

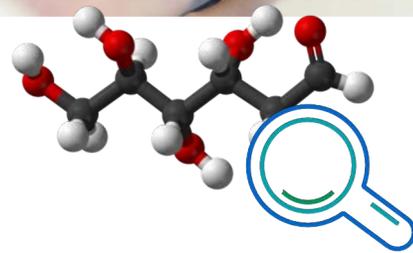
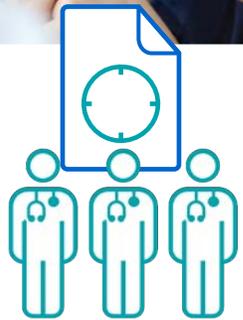
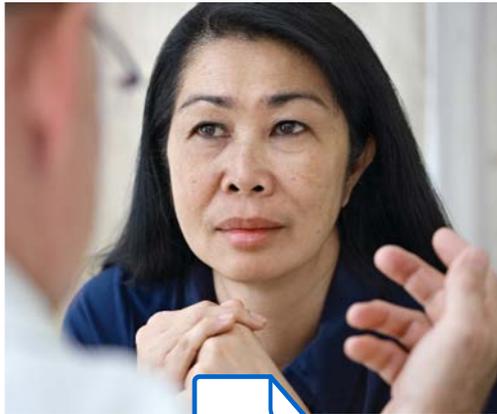


Roche Accu-Chek[®] Inform II solution

*Safe for patients. Simple for
professionals. Efficient for hospitals.*

Standard of medical care in hospital

The importance and relevance of blood glucose monitoring



**Monitoring
glucose levels**



**Monitoring
effectiveness of
glucose control**



**Stress
hyperglycemia?**



**Reduce risk of
adverse effects**



Source: 1. ADA Standards of Medical Care in Diabetes. (2021). Diabetes care 44: Suppl 1. 2. Dungan K et al. (2009). Lancet 373(9677): 1798-807.

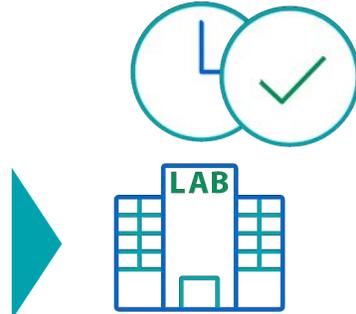
Point of care glucose monitoring in the hospital

Brings professional glucose testing bedside for multi-users

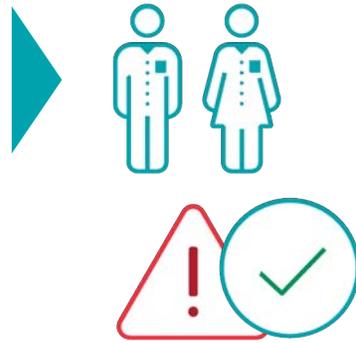
2



Test for glucose at point of care



Time-consuming
More efficient use of time



Burden on staff
Less need for specialist resources

Source: Management and Use of IVD Point of Care Devices, UK MHRA DB2010(02)

Types of hospital blood glucose meters

Connected glucose meters enable convenient accreditation

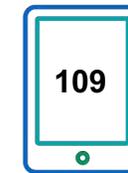


Make treatment decisions with confidence

Connected glucose meter



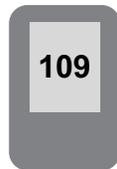
Results displayed within seconds



Documentation is fully automated

Compliant blood testing outside the laboratory

Non-connected glucose meter



Results displayed within seconds



Documentation happens manually

Roche Accu-Chek® Inform II solution

A complete hospital glucose solution to gain efficiency



**Accu-Chek®
Inform II meter**

**Accu-Chek® Inform II
test strips**

**Accu-Chek Performa
quality controls**

**Safe-T-Pro Plus
lancets**

cobas® infinity POC IT solution

Designed to work well together

Roche Accu-Chek® Inform II solution

An aid in monitoring the effectiveness of glucose control

Venous whole blood	Arterial whole blood	Neonatal whole blood	Capillary whole blood



Intended for multiple-patient use in professional healthcare settings

Source: Roche Accu-Chek® Inform II Test Strip Package Insert, 2019

Why Roche Accu-Chek® Inform II solution?

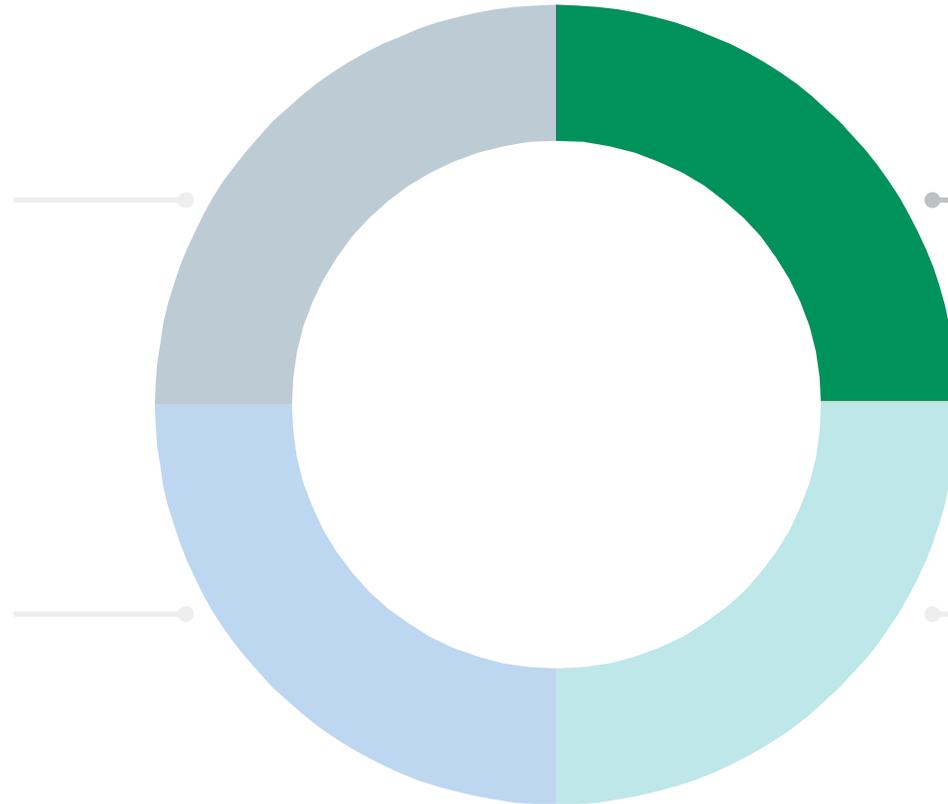
Safe for patients. Simple for professionals. Efficient for hospitals.



