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POINT OF CARE, SELF-MONITORING			
Instrument name	i-STAT 1	Coag-Sense PT/INR Monitoring System	Cascade Abrazo
First year sold	2000	2010	2014 (EU/CE; 510(k) submitted to FDA)
No. of units sold in U.S./Outside U.S.	—	—	—/>>200
No. of units sold in 2017	—	—	—
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	U.S./Canada	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC	POC and self-monitoring	POC
Specimen type	fresh whole blood from arterial, venous, or skin puncture	fingerstick	fingerstick, venipuncture (whole blood, anticoagulated whole blood, plasma)
Model type	handheld/portable	handheld/portable	handheld/portable
Dimensions in inches (H × W × D)/Weight	9.25 × 3.03 × 2.85/22.56 oz	3 × 6.5 × 5.75/1.2 lb (with 4 AA 1.5V alkaline batteries)	3.4 × 3.5 × 8.5/1.65 lb
Specimen volume needs	17 µL–95 µL	10 µL via cap sample transfer tube	accurate volume not necessary (drop)
Clotting-based tests for which device has FDA-cleared applications	PT-INR, ACT kaolin, ACT celite	PT (reportable range—low: 7 seconds; high: 180 seconds; INR—low: 0.8 seconds; high: 8.0 seconds)	—
Tests using other methodologies for which device has FDA-cleared applications	chemistries/electrolytes (sodium, potassium, chloride, TC02, anion gap, ionized calcium, glucose, urea nitrogen, creatinine, lactate); hematology (hematocrit, hemoglobin); blood gases (pH, PCO2, PO2, TCO2, HCO3, base excess, sO2); cardiac markers (cTnl, CK-MB, BNP), β-hCG	—	—
FDA-cleared tests but not yet clinically released	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted for clearance	—	—	PT-C, APTT, c-ACT, c-ACT-LR, direct thrombin inhibitors, LMWH, fibrinogen, heparin titration, protamine titration, direct oral anticoagulants (DOACs)
Method of endpoint detection	electrogenic	direct micromechanical clot detection, measures actual time required for clotting	optical/mechanical
Quality control methods			
• Electronic	yes	—	yes
• Liquid	yes	yes	—
• Lyophilized	yes (plasma)	yes	yes (plasma)
• Integrated QC with each analysis	yes	no	yes
• Automatic lockout for QC failure	yes	yes	yes (available feature)
• Other	—	—	—
Time (in minutes) to perform control plus specimen test			
• PT	>3	<1	2
• PT and PTT	—	—	2–5
• ACT	>3	—	variable per heparin concentration; calculated value faster than real time at therapeutic levels
Data-management capability	optional add-on	onboard	onboard, optional add-on
• Includes QC	yes	yes	yes
System can automatically transfer data to information system			
• Patient data	yes	yes	yes
• QC data	yes	yes	yes
Interface supplied by instrument vendor	yes	yes	no
Commercially available systems for which interfaces are up and running in active user sites	Sunquest, Cerner, SCC Soft Computer, McKesson, Meditech, GE, Siemens, Vista, more	RALS, Telcor	—
LOINC codes transmitted with results	no	no	no
How labs get LOINC codes for reagent kit	package insert	website, package insert, email query	—
Lab can control analyzer remotely	yes	no	yes
Real-time wireless linkage to LIS or HIS	yes	yes, optional	yes (radio frequency, infrared)
Positive identification system (e.g. barcode) for:			
• Patient specimen	yes	yes, optional	yes
• Reagent	yes	yes	yes (2D barcode reader)
Onboard system for automatic error detection	yes	yes, for sample (volume), reagent stability	yes, for sample (volume), reagent/cuvette expiration date
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approximate number of training hours needed for:			
• Medical staff	1	1	1
• Patient	—	1	—
Patient self-testing program is available	no	yes, available through IDTF	no
Instrument list price	—	\$1,062.50	\$5,995
Reagent rental or lease only	no	no	—
Cost per sample:			
• PT: for reagent rental	—	—	variable
if device purchased	—	<\$4 per strip	variable
• PTT: for reagent rental	—	—	variable
if device purchased	—	—	variable
• ACT: for reagent rental	—	—	variable
if device purchased	—	—	variable
CLIA '88 complexity rating	moderate	CLIA waived	nonwaived
Distinguishing features (supplied by company)	broad testing menu; many data-management and interfacing options; easy to use; integrated wireless capability for real-time transmission to EMR	directly detects clot formation; emulates WHO reference tilt-tube method using micromechanical means of clot detection; system not affected by low hemoglobin or hematocrit levels; % CVs of 2.5%; runs true plasma controls with the actual thromboplastin and plasma of known INR; two levels of controls included with each box of strips; individually wrapped, nonrefrigerated, barcoded test strips with 24-month dating and ISI of 1.0	uses a card-based technology that affords a smaller reagent storage footprint; true smart-card type technology by using a 2D barcode labeling system; incorporates enabling technology in an ergonomic package; running a test is user friendly, requiring only 3 steps: scan the reagent card barcode, insert the reagent card, present the sample via hanging drop; digital device offers versatility and features unique to its class, such as a color touchscreen monitor and connectivity via USB configuration or wireless (such as Wi-Fi and Bluetooth)
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 2 of 5

