

AQT90 FLEX

Product specification

TnI | NT-proBNP | CK-MB | Myo | D-dimer | CRP | β -hCG | PCT



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Troponin I

TnI tests are used as an aid in diagnosing myocardial infarction and in the stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

LoD (µg/L)	< 0.010
Reportable range (µg/L)	0.010 - 25

Reference value

Whole-blood samples and plasma samples were obtained from 231 apparently healthy individuals (106 women and 125 men) and analyzed using the TnI assay. The 99th percentile was determined to be 0.023 µg/L (ng/mL).

Imprecision

Five levels of plasma pools were analyzed at 4 test sites, on one analyzer. Three Test Kit lots were used per site. Each level was analyzed in duplicate in 2 separate runs for a minimum of 20 test days.

Plasma mean, µg/L	CV% (all sites)	
	Within-run	Within-lab
0.021	11.9%	12.9%
0.035	6.7%	7.7%
0.37	2.0%	4.4%
9.2	1.5%	3.1%
24	1.5%	3.1%

Five levels of whole blood pools were analyzed at 3 test sites, on one analyzer. One Test Kit lot was used per site. Each level was analyzed in 5 replicates in 5 separate runs within a 2-hour period. Data is from test site 1.

Whole blood mean, ug/L	CV% (Site 1)	
	Within-run	Within-lab
0.023	10.7%	10.7%
0.030	10.2%	11.8%
0.51	2.8%	2.8%
3.4	2.8%	2.8%
16	5.4%	5.4%

NOTE: Please see the IFU (package insert) for more information regarding site 2 and 3

Clinical performance

Clinical sensitivity and specificity of the TnI assay was evaluated analyzing a clinically characterized panel consisting of lithium-heparin plasma specimens of 390 patients. Of this patient population, 79 patients were according to World Health Organisation (WHO) MONICA criteria diagnosed as definite AMI patients and 311 were diagnosed as possible or non-AMI patients.

The specimens included in the analysis were collected at the following time points:

- On admission to the hospital (0-2 hours)
- 6-9 hours after admission

The biochemical marker assay used was Elecsys Troponin T (3rd generation) and the cut-off for AMI was 0.10 µg/L.

Cut-off (99 th percentile)	Hours after admission			
	0-2 hours		6-9 hours	
	Sens. ^a	Spec. ^b	Sens.	Spec.
0.023 µg/L (ng/mL)	65%	91%	91%	88%

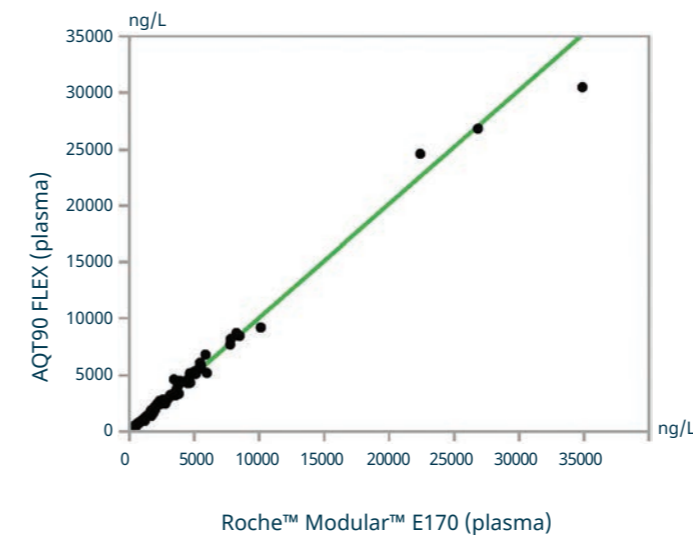
^aSensitivity; ^bSpecificity

NT-proBNP

It is intended for use as an aid in the diagnosis of heart failure. The test is also intended for use as an aid in the risk stratification of patients with acute coronary syndrome and heart failure.