By your side support



Automated re-certification



Increased patient safety

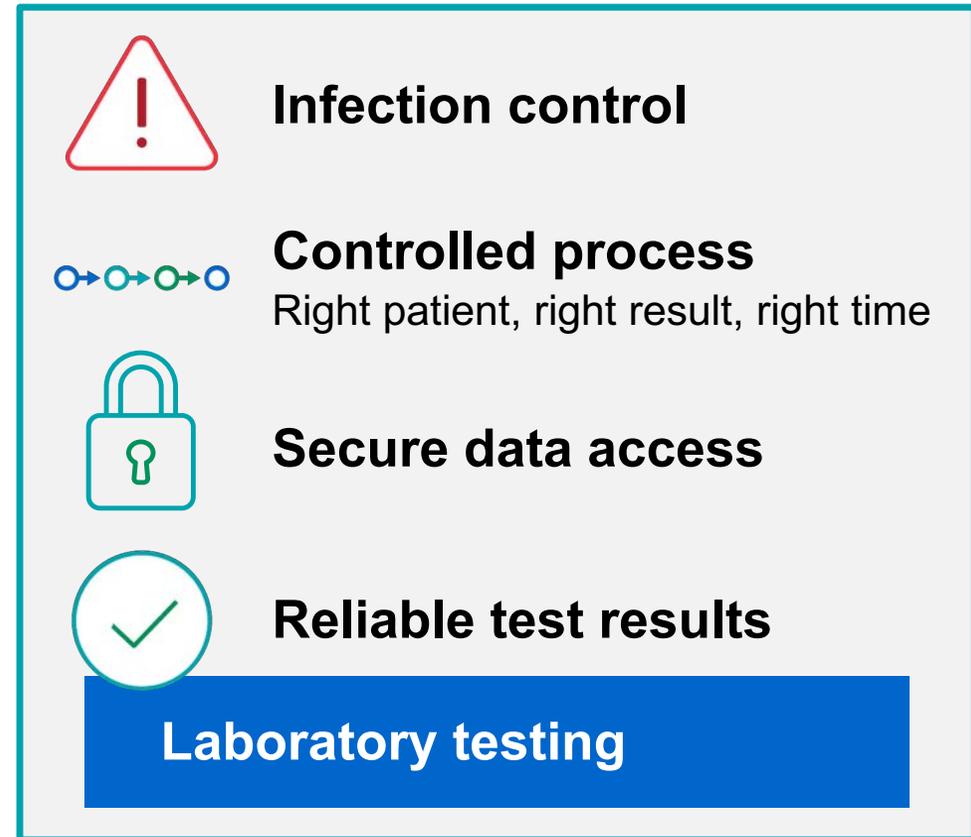


Premium quality of results



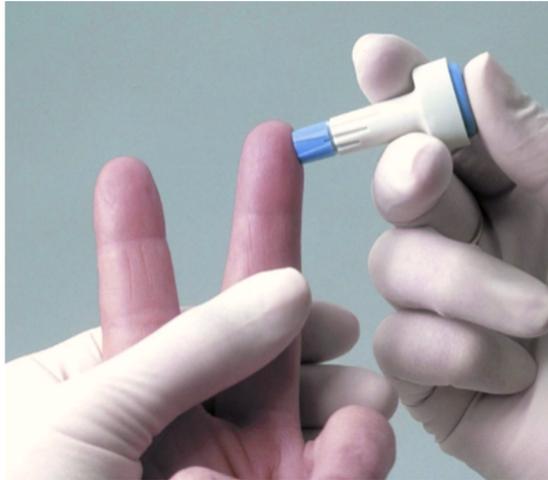
The challenge of patient safety in Point of Care (POC)

