piccolo xpress
chemistry analyzer

FAST, EASY, ACCURATE ON-SITE CHEMISTRY TESTING

CENTRIFUGATION AND CAPILLARITY INTEGRATED INTO A MULTIPLE ANALYTE WHOLE BLOOD ANALYZER

In this whitepaper, the Piccolo Xpress™ unique centrifugation and capillarity functions are described. The Piccolo processes 100µl of whole blood into multiple aliquots of diluted plasma and reports the results of up to 14 tests on a single reagent disc in about 12 minutes. To perform a panel of tests, the operator applies the unmetered sample directly into a single use, 8 cm diameter plastic disc which contains the required liquid diluent and lyophilized reagents. Using centrifugal and capillary forces, the disc meters the required amount of blood, separates the red cells, meters the plasma, meters the diluent, mixes the fluids, distributes the fluid to the reaction cuvettes and mixes the reagents and the diluted plasma in the cuvettes. The instrument monitors the reactions simultaneously using nine wave-lengths, calculates the results from the absorbance data, and reports the results on a convenient sticky-backed thermal roll-tape printer.

INTRODUCTION

Rapid availability of in vitro diagnostic results is advantageous to both the physician and the patient. An illness can be diagnosed more quickly and costs due to the illness can be decreased. Turnaround times are shortened, which reduces the likelihood that test results are no longer valid by the time they are received by the physician. Errors inherent in the laboratory testing cycle are also minimized by performing tests near the patient. Eliminating the need to transport samples to a central laboratory reduces such problems as misplaced samples, inaccurate labeling and transcription, improper icing and bagging, and sample degradation.

Test system must produce reliable results, independent of the user's skill, as well as shorten turnaround time and eliminate several sample handling steps. An important criterion is ease of use, since it has been demonstrated that medical office personnel can produce reliable results when using systems with simple protocols.

Test systems using whole blood and requiring no pipetting or diluting steps are also more accurate than systems which require specimen manipulation steps. This paper reports on near-patient, portable, clinical chemistry system that provides the clinician with rapid availability of in vitro diagnostic results. The Piccolo system reports results for panels of blood tests within 14 minutes of sample application to the consumable. The system consists of the single use reagent disc and the Piccolo analyzer.

An operator applies a few drops of capillary or venous whole blood to the reagent disc and places it into the analyzer. Using capillary action and centrifugal force acting from the center of the disc, the system completes all sample processing and optically analyzes the cuvettes for multiple chemistries simultaneously. The panel of results is printed on an adhesive-backed card for easy application to patient charts. The design of this system, with emphasis on the consumable, which converts the unmetered blood sample into multiple aliquots of precisely diluted plasma, is described here.