LoD (ng/L)	≤ 20
Reportable range (ng/L)	70-35,000 ng/L
Correlation vs. Roche Modular	y=1.008x - 8.196 R ² =0.99 n=104

Figure 1. NT-proBNP method comparison



Reference value

Whole blood (lithium heparin and EDTA) and plasma (lithium heparin and EDTA) were obtained from 497 apparently healthy individuals (248 women and 249 men) and analyzed using the AQT90 FLEX NT-proBNP assay. The 95th percentile was determined to be 133 ng/L.

Imprecision

Within-day and total imprecision was determined by analyzing plasma pools over 20 days, twice a day, two replicates per run.

The concentration giving the CV of 10% of the AQT90 FLEX NT-proBNP assay is approximately 73 ng/L.

Plasma mean, ng/L	CV%	
	Within-run	Within-lab
101	6.7%	7.2%
2,366	2.3%	3.7%
31,817	2.8%	3.3%

CK-MB

It is intended for use as an aid in the diagnosis of myocardial infarction.

LoD (µg)	1
Reportable range (µg/L)	2 - 500

Reference value

Whole blood and plasma were obtained from 691 apparently healthy individuals from US adult population (388 women and 303 men). The 97.5th percentile was determined to be 8.7 µg/L (ng/mL) for women and 13 µg/L (ng/mL) for men. The 99th percentile was determined to be 11 µg/L (ng/mL) for women and 17 µg/L (ng/mL) for men.

Imprecision

For plasma, 5 levels were analyzed at 3 sites, 1 analyzer and 3 test kit lots per site. Each level was analyzed in duplicate in 2 separate runs per day for 20 test days.

Plasma mean, µg/L	CV% (all sites)	
	Within-run	Within-lab
3.0	6.5%	8.2%
5.4	4.0%	6.5%
15	2.8%	4.3%
56	2.4%	4.1%
372	2.3%	3.9%

For whole blood, 5 levels were analyzed at 3 sites, 1 analyzer and 1 test kit lot per site. Each level was analyzed in 5 replicates in 5 separate runs within 3-hour period.

Whole blood mean, µg/L	CV% (Site 1)	
	Within-run	Within-lab
2.4	6.0%	6.0%
6.0	5.4%	5.9%
22	2.1%	2.4%
72	1.7%	1.7%
416	3.3%	3.3%

NOTE: Please see the IFU (package insert) for more information regarding site 2 and 3

Myo

It is intended for use as an aid in the rapid diagnosis of heart disease, for example, acute myocardial infarction.

LoD (µg/L)	1.0
Reportable range (µg/L)	20 - 900

Reference value

Whole blood and plasma samples were obtained from 343 apparently healthy individuals from US adult population (182 women and 161 men). The 97.5th percentile was determined to be 75 µg/L (ng/mL) for women and 142 µg/L (ng/mL) for men.

Imprecision

For plasma, 5 levels were analyzed at 3 sites, 1 analyzer and 3 test kit lots per site. Each level was analyzed in duplicate in 2 separate runs per day for 20 test days.

Plasma mean, µg/L	CV% (all sites)	
	Within-run	Within-lab
43	2.0%	5.0%
97	2.1%	5.2%
203	2.1%	4.3%
285	2.5%	4.3%
717	2.5%	4.8%

For whole blood, 5 levels were analyzed at 3 sites, 1 analyzer and 1 test kit lot per site. Each level was analyzed in 5 replicates in 5 separate runs within 3-hour period.

Whole blood mean, µg/L	CV% (Site 1)	
	Within-run	Within-lab
40	3.6%	3.6%
107	3.7%	3.7%
175	3.3%	3.4%
293	2.8%	2.8%
585	3.1%	3.1%

NOTE: Please see the IFU (package insert) for more information regarding site 2 and 3

D-Dimer

D-Dimer is intended as an aid in the diagnosis of venous thromboembolism (deep vein thrombosis and pulmonary embolism).

