

Instructions for Downloading AU Application Documents (Version 3)

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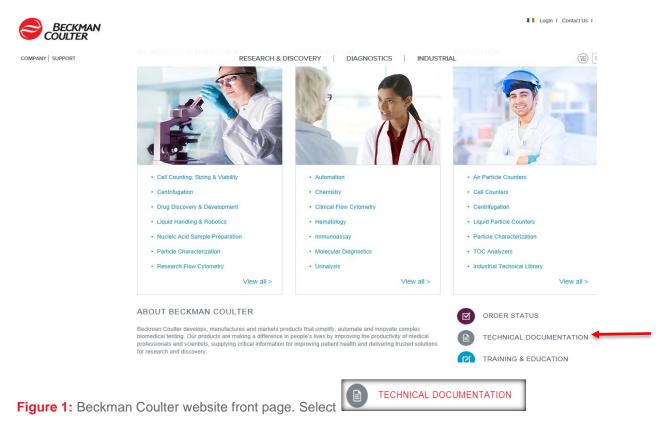
1 Introduction

The Beckman Coulter website contains information for all Beckman Coulter products. End users can access the website to search or download official AU documentation including Reagent Instructions For Use (IFUs) documents, Setting Sheets, Safety Data Sheets, Value Assignment Sheets etc. As documents are revised and approved, they are uploaded to the website, so that the latest information is available. Beckman Coulter recommends accessing the website to download documentation following system installation and at any time notification is provided via the *My Technical Documents* email notification tool. This ensures use of the most current version of all documents. This document does not apply to products not manufactured by Beckman Coulter.

If there is any issue with accessing any documents on the website please contact Beckman Coulter Customer Support at 1-800-854-3633 from the United States and Canada, or your local Beckman Coulter representative.

2 Access to the Website

You can access the Beckman Coulter website using the following web address <u>www.beckmancoulter.com</u>. All Beckman Coulter technical documentation is available in the **TECHNICAL DOCUMENTATION** section as shown in Figure 1.



3 My Technical Documents

To receive automatic email notification whenever a document is updated on the Beckman Coulter website, select the "register" link or *My Technical Documents* tab, both of which are indicated by red boxes on the screen capture below.

For information on *My Technical Documents*, select the links, My Technical Documents User Guide and My Technical Documents Virtual Tutorial, indicated by a red arrow in the image below.

Technical Documents Search	Introducing "My Technical Documents"
 Instructions for Use (IFUs) Customer Notifications Safety Data Sheets (SDS/MSDS) CE Declarations of Conformity To learn more about our products: Please click here for information regarding labeling in compliance with the Globally Harmonized System (GHS). Please click here for Bibliography or literature (brochures, data sheets, applications information and more). The availability of a product or software version in your country depends on the status of submissions to local regulatory agencies. For some Consumable IFUs, a product may not be available for use on all systems. Contact your Beckman Coulter representative if you have questions about the availability of a particular product. 	 Innovative electronic technical document notifications tool. Centralized location complete with your customized preferences. Instant updates on document releases and changes. To learn more click on: My Technical Documents User Guide My Technical Documents Virtual Tutorial To access My Technical Documents, please login or register.

Note: The *My Technical Documents* email notification tool is designed as a global notification system. Selection criteria for notifications are based on product and not geography. When receiving automatic email notifications, please pay attention to the documents that relate specifically to your region and laboratory. Refer to Table 1 or 2 within this document for the specific prefixes for each geographical area.

The Beckman Coulter website and automatic email notification offer an efficient method for keeping documentation updated. Additionally, changes made to Reagent IFUs are highlighted by change bars and detailed in the Revision History section of the IFU.

4 For US Markets

4.1 Downloading AU Reagent IFUs (including Reagent IFU Guide), Setting Sheets, Contamination Avoidance Parameters, Value Assignment Sheets

> To download all or a selected number of AU documents use the "Search by **Item/REF/Document Number**" under the Technical Documents tab, as shown below.

