

PRODUCT BULLETIN

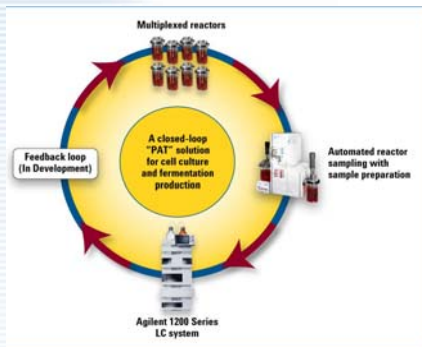
GROTON BIOSYSTEMS AUTOMATED REACTOR SAMPLING SYSTEM AND AGILENT 1200 SERIES LC SYSTEM FOR ONLINE HPLC ASSAYS

SAMPLE FROM MULTIPLE
REACTORS 24 HOURS A
DAY, 7 DAYS A WEEK

FULLY PROGRAMMABLE

FULLY AUTOMATIC

CELL CULTURE
FERMENTATION
PROCESS STREAM



A closed-loop system for monitoring reactor nutrients helps to ensure proper feeding of reactors to optimize product yields (feedback loop in development).

TWO GREAT COMPANIES HAVE COLLABORATED
TO PROVIDE A TOTAL SOLUTION FOR ONLINE HPLC



Agilent Technologies



INCREASE PRODUCTIVITY. The Groton Automated Reactor Sampling (ARS) system and Agilent 1200 Series LC system provide a high level of automation for development, scale-up, and production within biopharmaceutical facilities. Enjoy labor savings and productivity gains in sampling and assay of reactors.

INCREASE SAMPLE FREQUENCY. Market research indicates that most companies do not sample frequently because it is expensive and increases the risk of bioreactor contamination. However, companies would like to sample more often to acquire improved process knowledge. The PAT initiative is based on increasing data collection and sample frequency in order to better understand and control process parameters ultimately leading to an improvement in process control, quality and product yield.

OPTIMIZE YOUR PROCESS. Realize labor efficiency and speed of analysis when compared with traditional manual sampling, manual sample prep, and bench top analysis. Increase process knowledge through the acquisition of real time data with the ARS and Agilent 1200 Series LC systems. Online monitoring bridges the gap between the QC Analytical Lab and Method Development/Production by automating the process. Continuous automated process monitoring allows for labor efficiencies and prompt process decision making ability.

REDUCE COSTS. Direct connection from your bioreactor to your HPLC system eliminates the need for time-consuming manual sampling, sample prep, and analysis – sample from your bioreactor any time, day or night, and send the sample directly to the Agilent 1200 Series LC System. Control of the ARS is integrated into the method of the Agilent 1200 Series LC system.



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SHORTEN DRUG
DEVELOPMENT
APPROVAL PROCESS

REDUCE PRODUCT
DEVELOPMENT
CYCLES

MAXIMIZE
PRODUCTIVITY

INCREASE YIELD

TRACE PRODUCT
QUALITY AND
REDUCE LABOR

PROCESS ANALYTICAL TECHNOLOGY INITIATIVE

- Control your Manufacturing through Timely Measurements
- Reduce the Time and Cost of Routine Bioreactor Sampling
- Get Rapid and Timely Feedback
- Benefit from Fully Programmable Clean-in-Place "CIP"



Agilent 1200-ARS Series - Online Bioreactor Sampling, Collection, and Analytical Tool Solution

SAMPLE FROM UP TO EIGHT REACTORS

...DELIVER TO THE AGILENT 1200 SERIES RAPID RESOLUTION LC SYSTEM

ANALYTICAL INTERFACE. The ARS also supports critical biotech assay requirements including Cell Counting, Nutrient Monitoring, and Fraction Collection. Groton provides optional sample prep for filtration, dilution, concentration, derivatization, buffer exchange, and pH titration.

COMPLETE, SANITARY BIOREACTOR ISOLATION. Sample from multiple bioreactors/fermentors, biotech downstream processes, and pharmaceutical process streams. The ARS automatically provides clean-in-place capabilities. Steam-in-place available for large scale systems.