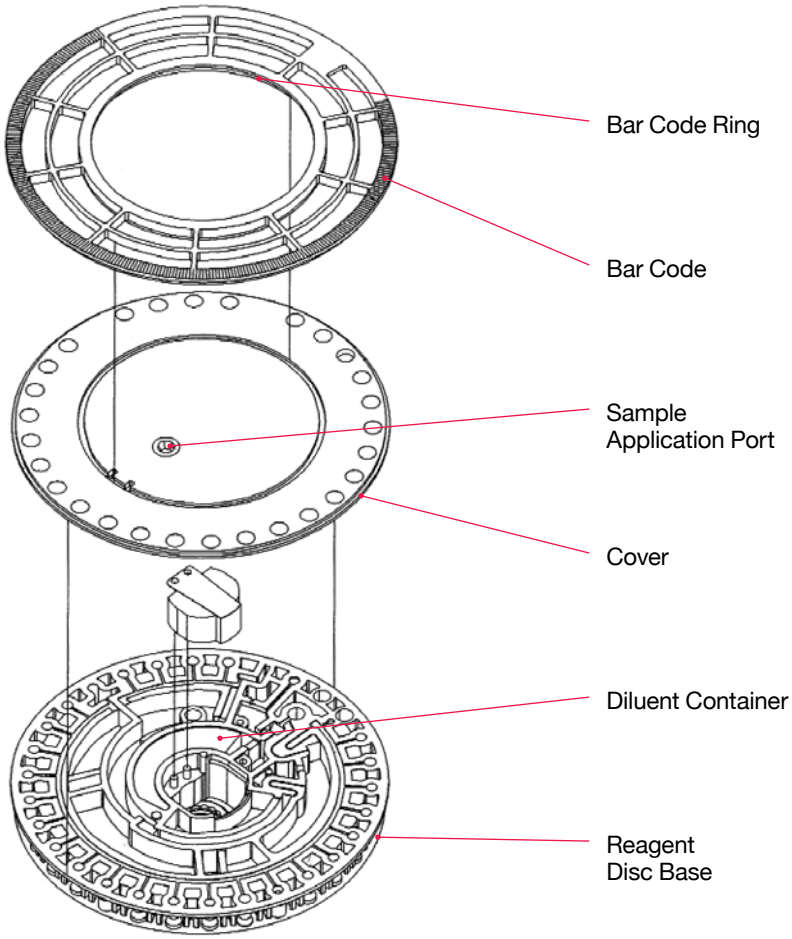
ABAXIS

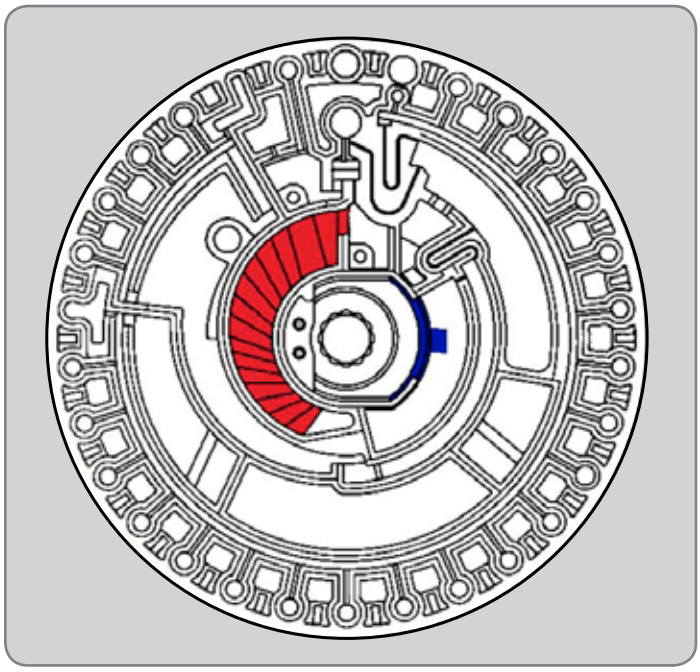
MATERIALS AND METHODS

The Reagent Disc

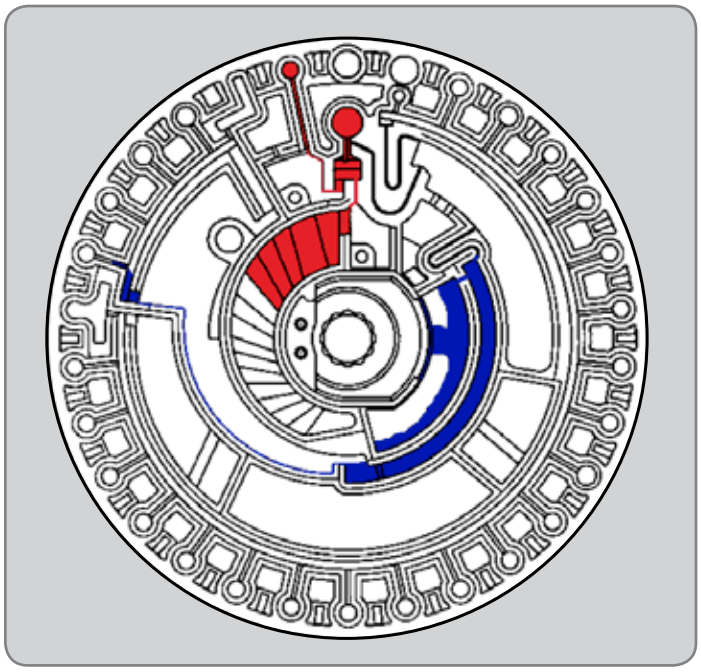
The reagent disc is an 8 cm diameter consumable containing all the required diluent and dry reagents to perform a panel of tests. Three injection-molded plastic parts are ultrasonically welded together to form the reagent disc. The base and middle layer are molded from polymethylmethacrylate plastic and the top layer is molded from ABS plastic. The welded base and middle layers form the cuvettes, chambers and passageways which allow the fluids to be processed. The top layer protects the cuvette windows from fingerprints, prevents contamination of the analyzer by any sample spilled on the disc surface, and provides imprinted bar-coded, disc specific calibration information to the analyzer.

A sealed container in the center of the disc contains 474 µl of diluent. Fluid loss from the container is less than 5 µl per year when stored at 8°C. The disc contains 21 cuvettes that will be filled with diluted plasma and four cuvettes that will be filled with diluent. The cuvettes have five pathlengths (1.7 mm, 2.1 mm, 3.1 mm, 4.3 mm and 5.0 mm) to accommodate different reagent sensitivities and analyte concentrations. Pre-measured, lyophilized reagent beads for each chemistry in the panel are placed in the cuvettes at the time of manufacture.