COMPANY SUPPORT questions about the availability of	RESEARCH & DIS	SCOVERY	DIAGNOSTICS	IND	USTRIAL	æ	Enter product, item number
Technical Documents	echnical Documents	Safety Data Sh	eets (SDS/MSDS)	Softwar	e Download		* Indicates required fields
Search By Product							
Search By Reagents/Ca	librators/Contro	ols					
Search By Item/REF/Do	cument Number						
Item/REF/Document Number	Document Category		Language				
BAOS	Consumable IFU/CIS	S/Setting Sheet	English	\checkmark	-		_
Search Search Tips	A	ll ssay Sheets					
Search By Lot Number	C	E Declaration of C	Conformity - Consur Conformity - Hardwa				
Search By Serial Numb	er C	ertificate of Comp ertificates of Anal	liance /sis	are			
Search By Keyword	C	onsumable IFU/C onsumable Inform ustomer Notificati	ation				
	In N O	strument IFU/Mar	ual d Testing Laborato	гу			

- > Refer to Table 1 on page 5 to determine the document type. Each IFU, Setting Sheet, Contamination Avoidance Parameters, etc., has an "Item/REF/Document Number" and associated "Document Category" entry details.
- > Enter the appropriate "Item/REF/Document Number"
- From the Document Category drop-down window, select the appropriate option identified from Table 1 below.
- > From "Language" drop-down window, select the required language
- > Select "Search"
- > From the "View" drop-down window, select "100 per page" to maximize the view/download
- > Select "Search" again to view all documents
- > Select all desired documents

Technical Document Search Results

First	Prev 1 Next Last	Document Category All								
	Document Name -	Document Type	Line/Series/Product	Document No.	Item/REF No.	<u>Lot</u> No.	<u>Serial</u> <u>No.</u>	<u>Release</u> <u>Date</u>	Product Use	Language
	ALANINE AMINOTRANSFERASE (ALT) (AU US) (.doc version)	Consumable IFU CIS Setting Sheet	AU Test Menu	BAOSR6X0707	<u>OSR6107</u>			12-19- 2016	IVD	English
	CALCIUM (ARSENAZO) (AU US) (.doc version)	Consumable IFU CIS Setting Sheet	AU Test Menu	BAOSR6X11709	<u>OSR60117</u> .			12-21- 2016	IVD	English

> Scroll to the bottom of the webpage and select the "Standard zip file (.zip)". Do not select the "Selfextracting zip file" option



- Enter the captcha phrase, typing both words with or without a space. There is no case sensitivity. Select "Download"
- > A new, blank window may open; however, navigate back to the original search page and use the dialog box that appears at the bottom of the screen, as shown below

			Save	
			Save as	
Star	Do you want to open or save _tmp_FDelXKkCxj_techDocs-1491474997379.zip (17.7 MB) from beckmancoulter.com?	Open Save 🔻	Save and open	2017 B

- > Select "Save As" from the "Save" drop-down window to save the file(s) to the appropriate location on your computer hard drive.
- > Download the search results for each page separately, as required by the system

<u>Note:</u> When Downloading Reagent IFUs, the Microsoft® Word versions of the Reagent IFUs (formally referred to as CLSI documents) are automatically included in the final.zip file

<u>Note:</u> An Index file is also downloaded within the .zip file which provides you with a list of all documents downloaded within the zip file. This index file lists documents in alphabetical order with the Document type, Document No., Item/REF No., and Release date.

Table 1: Search Criteria for US Market

Document Type	Item/REF/Document Number	Document Category
Reagent IFU Guide*	BAGuide	All or Consumable
		IFU/CIS/Setting Sheet
Complete Download	BA	Consumable
Reagent/Calibrator/Control IFU		IFU/CIS/Setting Sheet
Reagent IFU (.pdf and	BAOS	All or Consumable
Microsoft® Word)		IFU/CIS/Setting Sheet
Calibrator/Control IFU	BAOD	All or Consumable
		IFU/CIS/Setting Sheet
Setting Sheets	BAS	All or Consumable
		IFU/CIS/Setting Sheet
Contamination Avoidance	BACAP	Instrument IFU/Manual
Parameters		
Value Assignment Sheets	*_ML	All or Consumable
		IFU/CIS/Setting Sheet

*The Reagent IFU Guide, REF BAGuide contains supplementary information (IFU symbols, disclaimers and setting sheet translations) and also must be downloaded for laboratory use.

