Addendum

AU480 Chemistry Analyzer

CE IVD

B58153AA
November 2014
Manufactured by
Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821 U.S.A.

BECKMAN COULTER

Addendum
AU480 Chemistry Analyzer
PN B58153AA (November 2014)

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Original Instructions

Contents

Contents

CHAPTER 1

AU480 User's Guide Addendum

Closed and Open Test Numbers

A maximum of 120 test numbers are available on the AU480 with the following programming options.

Test Number	Programming Options	Description
1 to 90	Closed or Open	Customer specific
91 to 95	None	FSE troubleshooting
96 to 99	None	LIH, Na, K, Cl
100 to 102	None	Currently unavailable
103 to 120	Closed or Open	Customer specific

- Closed Test Numbers

  Beckman Coulter assay parameters are available on a validated CD that a Beckman Coulter Representative loads at installation. The Beckman Coulter assays are loaded onto closed test numbers. Closed test numbers offer the benefits of reducing manual programming time and possible programming errors, also high-quality reagents and support of Beckman Coulter.
- Open Test Numbers

  We continue to support the ability to add non-Beckman Coulter assays. Open test numbers are available for non-Beckman Coulter reagents. Open test numbers must be manually programmed.

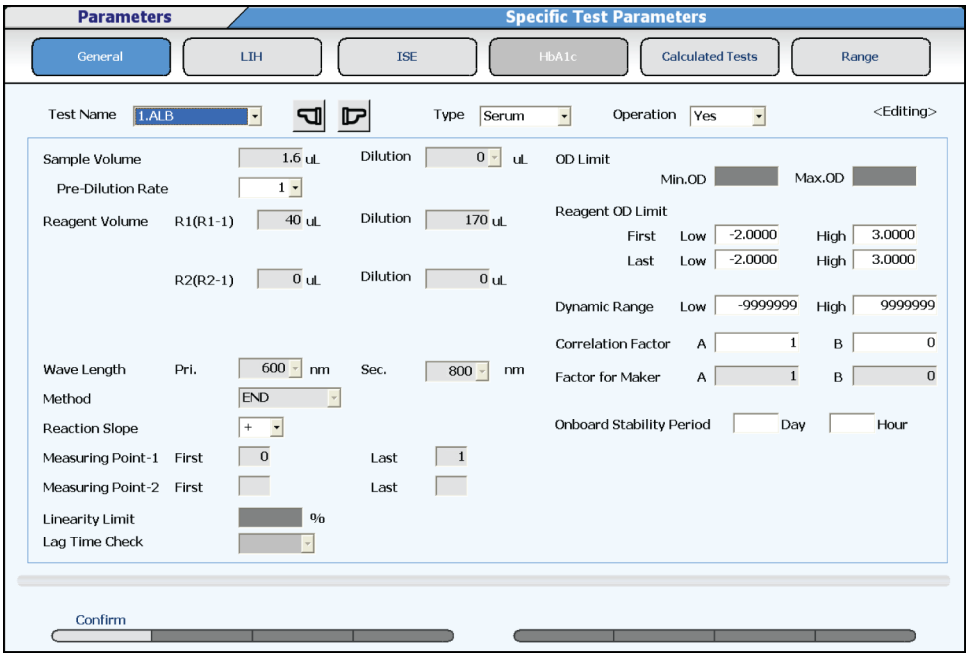
Some fields in **Specific Test Parameters** are not programmable for closed test numbers.

Specific Test Parameter > General

Test numbers 1 to 90 and 103 to 120 have been pre-programmed as closed or open to meet the specific requirements of your laboratory. The only difference in programming a closed or open test number is the programmable parameters in the **Specific Test Parameter** menu.

- Closed test numbers have fixed parameters (not programmable) and programmable parameters. After selecting **Edit (F1)**, the background color is grey for fixed parameters and white for programmable parameters.

Closed Test Number			
Fixed Parameters (Not Programmable)	Background after selecting **Edit (F1)**: Grey	Programmable Parameters	Background after selecting **Edit (F1)**: White
Sample Volume and Dilution		Pre-Dilution Rate	
Reagent Volume R1 (R1-1) and Dilution		Reaction Slope	
Reagent Volume R2 (R2-1) and Dilution		Reagent OD Limit First (Low and High) Reagent OD Limit Last (Low and High)	
Wavelength (Primary and Secondary)		Dynamic Range	
Method		Correlation Factor	
Measuring Point-1 (First and Last) Measuring Point-2 (First and Last)		Onboard Stability Period	



- All parameters are programmable for open test numbers.
- All other **Parameters** menus, including **Common Test Parameters** (Test Name, Long Name, Reagent ID, Alarm Shots, and Multi-Reagent Switch) are programmable for closed or open test numbers.

Caution When Saving or Loading Parameters

Follow all cautions in the AU480 User's Guide when using external media to save or load parameters. One CD-R or USB flash drive is required for saving parameters for each AU480.

The configuration of test numbers from 1 to 90 and 103 to 120 pre-programmed as closed or open can vary on each AU480 to meet specific laboratory requirements. The test number configuration for closed or open is saved with parameters on the external media. If the

parameters from one AU480 are loaded onto another AU480 with a different configuration of closed and open test numbers, the following message displays after 30 days when the AU480 is turned on. If the following System Start message displays, contact your Beckman Coulter Representative.

IVD Compliance

IVD Symbol

IVD This symbol is for “IN VITRO DIAGNOSTIC MEDICAL DEVICE.”

Electromagnetic Compatibility

- This AU480 IVD complies with the emission and immunity requirements described in this part of the EN/IEC 61326 series.
- This AU480 analyzer was designed and tested to CISPR 11 Class A for emissions. Take actions to mitigate the interference if emissions occur in the domestic environment.
- Beckman Coulter recommends evaluating the electromagnetic environment before operation of the AU480 analyzer.
- Do not use the AU480 analyzer in close proximity to sources of strong electromagnetic radiation. For example: Unshielded intentional RF sources, as these sources can interfere with correct operation.

Part Numbers

Reagent Tray Adapter

- MU812300 Adapter, 15 mL Bottle / 30 mL Position
- MU812400 Adapter, 15 mL Bottle / 60 mL Position
- MU998600 Adapter, 30 mL Bottle / 60 mL Position

Cleaning Solution for ISE

- AUH1019 ISE Cleaning Solution (US)
- 66039 Cleaning Solution (Outside US and Japan)
- MS0095 ISE 用クリーニング液 (Japan, for A&T Electrode)
- MS0329 洗浄液 (Japan, for AU Electrode)

ISE Reagent for Outside US and Japan

The "OE" has been obsoleted from the OE part numbers as listed in the AU480 User's Guide.

- OE66039 to 66039
- OE66313 to 66313
- OE66314 to 66314
- OE66315 to 66315
- OE66316 to 66316
- OE66317 to 66317
- OE66318 to 66318
- OE66319 to 66319
- OE66320 to 66320

Additional Cup Nested (Inserted) in Tube Available for Racks

The 1.0 mL Access 2 cup (81915) with 13 x 100 mm BD tubes (BD367962 / BD367886 / BD367815) is validated and available to use in racks. The required dead volume is 140 uL.

CAUTION

The 1.0 mL Access 2 cup (81915) with 13 x 100 mm BD tubes (BD367962 / BD367886 / BD367815) is not approved for use on the STAT table.

For other available validated tubes and cups, refer to the AU480 User's Guide, 6.1.1 Sample Cup, and Tube Preparation.

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