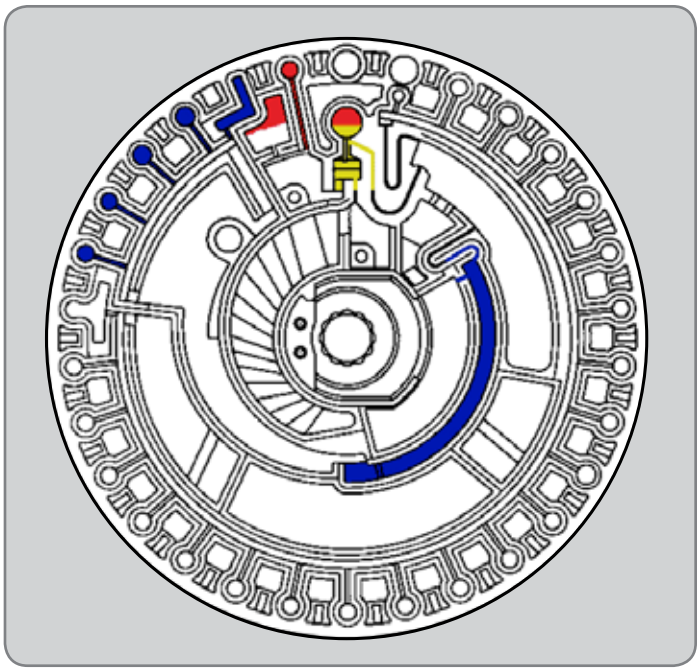




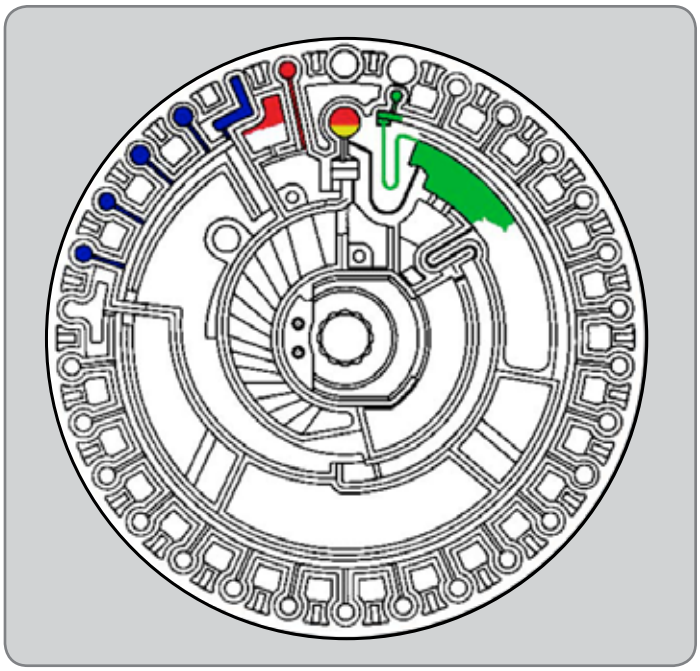
1. SCHEMATIC DIAGRAM OF THE DISC SHOWING THE SAMPLE IN THE APPLICATION CHAMBER.



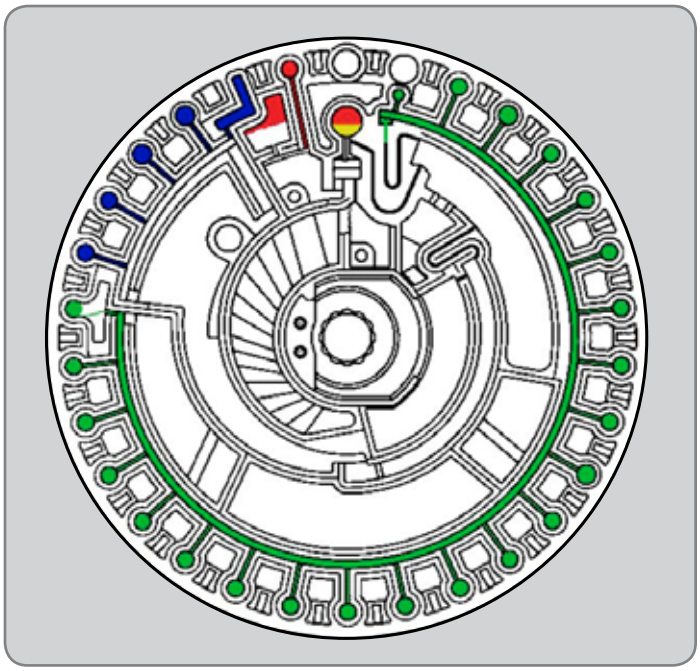
2. SCHEMATIC DIAGRAM OF THE DISC SHOWING BLOOD ENTERING THE PLASMA METERING CHAMBER AND DILUENT BEING RELEASED.



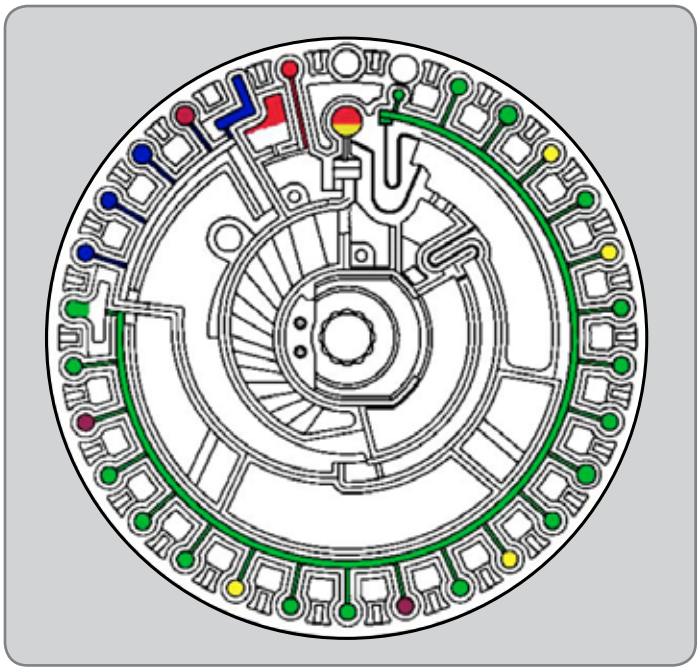
3. SCHEMATIC DIAGRAM OF THE DISC SHOWING THE PLASMA SEPARATION, DILUENT METERING, SIPHONS PRIMED, IQC CUVETTES FILLED AND QC CHECKS PERFORMED.



4. SCHEMATIC DIAGRAM OF THE DISC SHOWING THE MIXING OF THE PLASMA AND THE DILUENT. DILUTED PLASMA SIPHON IS PRIMED.



5. SCHEMATIC DIAGRAM OF THE DISC SHOWING THE DISTRIBUTION OF DILUTED PLASMA TO THE CUVETTES CONTAINING REAGENTS.



6. SCHEMATIC DIAGRAM OF THE DISC SHOWING THE HYDRATED REAGENT BEADS AND COLOR METRIC IQC CUVETTES.

The Analyzer

The analyzer is portable spectrophotometer measuring 32.4 cm high by 15.2 cm wide by 20.3 cm deep; it weighs 5.1 kg. A disc drawer extending from the front of the analyzer positions the disc on the center of the spindle at the beginning of each run. The analyzer's motor and controller drive the disc through the profile of rotational speeds needed to process the sample. The optical system consists of a xenon arc stroboscopic lamp and a beam-splitter/detector capable of reading nine wavelengths. A 16-bit analog-to-digital converter is used in signal processing. Two microprocessors control the functions of the analyzer. A heater maintains the disc at 37±1°C during the reaction portion of the analysis.