**POINT OF CARE,
SELF-MONITORING**

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Instrument name	Actalyke Mini II	Actalyke XL	Hemochron Signature Elite
First year sold	2004	2002	2005
No. of units sold in U.S./Outside U.S.	>450/>5,000	>300/>400	10,000/5,000
No. of units sold in 2017	—	—	2,000
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC	POC	POC
Specimen type	venipuncture (whole blood)	venipuncture (whole blood)	fingerstick, venipuncture (whole blood, anticoagulated whole blood)
Model type	portable	portable	handheld/portable
Dimensions in inches (H × W × D)/Weight	4.8 × 6.1 × 6.3/5.3 lb	8 × 10.7 × 12/15 lb	2 × 7.5 × 3.7/1.2 lb
Specimen volume needs	accurate volume required (fill line on cuvette)	accurate volume required (fill line on cuvette)	1–2 drops
Clotting-based tests for which device has FDA-cleared applications	activated clotting time (whole blood), MAX-ACT, celite, kaolin, glass	activated clotting time (whole blood), MAX-ACT, celite, kaolin, glass	PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR
Tests using other methodologies for which device has FDA-cleared applications	—	—	—
FDA-cleared tests but not yet clinically released	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted for clearance	—	—	—
Method of endpoint detection	two-point electromechanical soft-clot detection principle	two-point electromechanical soft-clot detection principle	optical mechanical true endpoint clot detection
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	yes	yes	yes (simulated whole blood)
• Lyophilized	yes	yes	yes (simulated whole blood)
• Integrated QC with each analysis	no	no	yes
• Automatic lockout for QC failure	no	yes	yes
• Other	—	data management for entering heparin dose, L-J chart generation for all controls	operator lockout, certification lockout, audit trail, patient identification lockout
Time (in minutes) to perform control plus specimen test			
• PT	—	—	2
• PT and PTT	—	—	2
• ACT	5	5	~4.5
Data-management capability	no	yes	onboard
• Includes QC	no	yes	yes
System can automatically transfer data to information system			
• Patient data	—	yes	yes
• QC data	—	yes	yes
Interface supplied by instrument vendor	—	interface specifications supplied, POCT1-A compliant	—
Commercially available systems for which interfaces are up and running in active user sites	—	—	Telcor QML, Alere RALS-Web 3, Aegis POC, Conworks UniPOC
LOINC codes transmitted with results	no	no	no
How labs get LOINC codes for reagent kit	—	—	email query
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	—	yes	yes, via connectivity partners
Positive identification system (e.g. barcode) for:			
• Patient specimen	no	yes	no
• Reagent	no	yes (all disposables have barcode for identification with use on any Actalyke model)	yes
Onboard system for automatic error detection	yes, for stuck magnet, printer problems	yes, for stuck magnet, no tube; mechanical instrument parameters only; well rotation, temperature, and detection settings	yes, for sample (volume), reagent expiration date
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approximate number of training hours needed for:			
• Medical staff	1	1–2	<1
• Patient	—	—	—
Patient self-testing program is available	no	no	—
Instrument list price	\$1,107–\$1,442	\$4,114	inquire
Reagent rental or lease only	purchase, lease, or reagent rental	purchase, lease, or reagent rental	purchase and usage agreement available (reagent rental)
Cost per sample:			
• PT: for reagent rental	—	—	volume dependent
if device purchased	—	—	—
• PTT: for reagent rental	—	—	—
if device purchased	—	—	volume dependent
• ACT: for reagent rental	—	—	—
if device purchased	\$0.74–\$1.76	\$0.74–\$1.76	volume dependent
CLIA '88 complexity rating	nonwaived	moderate	moderate
Distinguishing features (supplied by company)	two-point electromechanical soft-clot detection; magnetic detection device—electronic QC/revolution; MAX-ACT tubes, 0.5 mL volume and linear to 6 U/mL; linear up to 6 U/mL of heparin; electronic clotting tube available	two-point electromechanical soft-clot detection principle; MAX-ACT test, 0.5 mL blood volume, linear up to 10 units of heparin, safer plastic tube construction, for use on Actalyke and Hemochron instruments; electronic clotting tube that simulates and mimics actual blood-clot formation for accurate ECT challenges; integrated printer; 3.5-inch diskette storage	comprehensive microcoagulation test menu allows for standardization; integrated barcode scanner; compliance technology; QC, PID, and OID; lockout and tracking; data-management storage and printing; optimal connectivity options; 45 µL blood volume; Ethernet and RS232 ports; standardizes anticoagulation therapy monitoring across the continuum of care while enhancing compliance and patient safety and maximizing efficiencies
