Allegro®

A Fast, Simple, Capillary Blood Analyzer

HbA1c | GLU | Lipids | CREAT | UACR | PT/INR | CRP

Capillary fingerstick samples for all blood tests

Immediate test results during the patient visit

Reduces follow-up visits and costs

nova® biomedical

CE marked, not yet FDA cleared.

Allegro®

A Fast, Simple, Capillary Blood Analyzer

Allegro is a compact point-of-care (POC) analyzer that features a clinically important menu of ten measured and individually selectable tests, plus seven calculated tests. All measured tests are analyzed using disposable, ready-to-use cartridges or test strips, and are easily performed by non-technical personnel.

A very small capillary blood drop is used for all blood tests and eliminates the need for a venipuncture or a trained phlebotomist. *Allegro's* six-to-nine minute cartridge test times and ability to measure two cartridges simultaneously provide rapid results. Having results during the patient visit–not after–makes the patient/clinician meeting more effective. It also reduces the cost of patient follow up calls, letters, and office visits to discuss laboratory test values.

A comprehensive test menu for monitoring glycemic control and diabetes risk factors

Allegro provides a comprehensive test menu to monitor the effectiveness of glycemic control, assess the risk or progression of diabetes complications, and make therapeutic adjustments for patients.

Glycemic Control
HbA1c
Glucose
Estimated avg. Glu

Kidney Function
Blood Creatinine
eGFR
Urine Creatinine
Urine Albumin
Albumin/Creatinine ratio

Inflammation
CRP

Lipids/Cardiac Risk
Total Cholesterol
HDL Cholesterol
Cholesterol HDL Ratio
Non-HDL Cholesterol
LDL Cholesterol
Triglycerides

Coagulation
PT/INR

CE marked, not yet FDA cleared.

The only analyzer that measures all blood tests from a capillary sample

Capillary sampling is easily performed by staff members, eliminating the need for venipunctures, trained phlebotomists, and blood drawing tubes and needles. *Allegro*'s use of a small, 5.0 µl blood drop makes testing virtually painless for the patient.

Tests Available from Capillary Fingerstick Samples

Test	*Allegro*	DCA Vantage	Afinion
HbA1c	✔	✔	✔
Lipids Panel	✔		✔
Blood Glucose	✔		
Blood Creatinine	✔		
PT/INR	✔		
CRP	✔		✔

Tests Available from Urine Samples

Test	*Allegro*	DCA Vantage	Afinion
Urine Creatinine	✔	✔	✔
Urine Albumin	✔	✔	✔
Albumin/Creatinine Ratio	✔	✔	✔

Capillary sample meter tests

The *StatStripA* meter wirelessly transmits patient-identified test results to the analyzer where they are combined with the cartridge test results in a single patient report.

- Lab-like results
- The only glucose meter FDA cleared for critical care

StatStrip Tests

Glucose: 6 seconds
1.2 µL capillary blood

Creatinine: 30 seconds
1.2 µL capillary blood

Test Cartridge with Sampler

HbA1c
<6.5 minute assay **1.5 µL capillary blood**

Lipids
10.4 minute assay **5.0 µL capillary blood**

CRP
7 minute assay **5.0 µL capillary blood**

PT/INR
<8 minutes assay **5.0 µL capillary blood**

Urine albumin/creatinine
7.5 minute assay **25 µL urine**

Allegro® Fingerstick Blood Testing

ADA recommendations for blood testing in diabetes

Many government systems, insurers, and other healthcare payers have identified primary care as a focal point for treating patients with diabetes and provide testing reimbursement for important diabetes markers such as HbA1c, lipids, and urine micro-albumin/creatinine. The American Diabetes Association (ADA), Diabetes UK, and other diabetes professional societies recommend that HbA1c, lipids, and albumin levels be managed based on the following schedule:

Test	Patients meeting treatment goals	Patients not meeting treatment goals
HbA1c	Biannually	Quarterly
Lipids Total Cholesterol HDL Cholesterol LDL Cholesterol Cholesterol/HDL Ratio Non-HDL Cholesterol Triglycerides	Annually or as needed to monitor adherence or efficacy	Annually or as needed to monitor adherence or efficacy
Urine Albumin Urine Creatinine	Annually	Annually

ADA Standards of Care in Diabetes. Diabetes Care Volume 46, Supplement 1, S54-54, December 2022.

