

piccolo *xpress*
chemistry analyzer

Introducing the piccolo^{xp}pressTM chemistry analyzer

Fast, easy, accurate on-site chemistry testing



Exceptionally Fast

From sample to complete panel results in approximately 12 minutes

Simple as 1-2-3

1. Add sample
2. Insert disc
3. Read results

Exceptionally Easy

Fully automated system requires no special operating skills

- 0.1cc whole blood, serum or plasma
- Delivers multi-analyte panels including CLIA-waived lipids, liver enzymes and glucose monitoring
- Self calibrates with every test run
- Built-in iQCTM eliminates daily liquid control testing
- Walk-away operation
- Full-color touch screen with intuitive user interface
- Results are provided in a "hard copy" self-adhesive report or can be quickly transferred to a data management system, enabling physicians to rapidly obtain critical diagnostic information at the point-of-care



Step 1: Add sample



Step 2: Insert disc



Step 3: Read results

Exceptionally Accurate

Advanced technology ensures sound results

- Centrifugal and capillary forces mix and dilute the reagents and sample in a self-contained, disposable reagent disc — lessening opportunities for procedural errors
- Accuracy and precision comparable to larger, more expensive laboratory analyzers
- Built-in intelligent quality control (iQCTM) meets CLIA and NCCLS guidelines
- iQCTM system performs continuous quality control checks on every run
- Every self-contained reagent disc is barcoded for automatic self-calibration



Piccolo xpress™
Product Specification



Reagent Disc

Dimensions	Height 32.4 cm (12.75 in) Width 15.2 cm (6 in) Depth 20.3 cm (8 in)
Weight	Analyzer 5.1 kg (11.2 lbs) Power Adapter 0.7 kg (1.6 lbs)
Power Requirements	100-240 volts AC; 50-60 Hz; or 15 volts DC, 5.0A
Sample Size	0.1cc (100 µl)
Sample Type	Lithium heparin, whole blood, serum or plasma
Test Time	Approximately 12 minutes
Quality Control Features	Built-in intelligent Quality Control (iQC™) system
Communication	Bi-directional input/output
Consumables	8-cm diameter, single-use, self-contained plastic chemistry reagent discs. Each disc contains all reagents needed to perform a panel of tests on a single sample
Data Input Display	10-digit numeric –VGA color touchscreen
Printer	Built in thermal printer with adhesive backed paper External Printer/LIS/EMR capable
Memory Capacity	Up to 5000 patient and quality control results
Mode of Operation	Continuous
Protection Against Ingress of Fluids	Ordinary equipment (IPXO)
Analyzer Software	Comprised of two matched programs; one processes the information and controls the measurement engine itself, the other reports analyte concentrations Stores data related to each run (time, date, user ID, patient results, control data) Results can be uploaded to a computer using USB Ports
Analyzer Hardware	Xenon arc stroboscopic lamp and a beam-splitter/detector read nine wavelengths 16-bit analog-to-digital converter used in signal processing Two microprocessors control analyzer functions Heater maintains disc at 37 ± 1° C during reaction portion of analysis
Ambient Operating Temperature Range	15-32° C (59-90° F)
Reaction Temperature	37° C (98.6° F)
Operating Humidity	0-80%, noncondensing
Thermal Protection Rating	70° C (158°F)

piccolo^{xpress}[™]

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PANEL INFORMATION

On the spot lab results (without the lab)

With the Piccolo xpress[™] you can perform the most commonly requested chemistry panels using 0.1 cc of whole blood, serum, or plasma and get accurate results in approximately 12 minutes.

- Built-in intelligent quality control meets CLIA and NCCLS requirements for daily control testing
- Panel results are printed on an adhesive-backed paper that can be easily applied to patient charts or transferred to a data management system
- On-board calibration eliminates manual testing
- CLIA-waived lipids, liver enzymes and glucose monitoring

Single-use reagent discs make testing easy and reduce operator errors

The reagent disc is composed of three injection-molded plastic parts which are ultrasonically welded together and contain all the diluent and dry reagents necessary to perform a panel of tests. The layers form the cuvettes, chambers, and passageways in which the fluids are processed.

The top protective layer of the disc also provides bar-coded calibration information, the type of test panel, lot # and the expiration date; eliminating time-consuming, error-prone manual reagent calibrations and the possibility of using expired reagents.





