

Part 1 of 4	Abbott Diabetes Care Alameda, CA 877-643-2098 www.myfreestyle.com/fspp	Abbott Diabetes Care Alameda, CA 877-643-2098	Arkray Edina, MN 800-818-8877 www.arkrayusa.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold	Freestyle Precision Pro Blood Glucose and β -Ketone Monitoring System/2014	Precision Xceed Pro Blood Glucose and β -Ketone Monitoring System/2007	Assure Platinum/2010
Professional or home use	professional	professional	professional
Total units sold in U.S./Total units sold outside U.S.	—	—	—
No. of contracts for product signed in 2017	—	—	—
Dimensions (H \times W \times D)/Weight	length: 7.85 inches \pm .08; width: 2.93 inches \pm .08; thickness: 1.92 inches \pm .08/10.58 oz \pm .51	7.7 \times 2.96 \times 1.2 inches/9 oz	4.5 \times 2.5 \times 1.2 in/2.8 oz
Analytical method or technology or enzyme system used	glucose-specific GDH-NAD enzyme and low applied voltage to minimize interference; β -hydroxybutyrate, the predominant blood ketone associated with DKA	glucose-specific GDH-NAD enzyme and low applied voltage to minimize interference; β -hydroxybutyrate, the predominant blood ketone associated with DKA	glucose oxidase
No. of disposable reagent system units per basic package	glucose: 100 individually wrapped strips; ketone: 50 individually wrapped strips	glucose: 100 individually wrapped strips; ketone: 50 individually wrapped strips	50 or 100
Disposable units shelf life/Reagent unit storage requirements	18 months/39°–86°F (4°–30°C)	18 months/39°–86°F (4°–30°C)	18 months/39°–86°F
Digital readout character size/Keypad input capability	character size varies/alphanumeric keypad	character size varies/alphanumeric keypad	—
How results are displayed	plasma equivalent glucose values	plasma equivalent glucose values	true values
Specimen types/Sampling techniques	glucose and ketone: fresh capillary, venous, arterial, or neonatal whole blood/top-fill or end-fill sample application	glucose: fresh capillary, venous, arterial, or neonatal whole blood; ketone: fresh capillary and venous whole blood/top-fill or end-fill sample application	whole blood/drop
Minimum specimen volume required	glucose: 0.6 μ L; ketone: 1.5 μ L	glucose: 0.6 μ L; ketone: 1.5 μ L	0.5 μ L
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes	no/no
Time from sample introduction to result availability	glucose: 5 seconds; ketone: 10 seconds	glucose: 20 seconds; ketone: 10 seconds	7 seconds
Batteries used/No. used/Average life of one set of batteries	AA alkaline, lithium, nickel cadmium, or NiMH rechargeable/depends on type/depends on use	AA alkaline or NiMH rechargeable/depends on type/depends on use	AAA/2,5,000 tests with 4 tests per day
Average expected life of device/Mean time between failures	—	—	5 years/—
Device warranty/Service options/Loaners provided	1 year or contract term/replacement/no	1 year or contract term/replacement/no	5 years/—/yes
User list or user group	—	—	no
Toll-free No. for customer questions/Hours of operation	877-529-7185/24 hours, 7 days, all year	877-529-7185/24 hours, 7 days, all year	800-818-8877/24 hours, 7 days
Training and certification program/No. of training days provided	yes/based on implementation plan	yes/based on implementation plan	yes/one on site
Average time for lab to complete maintenance	no maintenance required	no maintenance required	—
Internal QC recommended or required	as defined by facility or institutional policy	as defined by facility or institutional policy	control solution testing
Between instrument CV (based on PT) at the following glucose levels:			
• <50 mg/dL	—	—	—
• 100–200 mg/dL	—	—	—
• >400 mg/dL	—	—	—
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	—	—
Accuracy/Compared with what reference method or device	capillary blood glucose results: 100% within \pm 15 mg/dL or \pm 15%; 95.1% within \pm 10 mg/dL or \pm 10%/YSI glucose analyzer	capillary blood glucose results: 97% within \pm 15 mg/dL or \pm 20%/YSI glucose analyzer	slope=1.0, y-inter.= -2.33, r=0.99/YSI model 2300 glucose analyzer