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Part 3 of 5	Instrumentation Laboratory Linh Phanroy Lphanroy@ilww.com San Diego, CA 800-955-9525 www.instrumentationlaboratory.com	Medtronic Cardiac Surgery Minneapolis, MN 800-328-3320 www.medtronic.com	Medtronic Cardiac Surgery Minneapolis, MN 800-328-3320 www.medtronic.com
POINT OF CARE, SELF-MONITORING			
Instrument name	Hemochron Response	ACT Plus	HMS Plus
First year sold	2000	2003	1999
No. of units sold in U.S./Outside U.S.	1,000/2,000	—	—
No. of units sold in 2017	400	—	—
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC	POC	POC
Specimen type	venipuncture (whole blood, anticoagulated whole blood)	venipuncture (whole blood)	venipuncture (whole blood)
Model type	portable	benchtop	benchtop
Dimensions in inches (H × W × D)/Weight	8.7 × 10.5 × 7.5/6.4 lb	11 × 8 × 13/11.5 lb	15.7 × 15 × 13/34 lb
Specimen volume needs	0.4–2 mL (test dependent)	accurate volume required (fill line on cuvette and optional easy fill accessory)	accurate volume required (automated dispensing)
Clotting-based tests for which device has FDA-cleared applications	ACT (HRFTCA510, HRFTK-ACT, P214), HRT, PRT, PDAO	ACT (high range, low range, recalcified, high-range heparinase)	ACT, heparin dose response, heparin protamine titration
Tests using other methodologies for which device has FDA-cleared applications	—	—	—
FDA-cleared tests but not yet clinically released	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted for clearance	—	—	—
Method of endpoint detection	mechanical clot detection	mechanical clot detection	mechanical clot detection
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	yes (simulated whole blood)	no	no
• Lyophilized	yes (simulated whole blood)	yes	yes
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	yes	optional (user defined)	optional (user defined)
• Other	operator lockout	optional operator lockout	optional operator lockout
Time (in minutes) to perform control plus specimen test			
• PT	—	—	—
• PT and PTT	—	—	—
• ACT	~8	up to 12 (depending on patient sample)	up to 12 (depending on patient sample)
Data-management capability	onboard	yes	yes
• Includes QC	yes	yes	yes
System can automatically transfer data to information system			
• Patient data	yes	yes	yes
• QC data	yes	yes	yes
Interface supplied by instrument vendor	available via connectivity partners	no	no
Commercially available systems for which interfaces are up and running in active user sites	Telcor QML, Alere RALS-Web 3, Aegis POC, Conworks UniPOC	Telcor, Alere Informatics	Telcor, Alere Informatics
LOINC codes transmitted with results	no	—	—
How labs get LOINC codes for reagent kit	email query	available from technical support	available from technical support
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	no
Positive identification system (e.g. barcode) for:			
• Patient specimen	no	yes	yes
• Reagent	yes	yes	yes
Onboard system for automatic error detection	yes, for sample (volume), reagent expiration date	yes	yes
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approximate number of training hours needed for:			
• Medical staff	1–2	1	6
• Patient	—	—	—
Patient self-testing program is available	—	no	no
Instrument list price	inquire	\$4,400	\$29,000
Reagent rental or lease only	purchase and usage agreement available (reagent rental)	purchase and rental available	purchase and rental available
Cost per sample:			
• PT: for reagent rental	—	—	—
if device purchased	—	—	—
• PTT: for reagent rental	—	—	—
if device purchased	—	—	—
• ACT: for reagent rental	volume dependent	—	—
if device purchased	—	customer dependent, per contract	customer dependent, per contract
CLIA '88 complexity rating	moderate	moderate (nonwaived)	moderate (nonwaived)
Distinguishing features (supplied by company)	QC lockout; data-management storage; connectivity options; Rx/Dx heparin/protamine dosing system	data-management software application; duplicate test results; optional barcode scanner; optional easy filling accessory; ACT Plus Education Program CD	automated sample dispensing; constant temperature control; multiple testing capability; heparin dose response; heparin protamine titration; high-range ACT; optional barcode scanner; optional data-management software; HMS Plus Education Program CD
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Part 4 of 5