Allegro test menu reimbursement

HCPCS	Rate	Test
82043QW	$5.78	Urine microalbumin
82565QW	$5.12	Blood creatinine
82570QW	$5.18	Urine creatinine
82947QW	$3.93	Blood glucose
83036QW	$9.71	Hemoglobin A1C
85610QW	$4.29	Prothrombin time
86140	$5.18	C-reactive protein
82465QW	$4.35	Total cholesterol
80061QW	$13.39	Lipid Panel Includes: Total cholesterol, HDL cholesterol, LDL cholesterol, Triglycerides

QW suffix indicates CLIA waved status.

Clinical benefits for patients

Allegro allows the clinician to provide therapeutic adjustments and consultation in the same visit with real-time blood test results from a capillary fingerstick.

Immediate HbA1c results during the patient visit has been shown to provide important clinical benefits.

- Lower HbA1c at six-month follow-up visit.[1-3]
- Improved clinical intervention to intensify therapy when HbA1c is elevated.[1-3]
- Improved patient satisfaction with their primary care provider.[1-3]

Simplifies workflow for primary care settings

Testing for HbA1c, glucose, lipids, and kidney function is commonly required for people with diabetes during primary care visits. *Allegro*'s test menu and capillary blood sampling allows clinicians to have these tests available during the patient visit. This eliminates numerous follow-up calls and visits and creates significant cost savings.

- Eliminates the need for follow-up patient contact with blood test results.
- Eliminates scheduling and conducting another visit if the blood tests indicate a need for therapy changes.
- Eliminates follow up with non-compliant patients who do not get their laboratory blood tests.

Reduces costs

Contacting patients with blood test results creates significant work for a primary care clinic. A study at a primary care clinic at Massachusetts General Hospital in Boston, MA, reported a reduction in workload when testing was performed during the patient visit.[1]

89% decrease in the number of telephone follow-up calls to patients

85% decrease in the number of test result letters and emails sent to patients

62% decrease in the number of follow-up visits for an abnormal laboratory result

The operational cost saving for the primary care clinic was calculated to be $24.64 per patient visit, through reductions in follow-up contact with patients for blood test results.

Data storage

An onboard barcode scanner automatically enters patient ID and test assay information. When an analysis is completed, the results are automatically printed and stored in the *Allegro* database and can be transmitted to the electronic medical record (EMR) for clinician viewing.

Reduces patient visits

Real-time HbA1c, lipids, PT/INR, and kidney function results eliminates the need for additional laboratory and primary care visits to modify therapy. Having immediate results during patient visits provides a face-to-face opportunity for the clinician to modify therapy in a single visit.

Allegro® Point-of-Care Office Visit	Conventional Office Visit
1. Test(s) performed and results ready during patient visit 2. Clinician modifies therapy	1. Patient office visit 2. Clinician orders blood tests 3. Patient goes for lab testing 4. Clinician reviews results 5. Clinician requests follow-up visit 6. Staff contacts patient 7. Patient schedules follow-up visit 8. Clinician modifies therapy
1 Office visit	1 Office visit 1 Lab visit 1 Staff contact 1 Follow-up office visit

Cartridge testing

Scan cartridge | Perform fingerstick | Touch sampler to blood | Place sampler in cartridge | Insert cartridge and press "Analyze"