Bringing laboratory safety standards to the bedside

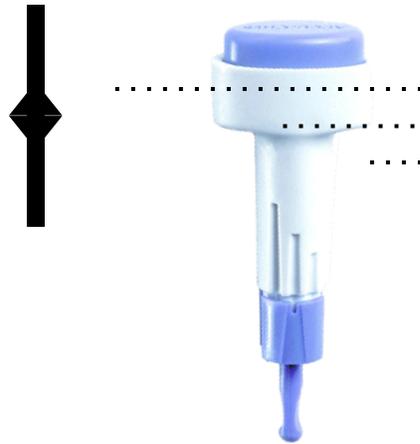


Roche Accu-Chek® Inform II solution

Comfort for patients and safe for professionals



Lancets designed and supplied by Roche



Automatic retraction and multiple depth settings

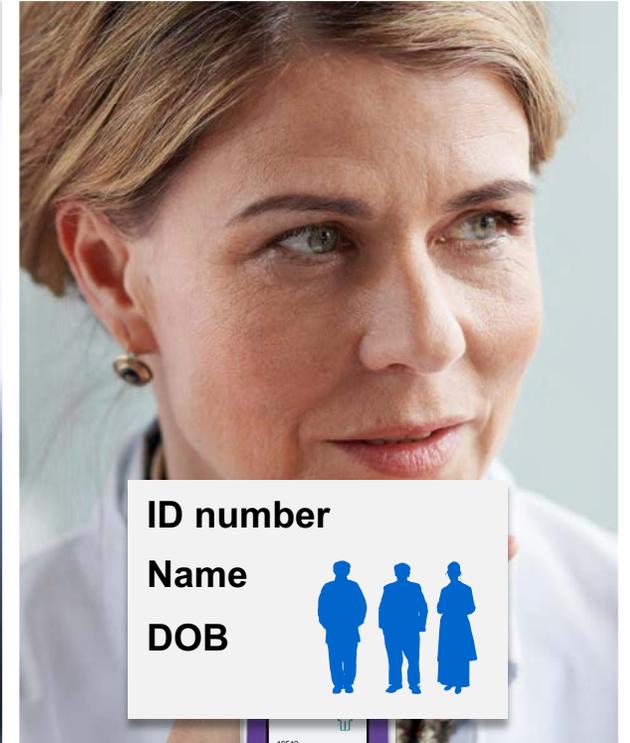


Only Roche offers a complete solution

Patient comfort and infection control with high quality product design

Roche Accu-Chek® Inform II solution

Restriction of data access for patient information security



Roche Accu-Chek® Inform II solution

Designed for fast and easy cleaning - time after time

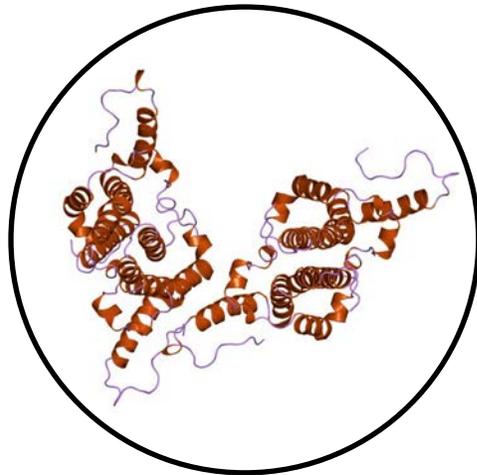


Source: Roche Evaluation Report Instrument: Disinfection Robustness Study, 2011

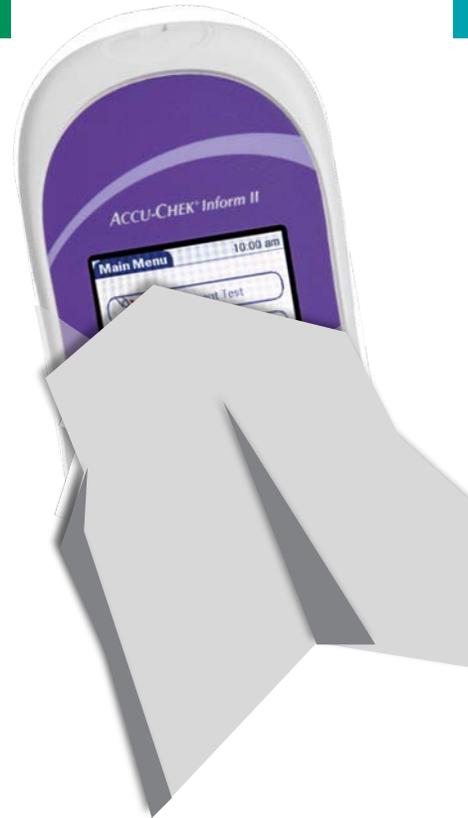
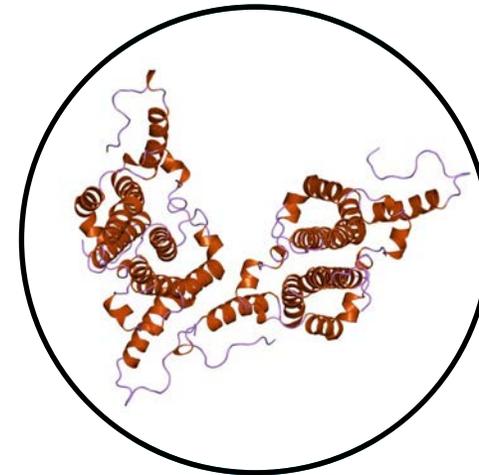
Roche Accu-Chek® Inform II solution

Studies prove inactivation of harmful virus when properly applying designated disinfectants, for operators and patients safety

Live virus



3 log reduction in
cytotoxic level



Source: FDA 510(k) Clearances for Accu-Chek® Inform II, 2012, 2013

Roche Accu-Chek® Inform II solution

Three-step patient identification - safety first.



**Patient
name**

**ID
number**



**Date of
birth**

**Less risk of error
Easier compliance and patient safety**

Roche Accu-Chek® Inform II solution

Export patient result queries into Excel

Permission-based results export into Excel

Check patient events and record history for auditing

Date & Time	Patient ID	Visit ID	Last Name	Location	Test	Result	Validation
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	PCO2.VB	8	Pending
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	Na+ VB	145.1	Validated
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	Lac VB	1.4	Validated
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	K+ VB	3.35	Validated
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	Hct VB	50.7	Validated
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	GLUG VB	5.2	Validated
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	VB	106.9	Validated
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	VB	-	Validated
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	-	-	Validated
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	Syringe	-	Validated
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	Prnt	A	Validated
03/24/2015 15:29	P004	P004	Smith	ROCHE - Roche	SO2	44.4	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	thb	16.7	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	PO2	2.7	Pending
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	pH VB	7.355	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	PCC	7.9	Pending
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	Na	143.2	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	L	1.4	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	VB	3.25	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	VB	49.7	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	VB	5.4	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	VB	5.2	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	Ca++	-	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	Phys. VB	-	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	SCont VB	-	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	Prnt.StVB	-	Validated
03/23/2015 13:31	P004	P004	Smith	ROCHE - Roche	SO2.VB	-	Validated
03/22/2015 13:01	P004	P004	Smith	ROCHE - Roche	thb VB	16.5	Validated
03/22/2015 13:01	P004	P004	Smith	ROCHE - Roche	PO2 VB	2.7	Pending
03/22/2015 13:01	P004	P004	Smith	ROCHE - Roche	pH VB	7.345	Validated
03/22/2015 13:01	P004	P004	Smith	ROCHE - Roche	PCO2 VB	7.9	Pending



Location



Tests performed



Results



Validation

Roche Accu-Chek® Inform II solution

Reliable, trustworthy test results for all in-hospital patients



General population



Evaluation Report: Accu-Chek® Inform II Test Strips (2020)



Neonate population



Nichols J.H., et. .al, J Appl Lab Med, Vol 6, Issue 4, (2021)



Dietzen D.J. et al, Diabetes Technology & Therapeutics, Vol 15, Issue 11 (2013)



Study from FVZH and MMC hospitals, Netherlands (Roche white paper, 2012)



ICU population



Gijzen K. et. al, Clin Chem Lab Med, Vol 50, Issue 11, (Nov 2012)



Creed G.M. et al, Point of Care, Vol 10, No.1, (March 2011)



Mitsios et al, J Diabetes Sci Technol, Vol 7, (2013)

Why Roche Accu-Chek® Inform II solution?