LoD (µg/L)	< 80
Reportable range (µg/L)	80 - 100,000

Reference value

Whole blood (lithium-heparin, EDTA and citrate) was obtained from 268 apparently healthy individuals (47 % men and 53 % women: 131 individuals <50 years of age; 137 individuals >50 years of age). The samples were analyzed with the D-dimer assay. The 95th percentile for whole-blood samples was determined to be 630 µg/L for persons <50 years of age and 654 µg/L for persons >50 years of age.

Imprecision

Three levels of spiked whole blood were tested with 3 Test Kit lots, on 6-10 AQT90 FLEX analyzers.

Whole Blood mean, µg/L	CV%	
	Within-run	Within-lab
194	15.2%	15.3%
572	12.7%	12.8%
61,614	7.3%	7.4%

Clinical performance

Clinical performance of the AQT90 FLEX D-dimer assay was evaluated analyzing a clinically characterized panel consisting of citrate specimens of 170 patients. Of this patient population, 64 were diagnosed as having deep venous thrombosis (DVT) based on phlebography according to Rabinov [8], performed without compression during injection of at least 100 mL iodine 240 mg/mL. The leg that was examined was not weight bearing.

DVT restricted to the calf veins was classified as distal, whereas DVT in the popliteal, femoral, iliac or inferior caval veins was classified as proximal.

Cut-off	DVT	NPV	Specificity
500 µg/L	Distal	0.88	0.71
	Proximal	0.99	0.71

These values should only be used as examples. Each laboratory should establish its own diagnostic cut-off values for venous thromboembolism.

Figure 2. The method comparison with the Stago STALIATEST D-dimer assay, the BioMerieux Vidas D-dimer new (DD2) v R4.10 assay, the Biopool Auto-Dimer assay, and the Abbott AxSYM D-dimer assay with focus on proximal DVT*.

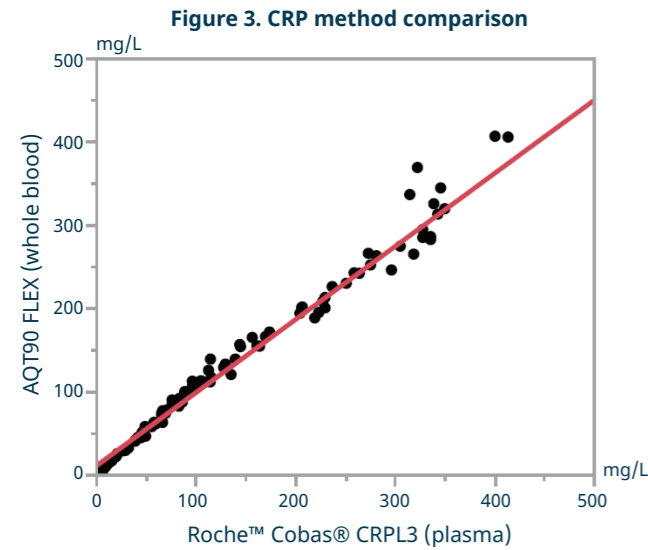


*Sidelmann JJ, Gram J, Jespersen J. Diagnostic performance of AQT90 FLEX D-Dimer in patients suspected for deep venous thrombosis – comparison with four well-established D-dimer tests. International Society on Thrombosis and Haemostasis 2009; 7, 2. Poster PP-WE-515

CRP

The measurement of CRP is intended as an aid in the detection and evaluation of infection, tissue injury, and inflammatory disorders and associated diseases.

LoD (mg/L)	<1
Reportable range (mg/L)	5 - 500
Correlation vs. Roche cobas®	$Y = 0.88x + 11.6$; $R^2 = 0.98$, $n = 110$



Reference value

EDTA whole blood and plasma were obtained from 272 apparently healthy individuals (143 women and 129 men) and analyzed using the AQT90 FLEX CRP assay. The 95th percentile for both whole-blood and plasma samples was determined to be < 5 mg/L.

Imprecision

For plasma, each level was analyzed in duplicate in 2 separate runs per day for 20 test days.