4.2 Downloading AU Safety Data Sheets (SDS)

> To download all or a selected number of AU SDS documents, Search by "**Part Number/REF**" under the Safety Data Sheets (SDS/MSDS) tab, as shown below.

Technical Documents					Enter product, Item number or keyword Q				
ecnnical Documents	My Technical Documents	afety Data Sheets (SDS/MSDS)	Software Download	* Indicates required fields					
Safety Data Sheet (SDS/MSDS) is designed to provide both workers and emergency personnel with the proper procedures for handling or working with a particular substance. DS/MSDS's include information such as physical data (melting point, boiling point, flash point etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective quipment, and spill/leak procedures.									
arch By	Search For OSR	Language English	Search Search Tip:	<u>s</u>					
Note: The presence of a Safety Data Sheet (SDS/MSDS) does not indicate commercial availability for a given product. Please contact Customer Support or your Beckman Coulter Representative for information regarding product availability.									
stributor and Emergency Contac	t Numbers								
tributor and Emergency Contac	t Numbers for Hemoccult products	1							

- > From the "Search By" drop-down window, select Part Number/REF.
- > Enter OSR
- > From the "Language" drop-down window, select the required language
- > Select "Search"
- > Select desired documents for downloading

Note: Select SDS documents specific to your laboratory/market based on AU part numbers.

Scroll to the bottom of the webpage and select the "Standard zip file (.zip)" from the "Select Zip File type" drop-down. Do not select the "Self-extracting zip file" option



- Enter the captcha phrase, typing both words with or without a space. There is no case sensitivity. Select "Download".
- > A new, blank window may open; however navigate back to the original search page and use the dialog box that appears at the bottom of the screen, as shown below.

		Save Save as	
Sta Do you want to open or save _tmp_FDelXKkCxj_techDocs-1491474997379.zip (17.7 MB) from beckmancoulter.com? Open Save T]	Save as	2017 8
Page 6			
or Beckman Coulter's worldwide office locations and phone numbers, please visit www.beckmancoulter.com/cor	atact	•	

- > Select "Save As" from the "Save" drop-down window, and save the file(s) to appropriate location on your computer hard drive.
- > Download the search results for each page separately, as required by the system

<u>Note:</u> An Index file is also downloaded within the .zip file which provides you with an list of all documents downloaded within the zip file. This index file lists documents in alphabetical order with the Description, Instrument and Part Numbers.

4.3 Downloading Microsoft® Word versions of the Reagent IFUs (formally referred to as CLSI documents) Individually

- > When Downloading Reagent IFUs, outlined in Section 4.1, the Microsoft® Word versions of the Reagent IFUs (formally referred to as CLSI documents) are automatically included in the final.zip file
- > Microsoft Word® versions /.doc versions of the Reagent IFUs can also be selected and saved individually
- > Refer to Section 4.1 Downloading AU IFUs (including Reagent IFU Guide), Setting Sheets, Contamination Avoidance Parameters, Value Assignment Sheets. Microsoft Word® / .doc versions of the Reagent IFUs appear for selection. Refer to the screen capture below and the red arrows that indicate available .doc versions

