are not recognized a message to Install a USB Flash Drive containing the new software is displayed.

If the USB drive and the new software are recognized you will be prompted to press Continue to update the software. Once the software has finished installing the analyzer will restart and the USB drive can be removed.

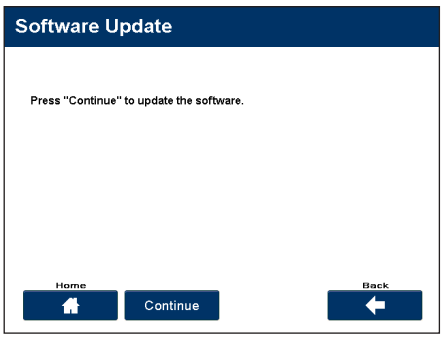


Figure 5.25. Software Update Screen

5.6.4 Left Door, Right Door

The Left Door and Right Door buttons open (if closed) or close (if open) the indicated cartridge bay door.

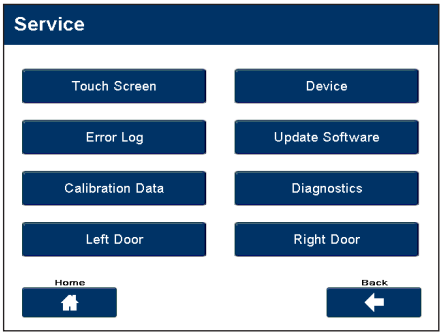


Figure 5.26. Service Menu Screen

5.6.5 Device, Calibration Data, Diagnostics

The Device, Calibration Data and Diagnostics buttons are for use by Technical Support and Service personnel and are not expected to be used by an operator unless it is at their direction.

5.7 Version Data

The Version Data button displays the currently installed version of the Host, Right Bay Module and Left Bay Module software.

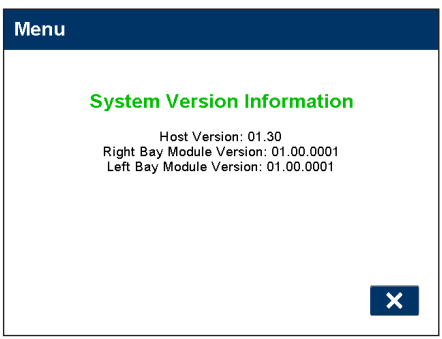


Figure 5.27. Service Menu Screen

6 Troubleshooting

If a system problem is detected an error code may be displayed on the screen and recorded in the error log. This section lists the errors and messages, what they mean and corrective actions.

FOR TECHNICAL ASSISTANCE, CALL TOLL FREE:

USA	1-800-545-NOVA
Canada	1-800-263-5999
Other Countries	Contact the local Nova Biomedical Sales Office or Authorized Nova Allegro Distributor

WARNING: Body fluids are potential sources of infectious agents. Handle all blood products and body fluids with care. Gloves and protective clothing are recommended.

6.1 Codes

Error Code	Description / Corrective Action
xxx Software (xxx will be reported as an actual number.)	The analyzer software runs continuously when the analyzer is powered on. In the event a software error is detected a numeric software code is displayed and logged in the error log. If a software error occurs: 1. Unplug the analyzer for 30 seconds then power it back on. 2. If the problem reoccurs please contact Technical Support.
xxx Hardware (xxx will be reported as an actual number.)	The analyzer monitors all internal electronic and electro-mechanical assemblies during operation. If a problem is detected a numeric hardware code is displayed and logged in the error log. If a hardware error occurs: 1. Unplug the analyzer for 30 seconds then power it back on. 2. If the problem reoccurs please contact Technical Support.
Door Failure	A cartridge bay door was not able to completely open or close. 1. Confirm there are no objects interfering with door operation. 2. If the problem reoccurs please contact Technical Support.

Temperature	The analyzer temperature was out of operational limits when an analysis was attempted. 1. If the analyzer has been turned off allow additional time for the internal heating circuit to warm up. 2. Check that there is sufficient ventilation around the analyzer. 3. Unplug the analyzer for 30 seconds then power it back on. 4. If the problem continues please contact Technical Support.
Tip Present	An internal Test Cartridge pipette tip was detected when not expected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
Tip Not Present	An internal Test Cartridge pipette tip was not detected when expected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
Capillary Holder Present	An internal Test Cartridge capillary holder was detected when not expected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
Capillary Holder Not Present	An internal Test Cartridge capillary holder was not detected when expected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.