Plasma mean, mg/L	CV%	
	Within-run	Within-lab
7.4	4.9%	5.3%
111	5.5%	5.6%
343	4.5%	4.8%

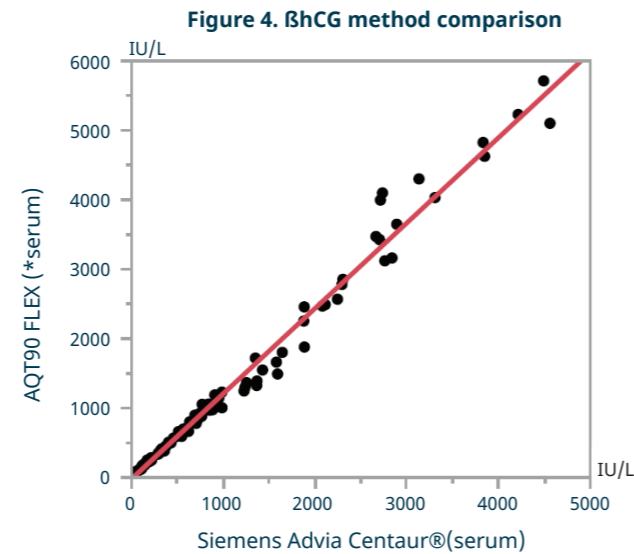
For whole blood, each level was analyzed by 3 test kit lots with 5-6 analyzers.

Whole blood mean, mg/L	CV%	
	Within-run	Within-lab
6.5	8.0%	12.8%
99	7.3%	11.1%
439	7.0%	12.8%

βhCG

The βhCG test is indicated for use as an aid in the early detection of pregnancy.

LoD (IU/L)	< 2
Reportable range (IU/L)	2 - 5,000
Correlation vs. Siemens Advia Centaur	$Y = 1.228x - 20.7$; $R^2 = 0.986$, $n = 116$



*A bridging study showed that serum samples gave the same results as plasma samples on the AQT90 FLEX analyzer.

Reference value

Low level βhCG values ≥ 25 IU/L may be indicative of early pregnancy but the results should always be evaluated in the context of the clinical situation [9].

Imprecision

For plasma, each level was analyzed in 4 replicates per run, twice a day for 20 test days.

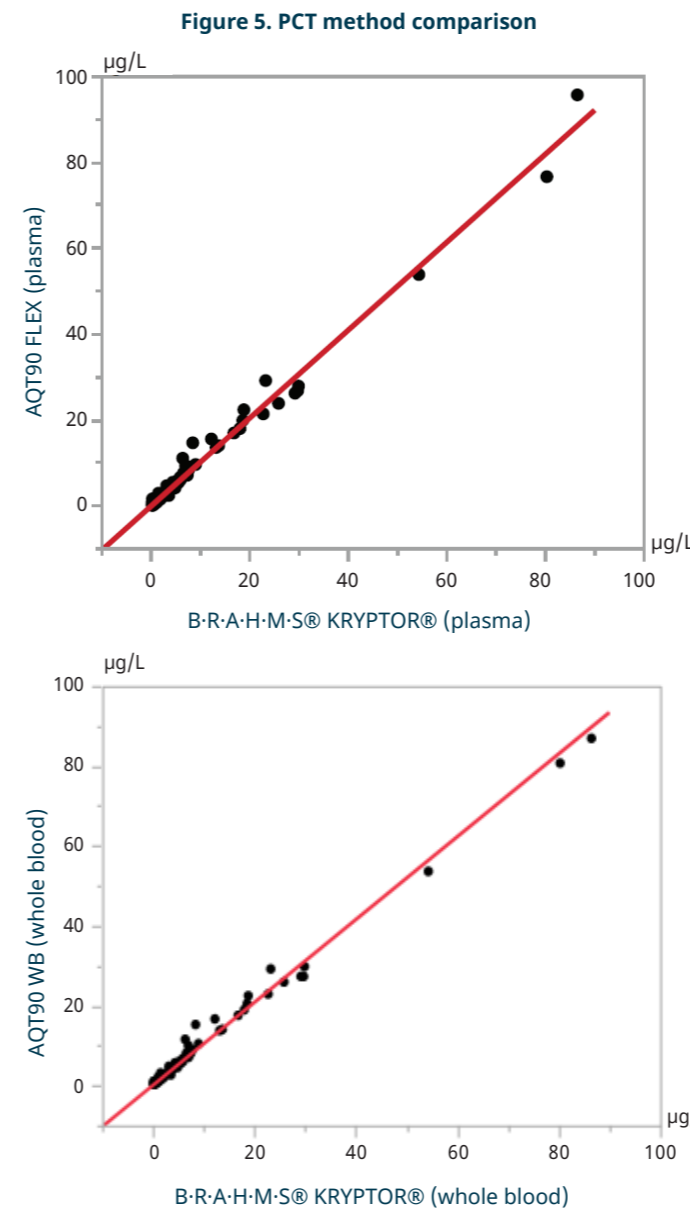
Plasma mean, IU/L	CV%	
	Within-run	Within-lab
3.1	15.4%	17.2%
13.0	5.2%	8.6%
4173	2.3%	3.3%

