December 2011

Important Product Information

ACE® and ACE Alera®

No Pretreatment Hemoglobin A1c

TO: All Alfa Wassermann Diagnostic Technologies (AWDT), LLC Customers
For ACE & ACE Alera Clinical Chemistry Systems

Dear Valued Customer:

Alfa Wassermann is pleased to inform you of the release of a new, no pretreatment HbA1c. This reagent has been certified by the National Glycohemoglobin Standardization Program (NGSP) and is traceable to the Diabetes Control and Complications Trial (DCCT). The new HbA1c assay eliminates pipetting, saving you time and improving precision, as well as an improved on-board stability (now 30 days).

Note: This is a new test and requires the addition of new parameters in the system.

After supplies of product numbers ACI-21 (HbA1c reagent) and S2-72 (HbA1c calibrator) are sold out, these products will be replaced by the new product numbers SA1044 (HbA1c reagent) and S2-86 (HbA1c calibrator). Pricing for both the reagent and calibrator will remain the same.

Please see below for very important product information regarding the new HbA1c calibrator, S2-86.

HbA1c Calibrator:

Please note that the new HbA1c assay (SA1044) can only be run with S2-86. Any remaining S2-72 calibrator cannot be used with the new HbA1c reagent and control.

The following page contains setup information. Should you have any additional questions or concerns, please contact our Customer Solution Center, Toll Free: (866) 419-ALFA (2532).

We are pleased to provide these product improvements; thank you for your continued support of Alfa Wassermann products.

Kind regards,

Lauren DiPrima
Marketing Manager
AUTOMATED PRETREATMENT HEMOGLOBIN A1C ASSAY OVERVIEW

The following instructions are intended to assist in proper performance of this test.

SETUP:
- Create the automated pretreatment Hemoglobin A1c assay under SETUP/BOTTLES and SETUP/TESTS according to the parameter sheet for PSTEP, THGB, HGBA1C, A1C and PHGB (as the offline test).
- Setup Normal and Abnormal Controls (SETUP/QUALITY CONTROL) with PHGB as the test name, entering means and standard deviation (SD) from the package insert.

PROCEDURE:
- Place both bottles of TOTAL HEMOGLOBIN REAGENT and each bottle of HbA1c AGGLUTINATOR REAGENT, HbA1c ANTIBODY REAGENT, DENATURANT and SALINE on the system.
- Request calibration for THGB and HGBA1C. This **DOES NOT** require the “PSTEP” test to be performed.
- To calibrate THGB and HGBA1C, add 2 drops of each calibrator to the properly labeled cups. HbA1c Calibrators (Reorder No. S2-86) are liquid and ready to use. Start the calibration run.
- To run controls, request the HbA1c NORMAL and ABNORMAL controls as patients. In each of the requisition, enter the test name “PSTEP”. **Note: This test does the automatic pretreatment dilution.** The HbA1c Controls (Reorder No. C2-86) are liquid and ready to use.
- Create a loadlist for the controls and run. Once the run is complete, each control will have “NEG” as the result for the “PSTEP” test. Go into each control requisition, delete the “PSTEP” test and insert the test “A1C”. The run will automatically resume. The “A1C” result is your reporting result.
- To store QC data in Levey - Jennings, manually enter the A1C results from the NORMAL/ABNORMAL CONTROL patient requisitions, as the PHGB QC results.
- Once controls are validated, process the patients in a separate loadlist. Process the patients in the same manner as the controls.

*Please note that due to the limited stability of a whole blood sample, the pre-treatment step must take place within 30 minutes after placement of a sample cup on board the instrument.*