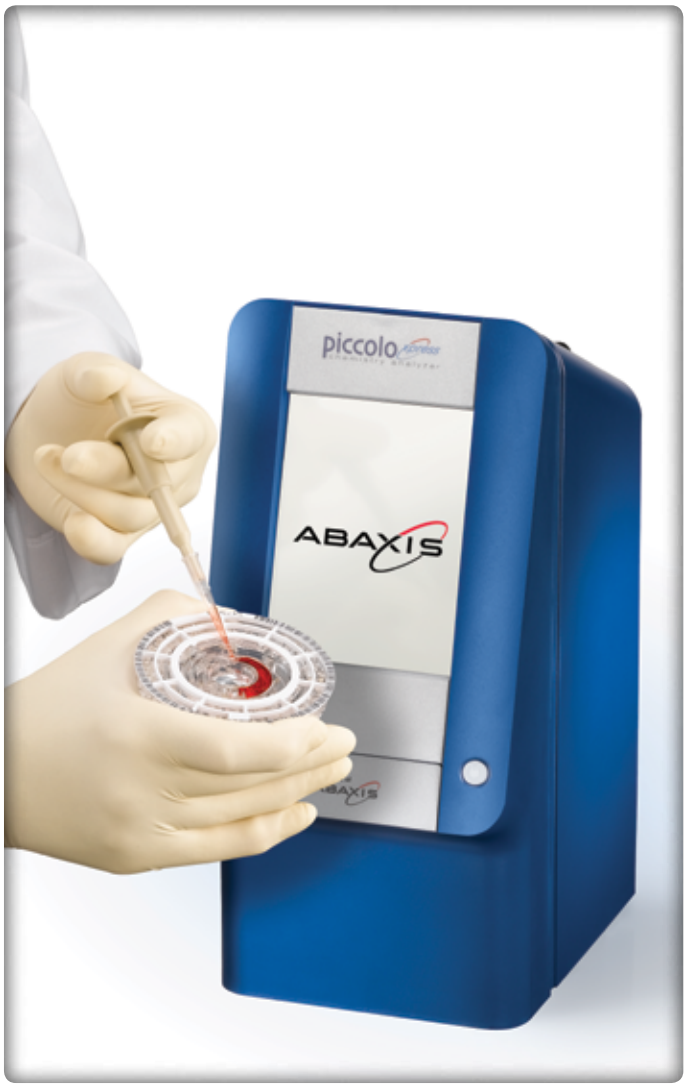
The Process

To perform an analysis, the operator obtains a whole blood sample, preferably via venipuncture. Whole blood samples obtained by venipuncture can be analyzed within 60 minutes of collection. 100 µl of sample is pipetted into the disc sample port. Sufficient sample is applied to the disc when leading meniscus of the sample creates a link between two arrows printed on the disc.

The operator need not to meter the sample prior to application. A minimum of 90 µl is required and up to 120 µl may be applied to the disc. The operator places the disc with applied sample in the analyzer drawer. The drawer closes and the analyzer automatically centers the disc on the spindle. The operator inputs a patient ID via the numeric keypad provided or with an optional alphanumeric keyboard. The disc is now completely controlled by the analyzer and no further involvement from the operator is required.

Transparent to the user, the diluent container is opened as the disc is loaded onto the spindle. The diluent container, a molded high-density polyethylene plastic container, is sealed with polyethylene-laminated aluminum foil. A tab on the foil is folded back across the top of the diluent container and heat staked to the disc base. A central post on the spindle enters the disc and pushes the diluent container up. This causes the foil to peel back from the edge and create an opening to release the diluent.