Safe for patients. Simple for professionals. Efficient for hospitals.



**By your
side
support**



**Automated
re-certification**



**Increased
patient safety**

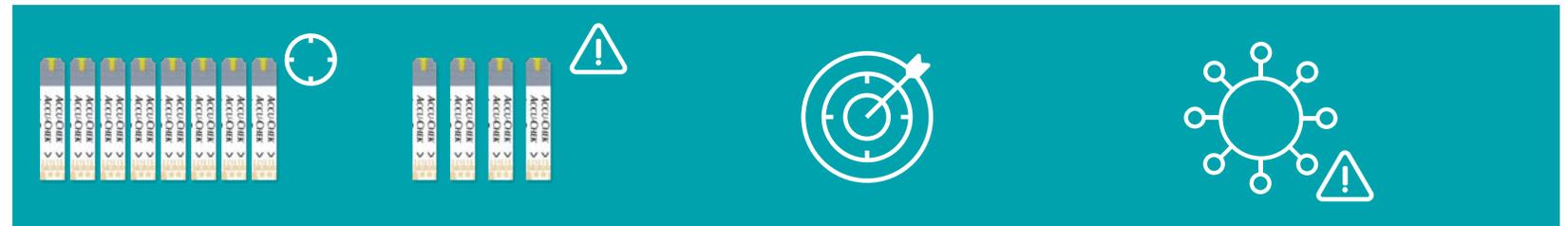


**Premium quality
of results**



The challenge of quality of results in POC

Meeting lab standards when clinicians and nurses run tests



Calibration

Detection

Accuracy & precision

Interferences

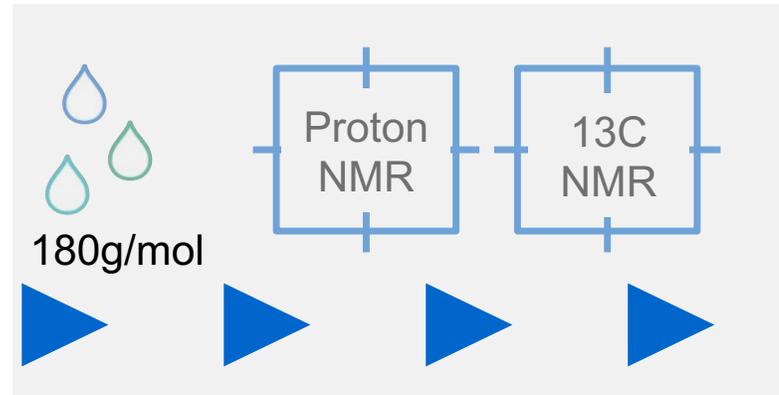


————— **Quality of results** —————>

Roche Accu-Chek® Inform II solution

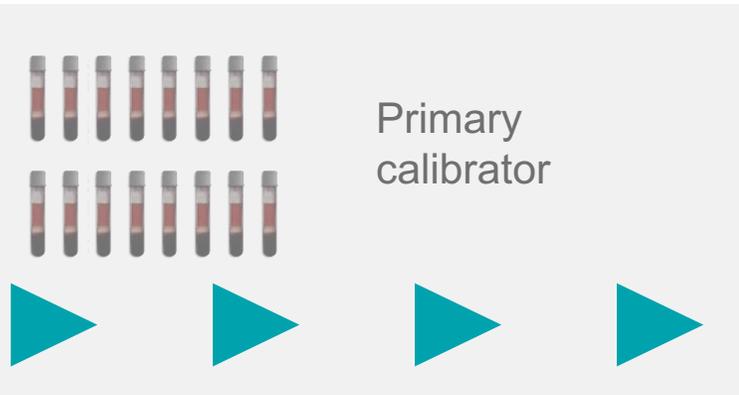
Traceability to NIST reference – calibration at its best

NIST



SRM 817Ba
(99.7% +0.2% glucose)

Manufacturer

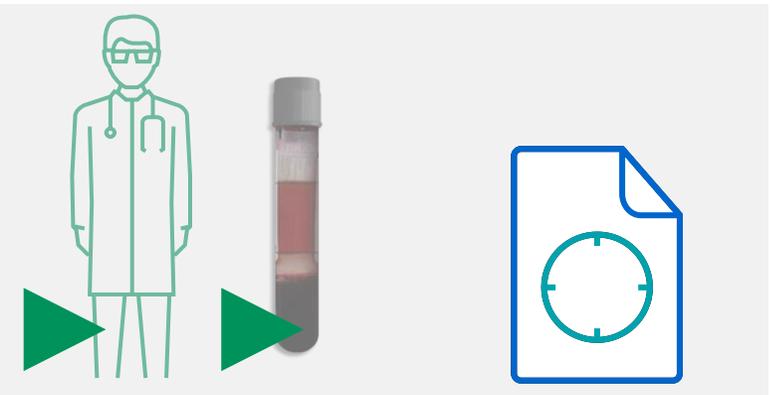


Primary calibrator



Hexokinase method
Glucose oxidase method

End-user

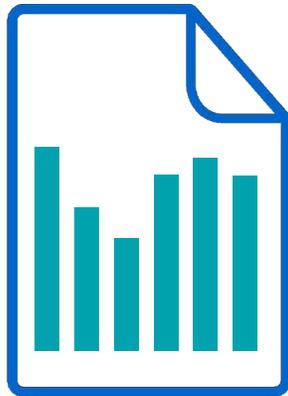
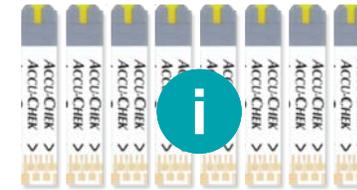
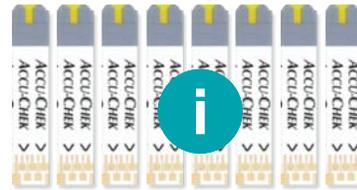