PANELS

CLIA WAIVED

Comprehensive Metabolic Panel

ALB, ALP, ALT, AST, BUN, Ca, Cl⁻, CRE, GLU, K⁺, Na⁺, TBIL, tCO₂, TP

Basic Metabolic Panel

BUN, Ca, Cl⁻, CRE, GLU, K⁺, Na⁺, tCO₂

Lipid Panel

CHOL, CHOL/HDL *, HDL, LDL *, TRIG, VLDL *

Lipid Panel Plus

ALT, AST, CHOL, CHOL/HDL *, GLU, HDL, LDL *, TRIG, VLDL *

Liver Panel Plus

ALB, ALP, ALT, AMY, AST, GGT, TBIL, TP

General Chemistry 6

ALT, AST, BUN, CRE, GGT, GLU

General Chemistry 13

ALB, ALP, ALT, AMY, AST, BUN, Ca, CRE, GGT, GLU, TBIL, TP, UA

Electrolyte Panel

Cl⁻, K⁺, Na⁺, tCO₂

Kidney Check

BUN, CRE

Basic Metabolic Panel Plus

BUN, Ca, Cl⁻, CRE, GLU, K⁺, Na⁺, tCO₂, Mg, Lactate Dehydrogenase

Renal Function Panel

ALB, BUN, Ca, Cl⁻, CRE, GLU, K⁺, Na⁺, PHOS, tCO₂

Hepatic Function Panel

ALB, ALP, ALT, AST, DBIL, TBIL, TP

MetLyte 8 Panel

BUN, CK, Cl⁻, CRE, GLU, K⁺, Na⁺, tCO₂

* Calculated

piccolo^{xpress}[™] chemistry analyzer

Fast, easy, accurate on-site chemistry testing

INTELLIGENT QUALITY CONTROL (iQC™)

Be confident in every test result

Meticulous quality control (QC) is essential for accurate test results. Which is why the Piccolo xpress™, uses “intelligent Quality Control” (iQC™), a unique process that monitors the analyzer, the reagent disc, and the sample during each run to verify correct electronic and chemistry performance.

- iQC™ automatically suppresses any single chemistry test or the entire panel if the analyzer electronics or optics, reagent stability, chemistry reactions, sample integrity or compliance to the procedural steps are compromised
- Error codes or messages immediately alert the operator to any problems
- iQC™ performs hundreds of QC checks automatically and simultaneously with every disc run

Continuous iQC™ ensures accurate and reliable results every time

iQC™ works from start to finish to ensure that each test run is absolutely accurate. 0.1cc of whole blood, serum, or plasma is inserted directly into the reagent disc, where sample preparation occurs automatically. All reactions, including analyte, reagent and instrument QC testing, occur in solution within tiny cuvettes on the periphery of the disc. The Piccolo xpress™ generates powerful flashes of full-spectrum white light and measures absorption for each reaction at multiple wavelengths. To ensure accurate results, iQC™:

- Verifies the composition and delivery within the disc of all substances involved in the chemical reactions
- Validates the performance of the light-generating and detection components of the analyzer
- Audits the conversion of the light absorbance into digital values for use in mathematical algorithms

Reagent disc and iQC™ work flawlessly together

- iQC™ verifies the integrity of the bar code information on the disc (disc identification code, lot number, and expiration date), eliminating the possibility of using expired reagents
- Calibration information is automatically transferred to the analyzer’s memory for accurate calculation of results
- Disc-specific information is stored along with the system QC data in the analyzer’s memory for easy reference



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Piccolo xpress
Comprehensive Metabolic
12 Jun 2006      03:50 PM
Sample Type:    Patient
Sample ID:      789
Alternate ID:   845
Gender:         Male
Age:            24 Years
Operator ID:    423
Disc Lot Number: 52000
Serial Number:  0000P02618
.....
Instrument QC:  100
iQC 1: 100 340 nm: 100
iQC 2: 100 405 nm: 100
iQC 3: 100 467 nm: 100
iQC 4: 100 500 nm: 100
iQC 5: 100 515 nm: 100
iQC 6: 100 550 nm: 100
iQC 7: 100 600 nm: 100
iQC 8: 100 630 nm: 100
Range: 90-110      95-105
    