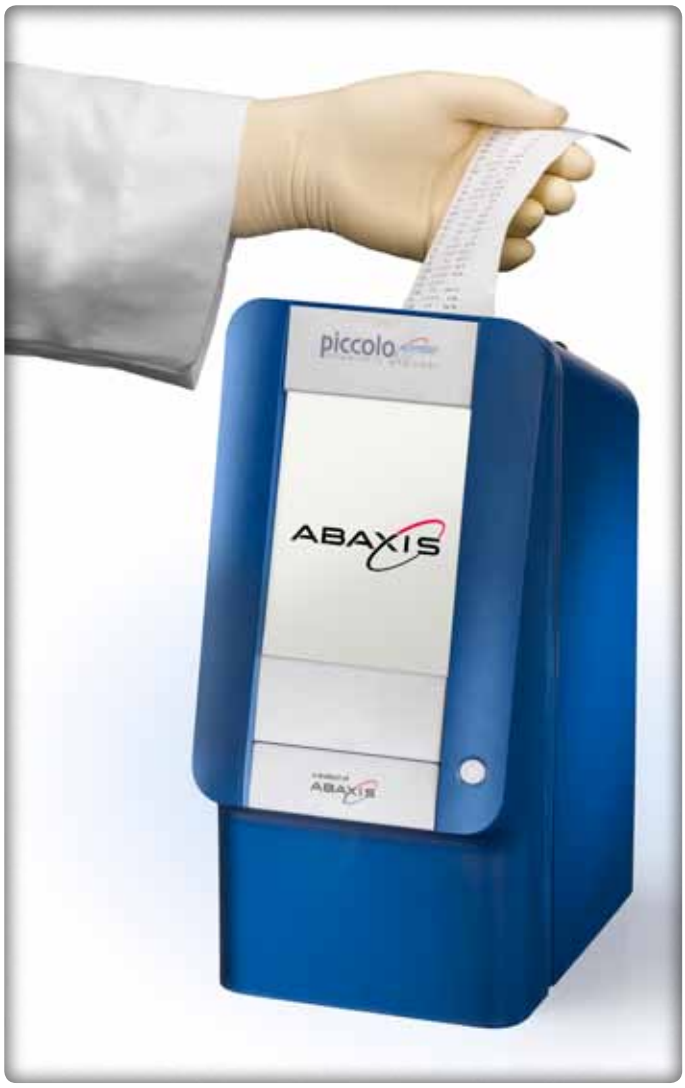
The sample and diluent begin the processing on separate but parallel, pathways. At the start of the analysis, the analyzer accelerates the disc to 5000 rpm counter-clockwise and holds this speed for 2.5 minutes. Centrifugal force causes the diluent to be thrown from the diluent container into a holding chamber. The small exit channel at the most radially outward point of the chamber allows the diluent to fill a metering chamber in a controlled manner. The chamber is filled completely with 365.25 µl of diluent. The remaining diluent overflows this chamber and moves through a channel which sequentially fills four cuvettes and places the remaining diluent into a dump isolated from the rest of the disc. The four cuvettes are used as part of the Intelligent Quality Control (IQC) process.



STEP 1. **100 µl OF WHOLE BLOOD IS PIPETTED INTO THE REAGENT DISC.**

Simultaneously with diluent metering, centrifugal forces cause the sample to exit the application chamber and move through a small channel into the plasma metering chamber. The chamber is filled completely by 75 µl of sample and the remainder overflows into a 'sufficient sample' cuvette. Any excess sample is trapped in an isolation dump. If no fluid is detected in the 'sufficient sample' cuvette, the analysis is aborted due to a deficient quantity sample. The precise quantity of blood metered into the plasma metering chamber is separated by centrifugal force into plasma and red blood cells. Adequate separation is achieved in 30 seconds for most samples. Samples with higher hematocrits require longer separation and packing times to provide the necessary 20 µl of clear plasma. Spinning the disc for 2.5 minutes is sufficient to separate samples up to a hematocrit of 62%.

STEP 2. **DRAWER IS OPENED AND FULL REAGENT DISC IS PLACED ONTO THE RECEIVING TRAY.**

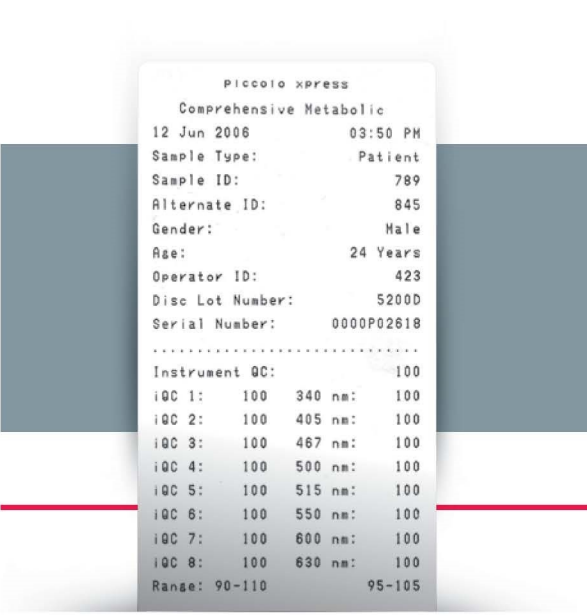


STEP 3. **AFTER 12 MINUTES OF PROCESSING TIME, THE RESULTS ARE PRINTED ONTO ADHESIVE-BACKED THERMAL ROLL TAPE.**

The next step combines the diluent and the plasma. A siphon entrance of capillary dimension, which is located at the radially outermost point of the diluent metering chamber. Another siphon entrance is located partway down the plasma metering chamber. Neither of these siphons fills during the first spin because the centrifugal force is far higher than the capillary force. After the separation step is completed, the disc stops spinning and capillary forces pull the fluids over the bend in the siphons. Both siphons exit into a single mixing chamber.

The disc is now spun at 5000 rpm clockwise. The diluent metering chamber is completely emptied since the exit of the siphon is further from the center of the disc then the extreme edge of the diluent metering chamber. The plasma metering chamber is emptied to a radial distance equaling the placement of the exit of the plasma metering siphon. The volume of plasma metered is 18.75 µl . The remaining 56.25 µl of sample and red blood cells is trapped in the lower portion of the plasma metering chamber.

The disc speed is varied to mix the metered diluent and plasma in the mixing chamber. The disc abruptly brakes to a speed of 750 rpm and then slowly climbs back to 4000 rpm, this pattern is repeated for 15 cycles. The abrupt deceleration provides sufficient tangential force to move and mix the fluid in the mixing chamber. A minimum speed of 750 rpm is required during the mixing process, to ensure that the applied centrifugal force exceeds the capillary strength of final siphon. This mixing profile prevents priming of the siphon until the fluids are homogeneously mixed.



The final siphon is primed by capillary action after mixing is complete and the disc is stopped. The disc is then spun at 3000 rpm clockwise for 40 seconds. The diluted plasma flows out of the mixing chamber and into a distribution channel which leads to 21 cuvettes and an isolation dump. The 21 cuvettes are filled sequentially and the remaining diluted plasma flows into the dump.