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Instrument name	CoaguChek Vantus System	CoaguChek XS Pro PT Test System	CoaguChek XS Plus PT Test System
First year sold	2018	2010	2007
No. of units sold in U.S./Outside U.S.	—	—	—
No. of units sold in 2017	—	—	—
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Is instrument POC or self-monitoring analyzer?	self-monitoring	POC	POC
Specimen type	fresh whole blood (fingerstick capillary)	fresh whole blood (venous or fingerstick capillary)	fresh whole blood (venous or fingerstick capillary)
Model type	handheld/portable	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/Weight	5.7 x 2.95 x 1.1/135 g	9.09 x 3.89 x 1.65/12.35 oz	7.28 x 3.89 x 1.65/12.35 oz
Specimen volume needs	8 µL	8 µL	8 µL
Clotting-based tests for which device has FDA-cleared applications	INR (0.8–6.0)	INR (0.8–8.0), PT seconds, % quick	INR (0.8–8.0), PT seconds, % quick
Tests using other methodologies for which device has FDA-cleared applications	—	—	—
FDA-cleared tests but not yet clinically released	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted for clearance	—	—	—
Method of endpoint detection	amperometric detection	amperometric detection	amperometric detection
Quality control methods			
• Electronic	no (not required, onboard QC)	no (not required, onboard QC)	no (not required, onboard QC)
• Liquid	no	yes (available as an option but not required due to onboard controls)	yes (available as an option but not required due to onboard controls)
• Lyophilized	no	no	no
• Integrated QC with each analysis	yes	yes	yes
• Automatic lockout for QC failure	no	yes	yes
• Other	—	optional operator lockout	optional operator lockout
Time (in minutes) to perform control plus specimen test			
• PT	<1	<1	<1
• PT and PTT	—	—	—
• ACT	—	—	—
Data-management capability	no	yes	yes
• Includes QC	no	yes	yes
System can automatically transfer data to information system			
• Patient data	no	yes	yes
• QC data	no	yes	yes
Interface supplied by instrument vendor	yes	POCT1-A	POCT1-A
Commercially available systems for which interfaces are up and running in active user sites	—	Roche cobas IT 1000, Alere RALS-Plus, Telcor QML	Roche cobas IT 1000, Alere RALS-Plus, Telcor QML
LOINC codes transmitted with results	no	no	no
How labs get LOINC codes for reagent kit	—	—	—
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	no
Positive identification system (e.g. barcode) for:			
• Patient specimen	no	yes	no
• Reagent	no	yes	no
Onboard system for automatic error detection	yes	yes	yes
Training provided with instrument purchase	yes	yes	yes
Approximate number of training hours needed for:			
• Medical staff	—	1.5	1.5
• Patient	trainer dependent	—	—
Patient self-testing program is available	yes	no	no
Instrument list price	—	—	—
Reagent rental or lease only	no	no	no
Cost per sample:			
• PT: for reagent rental	—	—	—
if device purchased	—	—	—
• PTT: for reagent rental	—	—	—
if device purchased	—	—	—
• ACT: for reagent rental	—	—	—
if device purchased	—	—	—
CLIA '88 complexity rating	CLIA waived	moderate	CLIA waived
Distinguishing features (supplied by company)	designed specifically for patient self-testing; transmit test results wirelessly via compatible smartphone or tablet application, program customizable INR target range, set test reminders; performs onboard QC and determines patient results in a single test chamber; neutralizes therapeutic levels of heparin and LMWH; INR corrected for hematocrit within specified range; top or side dosing; results in 1 minute or less	performs onboard quality control and determines patient results in a single test chamber; neutralizes therapeutic levels of heparin and LMWH; INR corrected for hematocrit within specified range; top or side dosing; results in 1 minute or less; icon-driven color screen interface, memory of 2,000 patient and 500 optional liquid QC tests, ability to add comments with each patient and liquid quality control test; integrated barcode scanner able to scan operator and patient IDs	performs onboard quality control and determines patient results in a single test chamber; neutralizes therapeutic levels of heparin and LMWH; INR corrected for hematocrit within specified range; top or side dosing; results in 1 minute or less; icon-driven color screen interface, memory of 2,000 patient and 500 optional liquid QC tests, ability to add comments with each patient and liquid quality control test