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PCT

PCT is indicated for use as an aid in the diagnosis of sepsis.

Analytical performance	Plasma	Whole blood
LoD (μg/L)	0.059	0.072
Reportable range (μg/L)	0.082 - 100	0.12 - 100
B·R·A·H·M·S® KRYPTOR®	$Y = 1.02x - 0.007$; $r = 0.99$, $n = 211$	$Y = 1.05 + 0.007$; $r = 1.00$, $n = 199$



Reference value

Lithium-heparin whole blood and plasma samples obtained from 252 apparently healthy individuals (128 women and 124 men, aged 18 years or older) were analyzed with the PCT assay. The 95th percentile was determined to be <0.12 ng/mL (μg/L) for whole blood and 0.087 ng/mL (μg/L) for plasma for both men and women.

Imprecision

For plasma, each level was analyzed in duplicate in 2 separate runs per day for a minimum of 20 test days, at 2 test sites.

Plasma mean, μg/L	CV% (all sites)	
	Within-run	Within-lab
0.092	11.9%	12.5%
0.30	3.5%	3.8%
0.52	3.0%	3.3%
2.0	1.8%	2.0%
67	1.5%	1.9%

For whole blood, each level was analyzed in 5 replicates in 5 separate runs within a 3-hour period, at 2 test sites. Data is from test site 1.

Whole blood mean, μg/L	CV%	
	Within-run	Within-lab
0.32	5.8%	5.8%
0.51	3.9%	4.0%
1.9	3.4%	3.6%
7.5	1.9%	1.9%
55	2.4%	2.4%

NOTE: Please see the IFU (package insert) for more information regarding site 2

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PCT

Clinical performance

The AQT90 FLEX PCT assay shows a high degree of concordance with the Elecsys® B·R·A·H·M·S PCT® assay at the diagnostic cut-offs of 0.50 and 2.0 µg/L [10], as shown in the tables respectively.

Concordance analysis for the cut-off 0.50 ng/mL

Plasma	Elecsys® B·R·A·H·M·S® ≤ 0.50 µg/L	Elecsys® B·R·A·H·M·S® > 0.50 µg/L	Total
AQT90 FLEX ≤ 0.50 µg/L	64	1	65
AQT90 FLEX > 0.50 µg/L	7	69	76
Total	71	70	141
Positive concordance	99%		
Negative concordance	90%		
Overall concordance	94%		

Whole blood	Elecsys® B·R·A·H·M·S® ≤ 0.5 µg/L	Elecsys® B·R·A·H·M·S® > 0.5 µg/L	Total
AQT ≤ 0.5	58	0	58
AQT > 0.5	10	70	80
Total	68	70	138
Positive agreement	100%		
Negative agreement	85%		
Overall agreement	93%		

Concordance analysis for the cut-off 2.0 ng/mL

Plasma	Elecsys® B·R·A·H·M·S® ≤ 2.0 µg/L	Elecsys® B·R·A·H·M·S® > 2.0 µg/L	Total
AQT90 FLEX ≤ 2.0 µg/L	110	0	110
AQT90 FLEX > 2.0 µg/L	7	24	31
Total	117	24	141
Positive concordance	100%		
Negative concordance	94%		
Overall concordance	95%		