Cover Present	An internal Test Cartridge cover was detected when not expected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
Cover Not Present	An internal Test Cartridge cover was not detected when expected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
HbA1c Bad Cartridge	A problem with the HbA1c test cartridge was detected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
HbA1c Bad Sample	A problem with the sample in the HbA1c test cartridge was detected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
U.Alb Bad Cartridge	A problem with the UACR test cartridge was detected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
U.Alb Bad Sample	A problem with the sample in the UACR test cartridge was detected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.

Lipid Bad Cartridge	A problem with the Lipids test cartridge was detected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
HDL Bad Cartridge	A problem with the Lipids test cartridge was detected. 3. Repeat the test using a new test cartridge. 4. If the problem reoccurs please contact Technical Support.
HDL Read	A problem with the sample in the Lipids test cartridge was detected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
TC Bad Cartridge	A problem with the Lipids test cartridge was detected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.
TC Read	A problem with the sample in the Lipids test cartridge was detected. 1. Repeat the test using a new test cartridge. 2. If the problem reoccurs please contact Technical Support.

Hct Range	During the analysis, sample readings detected a Hematocrit concentration outside the acceptable range. 1. Repeat the test using a new test cartridge. 2. If the error occurs only on one patient the sample may need to be tested on an alternate method. 3. If the problem continues please contact Technical Support.
Sample Type	During the analysis sample readings were not consistent with the expected sample type. 1. Repeat the test using a new test cartridge. 2. If the error occurs only on one patient the sample may need to be tested on an alternate method. 3. If the problem continues please contact Technical Support.
↑↑↑	The sample result is above the analytical measurement range. 1. Repeat the test using a new test cartridge. 2. If the error occurs only on one patient the sample may need to be tested on an alternate method. 3. If the problem continues please contact Technical Support.
↓↓↓	The sample result is below the analytical measurement range. 1. Repeat the test using a new test cartridge. 2. If the error occurs only on one patient the sample may need to be tested on an alternate method. 3. If the problem continues please contact Technical Support.

A. Appendix

Appendix A includes analyzer specifications, performance data, solutions and reagents, consumable lists, reference information, and warranty for the Nova Allegro Analyzer.

A.1 Specifications

Measurement Range:

HbA1c	
Operating Range	4.0 - 14.0 %
Sample Type	Whole Blood Capillary Finger Stick and Venous Whole Blood
Sample Volume	1.5 µL
Analysis Time	≤6.5 Minutes
Within Run Imprecision	≤4%
Day-to-Day Imprecision	≤5%

Urine Albumin Creatinine Ratio	
Operating Range Albumin	5 -300 mg/L 0.5-30 mg/dL
Operating Range Creatinine	1.3 - 44.2 mmol/L 15 - 500 mg/dL
Sample Type	Urine
Sample Volume	25 µL
Analysis Time	≤7 Minutes
Within Run Imprecision	≤6% Albumin
Day-to-Day Imprecision	≤6% Albumin
Within Run Imprecision	≤5% Creatinine
Day-to-Day Imprecision	<5.5% Creatinine

Lipid Operating Range	
Total Cholesterol	90 - 500 mg/dL 2.33 - 12.93 mmol/L
HDL Cholesterol	20 - 100 mg/dL 0.52 - 2.59 mmol/L
Triglycerides	50 - 600 mg/dL 0.57 - 6.78 mmol/L
LDL Cholesterol	Calculated
Non-HDL Cholesterol	Calculated
Cholesterol/HDL Ratio	Calculated
Sample Type	Whole Blood Capillary Finger Stick and Venous Whole Blood
Sample Volume	5 µL
Analysis Time	≤10 Minutes
Within Run Imprecision Total Cholesterol	≤4%
Within Run Imprecision HDL Cholesterol	CV%≤4% or SD ≤5.0 whichever is greater
Within Run Imprecision Triglycerides	≤5%
Day-to-Day Imprecision Total Cholesterol	≤5%
Day-to-Day Imprecision HDL Cholesterol	CV%≤6% or SD ≤5.0 whichever is greater
Day-to-Day Imprecision Triglycerides	≤7.5%