Precision/Compared with what reference method or device	repeatability: pooled whole blood SD 2.8 mg/dL at concentrations <75 mg/dL and <3.6% CV for concentrations \geq 75 mg/dL; intermediate precision: pooled whole blood SD 2.8 mg/dL at concentrations <75 mg/dL and <5.0% for concentrations \geq 75 mg/dL	repeatability: CV ranges from 3.0% to 4.9% across AMR	results for glucose concentration \geq 75 mg/dL: 100% within \pm 20%; 96% within \pm 15%; 79% within \pm 10%; 53% within \pm 5%; results for glucose concentration <75 mg/dL: 100% within \pm 15 mg/dL; 100% within \pm 10 mg/dL; 88% within \pm 5 mg/dL/YSI model 2300 glucose analyzer
Linear range	glucose: 20–500 mg/dL; ketone: 0.0–8.0 mmol/L	glucose: 20–500 mg/dL; ketone: 0.0–8.0 mmol/L	20–600 mg/dL
Suggested dynamic or measurement range	glucose: 20–500 mg/dL; ketone: 0.0–8.0 mmol/L	glucose: 20–500 mg/dL; ketone: 0.0–8.0 mmol/L	20–600 mg/dL
Contraindications	per labeling	per labeling	per labeling
Known interferences/High-altitude interference	per labeling/no (tested up to 7,200 ft)	per labeling/no (tested up to 7,200 ft)	yes/none, up to 10,000 feet
Restrictions based on hematocrit	hematocrit range: 15–65%	hematocrit range: 20–70%	yes, 30–55%
Electronic and optical function checks	battery, barcode scanner, database, and temperature checks performed during power-up	battery, barcode scanner, database, and temperature checks performed during power-up	automatic
Sample quantity checks	test strip contains fill-trigger electrode designed to start the test when sufficient sample is detected	test strip contains fill-trigger electrode designed to start the test when sufficient sample is detected	fill-trigger electrode on each test strip designed to start the test when sufficient sample is detected
When auto lock or shutdown occurs	configurable lockout for operator certification, strip lot, upload and QC requirements	configurable lockout for operator certification, strip lot, upload and QC requirements	control solution reminder and QC requirements
User defines QC lockout intervals/QC lockout can be circumvented	yes/no	yes/no	yes (on or off)/yes, and results will be flagged
Information for which device supports barcode scanning	operator ID, patient ID, strip lot, QC, comment code, and free text field data	operator ID, patient ID, strip lot, QC, comment code, and free text field data	—
Method of analyst ID/ID required	scan or manual entry/required	scan or manual entry/required	—
Internal memory size/Maximum No. of patient results stored	patient test results: 2,500; control test results: 1,000; patient IDs: 6,000; operator IDs: 6,000; test strip lots: 36 (18 glucose, 18 ketone)	patient test results: 2,500; control test results: 1,000; patient IDs: 6,000; operator IDs: 6,000; test strip lots: 36 (18 glucose, 18 ketone)	500/500 tests
Meter connections for information transfer	data-management system, which in turn connects to LIS/HIS	data-management system, which in turn connects to LIS/HIS	—
How meters are connected to external system to upload results	wireless data transfer post test or via docking station connected to ethernet	wireless data transfer via docking station connected to ethernet or wireless workstation	—
Information contained in transmission to external system	device unique identifier, operator ID, patient ID, reagent and QC lot numbers, test results, comment codes, and free text entry	device unique identifier, operator ID, patient ID, reagent and QC lot numbers, test results, comment codes, and free text entry	—
Hardware/software for data-management system	compatible with data-management systems from Abbott, Alere, Siemens, and Telcor	compatible with data-management systems from Abbott, Alere, Siemens, and Telcor	—
No. of different management reports system can produce	depends on data-management system	depends on data-management system	—
Contents downloaded from DMS to meter	operator list, patient list, strip lot list, adjusted QC ranges, and meter configuration settings	operator list, patient list, strip lot list, adjusted QC ranges, and meter configuration settings	—
LISs/HISs to which system is connected (live installs) using:			
• Screen animation/Screen scraping	—	—	—
• Standard HL7 interface	—	—	—
• Proprietary protocol interface	—	—	—
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	via Siemens, Telcor, or Alere	via Siemens, Telcor, or Alere	—
LOINC can be used to identify tests when communicating with LIS	yes	yes	—