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Easy-to-read iQC™ report

- Run-specific information
- Eight different system checks are carried out at the beginning of each run. In order to pass iQC™, the values must fall between 90 and 110%
- Contains results obtained in the chemistry iQC™ testing. Any value above the minimum indicates disc was stored correctly and all chemistries were viable at time of testing
- Any run that remains in the analyzer memory may be recalled and printed
- Bi-directional analyzer stores up to 5000 results which may be transferred to a data management system



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REVENUE ENHANCEMENT

Expand efficiency and increase profitability in your practice

Incorporate the Piccolo xpress[™] into your practice, and discover how easy it is to realize a financial benefit—and not just from reimbursement for the lab test. We'll show you how to maximize your profitability and gain a competitive edge by offering your patients options that will ultimately improve their satisfaction.

Identify new revenue streams and enhance office profitability

Why send your patients to a lab when you can bring the lab to your patients? With on-the-spot chemistry testing, you can:

- Capture the revenue stream from commercial or hospital lab and put it back into your practice
- Collect insurance reimbursement including Medicare for all panels
- Expand patient visit time justifiably through lab review consultation
- Reduce staff time obtaining commercial or hospital lab results

Maximize your revenue without increasing your time

By providing on-site lab services with the Piccolo xpress[™], you control the testing, time to results and counseling at the time of the patient visit. This allows you to:

- Eliminate unbillable time reviewing labs and patient follow-up for further discussion at a later date
- Expand billable hours by reviewing lab results with the patient at the point-of-care
- Schedule your ongoing patient lab visits for maximum return on time



Improve patient care and satisfaction

Fast, accurate, on-the-spot test results allow you to:

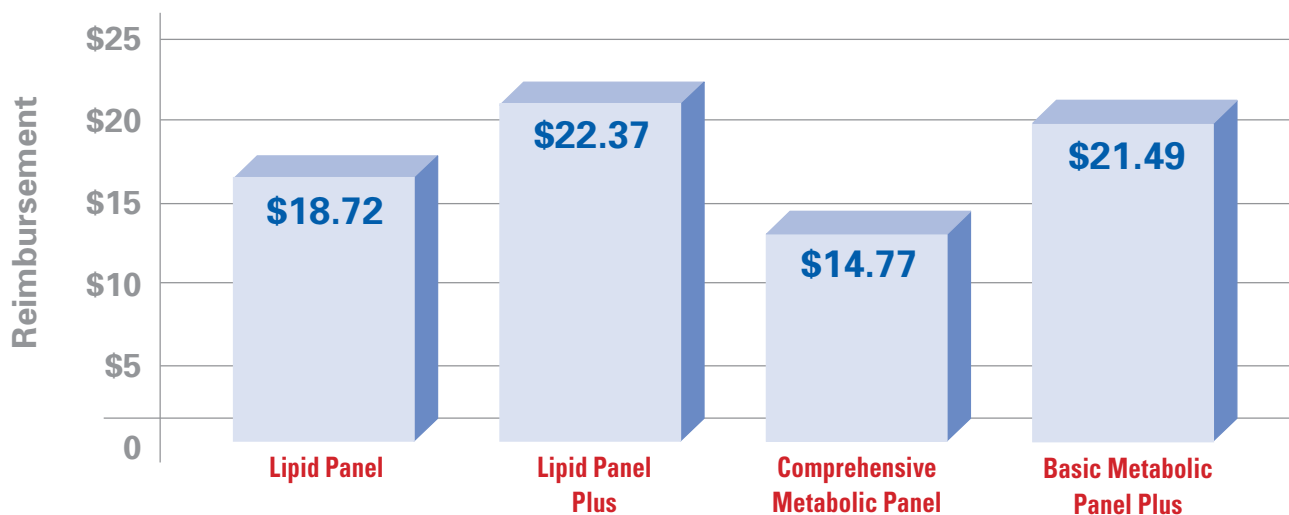
- Enhance the value of your services by offering lab results and treatment consultation to your patient in just one visit
- Eliminate patient having to take extra time off to be tested outside the practice
- Ensure your patients get their labs done and that the results are up-to-date

Ease your concerns about patient liability

Immediate lab results provide peace of mind for you and your patients. With the Piccolo xpress™, you can:

- Respond instantly to abnormal labs and treat or triage while the patient is still in your office
- Adjust medications based on real-time lab results
- Remove the risk of lost or delayed abnormal lab results