CHOOSE THE CONFIGURATION THAT BEST MEETS YOUR REQUIREMENTS

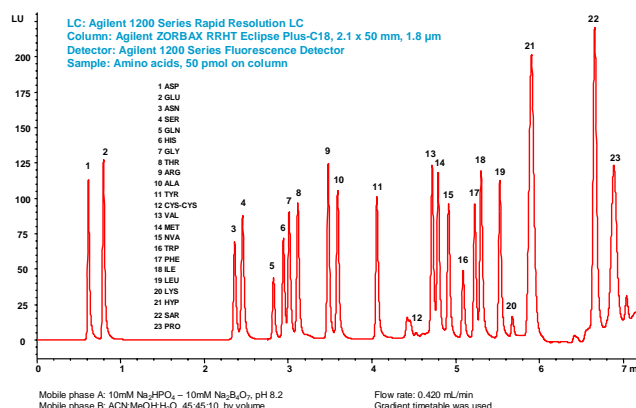
ARS800 – Sample from up to 8 Reactors and deliver to up to 4 Analytical Instruments

ARS400 – Sample from up to 4 Reactors and deliver to up to 4 Analytical Instruments

ARS100 – Sample from 1 Reactor and deliver to 1 Analytical Instrument

Fast analyses, such as the quantitation of amino acids, are the key to real-time monitoring and optimization of production processes.

Rapid Amino Acid Analysis



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KEY FEATURES AND BENEFITS OF THE ARS SERIES

Sanitary Interface	The dual isolated remote valve interface system provides complete isolation of the reactor from the ARS. This interface permits cleaning and flushing directly to the reactor port, protecting the reactor from contamination. CIP / SIP options are available.
Automated Operation	The ARS features method development software to allow a sequence of operations lasting hours, days, and even weeks. This permits scheduled sampling of up to eight bioreactors 24 hours a day, 7 days a week. The ARS eliminates the labor intensive, manual sampling processes.
Precision Sampling	The precision design of the ARS minimizes the amount of sample required from the reactor. The ARS pulls and delivers samples with outstanding consistency to ensure accurate assay results.
Sample Prep Options	In addition to pulling the samples, the ARS can prepare the samples for further processing or analysis. Sample Prep Options: cell lysing (enzymatic or chemical); sample filtration; molecular weight separation in fractions; buffer exchange; sample dilution; and reagent addition.
On-line Analysis and Sample Collection	The ARS interfaces to nutrient monitors, HPLC systems, and cell counters as well as a fraction collector. When interfacing to analytical instruments the ARS delivers the individual sample to the instrument, triggers the analysis, and displays and logs the results. The ARS automatically cleans and prepares the transfer line for the next sample.
OPC Data Exchange	An optional OPC software package supports the collection of ARS status and process analytical data by a wide range of supervisory systems.
21 CFR Part 11 Compliance	An optional 21 CFR Part 11 software module is available.
Modular, Flexible Design	The ARS acquires and delivers samples from any input port (maximum of eight) to any output port (maximum of four). There is no manual configuration required. The design allows for maximum flexibility under software control.
Comprehensive System Support	The technical staff at Groton Biosystems has the experience and expertise to adapt the ARS to unique operating environments and procedures to your specific workflow.

ONLINE INSTRUMENT OPTIONS

Fraction Collector	The ARS delivers samples to sterile vials in a fraction collector for post run analysis. Using Peltier temperature control, the fraction collector maintains temperature in a range of 4°C to 37°C. The standard rack supports 30 vials. Custom racks are available to meet individual requirements.
Nutrient Monitors	The ARS supports nutrient monitors from several vendors such as YSI and Nova, that can provide analysis for glucose, lactate, glutamate, glutamine, sucrose, ammonium, potassium, ethanol, lactose, methanol, and chlorine.
HPLC Systems	HPLC is one of the most widely used analytical tools in the biotech industry. The ARS delivers sample to any HPLC system that supports a simple digital interface. Dependent on the operation, the ARS can function as the master controller or as a slave to the HPLC.
Cell Counters	The ARS interfaces to industry-standard cell counters, such as Vi-Cell and Cedex, to ensure rapid delivery of samples as well as the recording and handling of the results.

Specifications current January 2007 – subject to change without notice. ©Groton Biosystems LLC



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