Distinguishing features (supplied by company)	individually foil-wrapped test strips support a no-touch procedure and vial-free solution, which assists in complying with CDC and CLSI recommendations; 1D/2D barcode reader; real-time dual band wireless data transmission; TrueID technology with active patient ID confirmation, which assists in complying with the Joint Commission's NPSG.01.01.01; replaceable strip port module	individually foil-wrapped test strips support a no-touch procedure and vial-free solution, which assists in complying with CDC and CLSI recommendations; TrueID technology with active patient ID confirmation, which assists in complying with the Joint Commission's NPSG.01.01.01; replaceable strip port module	hypoglycemic alert: audio alert is designed to improve resident safety; qcProGuard: control solution test notifications provides additional quality control; ProGrip: rubberized case design for secure handling; other features: auto coding, LCD backlit display, and test strip ejector
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 2 of 4	Arkray Edina, MN 800-818-8877 www.arkrayusa.com	HemoCue America web@hemocue.com Brea, CA 800-881-1611 www.hemocue.us	HemoCue America web@hemocue.com Brea, CA 800-881-1611 www.hemocue.us
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold	Assure Prism multi/2015	Glucose 201 DM Analyzer/2005	Glucose 201 Analyzer/2002
Professional or home use	professional	professional	professional
Total units sold in U.S./Total units sold outside U.S.	—	—	—
No. of contracts for product signed in 2017	—	—	—
Dimensions (H × W × D)/Weight	3.66 × 2.2 × 0.83 in/2.1 oz	6.7 × 3.7 × 2 in/0.77 lbs	6.3 × 3.4 × 1.7 in/0.77 lbs
Analytical method or technology or enzyme system used	glucose oxidase	absorbance photometry, glucose dehydrogenase	absorbance photometry, glucose dehydrogenase
No. of disposable reagent system units per basic package	50 or 100	25 in vial, 4 vials per package; 25 in box, 2 boxes per package	25 in vial, 4 vials per package; 25 in box, 2 boxes per package
Disposable units shelf life/Reagent unit storage requirements	expiration date printed on each bottle/34°–86°F	9 months from manufacture date/refrigeration	9 months from manufacture date/refrigeration
Digital readout character size/Keypad input capability	—	varies from 8 to 28 points/menu selection, numeric, alphabetic	0.5 in/none
How results are displayed	true values	plasma equivalent values	plasma equivalent values
Specimen types/Sampling techniques	whole blood/drop	whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force	whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force
Minimum specimen volume required	0.5 µL	5 µL	5 µL
Suitable for samples from well neonates/Sick neonates	no/no	yes/yes	yes/yes
Time from sample introduction to result availability	5 seconds	40–240 seconds	40–240 seconds
Batteries used/No. used/Average life of one set of batteries	3v lithium (disposable, type CR2032)/2/1,000 tests	rechargeable lithium ion supplied by HemoCue/—/several years	AA/4/150 hours
Average expected life of device/Mean time between failures	3 years/—	7 years/>5 years	7 years/>5 years
Device warranty/Service options/Loaners provided	3 years/—/yes	3 years at no extra cost/replacement of defective analyzer/yes	3 years at no extra cost/—/yes
User list or user group	no	no	no
Toll-free No. for customer questions/Hours of operation	800-818-8877/24 hours, 7 days	800-323-1674/6 AM–5 PM PST	800-323-1674/6 AM–5 PM PST
Training and certification program/No. of training days provided	yes/one on site	yes/as needed	yes/as needed
Average time for lab to complete maintenance	—	daily: ≤5 minutes	daily: ≤5 minutes
Internal QC recommended or required	control solution testing recommended for each new meter and bottle of test strips	as specified by accreditation	as specified by accreditation
Between instrument CV (based on PT) at the following glucose levels:			
• <50 mg/dL	—	—	—
• 100–200 mg/dL	—	3.8	3.8
• >400 mg/dL	—	≥272 mg/dL=2.9	≥272 mg/dL=2.9
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	Equalis (Swedish PT program), 2003/2003–03; 2003–07/272 mg/dL; 120 mg/dL	Equalis (Swedish PT program), 2003/2003–03; 2003–07/272 mg/dL; 120 mg/dL