	First	Prev 1 Next Last				Document C	ategory			View 100	per page 🗸
		Document Name ▼	Document Type	Line/Series/Product	Document No.	Item/REF No.	<u>Lot</u> <u>No.</u>	<u>Serial</u> <u>No.</u>	<u>Release</u> <u>Date</u>	Product Use	Language
_		ALANINE AMINOTRANSFERASE (ALT) (AU US) (doc version)	Consumable IFU CIS Setting Sheet	AU Test Menu	BAOSR6X0707	<u>OSR6107</u>			12-19- 2016	IVD	English
_	9	CALCIUM (ARSENAZO) (AU US) (.doc version)	Consumable IFU CIS Setting Sheet	AU Test Menu	BAOSR6X11709	<u>OSR60117</u> . 			12-21- 2016	IVD	English
_	9	ANTI-STREPTOLYSIN O (ASO) (.doc version)	Consumable IFU CIS Setting Sheet	AU Test Menu	BAOSR6X9404	OSR6194			11-23- 2016	IVD	English
		ASPARTATE AMINOTRANSFERASE (AST) (AU US) (.doc version)	Consumable IFU CIS Setting Sheet	AU Test Menu	BAOSR6X0905	<u>OSR6109</u>			12-19- 2016	IVD	English

- > Select the desired ".doc version"
- > Scroll to the dialog box that appears at the bottom of the screen, as shown below

	PHENOBARBITAL BAOSR4D229 US (AU US) (.doc version)	Consumable IFU CIS Setting Sheet	AU Test Menu	BAOSR4D22902	OSR4D229		04-29- 2012	IVD	Englis	h
ſ		Consumable						_		
	Do you want to open or save ALT BAOSR6X07_B/	AOSR6X07-07_EN_U	JS.doc (96.5 KB) from	m beckmancoulter.	com?	Open	Save	•	Cancel	×

Select "Save As" from the "Save" drop-down window to save the file(s) to the appropriate location on your computer hard drive.

5 For Outside US Markets

5.1 Downloading AU Reagent IFUs (including Reagent IFU Guide), Setting Sheets, Contamination Avoidance Parameters, Value Assignment Sheets

> To download all or a selected number of AU documents use the "Search by **Item/REF/Document Number**" under the Technical Documents tab, as shown below

Technical Documents	My Technical Documents	Safety Data Sheets (SDS/MSDS)	Software Download	* Indicates required fields					
Search By Pro	duct								
Search By Rea	Search By Reagents/Calibrators/Controls								
Search By Iter	Search By Item/REF/Document Number								
Item/REF/Document Nun BLOS	ber Document Category Consumable IFU/CIS								
Search Search Tips		।। .ssay Sheets E Declaration of Conformity - Consur	nable						
Search By Lot	Number C	E Declaration of Conformity - Hardwa Certificate of Compliance							
Search By Ser	ial Number 💽	Certificates of Analysis Consumable IFU/CIS/Setting Sheet Consumable Information							
Search By Key	word C	Customer Notifications							
	0	lational Recognized Testing Laborato Other Scientific Literature	гу						

- Refer to Table 2 on page 10 to determine the document type. Each IFU, setting sheet, contamination avoidance parameters, etc., has an "Item/REF/Document Number" and associated "Document Category" entry details
- > Enter the appropriate "Item/REF/Document Number"
- From the "Document Category" drop-down window, select the appropriate option identified from Table 2
- > From "Language" drop-down window, select the required language
- > Select "Search"
- > From the "View" drop-down window, select "100 per page" to maximize the view/download
- > Select "Search" again to view all documents
- > Select all desired documents for downloading.

First Prev 1 Next Last Document Category All							View 100 per page		
Document Name▼	Document Type	Line/Series/Product	Document No.	Item/REF No.	Lot No.	<u>Serial No.</u>	<u>Release</u> Date	Product Use	Language
Creatine Kinase (CK NAC)	Consumable IFU CIS Setting Sheet	AU Test Menu	BLOSR6X7907	<u>OSR6179</u>			05-08-2017	IVD	English
			Page 8						

Technical Document Search Results

Scroll to the bottom of the webpage and select the "Standard zip file (.zip)" from the "Select Zip File" type drop-down window. Do not select the "Self-extracting zip file" option



- > Enter the captcha phrase, typing both words with or without a space. There is no case sensitivity. Select "Download".
- > A new, blank window may open; however navigate back to the original search page and use the dialog box that appears at the bottom of the screen, as shown below.