Average Reimbursement Per Panel



*Bundled reimbursement may occur when running multiple reagent discs on a single patient.



piccolo^{xpress}[™]

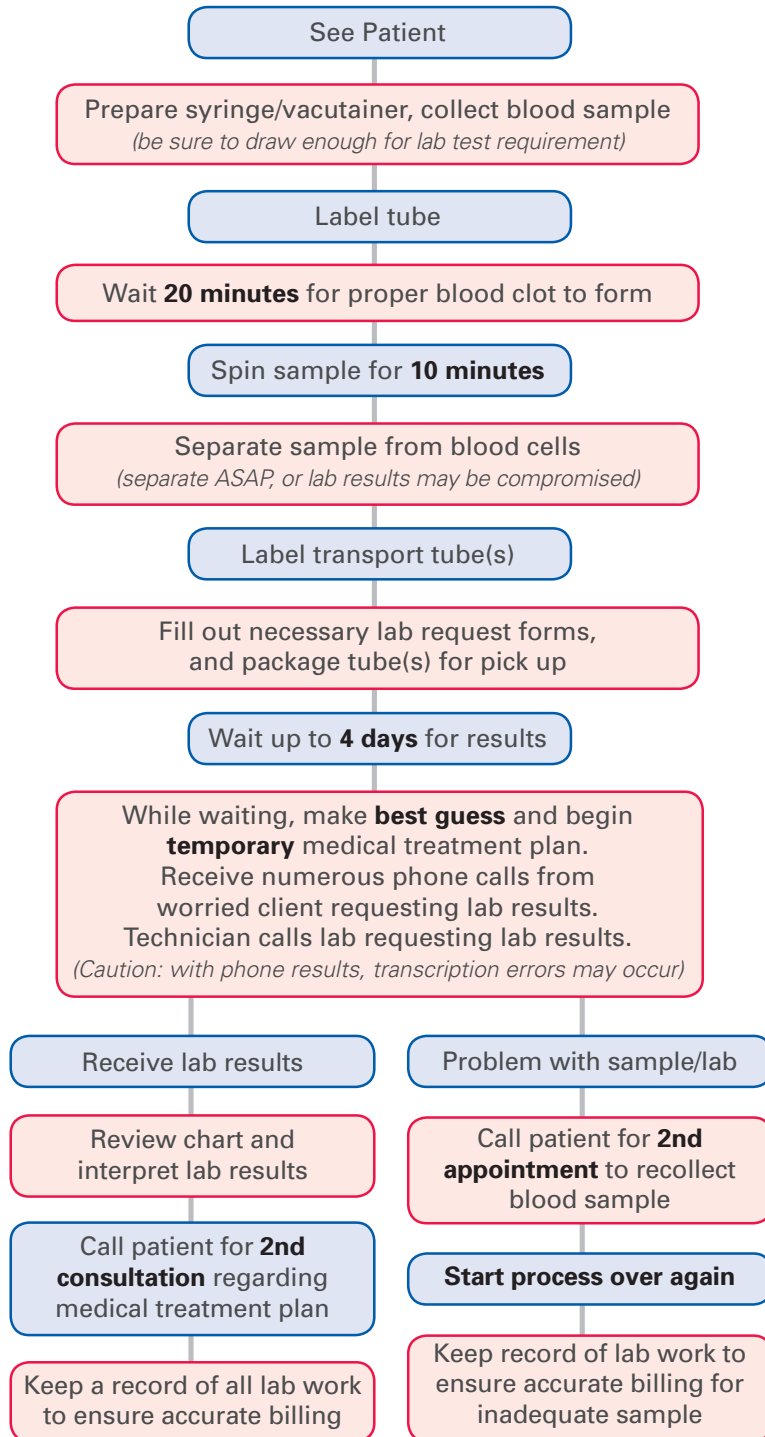
chemistry analyzer

	Piccolo xpress [™]	Alfa Wasserman ACE	i-Stat Analyzer	Cholestech LDX Analyzer
List Price	\$18,000	\$45,000	\$8,500	\$2,005
Data Management	On Board	External Computer Included	Via Central data station PC - \$25,000	Waived Instrument – Manual Charting
Storage Volume Patient/Tests	5000	500/2500	5000	Last patient only
QC Analysis – Levy Jennings	N/A	Yes	Yes, via central data station PC	No
Data Transfer	5 bi-directional USBs	RS232 bi-directional	Yes	None
Reagent	Self contained multi analyte reagent disk	Liquid	Dry	Dry (Cholesterol, Glucose & ALT & AST)
Reagent Stability	9- 18 months from date of manufacture	24 hrs – 30 days (open vial)	Minimum 4-6 months refrigeration	5-9 months
Daily QC	On board iQC w/each disc run	Liquid for each assay being tested	Electronic	Electronic
Calibration	Auto bar coded with each disc run	Auto bar coded with each disc run	Manual	Optics Check Cassette
System Footprint	9.5 " H x 6" W x 11.5"D	22" x 27" Bench top	2.5" x 2"	5" x 8" Benchttop, not including separate printer
System Weight	15 Lbs	201 lbs.	1 lbs.	N/A
Accurate Pipetting	No need	Yes (controls & calibrators)	No	No
Specimen Dilution	No need	Yes, automatic	No	No
Laboratory Technician	No need	Yes	Yes	No
Whole Blood Sample	Yes (plus serum and plasma)	No	Yes	Yes (Serum, Plasma ok but = CLIA Mod.)
Sample Analysis	Stat	Stat, Batch, Random Access	Stat (multi-test cassettes)	Stat (multi-test cassettes)
Hard Copy Printout	On board	External accessory item	included Via central data station PC	Attached print module
Electrolytes (Na,K,Cl)	Yes	Yes, on Board	Yes (ionized Calcium)	No
Electrolyte Methodology	Enzymatic	ISE	ISE	N/A
On-Board Refrigeration	No need	Yes	N/A	N/A
Plumbing Requirements	Not Required	No, on board wash solutions	N/A	N/A
Routine Maintenance Chemistry	No need	Wipe probe daily/\$250 electrodes every 6 months, tubing & parts \$5000 per year	None	None
Routine Maintenance Electrolytes	No need	Once per month-Auto Flushing	None	N/A
Chemistry Panels	Gen Chems, Lipids, Electrolytes, LD	Gen Chems, Lipids, Electrolytes, LD	Gen Chems, Electrolytes	Lipids, AST, ALT, Glu only