Accuracy/Compared with what reference method or device	slope=1.0, y-inter.= -7.39 mg/dL, r=0.99/YSI model 2300 glucose analyzer	±10% or ±6% mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS	±10% or ±6 mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS
Precision/Compared with what reference method or device	results for glucose concentration ≥75 mg/dL: 100% within ±20%; 98% within ±15%; 80% within ±10%; 42% within ±5%; results for glucose concentration <75 mg/dL: 100% within ±15%; 100% within ±10%; 100% within ±5%/YSI model 2300 glucose analyzer	within run CV 1.9% (108 mg/dL)/—	within run CV 1.9% (108 mg/dL)/—
Linear range	20–600 mg/dL	0–444 mg/dL	0–444 mg/dL
Suggested dynamic or measurement range	20–600 mg/dL	0–444 mg/dL	0–444 mg/dL
Contraindications	per labeling	no	no
Known interferences/High-altitude interference	yes, see labeling/none, up to 10,000 feet	grossly lipemic samples, methemoglobin, glucosamine/no	grossly lipemic samples, methemoglobin, glucosamine/no
Restrictions based on hematocrit	yes, 20–60%	no	no
Electronic and optical function checks	automatic	internal electronic self-test automatically checks the instrument's optronic unit is working properly	internal electronic self-test automatically checks the instrument's optronic unit is working properly
Sample quantity checks	fill-trigger electrode on each test strip designed to start the test when sufficient sample is detected	visual inspection	visual inspection
When auto lock or shutdown occurs	user flags control solution tests when conducted	user ID failure if configured to require operator ID, QC failure if configured to require quality control, number of device errors	every 24 hours
User defines QC lockout intervals/QC lockout can be circumvented	no/no	yes/no (stat testing may be allowed; 1–100 tests after QC interval)	no/no
Information for which device supports barcode scanning	no barcode scanner	operator ID, patient ID, reagent lot Nos., comments, log entries, lab ID	—
Method of analyst ID/ID required	—	alphanumeric manual entry or barcode scan entry/optional	—
Internal memory size/Maximum No. of patient results stored	500/500 tests	4,000 patient tests, 500 QC tests, 500 analyzer log entries/4,000	—
Meter connections for information transfer	—	analyzer connects to 201 DM docking stations data-management system, which can further transmit data	—
How meters are connected to external system to upload results	—	direct USB/hospital network	—
Information contained in transmission to external system	—	device-unique identifiers, operator and patient IDs, results, QC identifiers, POCT-1A standard compliant, test dates and times, lab ID, flags	—
Hardware/software for data-management system	—	PC, server/HemoCue 201 DM–DMS software	Basic Connect/Glucose 201 DMU docking station
No. of different management reports system can produce	—	15 different templates, custom reports based on templates, multiple export formats	—
Contents downloaded from DMS to meter	—	cuvette lot No., valid control values, valid operator IDs, comments, analyzer log entries, analyzer configuration	—
LISs/HISs to which system is connected (live installs) using:			
• Screen animation/Screen scraping	—	—	—
• Standard HL7 interface	—	Cerner, Orchard, Sunquest, EHS, SoftLab, M-Magic, Starlab, M-CS, HorizonLab	—
• Proprietary protocol interface	—	—	—
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	—	yes (MAS-RALS, LDS AegisPOC, Telcor, Sybase, RALS Web3, Radiometer Radiance)	no
LOINC can be used to identify tests when communicating with LIS	—	—	yes
Distinguishing features (supplied by company)	optimized readout display: large, thick numbers are intended to improve readability; compact design: small, lightweight design provides better portability; other features: auto coding, LCD backlit display, and test strip ejector	POCT-1A compliant; indicated for diagnosis of diabetes mellitus; not hematocrit dependent; CLIA waived; lab verification of patient home meter; no interference from maltose or galactose; no need to recalibrate	CLIA waived; indicated for diagnosis of diabetes mellitus; not hematocrit dependent; lab verification of patient home meter; no interference from maltose or galactose; no need to recalibrate
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