Each cuvette has a single channel for both flow of fluid into the cuvette and air venting. Under highly controlled conditions, the fluid flows down one side of the inlet channel while air vents from the other side. No special features of the cuvette inlet channel are required to achieve this control. The size of the fluid is controlled by the resistance of the siphon, the rotational speed of the disc, and the pressure head of the remaining fluid. The disc must also spin fast enough to overcome the capillary strength of the inlet channel which is 0.50 mm wide and 0.13 mm high. Each cuvette contains one or two beads of lyophilized reagents appropriate for the particular test to be run within that cuvette; these beads dissolve completely in the time required to fill the cuvette.

After all of the cuvettes are filled, and the excess diluted plasma is isolated in the dump, the disc is oscillated from 1000 rpm clockwise to 1000 rpm counterclockwise for 70 seconds. This oscillation cycle creates swirl patterns in the cuvettes which mix the chemistry and the diluted plasma.

The spectrophotometer monitors the reactions in all of the cuvettes for 3.5 minutes by flashing the xenon arc lamp synchronously with the spinning disc. The lamp is flashed approximately 5000 times for each disc.

The analyzer detects the presence of each cuvette by sensing 45 degree wedges of plastic placed every 12 degrees around the periphery of the disc. On each spin, the processor selects which cuvette to flash and which of the nine wavelengths to measure.

The results are calculated and printed on adhesive backed thermal printout for easy attachment to the patient's medical record. In addition, the results can be uploaded to a computer or automatically transported to an LIS/EMR system via the bi-directional USB ports located on the back of the analyzer.

piccolo xpress chemistry analyzer

FAST, EASY, ACCURATE ON-SITE CHEMISTRY TESTING

INTELLIGENT QUALITY CONTROL (IQC™) ON THE PICCOLO XPRESS™ POINT-OF-CARE CHEMISTRY ANALYZER

The Piccolo Xpress™ Point-of-Care Chemistry Analyzer is a lightweight portable instrument that processes whole blood, serum, or plasma samples in self-contained, single-use reagent discs. Along with fully automated processing and onboard data handling, the Piccolo Xpress™ incorporates a unique process called iQC ("intelligent Quality Control"). Transparent to the operator, iQC checks the analyzer, the reagent disc, and the sample during each run to verify correct electronic and chemistry performance. iQC automatically suppresses a single chemistry or the entire panel if it detects uncharacteristic performance, and immediately alerts the operator to any problems. From the self-test at power-up to the recording and printing of patient results, the Piccolo Xpress™ conducts multiple QC checks automatically with each run. iQC ensures that the operator reports only accurate and reliable results.

Demands for improved patient care and greater cost control are driving profound changes in the structure of health care delivery. Within and outside of traditional hospital environments, evolving technology is permitting some types of diagnostic testing and patient monitoring to move from the clinical laboratory to the near-patient environment. Many health care professionals whose roles have traditionally involved hands-on patient care are now being asked to take a role in clinical chemistry testing as well. Laboratorians, with their training and experience, know that rigorous quality control (QC) is an absolute necessity for accurate test results on which treatment decisions can confidently be based.

The Piccolo Xpress™ Point-of-Care Chemistry Analyzer incorporates a process called iQC ("intelligent Quality Control") that meets established QC standards independently of the operator's skill level. iQC is a series of sophisticated automatic checks that verify the chemistry, optics, and electronics functions of the analyzer during each run, and ensures that operators in a wide range of environments report only accurate and reliable results.

ABAXIS

piccolo xpress
chemistry analyzer

HOW IQC™ WORKS

In the Piccolo Xpress™, a tiny volume of patient sample is introduced directly into the single-use, self-contained reagent disc, where sample preparation is handled automatically. All reactions, including analyte, reagent, and instrument QC testing, occur in solution within tiny cuvettes on the periphery of the disc. In contrast to most laboratory photometers, which use light of only a single wavelength per measurement, the Piccolo Xpress™ generates powerful flashes of full-spectrum white light and measures absorption for each reaction at multiple wavelengths, from ultraviolet to near-infrared. To ensure accurate results, iQC verifies the composition and delivery within the disc of all substances participating in the reactions (chemistry); validates the performance of the light generating and detection components (optics); and audits the conversion of the light absorbance into digital values for use in mathematical algorithms (electronics).

CHEMISTRY AND IQC

Bar code

Time-consuming and error-prone reagent calibrations are not required with the Piccolo Xpress™ nor is there any chance of using expired reagents. The barcode on the top surface of each disc encodes the type of test panel, the expiration date, and the reagent calibration factors. At the beginning of the run, iQC verifies the integrity of the information in the bar code by the use of a cyclic redundancy check (CRC). It then checks the expiration date of the disc against the analyzer's clock to verify that the expiration date has not been exceeded. The calibration information is transferred into the analyzer's memory to be used in the calculation of results. Disc-specific information is maintained with the system QC data in the analyzer's memory.

Fluidics

The metering and movement of fluids (sample, diluent, and diluted sample) are controlled at all stages of the run by the analyzer's motor and design features of the disc. In several precisely timed cycles, the disc is alternately spun to create centrifugal force, then held still to permit capillary action. These forces synchronize the movement of fluids into and out of the chambers, channels, and cuvettes within the disc as necessary for the correct timing of all reactions. They also control the rate of fluid movement, so that turbulence can be minimized or utilized, as appropriate for a particular function.