Comparison of traditional lab testing versus the Piccolo xpress™

TRADITIONAL LAB



PICCOLO XPRESS™



Step 1: Add sample - 0.1 cc



Step 2: Insert disc



Step 3: Read results

Exceptionally Fast

From sample to complete panel results in 3 simple steps and approximately 12 minutes



Exceptionally Easy

Fully automated system requires no special operating skills

- 0.1cc whole blood, serum or plasma
- Self calibrates with every test run
- Built-in iQC[™] eliminates daily control testing and meets CLIA and CLSI guidelines
- Full-color touch screen with intuitive user interface
- Results are printed on a self-adhesive hard copy or via electronic transfer, allowing immediate access to critical information at the point-of-care
- Large memory capacity stores up to 5000 patient records
- Externally accessible bi-directional input/output and USB data transfer technology

Exceptionally Accurate

Advanced technology ensures sound results

- Centrifugal action mixes the reagents and sample in a disposable self-contained disc – reducing procedural errors
- Accuracy and precision comparable to larger, more expensive laboratory analyzers
- iQC[™] system performs continuous quality control checks on every run
- Every self-contained reagent disc is barcoded for automatic self-calibration

Exceptionally Versatile

Wide range of available panels expand your on-site testing capabilities

CLIA WAIVED	Comprehensive Metabolic Panel	ALB, ALP, ALT, AST, BUN, Ca, Cl ⁻ , CRE, GLU, K ⁺ , Na ⁺ , TBIL, tCO ₂ , TP
	Basic Metabolic Panel	BUN, Ca, Cl ⁻ , CRE, GLU, K ⁺ , Na ⁺ , tCO ₂
	Lipid Panel	CHOL, CHOL/HDL*, HDL, LDL*, TRIG, VLDL*
	Lipid Panel Plus	ALT, AST, CHOL, CHOL/HDL*, GLU, HDL, LDL*, TRIG, VLDL*
	Liver Panel Plus	ALB, ALP, ALT, AMY, AST, GGT, TBIL, TP
	General Chemistry 6	ALT, AST, BUN, CRE, GGT, GLU
	General Chemistry 13	ALB, ALP, ALT, AMY, AST, BUN, Ca, CRE, GGT, GLU, TBIL, TP, UA
	Electrolyte Panel	Cl ⁻ , K ⁺ , Na ⁺ , tCO ₂
	Kidney Check	BUN, CRE
	Basic Metabolic Panel Plus	BUN, Ca, Cl ⁻ , CRE, GLU, K ⁺ , Na ⁺ , tCO ₂ , Mg, Lactate Dehydrogenase
Renal Function Panel	ALB, BUN, Ca, Cl ⁻ , CRE, GLU, K ⁺ , Na ⁺ , PHOS, tCO ₂	
Hepatic Function Panel	ALB, ALP, ALT, AST, DBIL, TBIL, TP	
MetLyte 8 Panel	BUN, CK, Cl ⁻ , CRE, GLU, K ⁺ , Na ⁺ , tCO ₂	