SAVE THE DATE

Saturday, Sept. 15, 2018
7 a.m.–6 p.m.

Sunday, Sept. 16, 2018
7 a.m.–Noon

Presented by



Houston Methodist Department of Pathology and Genomic Medicine

PROGRAM OVERVIEW

Since the last Cancer Biomarkers Conference, new tests have emerged for predictive biomarkers used to select cancer patients for new molecular-targeted therapies. New immune therapies for their cancer treatment have also emerged. New technologies, such as liquid biopsy, have advanced. Revised guidelines, as well as new guidelines, have also been published.

Pathologists and oncologists need to know the answers to a host of questions in this rapidly developing field of biomarkers in order to offer the best patient care.

These questions include:

- Which cancer patients should have biomarker testing?
- Which biomarker tests should be done for a given patient?
- What tissue samples are appropriate for a given biomarker test?
- How should the biomarker tests be performed, and how should they be interpreted, reported, and used for patient care?

Visit our website for more information. See our list of topics and speakers at right.

Houston Methodist Research Institute
6670 Bertner Ave.
John F. Bookout Auditorium
2nd Floor
Houston, TX 77030



events.houstonmethodist.org/cancerbiomarkers

Part 3 of 4	Nova Biomedical Nova Sales info@novabio.com Waltham, MA 781-894-0800 or 800-458-5813 www.novabiomedical.com	Nova Biomedical Nova Sales info@novabio.com Waltham, MA 781-894-0800 or 800-458-5813 www.novabiomedical.com
See captodayonline.com/productguides for an interactive version of guide		
Name of instrument/First year sold	StatStrip Xpress2 Glucose Hospital Meter System/2016	StatStrip Glucose Hospital Monitoring System/2006
Professional or home use	professional	professional
Total units sold in U.S./Total units sold outside U.S.	—	—
No. of contracts for product signed in 2017	—	—
Dimensions (H x W x D)/Weight	3.9 x 2.4 x 0.9 in/2.77 oz (78.5 g)	5.8 x 3.1 x 1.18 in/0.49 lb (220 g)
Analytical method or technology or enzyme system used	electrochemical	electrochemical
No. of disposable reagent system units per basic package	50 test strips per vial	50 test strips per vial
Disposable units shelf life/Reagent unit storage requirements	24 months from date of manufacture/ room temperature	24 months from date of manufacture/ room temperature
Digital readout character size/Keypad input capability	variable, defined by the particular field or menu/menu selection	variable, defined by the particular field or menu/ menu selection, numeric, alphabetic
How results are displayed	plasma equivalent values	plasma equivalent values
Specimen types/Sampling techniques	whole blood/drop, capillary transfer	whole blood/drop
Minimum specimen volume required	1.2 µL	1.2 µL
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Time from sample introduction to result availability	6 seconds	6 seconds
Batteries used/No. used/Average life of one set of batteries	AAA/2/minimum 600 tests	3.7v Li-polymer (rechargeable, replaceable)/1/ 24–36 months
Average expected life of device/Mean time between failures	5+ years/—	5+ years/—
Device warranty/Service options/Loaners provided	2 years (optional 5-year extended warranty)/meter replacement/yes	2 years (optional 5-year extended warranty)/meter replacement/yes
User list or user group	no	no
Toll-free No. for customer questions/Hours of operation	800-458-5813/24 hours, 7 days, all year	800-458-5813/24 hours, 7 days, all year
Training and certification program/No. of training days provided	yes/defined during implementation planning	yes/defined during implementation planning
Average time for lab to complete maintenance	no user maintenance required	no user maintenance required