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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POINT OF CARE, SELF-MONITORING		
Instrument name	CoaguChek XS PT Test System	Xprecia Stride Coagulation Analyzer
First year sold	2006 (outside U.S.)/2007 (U.S.)	2015 (outside U.S.)
No. of units sold in U.S./Outside U.S.	—	—
No. of units sold in 2017	—	—
• units sold to:	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Australia/Malaysia
Is instrument POC or self-monitoring analyzer?	POC and self-monitoring	POC
Specimen type	fresh whole blood (venous or fingerstick capillary)	fingerstick
Model type	handheld/portable	handheld/portable
Dimensions in inches (H × W × D)/Weight	5.43 × 3.07 × 1.10/4.48 oz	6.7 × 2.8 × 1.6/10.6 oz (with batteries)
Specimen volume needs	8 µL	accurate volume not necessary (drop, 6 µL)
Clotting-based tests for which device has FDA-cleared applications	INR (0.8–8.0), PT seconds, % quick	PT (INR 0.8–4.5)
Tests using other methodologies for which device has FDA-cleared applications	—	—
FDA-cleared tests but not yet clinically released	—	—
Tests submitted for 510(k) clearance	—	—
Tests in development but not yet submitted for clearance	—	—
Method of endpoint detection	amperometric detection	electrochemical technology with amperometric (electric current) detection of thrombin activity
Quality control methods		
• Electronic	no (not required, onboard QC)	yes
• Liquid	no	yes
• Lyophilized	no	—
• Integrated QC with each analysis	yes	—
• Automatic lockout for QC failure	no	yes
• Other	—	—
Time (in minutes) to perform control plus specimen test		
• PT	<1	~1 minute (depending on clotting time)
• PT and PTT	—	—
• ACT	—	—
Data-management capability	no	data-management software CD provided with analyzer for managing patient, QC results, transmitting to EMR/LIS/HIS, managing operators, and software upgrades
• Includes QC	no	yes
System can automatically transfer data to information system		
• Patient data	no	yes
• QC data	no	yes
Interface supplied by instrument vendor	with license	yes
Commercially available systems for which interfaces are up and running in active user sites	yes	—
LOINC codes transmitted with results	no	no
How labs get LOINC codes for reagent kit	—	5902-2 (www.loinc.org)
Lab can control analyzer remotely	no	no
Real-time wireless linkage to LIS or HIS	no	no
Positive identification system (e.g. barcode) for:		
• Patient specimen	no	yes
• Reagent	no	yes (integrated barcode scanner records strip and QC lot numbers with calibrated values; operator and patient IDs may be scanned or entered manually on the touchscreen)
Onboard system for automatic error detection	yes	yes (detects test-strip degradation due to exposure to environmental conditions; electronic, signal, software, and memory integrity checks; performs various checks along the entire testing procedure to ensure process integrity)
Training provided with instrument purchase	yes	—
Approximate number of training hours needed for:		
• Medical staff	1	1
• Patient	trainer dependent	—
Patient self-testing program is available	yes	—
Instrument list price	—	—
Reagent rental or lease only	no	—
Cost per sample:		
• PT: for reagent rental	—	—
if device purchased	—	—
• PTT: for reagent rental	—	—
if device purchased	—	—
• ACT: for reagent rental	—	—
if device purchased	—	—
CLIA '88 complexity rating	CLIA waived	moderately complex
Distinguishing features (supplied by company)	performs onboard quality control and determines patient results in a single test chamber; neutralizes therapeutic levels of heparin and LMWH; INR corrected for hematocrit within specified range; top or side dosing; results in 1 minute or less	usability: touchscreen features include bright-color interface with step-by-step instructions, display shows clear, easy-to-read results, lot calibration is simple using integrated barcode scanner; safety: test-strip eject button, operator lockout feature, data transfer occurs seamlessly and securely via USB connection; accuracy: Xprecia PT/INR test strips and Siemens' central lab analyzers use same Dade Innovin reagent and liquid QC, barcode scanner offers fast, accurate patient and operator ID entry with optional manual entry on touchscreen
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>		

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.

In the market for laboratory software or instrumentation?

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- Chemistry and immunoassay analyzers for mid- and high-volume laboratories
- Chemistry and immunoassay analyzers for point-of-care and low-volume laboratories
- Coagulation analyzers
- Coagulation analyzers—point of care, self-monitoring
- Hematology analyzers
- In vitro blood gas analyzers
- Laboratory automation systems and workcells
- Next-generation sequencing instruments
- Urinalysis instrumentation

SOFTWARE SYSTEMS

- Anatomic pathology computer systems
- Billing/Accounts receivable/RCM systems
- Blood bank information systems
- Laboratory information systems
- Laboratory-provider links software
- Positive patient identification products