



Atellica Solution Diabetes Assays



Diabetes is a chronic disease that occurs when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. According to the World Health Organization, an estimated 422 million adults were living with diabetes globally in 2014, and 10% of the global population is expected to have the disease by 2030.¹ The longer a person lives with untreated diabetes, the worse his or her outcome will likely be. Glycemic states can be measured by fasting blood glucose, serum fructosamine, or glycated hemoglobin (HbA1c). Differentiation between type 1 and type 2 diabetes and the effectiveness of insulin therapies can be managed by the c-peptide and insulin assays. The Atellica® Solution provides comprehensive diabetes testing using proven detection technologies of highly specific, sensitive assays to help drive better clinical and business outcomes.



Chemistry

Fructosamine
Glucose (Hexokinase)
Glucose (Oxidase)
HbA1c (Enzymatic)
Microalbumin



Immunoassay

C-Peptide
Insulin

- Deliver clinical excellence with the comprehensive diabetes portfolio designed to monitor glycemic control and treatment strategies
- Achieve clinical relevance when diagnosing and monitoring diabetic patients with the IFCC standardized and NGSP certified Atellica CH Hemoglobin A1c_E Assay
- Aids in the classification of diabetes mellitus differentiating insulin-dependent patients from non-dependent patients, the determination of the level of insulin resistance and the assessment of abnormalities in beta cell secretory function.

The Atellica Solution provides a broad and expanding menu to help your lab drive better clinical and business outcomes. The Atellica® CH Analyzer combines the proven technologies of IMT, EMIT, PETINIA, and photometry, delivering a menu of over 110 Chemistry assays. The Atellica® IM Analyzer utilizes proven Advanced Acridinium Ester (AE) technology, with over 50 patents granted or pending.

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Product availability may vary by country.
1. <http://www.who.int/mediacentre/factsheets/fs312/en/> (accessed 9/18/17)

Assay characteristics

Assay Name	Specimen Types	Sample Volume (µL)	Time to First Result (min)	Measuring Interval	Extended Measuring Interval	Expected Values	Detection Capabilities	Reagent Onboard Stability (days per well)	Lot Calibration Interval (days)
Chemistry									
Fructosamine	Serum, plasma (lithium heparin, potassium EDTA)	16	10	30–1000 µmol/L	NA	122–236 µmol/L for adults	LoB: 6 µmol/L LoD: 10 µmol/L LoQ: 28 µmol/L	30	180
Glucose (Hexokinase)	Serum, CSF, plasma (lithium heparin, potassium EDTA, sodium fluoride/potassium oxalate), urine	3.4	7	4–700 mg/dL (0.2–38.9 mmol/L)	4–2100 mg/dL (0.2–116.6 mmol/L)	74–106 mg/dL (4.1–5.9 mmol/L) for adults	LoB: 0 mg/dL (0.0 mmol/L) LoD: 1 mg/dL (0.1 mmol/L)	30	182
Glucose (Oxidase)	Serum, CSF, plasma (lithium heparin), urine	4	10	6–750 mg/dL (0.3–41.6 mmol/L)	6–1500 mg/dL (0.3–83.3 mmol/L)	74–106 mg/dL (4.1–5.9 mmol/L) for adults	LoB: 0 mg/dL (0.0 mmol/L) LoD: 1 mg/dL (0.1 mmol/L)	30	35
HbA1c (Enzymatic)	Whole blood, hemolysate	4.5	10	3.80–14.00% (18.03–129.50 mmol/mol)	NA	Normal: <5.7% (<39 mmol/mol) Prediabetes: 5.7–6.4% (39–47 mmol/mol) Diabetic: ≥6.5% (≥48 mmol/mol)	LoB: 3.11% LoD: 3.53%	63	180
Microalbumin	Urine	13.7	10	0.3–38.0 mg/dL (3–380 mg/L)	0.3–380.0 mg/dL (3–3800 mg/L)	<30 mg/day for adults	LoB: 0.0 mg/dL (0 mg/L) LoD: 0.1 mg/dL (1 mg/L)	30	180
Immunoassay									
C-Peptide	Serum, urine	50	14	Serum: 0.05–30.00 ng/mL Urine: 0.50–300.00 ng/mL	NA	Serum: 0.81–3.85 ng/mL Urine: <156.46 µg in 24 hours	LoB: 0.09 ng/mL LoD: 0.11 ng/mL Analytical Sensitivity: 0.03 ng/mL	28	50
Insulin	Serum	25	14	0.5–300.0 mU/L	NA	3.0–25.0 mU/L	LoB: 0.6 mU/L LoD: 0.8 mU/L Analytical Sensitivity: 0.3 mU/L	21	91

All performance data shown are serum samples unless otherwise noted.

Method comparison equations

Assay	Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N	r
Chemistry						
Fructosamine	Serum	ADVIA® Chemistry 1800 FRUC	$y = 1.02x + 3 \mu\text{mol/L}$	48–961 µmol/L	112	0.994
Glucose (Hexokinase)	Serum	ADVIA Chemistry 1800 GLuH_3	$y = 1.03x - 1 \text{ mg/dL}$ ($y = 1.03x - 0.1 \text{ mmol/L}$)	34–665 mg/dL (1.9–36.9 mmol/L)	105	1.00
	Urine	ADVIA Chemistry 1800 GLuH_3	$y = 1.04x - 1 \text{ mg/dL}$ ($y = 1.04x - 0.1 \text{ mmol/L}$)	5–667 mg/dL (0.3–37.0 mmol/L)	100	1.00
	CSF	ADVIA Chemistry 1800 GLuH_3	$y = 1.03x + 2 \text{ mg/dL}$ ($y = 1.03x + 0.1 \text{ mmol/L}$)	6–668 mg/dL (0.3–37.1 mmol/L)	110	1.00