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Whole blood	Elecsys® B·R·A·H·M·S® ≤ 2.0 µg/L	Elecsys® B·R·A·H·M·S® > 2.0 µg/L	Total
AQT ≤ 2.0	106	0	106
AQT > 2.0	8	24	32
Total	114	24	138
Positive agreement	100%		
Negative agreement	85%		
Overall agreement	93%		

Hook effect and carry over

	TnI	CKMB	Myo	NTpro	D-Dimer	CRP	βhCG	PCT
No hook effect threshold (µg/L)	Up to 1,470	Up to 9,800	Up to 1,950	Up to 500	Up to 286,000	Up to 2,000,000	Up to 233,000 IU/L	Up to 1,600
Carry over (ppm)	< 500	< 500	< 500	< 100	< 100	< 100	< 50	< 0.25 µg/L

Interfering substances

Potential interfering substances (at concentrations listed in the table of each individual IFU) were found to have no notable effect on the assays.

The biotin concentration below 2.6 mg/L (2600 ng/mL) was found to have no notable effect on the assays (interference ≤10%).

Please refer to the IFU (package insert) to find more about individual assay's information about interfering substances.

References

- Katus HA, Remppis A, Looser S, *et al.* Enzyme linked immunoassay of cardiac troponin T for the detection of acute myocardial infarction in patients. *Mol Cell Cardiol* 1989;21(7): 1349-53.
- Katus HA, Scheffold T, Remppis A, Zehelein J. Proteins of the troponin complex. *Laboratory Medicine* 1992; 23(5):311-17.
- Hamm CW, Ravkilde J, Gerhardt W, Jorgensen P, Peheim E, Ljungdahl L, *et al.* The prognostic value of serum troponin T in unstable angina. *N Engl J Med* 1992; 327(3):146-50.
- Ohmann EM, *et al.* Risk stratification with admission cardiac troponin T levels in acute myocardial ischemia. *N Engl J Med* 1996; 335: 1333-34.
- Christenson RH, Duh SH, Newby LK, Ohman EM, Califf RM, Granger CB, *et al.* Cardiac troponin T and cardiotroponin I: relative values in short-term risk stratification of patients with acute coronary syndromes. *Clin Chem* 1998; 44(3): 494-501
- Lindahl B, Diderholm E, Lagerqvist B, Venge P, Wallentin L, the FRISC II investigators. Mechanisms behind the prognostic value of Troponin T in unstable coronary artery disease: a FRISC II substudy. *J Am Coll Card* 2001; 38: 979-86
- Aviles RJ, Askari AT, Lindahl B, Wallentin L, Jia G, Ohman EM, Mahaffey KW, Newby LK, Califf RM, Simoons ML, Topol EJ, Lauer MS. Troponin T levels in patients with acute coronary syndromes, with or without renal dysfunction. *N Engl J Med* 2002; 346: 2047-52
- Rabinov K, Paulin S. Roentgen diagnosis of venous thrombosis in the leg. *Arch Surg* 1972;104:134-144.
- Burtis CA, Ashwood ER, Bruns DE. *Clinical Chemistry of Pregnancy*. In: Tietz textbook of clinical chemistry and molecular diagnostics, fourth edition. St. Louis: Elsevier Saunders, 2006.
- DC-085497 - Data-on-file: PCT concordance studies, (Rev. 1).

Comprehensive cardiac panel and markers for coagulation, infection and pregnancy

Test menu

Marker	Reportable range	Traceable to	Measuring time min:sec
Troponin I	0.010–25 µg/L	NIST, SRM 2921	18:19
CKMB	2–500 µg/L	IRMM, 455	18:09
Myoglobin	20–900 µg/L	Scripps, M0725	18:09
NT-proBNP	70–35,000 ng/L	**	10:10
CRP	5–500 mg/L	ERM – DA472/IFCC	12:11
βhCG	2–5000 IU/L	WHO, 75/589	18:09
D-dimer	80–100,000 µg/L	Hystest, 8D70	20:10
PCT	0.12–100 ng/mL (whole blood), 0.082–100 ng/mL (plasma)	**	20:18

** Traceable to in-house reference calibrators, which have been value-assigned to correlate with other commercially available assays.
NT-proBNP: Roche MODULAR ANALYTICS E170 / PCT: B-R-A-H-M-S PCT® sensitive KRYPTOR® assay.