			Save	
Sta	Do you want to open or save _tmp_FDelXKkCxj_techDocs-1491474997379.zip (17.7 MB) from beckmancoulter.com?	Open Save 🔻	Save as Save and open	2017 E

- > Select "Save As" from the "Save" drop-down window, and save the file(s) to appropriate location on your computer hard drive.
- > Download the search results for each page separately, as required by the system

<u>Note:</u> An Index file is also downloaded within the .zip file which provides you with a list of all documents downloaded within the zip file. This index file lists documents in alphabetical order with the Document type, Document No., Item/REF No., and Release date.

Table 2: Search Criteria for Outside US Market

Document Type	Item/REF/Document Number	Document Category
Reagent IFU Guide*	BLGuide	All or Consumable
		IFU/CIS/Setting Sheet
Complete Download	BL	Consumable
Reagent/Calibrator/Control IFU		IFU/CIS/Setting Sheet
Reagent IFU	BLOS	All or Consumable
		IFU/CIS/Setting Sheet
Calibrator/Control IFU	BLOD	All or Consumable
Cleaning solution IFU		IFU/CIS/Setting Sheet
Setting Sheets	BS	All or Consumable
		IFU/CIS/Setting Sheet
Contamination Avoidance	BLCAP	Instrument IFU/Manual
Parameters		
Value Assignment Sheets	*_ML	All or Consumable
		IFU/CIS/Setting Sheet

*The Reagent IFU Guide, REF BLGuide contains supplementary information (IFU symbols, disclaimers and setting sheet translations) and also must be downloaded for laboratory use.

5.2 Downloading AU Safety Data Sheets (SDS)

> To download all or a selected number of AU SDS documents. Search by "**Part Number/REF**" under the Safety Data Sheets (SDS/MSDS) tab as shown below.

	RESEARCH & DISC	OVERY DIAGNOSTICS	INDUSTRIAL	(H)	Enter product, item number or keyword Q
Technical Documents	My Technical Documents	Safety Data Sheets (SDS/MSDS)	Software Download	* Indicates required fields	
A Safety Data Sheet (SDS/MSDS) is designed to provide both workers and emergency personnel with the proper procedures for handling or working with a particular substance. SDS/MSDS's include information such as physical data (melting point, boiling point, flash point etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment, and spill/leak procedures.					
Search By Part Number/REF	Search For OSR	English	Search Search Tips		
Note: The presence of a Safety Data Sheet (SDS/MSDS) does not indicate commercial availability for a given product. Please contact Customer Support or your Beckman Coulter Representative for information regarding product availability.					
Distributor and Emergency	Contact Numbers				
Distributor and Emergency	Contact Numbers for Hemoccult prod	lucts			

- > From the "Search By" drop-down window, select Part Number/REF.
- > Enter OSR
- > From the "Language" drop-down window, select the required language
- > Select "Search"
- > Select desired documents for downloading

Note: Select SDS documents specific to your laboratory/market based on AU part numbers

Scroll to the bottom of the webpage and select the "Standard zip file (.zip)" from the "Select Zip File type" drop-down window. Do not select the "Self-extracting zip file" option



- > Enter the captcha phrase, typing both words with or without a space. There is no case sensitivity. Select "Download".
- > A new, blank window may open; however navigate back to the original search page and use the dialog box that appears at the bottom of the screen, as shown below.

Sta	Do you want to open or save _tmp_FDelXKkCxj_techDocs-1491474997379.zip (17.7 MB) from beckmancoulter.com? Open Save 🔻		Save Save as Save and open	2017 E
	Page 11			
For Be	eckman Coulter's worldwide office locations and phone numbers, please visit www.beckmancoulter.com/cont	act		

- > Select "Save As" from the "Save" drop-down window, and save the file(s) to appropriate location on your computer hard drive.
- > Download the search results for each page separately, as required by the system

<u>Note:</u> An Index file is also downloaded within the .zip file which provides you with an list of all documents downloaded within the zip file. This index file lists documents in alphabetical order with the Description, Instrument and Part Numbers.

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