Demonstrate testing quality and stay compliant

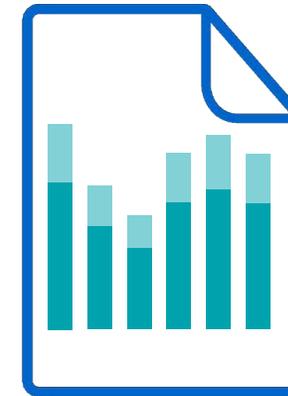
Source: EN ISO Standard 15197:2013: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

Roche Accu-Chek® Inform II solution

Lot-by-lot calibration for consistent and accurate results



**Measuring
range
parameters**



Small differences not clinically relevant

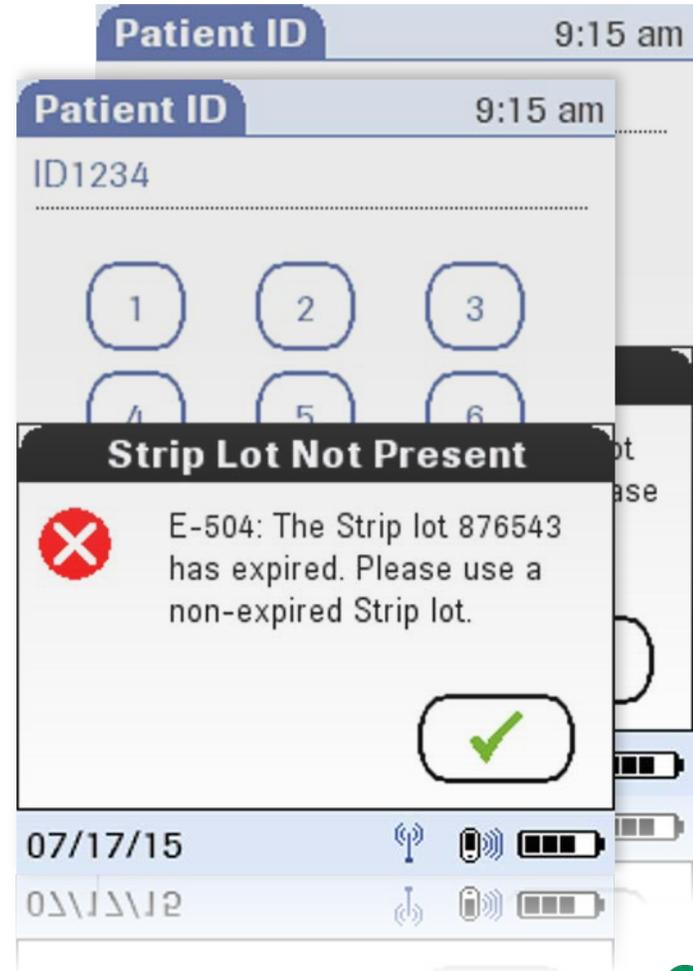
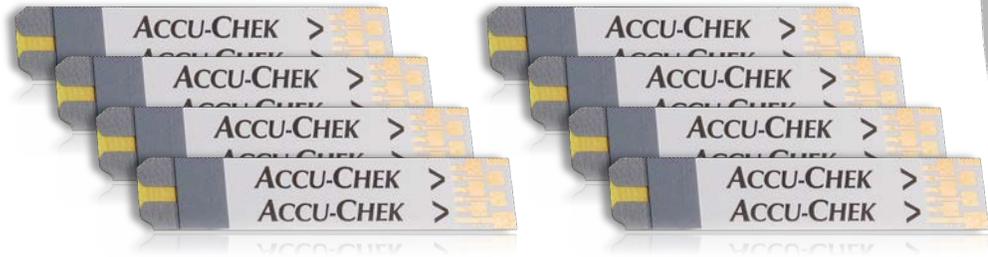
Improved consistency and accuracy