At the start of the run, the sample and the diluent are moved along separate but parallel pathways within the disc. The sample (~100 µL of serum, plasma, or whole blood) is drawn by capillary action from the sample port into the application chamber, then through a small channel into the plasma metering chamber. During the first spin cycle, the red cells are separated from whole blood samples and sequestered in a cell trap chamber. The analyzer verifies the presence of adequate sample volume by sensing overflow into the "sufficient-sample" cuvette. iQC will abort the run if the presence of sufficient sample cannot be verified.

Centrifugal force transfers the diluent from a reservoir within the disc into the diluent metering chamber and four system cuvettes where reagent and system iQC reactions take place. (Refer to iQC reactions, below.) The run will also abort if insufficient volume of diluent is detected, or if the reactions indicate reagent degradation.

When spinning stops, capillary forces pull precise quantities of sample and diluent into a mixing chamber. A spin cycle that alternately accelerates and decelerates the disc ensures complete mixing. At the end of this cycle, the aliquot (diluted sample) flows through the exit siphon and along the distribution channel to the reaction cuvettes. The design of the cuvettes permits air to outflow and aliquot to inflow, preventing the formation of air bubbles inside the cuvette and ensuring the correct concentration of the reaction solution. If iQC detects no aliquot in a reservoir beyond the last reaction cuvette, the presence of sufficient aliquot in all reaction cuvettes cannot be verified, and the run will abort. Otherwise, the disc spins alternately clockwise and counterclockwise to dissolve the reagent beads in the diluted sample and start the reactions.

iQC reactions

Four system cuvettes are used for reagent and system testing. Chemistry QC reagent beads reveal and quantify any degradation of the analyte-specific reagents in the disc due to suboptimal storage conditions (moisture and temperature). If degradation exceeds a defined level, the run is aborted and an error message is displayed on the analyzer screen. System cuvettes containing a dye are used to verify the accuracy and precision of the instrument. An individual chemistry or the entire panel will be suppressed if any abnormality is detected. System and reagent QC data from each run are stored in the analyzer's memory with the sample results. Standard information storage and retrieval techniques are employed to ensure the integrity of the data. All QC data stored in memory can be called up for review at any time.

Sample evaluation

iQC eliminates the need for visual evaluation of the sample for physical interferents (hemolysis, lipemia, and icterus), a task that may be impossible when dealing with whole blood or a very small sample. The Piccolo Xpress™ evaluates the quality of the sample, and reports the measured values for each interferent. Different chemistries within one type of disc may have different sensitivities to physical interferents. If a limit is reached for one or more analytes, results are suppressed for those analytes only; the level of interference is indicated on the Result card. Results for analytes less sensitive to that interferent are reported normally.

Reaction monitoring

iQC monitors the analyte-specific reactions. For rate chemistries, it confirms that the reactions are linear; that the absorbencies from which the rates are calculated, as well as the rates themselves, are within defined ranges; and whether the substrate has been depleted. In endpoint chemistries, the analyzer verifies that all measurements are within the dynamic range of the photometer and that the reaction has reached completion.

OPTICS AND IQC

Controlling and measuring the light

The optical system consists of a xenon arc stroboscopic lamp that generates the incident beam; a family of beam splitters and filters that select defined wavelengths; and photodetectors that convert the light intensity at each wavelength into electric current. The current is routed to one of two microprocessors, which select the signals of interest and send them through variable-gain amplifiers. The amplified signal goes on to the analog-to-digital converter where the light intensity is converted to a digital number that can be used in the calculations.

Because the Piccolo Xpress™ measures absorbance at multiple wavelengths, the full spectrum of the reactions can be utilized in the determination of the analyte concentration. For analytes known to be present in a wide range of concentrations in clinical samples, e.g., glucose, chemistries optimized at several different wavelengths can be included on a single disc and results measured simultaneously in the same sample. The ability to measure absorption at several wavelengths gives the Piccolo Xpress™ an extremely wide dynamic range.

Signal adjustments

The uniquely designed variable-gain front-end amplifiers define the noise performance of the system and its dynamic range. The dynamic range and the noise performance of the analyzer are optimized through a complex set of measurements that involve both the disc and the electronics.

The brightness of the lamp flash changes very gradually with time and use (declining to 50% intensity after a minimum of 50 million flashes, or 7 years of normal use). These changes are normal and expected, and generally affect all wavelengths more or less equally. However, to retain maximum sensitivity, the analyzer adjusts for those changes. iQC includes a series of flashes through the "minimum-absorbance" cuvette at the beginning of each run that prompts the variable gain amplifiers to adjust for maximum dynamic range (1 to ~64,000). Simultaneously with the adjustment of the gain, the analyzer verifies that the noise associated with the light intensity at any wavelength is within acceptable limits. When changes in the lamp intensity exceed the range of the variable-gain amplifiers for any wavelength, iQC will abort the run and display an error message.

Background noise is ever-present in every system. iQC includes a series of flashes through the "maximum absorbance" cuvette at the beginning of each run to measure the amount of background noise registered by the photometer at each wavelength. Higher than expected background noise at the different wavelengths usually indicates problems associated with the electronics in the analyzer or variable light leaks into the photometer from sources other than the primary light path. These problems can degrade the accuracy and precision of the readings, especially at higher absorbencies. When the level or the noise in the background signal is outside acceptable limits, iQC will abort the run and display an error message. The effect of the inherent flash-to-flash variation in light intensity is eliminated by the use of a reference wavelength. This reference wavelength also minimizes the inherent variability in the disc due to the manufacturing process or introduced by handling (scratches, fingerprints).

