



Tosoh Inc.

News and Information from Tosoh Bioscience, Inc.

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One Instrument - Three Configurations Which Analyzer is Just Right for Your Laboratory?



AIA-900
Loader Model



AIA-900
with 9 Tray Sorter



AIA-900
with 19 Tray Sorter

The latest addition to Tosoh's family of AIA immunoassay analyzers is available in three configurations, allowing you to choose a system that's *just right* for your laboratory workload.

AIA-900 AUTOMATED IMMUNOASSAY ANALYZER

Tosoh's next generation system, the AIA-900 Automated Immunoassay Analyzer, features three system configurations; the AIA-900, the AIA-900 with the 9 tray sorter, and the AIA-900 with the 19 tray sorter. The 3 configurations present customers with a unique opportunity to grow with their testing volumes.

Running 90 tests per hour, the analyzer's user-friendly operations provide extremely efficient immunoassay results. The AIA-900 utilizes the same Unit Dose Test Cup reagent technology as all Tosoh AIA immunoassay analyzers; and is being launched with the full AIA-Test Menu (Pending FDA Clearance for ST AIA-PACK PA).



AIA-900 with 9 tray sorter

On the back...

New Assays • Tech Talk • G8 Lot Change • G7 Beta-thalassemia

HbA1c Testing: The Importance of Being Accurate

It is becoming more important for laboratories to measure HbA1c on analyzers which have high levels of both accuracy and precision. In order to achieve these goals, analyzers should have low



G8 HPLC Analyzer

CVs and little to no bias. The Tosoh G8 analyzer leads the industry in precision with CVs of less than 2% and is utilized by physicians to monitor the long-term efficacy of glycemic control. A high quality HbA1c result is essential because it ultimately decides the course of treatment for a diabetic patient.

To help improve the quality of the HbA1c result the College of American Pathologists (CAP) has further tightened their proficiency grading criteria to $\pm 7\%$ for 2011 and the National Glycohemoglobin Standardization Program (NGSP) has tightened manufacturer certification criteria to $\pm 8\%$. These efforts are intended to urge manufacturers to improve the quality of the HbA1c and encourage laboratories to use analyzers that provide high quality results.

When laboratories participate in CAP surveys they are comparing the results obtained on their system to a target value. Since grading criteria is dropping each year, it will be more difficult for laboratories to pass their CAP survey if they are using an analyzer which gives them results outside of the acceptable grading limit. Tosoh is already ahead of the accuracy grading curve as demonstrated by current and future pass rates.

TOSOH BIOSCIENCE

TBI Tech Talk

TBI is pleased to introduce Carolyn Steinberg, Manager, Technical Support. Carolyn comes to Tosoh with several years of compliance experience. In our highly regulated industry, TBI, as well as other medical device companies are required to fully document all calls that are taken by either the Technical Support Group, or other technical personnel within the company.



Carolyn Steinberg
Technical Support Manager

Why does Technical Support ask so many questions?

Tosoh is required by law to investigate all calls that are received by the Technical Support call center to determine whether or not they are complaints. Obviously, if your instrument is not working properly, or if the reagents are misbehaving, you have a complaint. However, until the root cause of the problem is identified, there may or may not be a complaint as defined by the regulations.

In order to properly investigate and document each call, there are specific questions that need to be answered. The only way to get the answer is to ask the questions. Common questions include asking which lot numbers you are using for reagents, calibrators and controls. Other operational questions may be asked depending on what you are reporting at the time of the call.

We are aware that many of you are experienced in troubleshooting, and may have tried routine troubleshooting techniques prior to calling the Technical Support hotline. If that is the case, feel free to advise the person taking the call what you have already attempted in order to identify the root cause or resolve the issue. There will always be the basic questions (i.e. lot numbers), but this will allow everyone to focus on the issue at hand. We thank you for your understanding, and are committed to resolving all issues as quickly and efficiently as possible.

Updated G7 Beta-thalassemia Analysis Mode Chromatogram Interpretation Guide on CD is now available

The newest version of the G7 Beta-thalassemia Analysis Mode Chromatogram Interpretation Guide on CD has been updated to include more than 75 chromatograms and features hyperlinked Retention Time and Alphabetical indices for easy navigation.



The "Chromatogram Interpretation Guide" is intended to provide a brief overview of Hemoglobinopathies and Thalassemias. Unusual chromatography must be reviewed by a pathologist or their designee.

This new version is available on the G7 Docs on CD (Part Number 997011) from Customer Service or through your Sales Representative.



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TBI Launches DHEA-S

Tosoh Bioscience, Inc. introduces the ST AIA-PACK DHEA-S assay for use on Tosoh automated immunoassay analyzers including the AIA-360, AIA-600 II, AIA-1800, AIA-2000 and the new AIA-900.



Utilizing Tosoh's unit dose test cup reagent technology, ST AIA-PACK DHEA-S has an assay time of approximately 20 minutes. Single, unitized test cups require no pre-mixing, no pre-measuring and no on-board refrigeration. Dry reagent format ensures 90 day calibration stability for minimal waste and cost effective testing. Test cups are bar-coded for easy identification and inventory management.

ST AIA-PACK DHEA-S is designed for In Vitro Diagnostic Use Only for the quantitative measurement of dehydroepiandrosterone sulfate (DHEA-S) in human serum, heparinized or EDTA plasma.

DHEA-S is used as an aid in diagnosis of various disease of the adrenal cortex, and is especially useful for the differential diagnosis of Cushing's syndrome. Concentrations of DHEA-S are often measured, along with other hormones such as FSH, LH, prolactin, estrogen, and testosterone, to help diagnose polycystic ovarian syndrome (PCOS) and to help rule out other causes of infertility, amenorrhea, and hirsutism. DHEA-S levels may be ordered, along with other hormones, to investigate and diagnose the cause of virilization in young girls and early (precocious) puberty in young boys.

ST AIA-PACK DHEA-S has been designed for a variety of clinical diagnostic applications including: Pediatric/Children's Hospitals, Endocrinologist, GP, Reproductive Clinic, and Metabolic.

Coming Soon: ACTH (Pending FDA clearance)



Attention: Tosoh G8 Glycohemoglobin Analyzer Customers

Tosoh Bioscience, Inc. will be phasing in the new lot of 'D' reagents in Q2 2012. Please use the remaining inventory of 'B' reagents first. When your supplies of 'B' reagents have been depleted, replace the column and elution buffers with lot 'D' as reagent lots are not interchangeable.

Tosoh's Technical Support Hotline at 1-800-248-6764 is available to assist you with any questions or concerns you may have regarding this new information. Your Tosoh System Sales Specialist is also available to assist in inventory management.