Roche Accu-Chek® Inform II solution

Detection of expired strips for compliance and patient safety

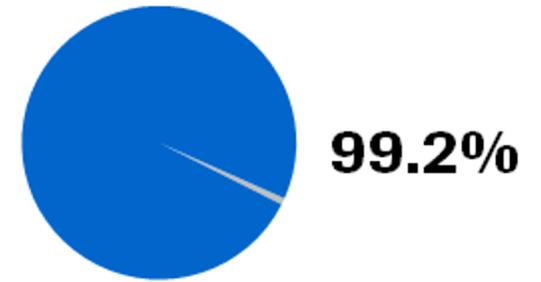
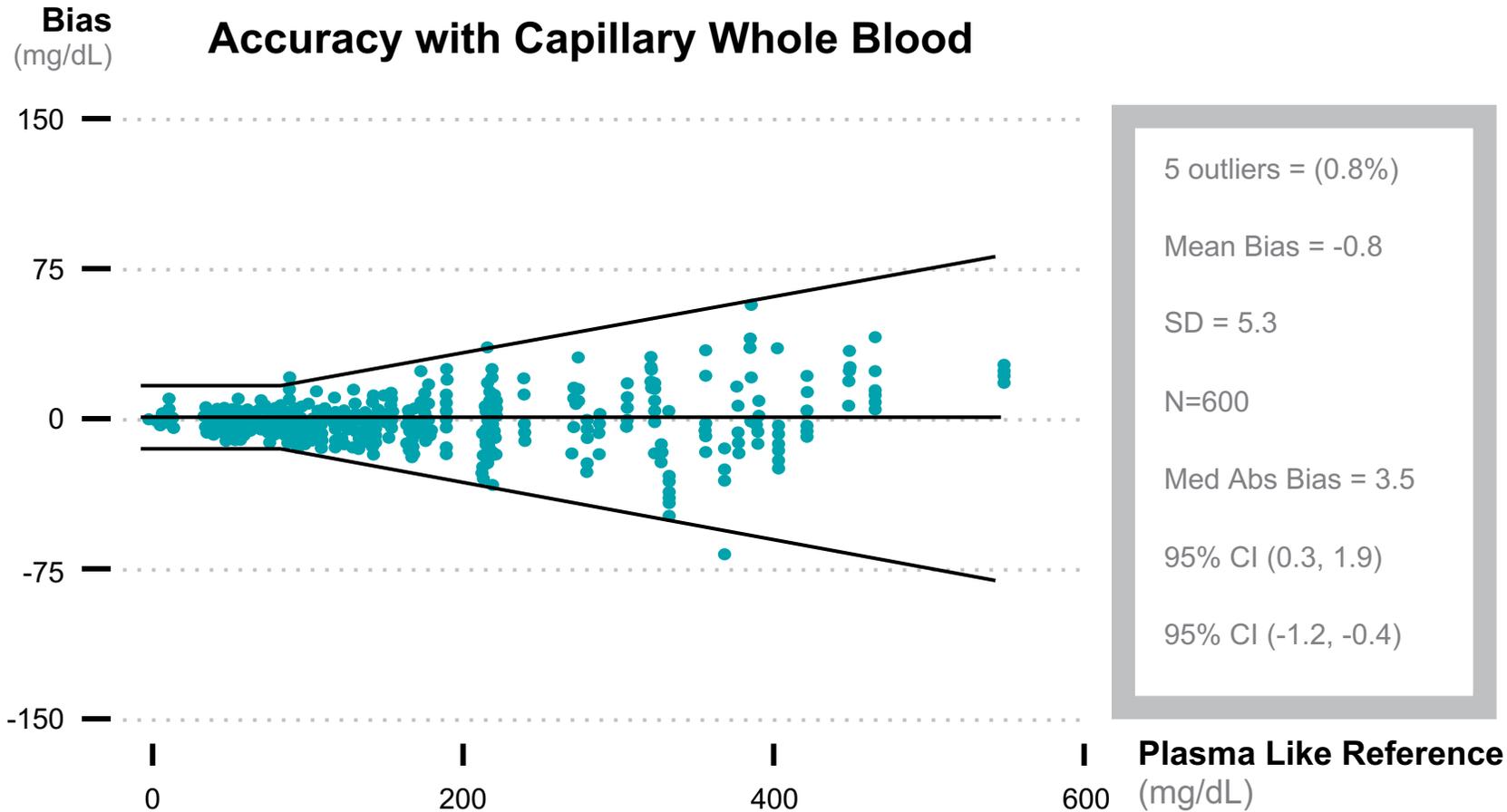
Testing cannot be carried out using non-valid/expired strips

Reduced risk of non-compliance, enhanced risk mitigation



Roche Accu-Chek® Inform II solution

99.2% correlation with plasma-like reference values



Data within bias requirements

Source: Evaluation Report: Accu-Chek® Inform II Test Strip, 2020. (ISO 15197:2013)

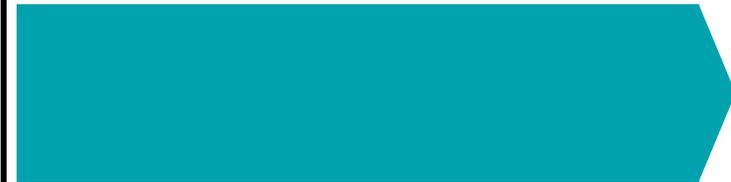
Roche Accu-Chek[®] Inform II solution

Accurate test results in the presence of more than 190 substances tested



Accu-Chek[®]
Inform II System

Potential interferents



190+

The following compounds, when tested with the Accu-Chek[®] Inform II system, were found to be interfering substances [threshold (mg/dL)]:

- Lipidemia (Triglycerides) > 1800
- Galactose > 15
- Ascorbic Acid > 3

Source: Roche Accu-Chek[®] Inform II Test Strip Package Insert, 2019.

Roche Accu-Chek® Inform II solution

Excellent repeatability and precision



Repeatability:

Mean value	[mg/dL]	41.6	67.5	122.4	186.7	316.8
	[mmol/L]	2.3	3.7	6.8	10.4	17.6
Standard deviation	[mg/dL]	1.8	3.0	4.8	7.4	11.3
	[mmol/L]	0.1	0.2	0.3	0.4	0.6
Coefficient of Variation [%]		—	—	3.9	4.0	3.6

Intermediate Precision:

Mean value	[mg/dL]	44.9	117.9	306.4
	[mmol/L]	2.5	6.5	17.0
Standard deviation	[mg/dL]	1.2	2.1	5.1
	[mmol/L]	0.1	0.1	0.3
Coefficient of Variation [%]		—	1.8	1.7

Source: Roche Accu-Chek® Inform II Test Strip Package Insert, 2019.

Why Roche Accu-Chek® Inform II solution?

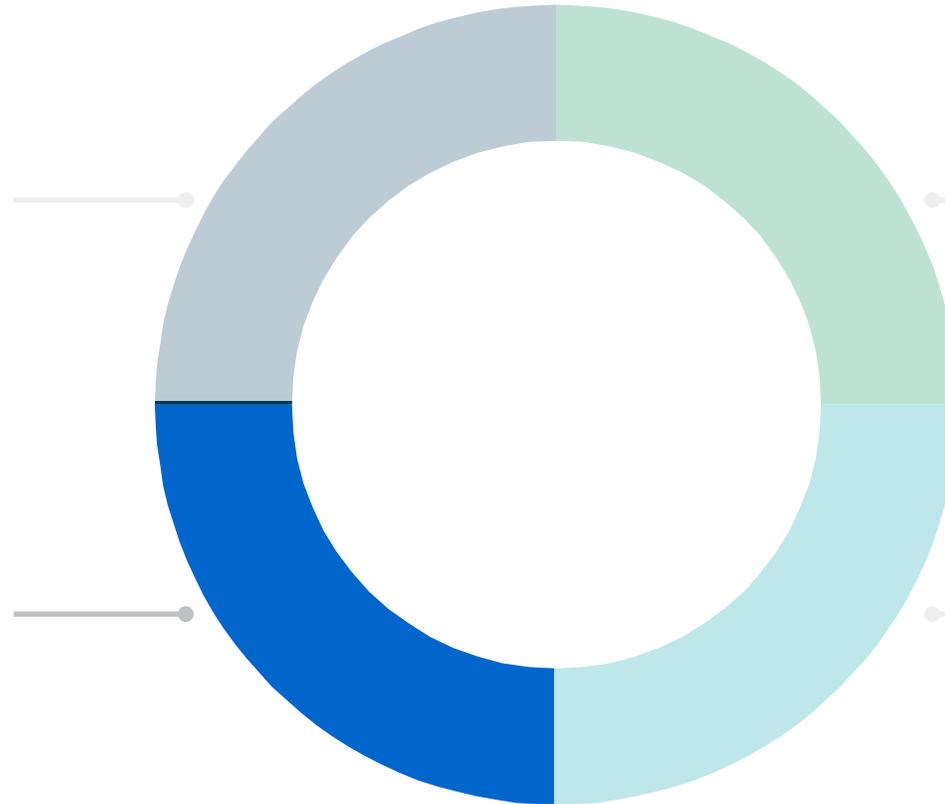
Safe for patients. Simple for professionals. Efficient for hospitals.