ELECTRONICS AND IQC

Microprocessors and memory

The architecture of the instrument consists of two microprocessors: a real-time controller that monitors and controls all the measurements; and an I/O (input/output) controller for memory management, calculations, and data storage. The two processors interact continuously, which allows a very high level of confidence in the workings of the instrument, and consequently in the integrity of the data and in the results. The analyzer stores 5000 results and system QC data.

Software

The analyzer software comprises two matched programs. One program processes the information and controls the measurement engine itself, i.e., it synchronizes the flashing of the lamp with the position of specific cuvettes, and collects the light intensity data for different cuvettes at different times during the run; and it collects all the information generated in the analytical part of the instrument. The second program reports analyte concentrations. It also stores data related to each run (time, date, user ID, patient results, and control data).

Calculations from absorbance data

In normal functioning, each reported absorbance is calculated from a series of 10 flashes through the cuvette. Before being reported, the calculations are verified by a series of rigorous mathematical algorithms programmed into the analyzer software. These algorithms can detect errors in the absorbance data resulting from excess noise in the intensity of the flashes or from abnormalities in the reaction itself, as well as the integrity of the calculations. When such errors are detected, results for a particular analyte, or, in certain cases, for the entire panel, are suppressed. Point-of-care testing is a rapidly evolving area of laboratory diagnostics. iQC on the Piccolo system provides the health care facility with innovative solutions that ensure quality testing while meeting regulatory requirements.

THE PICCOLO® REAGENT DISC IN IQC

The Piccolo reagent disc contains components that are integrated with the optical, electronic, and mechanical functions of the analyzer, and takes part in all phases of the analysis of the sample.

A bar code ring on the top of the disc contains the ID code, lot number, expiration date, and calibration data. The transfer of this data to the analyzer software is verified by a cyclic redundancy check (CRC).

The disc works with the analyzer's optical and electronic components in the calibration of the signals and rigorous checks of system functioning.

Sophisticated fluidics are employed to measure and mix the sample and diluent, and deliver them at precisely the right time to cuvettes located around the disc periphery.

THE CUVETTES HAVE SPECIALIZED FUNCTIONS:

- A minimum-absorbance cuvette is used in signal adjustments that optimize sensitivity
- A maximum-absorbance cuvette is used in quantifying the noise performance of the electronic components to ensure the accuracy of all readings
- 1 cuvette contains reagent beads for chemistry QC
- 2 cuvettes contain dye beads for instrument QC
- 1 "empty" cuvette fills with diluent only, as a control on the system cuvettes
- 21 cuvettes contain test-specific lyophilized reagent beads
- 2 cuvettes verify the presence of sufficient sample and diluent, respectively
- 1 cuvette verifies that diluted sample was delivered to all the reaction cuvettes
- The disc contains miscellaneous reservoirs to isolate excess fluids

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:				5200D
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

HOW TO READ THE QC REPORT

Run-specific information is found at the top of the QC Report Instrument QC data are arranged in two columns below the run-specific information. Level 1 iQC 1 through 8 refers to the eight different system checks that the analyzer carries out at the beginning of each run. The allowable values for all components are normalized, with 90% equaling the minimum allowed value and 110% equaling the maximum allowed value. For the run to pass iQC, the values obtained by flashing through the minimum- and maximum-absorbance cuvettes at the beginning of the run must be within these limits for all components.

Level 2 QC data concerns precision. Two system cuvettes contain 1 dye bead and 2 dye beads, respectively. At the beginning of the run, the analyzer calculates the ratio of the absorbances in the 1-bead and the 2-bead cuvettes at all wavelengths. It then averages the ratios and determines the precision of the measurements. The precision is reported to the right of “LEVEL 2.” The values to the right of each specified wavelength indicate the mathematical relationship between the normalized ratio obtained at that wavelength and the average for all wavelengths. For the run to pass iQC, the precision must be between 95 and 105% overall and for each specific wavelength.

The results obtained in the chemistry iQC testing are given at the bottom of the card, along with the minimum acceptable value for this test. Any value above the minimum indicates that the disc was stored correctly and all chemistries in the disc were viable at the time of testing.

HOW TO RECALL AND PRINT THE QC REPORT

System QC data are compiled for each run and stored in the analyzer memory with the run results. For any run that remains in memory, these data can be recalled and a copy of the QC Report can be printed. Refer to the Piccolo Operator’s Manual for instructions on recalling and printing system QC data.

piccolo xpress chemistry analyzer

SUMMARY OF IQC CHECKS

BAR CODE
- Verifies current dating
- Cyclic redundancy check verifies accurate transfer of the reagent calibration data to the analyzer software

CHEMISTRY
- Confirms the viability of the analyte-specific reagents
- Monitors all reactions in process

FLUIDICS
- Verifies the presence of sufficient sample and diluent
- Verifies the presence of diluted sample in all reagent cuvettes

SAMPLE
- Quantifies physical interferents (hemolysis, lipemia, icterus)
- Suppresses results for any reaction where the limits of sensitivity to an interferent have been exceeded

SIGNAL ADJUSTMENT
- Monitors changes in flash intensity and adjusts for maximum dynamic range
- Monitors the noise associated with the lamp intensity at all wavelengths
- Measures the background noise to detect electrical and other problems
- Uses a reference wavelength to minimize the effect of flash-to-flash intensity variation

SOFTWARE / MEMORY
- The architecture of the two microprocessors optimizes real time performance
- Synchronizes the flashing of the lamp with the position of specific cuvettes
- Detects errors in absorbance data and errors in the calculations

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INTER MEDICO
50 Valleywood Drive
Markham, Ontario L3R 6E9
800.387.9643
800.268.1150 Français
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