*Calculated

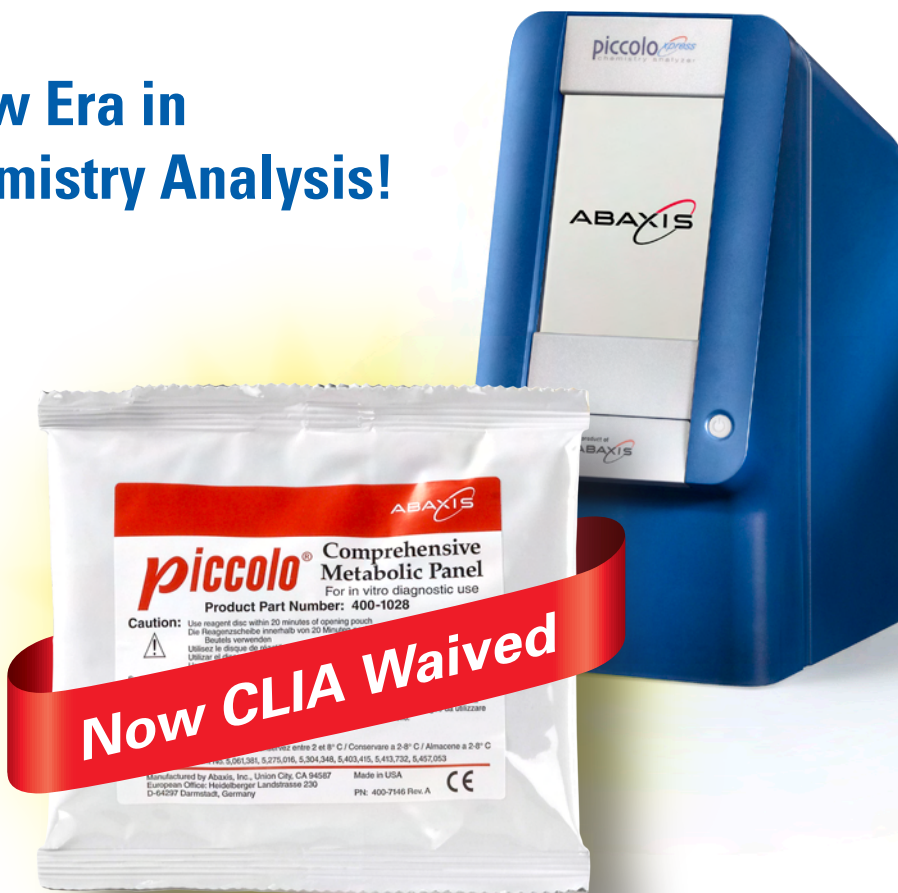


SAY HELLO to a New Era in Waived Chemistry Analysis!

Piccolo xpress™ CLIA Waived Reagent Panels:

Comprehensive Metabolic Panel
Basic Metabolic Panel
Lipid Panel
Lipid Panel Plus
Liver Panel Plus
General Chemistry 6
General Chemistry 13
Electrolyte Panel
Kidney Check

*Piccolo xpress™ waived
menu represents over 90%
of all requested chemistries*



WAVE GOODBYE to:

- Moderate complexity requirements
- Proficiency testing
- Laboratory inspections
- Instrument verifications
- Linearity tests
- Laboratory director requirements
- And... the reference laboratory

Clinical chemistry has arrived at the POL! Now's your chance to bring comprehensive chemistry capabilities into your practice.