Internal QC recommended or required	CLIA requirements, two levels per day or per hospital policy	CLIA requirements, two levels per day or per hospital policy
Between instrument CV (based on PT) at the following glucose levels:		
• <50 mg/dL	—	—
• 100–200 mg/dL	—	—
• >400 mg/dL	—	—
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	—
Accuracy/Compared with what reference method or device	>97% versus IDMS-traceable laboratory reference method/tested to CLSI POCT 12-A3 criteria (r2=0.994)	>97% versus IDMS-traceable laboratory reference method/tested to CLSI POCT 12-A3 criteria (r2=0.994)
Precision/Compared with what reference method or device	within run=1.9–3.6% (whole blood) and day to day=3.4–4.7% (linearity standards)/—	within run=1.9–3.6% (whole blood) and day to day=3.4–4.7% (linearity standards)/—
Linear range	10–600 mg/dL (0.5–33.3 mmol/L)	10–600 mg/dL (0.5–33.3 mmol/L)
Suggested dynamic or measurement range	10–600 mg/dL (0.5–33.3 mmol/L)	10–600 mg/dL (0.5–33.3 mmol/L)
Contraindications	no	no
Known interferences/High-altitude interference	none/none, up to 15,000 feet	none/none, up to 15,000 feet
Restrictions based on hematocrit	no	no
Electronic and optical function checks	electronic checks for out-of-range glucose results, dosing, out-of-range Hct results	electronic checks for out-of-range glucose results, dosing, out-of-range Hct results
Sample quantity checks	RapidFill sampling electronically checks for correct strip dosing	RapidFill sampling electronically checks for correct strip dosing
When auto lock or shutdown occurs	—	user ID failure, QC failure, required docking for data transfer (if configured)
User defines QC lockout intervals/QC lockout can be circumvented	no/—	yes/no
Information for which device supports barcode scanning	no barcode scanner	operator ID, patient ID, reagent lot No., QC lots
Method of analyst ID/ID required	none/—	barcode scan or virtual keypad input/required
Internal memory size/Maximum No. of patient results stored	400 tests total (FIFO)/400 tests total (FIFO) patient and QC tests	1,000 patient samples, 200 QC samples, 4,000 operators/1,000 patient samples
Meter connections for information transfer	—	data-management system, which in turn connects to LIS/HIS
How meters are connected to external system to upload results	—	hospital network, real-time wireless (RF Nova)
Information contained in transmission to external system	—	device unique identifier, operator ID, patient ID, result, QC identifier
Hardware/software for data-management system	none	connects to Telcor QML, RALS, RALS Plus, RALS Freedom, Orchard Trellis, Conworx POCcellerator
No. of different management reports system can produce	none	provided by middleware
Contents downloaded from DMS to meter	—	strip lot numbers, valid control values, valid operator IDs, patient demographics (with ADT interface), configuration files, physician ID, diagnostic codes, physician notes
LISs/HISs to which system is connected (live installs) using:		
• Screen animation/Screen scraping	—	—
• Standard HL7 interface	—	—
• Proprietary protocol interface	—	—
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	—	yes, Telcor QML, RALS Freedom, RALS Plus
LOINC can be used to identify tests when communicating with LIS	—	yes
Distinguishing features (supplied by company)	FDA cleared for use with critically ill patients; measures and eliminates interferences from hematocrit, oxygen, acetaminophen, ascorbic acid, uric acid, and other electrochemical substances; CLIA waived for use with all patients, in all departments	FDA cleared for use with critically ill patients; measures and eliminates interferences from hematocrit, oxygen, acetaminophen, ascorbic acid, uric acid, and other electrochemical substances; no interference from maltose, galactose, or xylose; unlimited manual test entry; CLIA waived for use with all patients, in all departments