Meter testing

Insert test strip in meter | Perform fingerstick | Touch strip to blood

Allegro® Accurate Results

HbA1c

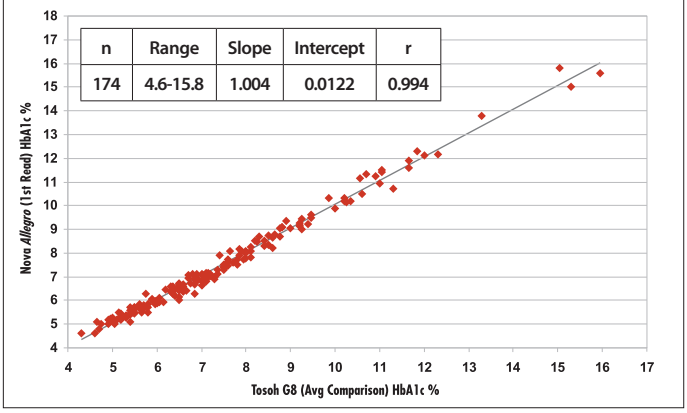
Allegro uses laboratory-quality immunoassay technology for cartridge-based tests. Allegro's HbA1c accuracy is certified by the National Glycohemoglobin Standardization Program (NGSP) and the International Federation of Clinical Chemistry. The purpose of these programs is to eliminate method-to-method variability of HbA1c results and to provide results traceable to those of the Diabetes Control and Complications Trial (DCCT) and United Kingdom Prospective Diabetes Study (UKPDS), which established the direct relationship between HbA1c levels and outcomes.

Allegro bias at HbA1c medical decision levels

Medical Decision Level	95% Confidence Interval of Bias	
	Lower Limit	Upper Limit
38.8 mmol/mol (5.7%)	38.8 mmol/mol (5.7%)	39.9 mmol/mol (5.8%)
47.5 mmol/mol (6.5%)	47.5 mmol/mol (6.5%)	48.6 mmol/mol (6.6%)
53.0 mmol/mol (7.0%)	53.0 mmol/mol (7.0%)	54.1 mmol/mol (7.1%)

Allegro HbA1c method comparison

Nova *Allegro* v. Tosoh G8 (HPLC)



No interference from hemoglobin variants

The following hemoglobin variants do not affect *Allegro*'s HbA1c test result:

- Hb A_2, HbAG, HbAC, HbAS, HbF, HbAD, HbAE, HbA_0
- Pre-glycated and acetylated hemoglobin

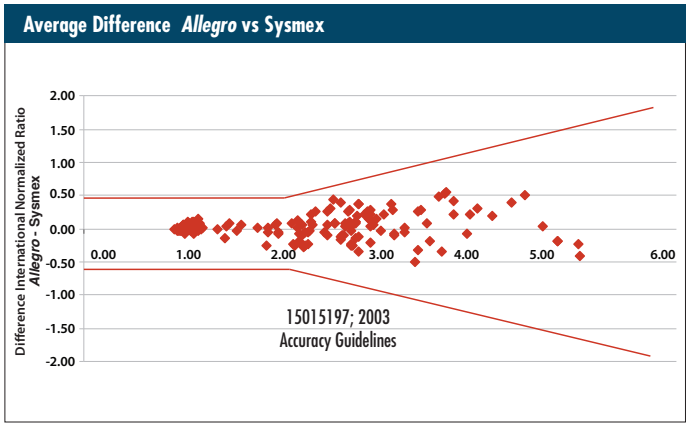
Total Cholesterol/HDL Cholesterol

Allegro lipid cartridge accuracy for total cholesterol and HDL cholesterol is certified by the U.S. Centers for Disease Control, Cholesterol Reference Method Laboratory Network (CRMLN).

Total cholesterol	HDL cholesterol
Bias from CRMLN reference: ≤3%	Bias from CRMLN reference: ≤5%
Coefficient of variation: ≤3%	Coefficient of variation: ≤4% at >1.1 mmol/L ≤0.04 mmol/L at ≤ 1.1 mmol/L

International Normalized Ratio

Bland Altman Plot Versus 115017593; 2007 Accuracy Guidelines



Glucose biosensor

The biosensor used for the glucose test is Nova StatStrip, which the U.S. Food and Drug Administration has determined is the only glucose test strip accurate enough for use on critically ill hospitalized patients. It is the only glucose test strip technology that has no known clinical interferences.