Assay	Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N	r
Chemistry (continued)						
Glucose (Oxidase)	Serum	ADVIA Chemistry 1800 GLUO	$y = 0.99x - 3$ mg/dL ($y = 0.99x - 0.2$ mmol/L)	9–724 mg/dL (0.5–40.2 mmol/L)	101	0.999
	Urine	ADVIA Chemistry 1800 GLUO	$y = 1.00x + 4$ mg/dL ($y = 1.00x + 0.2$ mmol/L)	6–695 mg/dL (0.3–38.6 mmol/L)	105	0.998
	CSF	ADVIA Chemistry 1800 GLUO	$y = 0.98x + 3$ mg/dL ($y = 0.98x + 0.2$ mmol/L)	34–650 mg/dL (1.9–36.1 mmol/L)	122	1.000
HbA1c (Enzymatic)	Whole blood	NGSP Reference Method	$y = 0.986x - 0.030\%$ ($y = 0.986x - 0.664$ mmol/mol)	4.00–13.60% (20.20–125.14 mmol/mol)	172	0.995
Microalbumin	Urine	ADVIA Chemistry 1800	$y = 1.05x + 0.1$ mg/dL ($y = 1.05x + 1.0$ mg/L)	0.3–41.5 mg/dL (3–415 mg/L)	112	0.998
Immunoassay						
C-Peptide	Serum	ADVIA Centaur® CpS	$y = 0.98x - 0.03$ ng/mL	0.20–29.56 ng/mL	114	1.00
	Urine	ADVIA Centaur CpS	$y = 1.05x + 0.10$ ng/mL	0.55–277.84 ng/mL	133	1.00
Insulin	Serum	ADVIA Centaur Insulin	$y = 0.99x + 0.06$ mU/L	1.8–266.5 mU/L	142	0.99

Ordering information

Assay	SMN No.	Tests per kit	Contents	
Chemistry				
Fructosamine	Atellica CH Fruc	11097637	400 (2 x 200)	Pack 1 (P1) Well 1 (W1) 12.0 mL of Atellica CH Fruc Reagent 1 Well 2 (W2) 12.0 mL of Atellica CH Fruc Reagent 1
				Pack 2 (P2) Well 1 (W1) 5.0 mL of Atellica CH Fruc Reagent 2 Well 2 (W2) 5.0 mL of Atellica CH Fruc Reagent 2
	Atellica CH Fruc CAL	11099432		3 x 1.0 mL calibrator
Glucose (Hexokinase)	Atellica CH GluH_3	11097592	6240 (4 x 1560)	Pack 1 (P1) Well 1 (W1) 23.3 mL of Atellica CH GluH_3 Reagent 1 Well 2 (W2) 23.3 mL of Atellica CH GluH_3 Reagent 1
				Pack 2 (P2) Well 1 (W1) 23.5 mL of Atellica CH GluH_3 Reagent 2 Well 2 (W2) 23.5 mL of Atellica CH GluH_3 Reagent 2
	Atellica CH CHEM CAL	11099411		12 x 3.0 mL calibrator
Glucose (Oxidase)	Atellica CH GluO	11097621	5600 (4 x 1400)	Pack 1 (P1) Well 1 (W1) 19.3 mL of Atellica CH GluO Reagent 1 Well 2 (W2) 19.3 mL of Atellica CH GluO Reagent 1
	Atellica CH CHEM CAL	11099411		12 x 3.0 mL calibrator
HbA1c (Enzymatic)	Atellica CH A1c_E	11097536	600 (2 x 300)	Pack 1 (P1) Well 1 (W1) 16.5 mL of Atellica CH A1c_E Reagent 1 Well 2 (W2) 16.5 mL of Atellica CH A1c_E Reagent 1
				Pack 2 (P2) Well 1 (W1) 8.0 mL of Atellica CH A1c_E Reagent 2 Well 2 (W2) 8.0 mL of Atellica CH A1c_E Reagent 2
				Vial 1 (A1c_E PRE) 2 x 36.65 mL of Atellica CH A1c_E PRE
	Atellica CH A1c_E CAL	11099338		3 levels (Level 1: 1 x 5.0 mL; Level 2 and 3: 2 x 1.0 mL)
Microalbumin	Atellica CH Microalbumin_2 (μALB_2)	11097610	840 (4 x 120)	Pack 1 (P1) Well 1 (W1) 14.0 mL of Atellica CH μALB_2 Reagent 1 Well 2 (W2) 14.0 mL of Atellica CH μALB_2 Reagent 1
				Pack 2 (P2) Well 1 (W1) 4.3 mL of Atellica CH μALB_2 Reagent 2 Well 2 (W2) 4.3 mL of Atellica CH μALB_2 Reagent 2
	Atellica CH μALB_2 CAL	11099435		1 x 2.0 mL calibrator level 2–6
Immunoassay				
C-Peptide	Atellica IM CpS	10995541	100	1 Atellica IM CpS ReadyPack primary reagent pack
	Atellica IM Cps CAL	10995542		2 x 1.0 mL low calibrator 2 x 1.0 mL high calibrator
Insulin	Atellica IM IRI	10995628	100	1 Atellica IM IRI Ready Pack primary reagent pack
	Atellica IM IRI CAL	10995629		2 x 1.0 mL low calibrator 2 x 1.0 mL high calibrator

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An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

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