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

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

Part 4 of 4	Roche Diagnostics Accu-Chek Customer Care Service Center Indianapolis, IN 800-440-3638 www.thatsthepointofcare.com	Roche Diagnostics Accu-Chek Customer Care Service Center Indianapolis, IN 800-440-3638 www.thatsthepointofcare.com
See captodayonline.com/productguides for an interactive version of guide		
Name of instrument/First year sold	Accu-Chek Performa System/2013	Accu-Chek Inform II System/2012
Professional or home use	professional	professional
Total units sold in U.S./Total units sold outside U.S.	—	—
No. of contracts for product signed in 2017	—	—
Dimensions (H × W × D)/Weight	22 × 52 × 93 mm/62 g	1.85 × 3.62 × 7.48 in/12.35 oz (350 g)
Analytical method or technology or enzyme system used	electrochemical (AC/DC), mutant variant quinoprotein glucose dehydrogenase	electrochemical (AC/DC), mutant variant quinoprotein glucose dehydrogenase
No. of disposable reagent system units per basic package	50 strips per vial	50 strips per vial
Disposable units shelf life/Reagent unit storage requirements	18 months/39°–86°F (4°–30°C)	18 months/39°–86°F (4°–30°C)
Digital readout character size/Keypad input capability	—/numeric, alphabetic	test results are 48-point font/menu selection, numeric, alphabetic
How results are displayed	plasma equivalent values	plasma equivalent values
Specimen types/Sampling techniques	fresh capillary, venous, arterial, whole blood/drop	fresh capillary, venous, arterial, neonate whole blood/drop
Minimum specimen volume required	0.6 µL	0.6 µL
Suitable for samples from well neonates/Sick neonates	no/no	yes/yes
Time from sample introduction to result availability	5 seconds	5 seconds
Batteries used/No. used/Average life of one set of batteries	3v lithium (type CR2032)/1/2,000 tests	3.7v Li-polymer (rechargeable)/1/5 years
Average expected life of device/Mean time between failures	—	5 years/—
Device warranty/Service options/Loaners provided	—	1 year or for term of contract/replacement/no
User list or user group	no	yes
Toll-free No. for customer questions/Hours of operation	800-440-3638/24 hours, 7 days, all year	800-440-3638/24 hours, 7 days, all year
Training and certification program/No. of training days provided	yes/—	yes/defined during implementation planning
Average time for lab to complete maintenance	—	none beyond cleaning and disinfection
Internal QC recommended or required	follow facility policy for control testing intervals	follow facility policy for control testing intervals
Between instrument CV (based on PT) at the following glucose levels:		
• <50 mg/dL	—	—
• 100–200 mg/dL	—	—
• >400 mg/dL	—	—
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	—
Accuracy/Compared with what reference method or device	—/hexokinase method traceable to NIST	capillary: r=0.993, venous: r=0.995, arterial: r=0.990, neonatal: r=0.976/hexokinase method traceable to NIST
Precision/Compared with what reference method or device	—/hexokinase method traceable to NIST	controls: low SD=1.2 mg/dL, mid SD=2.2, high SD=4.6, low CV=2.6%, mid CV=1.9%, high CV=1.5%; blood: 1 SD=1.2 mg/dL, 3 SD=4.2 mg/dL, 5 SD=9.5 mg/dL, 1 CV=3.3%, 3 CV=3.4%, 5 CV=3.0%/hexokinase method traceable to NIST
Linear range	20–600 mg/dL	10–600 mg/dL
Suggested dynamic or measurement range	20–600 mg/dL	10–600 mg/dL
Contraindications	yes, per labeling	yes, per labeling
Known interferences/High-altitude interference	per labeling/none, up to 10,000 feet	per labeling/none, up to 10,000 feet
Restrictions based on hematocrit	yes, 10–65%	yes, 10–65%
Electronic and optical function checks	150 integrity checks, including variation in hematocrit, temperature, and humidity	150 integrity checks, including variation in hematocrit, temperature, and humidity
Sample quantity checks	sampling checked electronically for complete sample dosing	sampling checked electronically for complete sample dosing
When auto lock or shutdown occurs	—	user ID failure, QC failure, download interval lockout
User defines QC lockout intervals/QC lockout can be circumvented	no/no	yes/no
Information for which device supports barcode scanning	—	operator ID, patient ID, reagent lot, QC lot
Method of analyst ID/ID required	—	alphanumeric or barcode scan/required
Internal memory size/Maximum No. of patient results stored	20 controls, 300 glucose results/300	1,000 results, 5,000 operator IDs, 4,000 patient IDs, 300 predefined comments/—
Meter connections for information transfer	—	data-management system, which connects to LIS/HIS direct serial, hospital network, real-time wireless (RF)
How meters are connected to external system to upload results	—	device unique identifier, operator ID, patient ID, result, QC identifier, strip lot numbers, proficiency and linearity samples, comments
Information contained in transmission to external system	—	
Hardware/software for data-management system	—	Cobas IT 1000 application for connection to third-party DMS, including Telcor QML, Alere RALS
No. of different management reports system can produce	—	varies by data manager (customer defined)
Contents downloaded from DMS to meter	—	strip lot numbers, valid control values, valid operator IDs, patient IDs, meter configuration, linearity lot numbers and values, comments
LISs/HISs to which system is connected (live installs) using:		
• Screen animation/Screen scraping	—	—
• Standard HL7 interface	—	yes
• Proprietary protocol interface	—	—
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	—	yes, Telcor QML or Alere RALS
LOINC can be used to identify tests when communicating with LIS	—	yes
Distinguishing features (supplied by company)	handheld meter cleared for multipatient use; easy-to-use technology provides automatic system, strip, and integrity checks; accurate results in 5 seconds with only 0.6 µL sample size; small, sleek design with a large, easy-to-read display	smooth, durable sealed housing designed for hospital use that withstands cleaning, disinfecting, and penetration of liquid; 150 individual quality checks are conducted prior to measuring the glucose concentration, including test strip, meter, data, and dosing; patented dual-current AC/DC meter technology checks a wide range of variables including compensation for hematocrit; meter-level wireless technology for real-time data transfer without need of docking the meter; code key ensures lot-specific calibration to minimize bias for consistent, accurate results; extensive studies to prove system performance in the presence of potential interferences following CLSI guidelines; award-winning, live 24/7/365 customer care service and support