**By your
side
support**



**Automated
re-certification**



**Increased
patient safety**



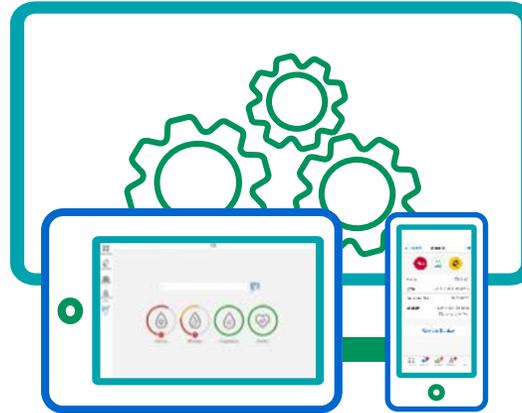
**Premium quality
of results**



Roche Accu-Chek® Inform II solution

The right test, on the right patient, with the right QC

Automatic lockout and alert to POC Coordinator



Clear audit trail for compliance



Training status



Device



User



Material lot



QC

Why Roche Accu-Chek® Inform II solution?

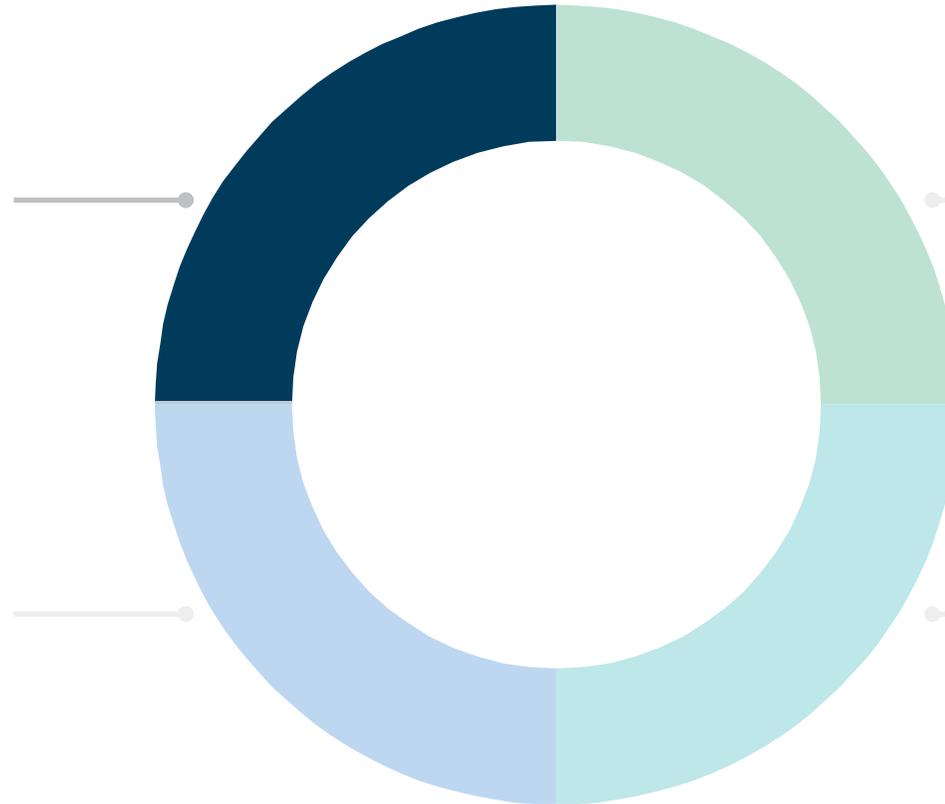
Safe for patients. Simple for professionals. Efficient for hospitals.



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**Increased
patient safety**



**Premium quality
of results**



Roche Accu-Chek® Inform II solution

Robust design - built to survive

Designed for hospital use

Drop test: harder than standard criteria

Proven water-resistance

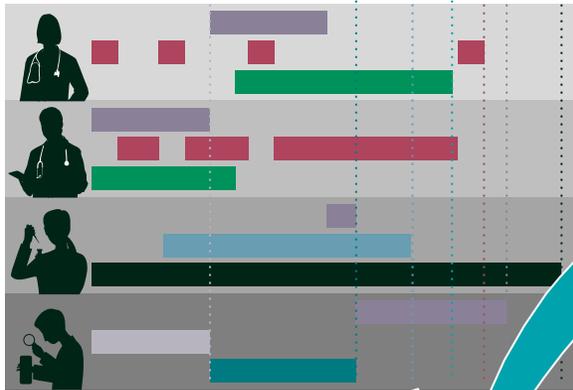


Source: Roche Data on File

Roche Accu-Chek® Inform II solution

By-your-side support, is a given at Roche Diagnostics

+20 years experience



Implement project to its full potential



Manage replacements while mobile



Side-by-side local support and contact

Why Roche Accu-Chek® Inform II solution?