Measuring system

Sample type	Whole blood and plasma*
Sample volume	2 mL minimum volume required
Throughput	Up to 30 results per hour

*Only whole-blood sample type can be used for D-dimer.

Test kit

Contains 10 test cartridges and 1 calibration-adjustment cartridge. Barcode secures automatic registration of new test kit. Storage temperature is 2–8°C as unopened.

Marker	On board stability (days)	Max. shelf life (months)	No. of tests per cartridge	Test kit item no.
Troponin I	17	12	16	942-903
CKMB	23	8	16	942-906
Myoglobin	16	8	16	942-909
NT-proBNP	24	12	16	942-930
CRP	20	12	8	942-936
βhCG	20	8	16	942-918
D-dimer	31	12	8	942-915
PCT	10	8	16	942-964
PCT	10	8	8	942-970

AQT90 FLEX Solution Pack

Fully closed pack that includes assay buffer and a waste container for up to 200 tests. ID chip secures automatic registration of a new Solution Pack.

Item no.	903-006
Storage temperature	2–32°C
Temperature during transport	Up to 40°C for a maximum of 2 weeks

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Specifications

Hardware

Computer specifications

CPU Onboard Intel® Atom™ E3815 1.46GHz CPU
AMI 64Mbit SPI BIOS
Intel® Atom™ SoC Integrated Graphics
System Memory Onboard 2GB DDR3L 1066/1333
32 GB SolidState storage
8" color TFT-LCD, resolution 800 × 600 SVGA Touch screen
112mm thermal-sensitive printer

Software

Software platform

Microsoft® embedded software

Data capacity

Patient Results Log	2500 records
Activity Log	7000 records
Calibration Log	5500 records
LQC Log	2000 records

Security and QA features

Data secured by password protection
Lockout feature for QC
7 different user profiles
User ID access verification

Start-up times

Type	Max. start-up time
Install solution pack	< 10 min.
Install test cartridges	< 1 min.

Additional information

Dimensions

Height	45 cm	17.7 in
Width	46 cm	18.1 in
Depth	48 cm	18.9 in
Weight	35 kg	77.2 lbs

Interface

Built-in barcode reader for operator & sample ID
Accepted codes: Code 128, Code 39, Code 93, I 2 of 5, Codabar
Serial interface RS232 with power for external barcode reader
3 USB 2.0 connections
Optional external keyboard
Optional external mouse
Optional external barcode reader

Communication

LIS/HIS communication

High-level protocols:
ASTM E1394, 1381
HL7 ver. 2.2
HL7 ver. 2.5
Low-level serial protocols:
Serial RAW
Low-level network protocols:
TCP/IP

Radiometer IT solution

Interface via Ethernet adapter

Accessories

Type	Item no.
Blank cartridge	942-962
Cleaning solution tubes	905-843
Empty tube kit – box of 50 tubes	944-230
Printer paper (8 rolls)	984-070
Solution Pack	903-006

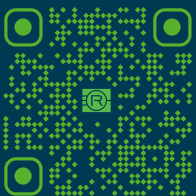
Other

Operating environment	15–30°C / 59–86°F, 20–80% RH
Altitude	0–2000 m / 6,562 feet above sea level
Power	100–240 V ±10%; 50/60 Hz ±5%



Whatever comes next, we make sure life comes first

Radiometer products and solutions are used in hospitals, clinics, and laboratories in over 130 countries, providing information on critical parameters in acute care diagnostics. Through connected solutions, expert knowledge, and trusted partnership, we help health care professionals make diagnostic decisions to improve patient care.



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