Creatinine sensor

Two large studies show Nova POC creatinine/eGFR technology is as accurate or more accurate than the laboratory methods.

1. Dubois JA. Creatinine standardization: a key consideration in evaluating whole blood creatinine monitoring systems for CKD screening. Analytical and Bioanalytical Chemistry (2022).
2. Currin S et al. Evaluating chronic kidney disease in rural South Africa: comparing estimated glomerular filtration rate using point-of-care creatinine to iohexol measured GFR. Clin Chem Med Lab (2021).the only glucose test strip technology that has no known clinical interferences.

Dual test bays provide rapid throughput

For patients on whom more than one test is required, *Allegro*'s two test bays allow two test cartridges to run simultaneously. This reduces operational time compared to single test bay analyzers.

HbA1c, Lipids, Glucose

Analyzer	HbA1c	Lipids	Glucose	Operator time and test results
Nova *Allegro*	<6.5 min	<10 min	6 sec	<10 min/9 tests
Alere Afinion*	3 min	10 min**	N/A	13 min/8 tests

HbA1c, Urine Albumin and Creatinine (UACR), Glucose

Analyzer	HbA1c	UACR	Glucose	Operator time and test results
Nova *Allegro*	<6.5 min	<7 min	6 sec	<7 min/6 tests
Siemens DCA*	6 min	7 min	N/A	13 min/5 tests

HbA1c, Lipids, Glucose, Blood Creatinine with eGFR, Hemoglobin And Hematocrit

Analyzer	HbA1c	Lipids	Glucose	Creatinine with eGFR	Operator time and test results
Nova *Allegro*	<6.5 min	<10 min	6 sec	30 sec	10 min/11 tests
Alere Afinion*	3 min	10 min**	N/A	N/A	13 min/8 tests

** Single-test-bay instrument*

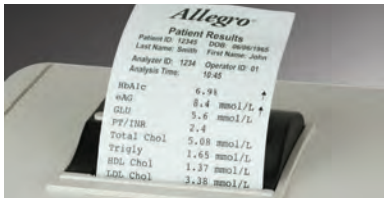
*** Includes 2 minutes to perform second fingerstick and prepare lipids cartridge after completing HbA1c test*

Customized test menus

Allegro's two test bays operate on separate optical wavelengths which provides the flexibility to customize the analyzer. For customers not requiring the full test menu, *Allegro* can be configured with a single test bay. For specialized needs such as high test volume applications, *Allegro* can be customized with two identical bays to double throughput on selected tests. Contact Nova for more details on customization options.

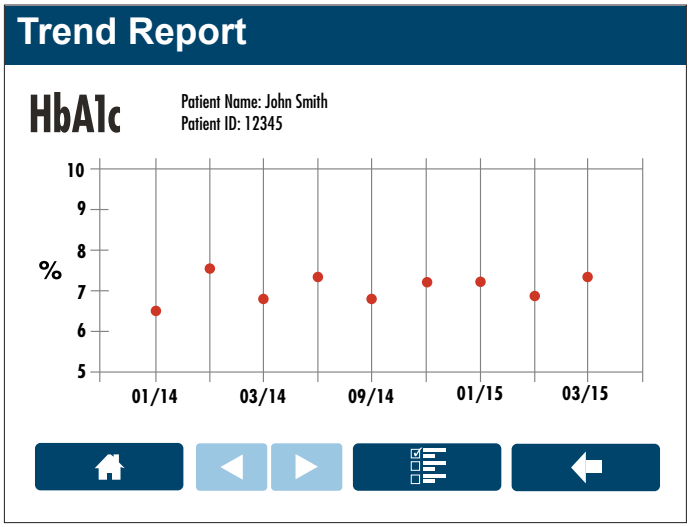
StatStrip A meter tests for glucose and creatinine, can be combined with any optical module and their test results are combined with the optical test results in a single patient report. Meter tests can be performed from the same capillary fingerstick as the *Allegro* tests.