Dimensions:		
	Width:	20.32 cm (8 in)
	Height:	35.6 cm (14 in)
	Depth:	38.1 cm (15 in)
Weight:		10.43 kg (23 lb)
Power:		90 - 264 VAC, 50/60 Hz
Interfaces:		ASTM Protocol, via serial RS323 TCP/IP, POCT1-A2,HL7
Printer:		Built-in thermal
Methodology:		
HbA1c:		Particle Enhanced Immuno-Agglutination Assay
T Cholesterol:		Immunoenzyme Colorimetric Assay
HDL Cholesterol:		Immunoenzyme Colorimetric Assay
Triglycerides:		Immunoenzyme Colorimetric Assay
Albumin:		Immunocolorimetric Assay
Creatinine:		Colorimetric Assay

A.2 Quality Control

Healthcare facilities should follow federal, state, and local guidelines for testing quality control materials. At a minimum, Nova Biomedical recommends that each laboratory performs the following minimum QC procedures on each analyzer:

Controls should be analyzed:

- With each new shipment of Nova Allegro Test Cartridges
- With each new lot of Nova Allegro Test Cartridges
- At least every 30 days
- When training new operators in the correct use of the Nova Allegro Test Cartridges
- Anytime an unexpected test result is obtained

A.3 Traceability of Calibrators, Controls, and Standards

Traceability:
The Nova Allegro HbA1c assay has successfully completed the NGSP certificate program and is traceable to the Diabetes Control and Complications Trial Reference method.

Nova Allegro HbA1c: The standard used for Nova Allegro HbA1c Test Cartridge is traceable to the CDC Designated Comparison Method (DCM), reference method used is Tosoh G8 (Tosoh Bioscience, San Francisco, CA).

Nova Allegro UACR (Urine Albumin, Creatinine): The microalbumin or albumin standards used for Nova Allegro UACR Test Cartridge are traceable to European Reference Material ERM DA 470K. The creatinine standards used for Nova's products are traceable to NIST SRM 914a Reference.

Nova Allegro Lipids (HDL, Total Cholesterol, and Triglycerides): The HDL standards used for Nova Allegro Lipids Test Cartridge are traceable to the CDC Designated Comparison Method (DCM) reference method of the CRMLN National Cholesterol Education Program accuracy base. The Cholesterol standards used for Nova's products are traceable to the National Reference System for Cholesterol CDC Abel Kendall method. They are also traceable to NIST Standard Reference Material 911. The Triglyceride standards are traceable to the American Chemical Society (ACS) glycerol anhydrous chemical.

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) Data:

UACR only

	Units	LOB	LOD	LOQ	Stdev for LOQ	Claimed Range
Albumin	(mg/L)	1.2	1.729	1.3	0.3227	5 - 300
Creatinine	(mg/dL)	0.0	0.925	2.3	0.5625	15 - 500

A.4 Reference Values

Each laboratory should establish and maintain its own reference values. The values given here should be used **only as a guide.**

Table A.1 Reference Values

Test	Value (Normal)
HbA1c[1]	Normal (no diabetes): Less than 5.7% Pre-diabetes: 5.7% to 6.4% Diabetes: 6.5% or higher
Total Cholesterol	<200 mg/dL
LDL	<100 mg/dL
HDL	>40 mg/dL (Males); >50 mg/dL (Females)
Triglycerides	<150 mg/dL
Urine Albumin	<20 mg/L (Spot Urine Collection)
Urine Creatinine	N/A
UACR	<30

References:

1. Crocker J. et al. Implementation of point-of-care testing in an ambulatory practice of an academic medical center. *Am J Clin Pathol*. 2014. 142:640-646.

A.5 Ordering Information

Nova Allegro Analyzer supplies and parts are available from Nova Biomedical.

DESCRIPTION	Part #
Allegro HbA1c Control Solution, L1,1 vial (0.5 mL)	56304
Allegro HbA1c Control Solution, L2,1 vial (0.5 mL)	57635
Allegro Lipid Control Solution, L1,1 Bottle (3 mL)	55698
Allegro Lipid Control Solution, L2,1 Bottle (3 mL)	58046
Allegro UACR Control Solution, L1,1 Bottle (3 mL)	51032
Allegro UACR Control Solution, L2,1 Bottle (3 mL)	51031
Allegro HbA1c Test Cartridge, 20 per pack	54215
Allegro Lipids Test Cartridge, 20 per pack	54652
Allegro UACR Test Cartridge, 20 per pack	54214
Thermal Paper	49200