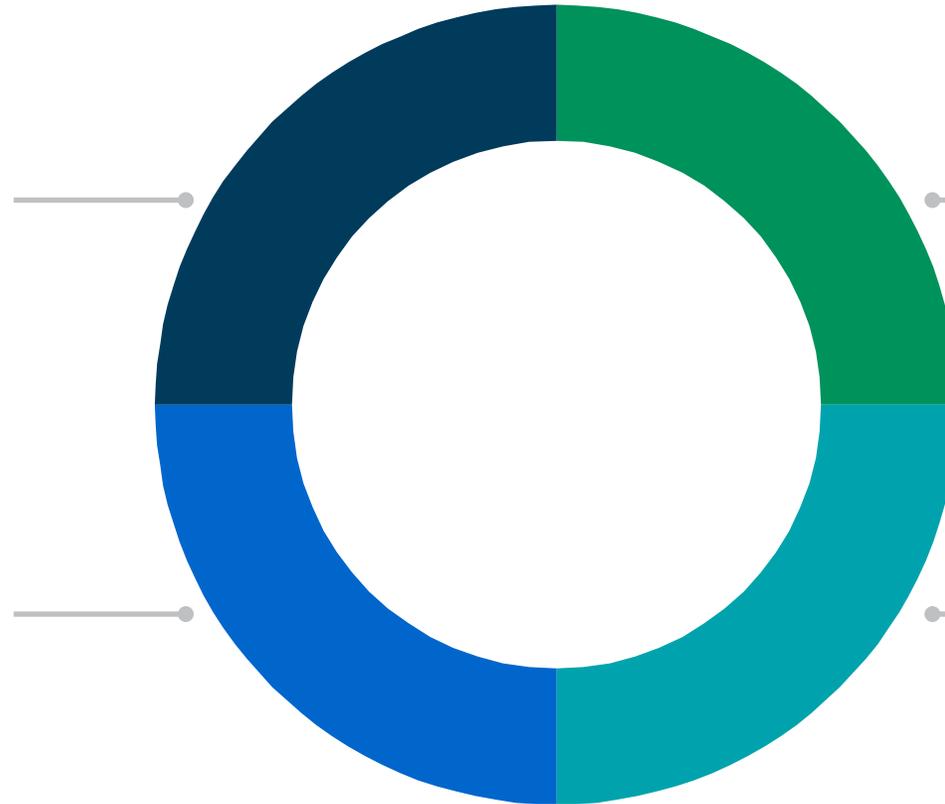
Safe for patients. Simple for professionals. Efficient for hospitals.



By your side support



Automated re-certification



Increased patient safety



Premium quality of results



Why Roche Accu-Chek® Inform II solution?

Safe for patients. Simple for professionals. Efficient for hospitals.



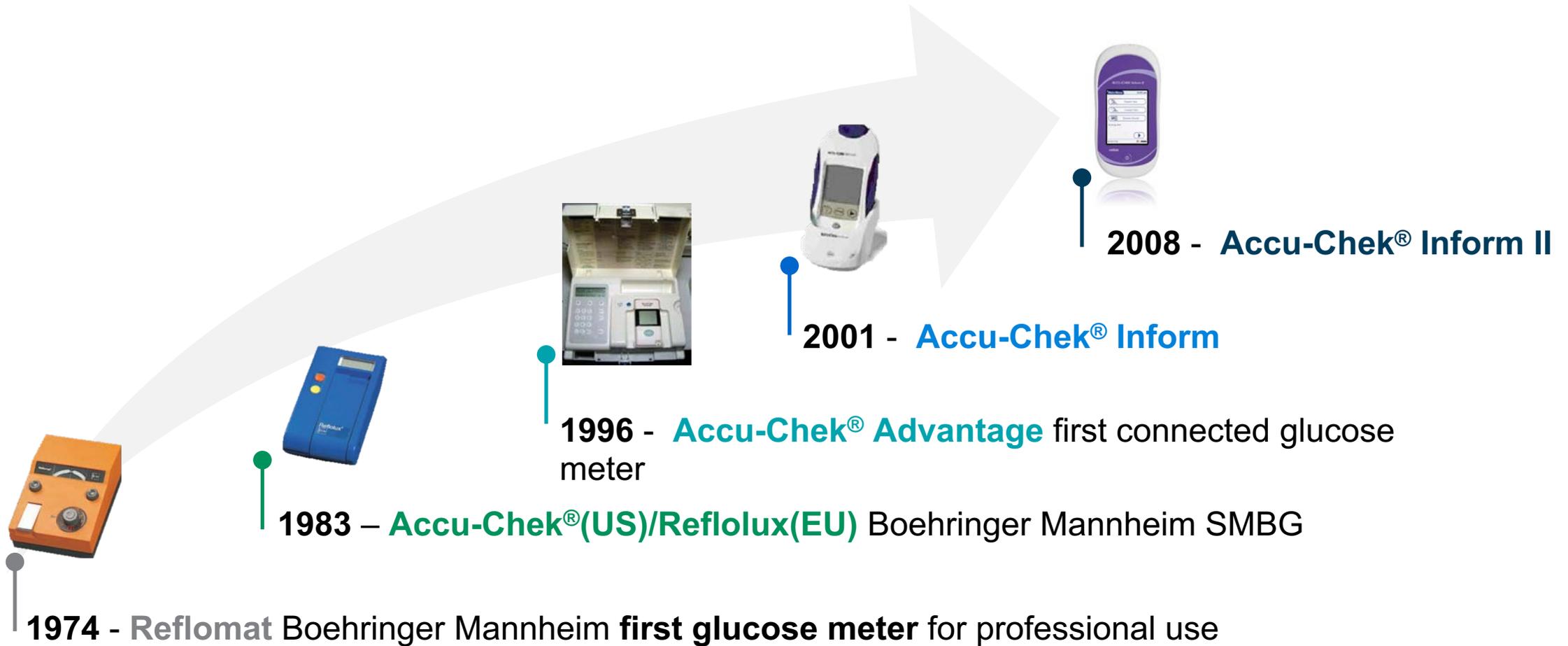
Designed to be simple for professional use

Developed to test all in-patients

Automated to fulfil laboratory standards

Hospital Blood Glucose

Accu-Chek a long story in Hospital glucose testing



Source: Clarke et al. A history of blood glucose meters and their role in self-monitoring of diabetes mellitus. British Journal of Biomedical Science 2012

Thank you

for your attention

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