Transmits and prints results immediately



Allegro transmits patient results to the medical records system and produces an immediate printout of patient results.

Patient trend report



Allegro provides on-screen and printed trend reports for patient values. The last nine results for the patient are presented as a trend graph.

A virtually unlimited number of patient results can be stored on board the analyzer. These results can be printed and/or transmitted to an EMR.

Connects to Electronic Medical Records

Results are instantly transmitted to the EMR by industry standard HL7 and POCT1A-2 interface formats for clinician retrieval. Results and trend data are also stored on the analyzer and can be accessed immediately from the *Allegro* database.

Allegro® Specifications

Test Menu	Method	Sample Volume	Time	Measurement Range
HbA1c	Particle Enhanced Immunoagglutination Assay	1.5 µL capillary whole blood	<6.5 mins	4.0 - 14.0%
UACR • Urine Albumin • Urine Creatinine	 Immunoenzyme-Colorimetric Assay Immunoenzyme-Colorimetric Assay	25 µL urine	<7 mins	 5-300 mg/L (0.5-30.0 mg/dL) 15-500 mg/dL (1.3- 44.2 mmol/L)
PT/INR	Optical Aggregation	5 µL capillary whole blood	< 8 mins	0.9-6.0 INR
Glucose	Electrochemistry	1.2 µL capillary whole blood	6 sec	10 - 600 mg/dL (0.6 - 33.3 mmol/L)
CRP	Immunoagglutination Assay	5 µL capillary whole blood	7 min	2 -250 mg/L
Lipids • T Cholesterol • HDL Cholesterol • Triglycerides • LDL Cholesterol • Non HDL Cholesterol • Total HDL Ratio	 Immunoenzyme-Colorimetric Assay Immunoenzyme-Colorimetric Assay Immunoenzyme-Colorimetric Assay Calculated Calculated Calculated	5 µL capillary whole blood	<10 mins	 90-500 mg/dL (2.33-12.93 mmol/L) 20-100 mg/dL (0.52-2.59 mmol/L) 50-600 mg/dL (0.57-6.78 mmol/L) N/A N/A N/A
Blood Creatinine with eGFR	Electrochemistry	1.2 µL capillary whole blood	30 sec	0.3 - 12.0 mg/dL (27 - 1061 µmol/L)

Compact size for POC use

Allegro's 8 in x 15 in footprint easily fits in clinician offices, clinics, and hospital outpatient locations. It can also be operated on an optional mobile cart.

Physical Specifications

Width	8 in (20.32 cm)
Height	14 in (35.6 cm)
Depth	15 in (38.1 cm)
Weight	23 lb (10.43 kg)

Printer
Built-in thermal

Display
Full color, touchscreen, 6 in (15.24 cm) diagonal

Barcode Laser Warning:

Electrical Power Requirements
90-264 VAC, 50/60 Hz

Interfaces
ASTM Protocol, via serial RS232
TCP/IP, POCT1-A2, HL7

CE Marked

FDA Labeling
For in-vitro diagnostic use, pending FDA clearance

Stat Strip®

Physical Specification

Weight	0.49 lb (220 g)
Size	5.8 in x 3.1 in x 1.18 in (147 mm x 79 mm x 30 mm)

Meter Data Storage

Patient Tests	3,000 Tests
QC Tests	200 Tests
Users	8,000 Users

Connectivity

Data Output	RJ-45 Ethernet Port
Protocol	TCP/IP Ethernet 100 Mbit
Standard	POCT1-A2 Compliant

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.
2. Crocker B et al. Patient satisfaction with point-of-care laboratory testing: Report of a quality improvement program in an ambulatory practice of a academic medical center. *Clin Chim Acta* 2013;424;8-11.
3. Miller C et al. Rapid A1c availability improves clinical decision-making in an urban primary care clinic. *Diabetes Care* 2003; 26:1158-1163.

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CE marked, not yet FDA cleared. *Specifications current as of revision date.*