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

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

CANCER BIOMARKERS CONFERENCE III

CONFERENCE DIRECTORS

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TOPICS AND SPEAKERS

KEYNOTE: The Oncologist's Approach to TKI Therapy, Bruce Johnson, MD, ASCO President

Current Approach to Using Cytology Specimens for Biomarker Testing, Sinchita Roy-Chowdhuri, MD, PhD

Review on Application of NGS to Biomarker Testing, Neal Lindeman, MD

Regulation and Billing for Molecular Testing, Dara Aisner, MD

Biomarker Testing in Community Practice, Richard Brown, MD

Update on Endometrial Cancer Biomarker Testing, Teri Longacre, MD

Update on Breast Cancer Biomarker Testing, Deborah Dillon, MD, PhD

KEYNOTE: Role of Preanalytics in Biomarker Development and Patient Care, Carolyn Compton, MD, PhD

Update on Upper Gastrointestinal Cancer Biomarker Testing, Kay Washington, MD, PhD

Update on Colon Cancer Biomarker Testing, Rhonda Yantiss, MD

Update on HPV Head and Neck Squamous Cell Carcinoma Molecular Testing, Mary Schwartz, MD

Update on Melanoma Biomarker Testing, Patricia Chevez-Barrios, MD

Update on Leukemia Biomarkers, Daniel Arber, MD

Update on Lymphoma Biomarkers, Genevieve (Eve) Crane, MD, PhD

The Revised Lung Cancer Biomarker Guidelines, Neal Lindeman, MD

Liquid Biopsy, John Iafrate, MD, PhD

Overview of PD-L1, Alain Borczuk, MD

Update on PD-L1 Testing for Lung Cancer, Mari Mino-Kenudson, MD

Update on PD-L1 Testing for Urologic Cancers, Donna Hansel, MD, PhD

Update on PD-L1 Testing for Melanoma, Janis Taube, MD

Update on Immune Therapy Biomarkers in Breast Cancer, Ashley Cimino Mathews, MD

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