A.6 Warranty

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails within one (1) year after delivery to the customer because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair to damage caused by accident, neglect, misuse, altering the Nova equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized Nova representative or any force of nature; (B) Work which, in the sole and exclusive opinion of Nova, is impractical to perform because of location, alterations in the Nova equipment or connection of the Nova equipment to any other device; (C) Specification changes; (D) Service required to parts in the system contacted or otherwise affected by expendables or reagents not manufactured by Nova which cause shortened life, erratic behavior, damage or poor analytical performance; (E) Service required because of problems, which, in the sole and exclusive opinion of Nova, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic purposes. **All parts replaced under the original warranty will be warranted only until the end of the original instrument warranty. All requests for warranty replacement must be received by Nova or their authorized distributor within thirty (30) days after the component failure.** Nova Biomedical reserves the right to change, alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. All service will be rendered during Nova's principal hours of operation. All requests for service outside Nova's principal hours of operation will be rendered at the prevailing weekend/ holiday rates after receipt of an authorized purchase order. Contact Nova for specific information.

The above warranties are invalid if:

1. The date printed on the package label has been exceeded.
2. Non-Nova Biomedical reagents or controls are used, as follows: Nova Biomedical will not be responsible for any warranties on parts if these parts are used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts. Reagent formulations not manufactured by Nova Biomedical may contain acids, concentrated salt solutions, and artificial preservatives that have been shown to cause problems such as shortened sensor/electrode life, sensor/electrode drift, erratic analytical results, and inaccurate instrument performance.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.

B. Principles of Measurement

This section explains the Principles of Measurement for the Nova Allegro Analyzer.

B.1 Measured Values

Measuring Technology:

B.1.1 HbA1c

Principle of Measurement

The Allegro HbA1c assay is a completely automated assay for the determination of the HbA1c in human whole blood. The sample containing hemoglobin A1c and total hemoglobin are nonspecifically absorbed to latex particles. Anti-human mouse HbA1c antibody is reacted forming a complex. Agglutination occurs when polyclonal antibody specifically reacts with the mouse antibody bound to the hemoglobin A1c on the surface of the latex particles. The amount of agglutination is measured as absorbance. The HbA1c value is obtained from a stored calibration curve and displayed on the Nova Allegro Analyzer.

B.1.2 Lipids

Principle Measurement

The Allegro Lipid assay is used for quantitative determination of Chol, HDL and Trig in whole blood. LDL, non-HDL and Chol/HDL Ratio are calculated by the Allegro Analyzer. The assay is completely automated and the Allegro Lipid Test Cartridge contains all the reagents necessary for testing. The methods utilized for determination of the lipid components are immuno, enzymatic and colorimetric. Final lipid values are obtained from a stored calibration curve and displayed on the Nova Allegro Analyzer.

In the first reaction of the assay, anti human B-lipoprotein antibody binds to lipoproteins (LDL, VLDL and cylomicron) other than HDL in the sample.

In the second reaction, this antigen-antibody complex blocks the action of cholesterol and detection enzymes and dyes contained in the cartridge and only the HDL form of cholesterol is detected. A blue color complex is formed by the reaction which can be measured by the analyzer.

The reagent in the third step of the assay frees the bound cholesterol forms and the cholesterol and detection enzymes and dyes contained in the cartridge react with the additional cholesterol and add this to the HDL amount. The blue color is intensified due to this increase and measured.

The final step of the assay again performs an enzymatic, colorimetric reaction resulting in an additional blue color complex being formed. This is measured and the triglyceride amount is calculated.

B.1.3 UACR

Principle of Measurement

When a urine sample containing albumin is reacted with antibody specific for albumin an antibody albumin complex is formed. The amount of complex is in direct proportion to the amount of albumin in the sample. The albumin is then quantified using a calibration curve.

The Benedict/Behre chemistry is the bases for the creatinine assay. 3,5-dinitrobenzoic acid at high pH reacts with creatinine to form a colored complex. The colored complex is in direct proportion to the amount of creatinine in the sample which is determined from a stored calibration curve. The albumin to creatinine ratio, UACR, is then calculated and displayed on the Nova Allegro Analyzer.

B.2 Calculated Parameters

LDL Cholesterol

LDL (all units are default)

LDL = ((TC - HDL) - (TG / 5.0))

Non-HDL Cholesterol

non-HDL (all units are default)

non-HDL = TC – HDL

Cholesterol/HDL Ratio

TC/HDL (all units are default)

TC/HDL = TC / HDL

Urine Albumin/Creatinine Ratio

UACR = UAlb(mg/dL) / (UCreat(g/dL) / 1000)

Estimated Average Glucose

eAG = (28.7 * HbA1c) - 46.7

eAG(all units are default)