

# Instructions for Downloading AU Application Documents (Version 3)

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® Microsft Word is a registered trademark of Microsoft

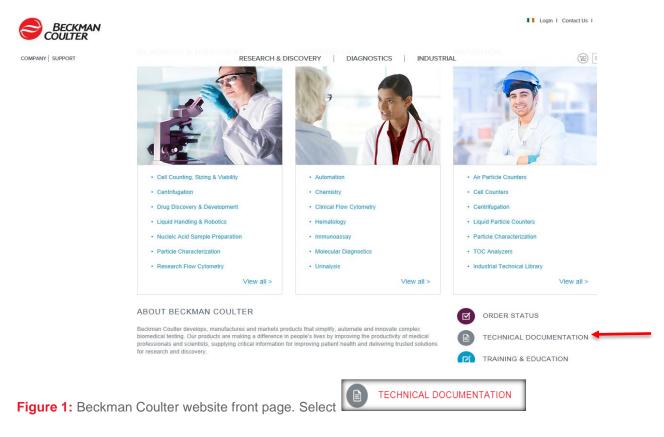
#### **1** Introduction

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"   |
|--|--|
| <ul> <li>Instructions for Use (IFUs)</li> <li>Customer Notifications</li> <li>Safety Data Sheets (SDS/MSDS)</li> <li>CE Declarations of Conformity</li> </ul> To learn more about our products: <ul> <li>Please click here for information regarding labeling in compliance with the Globally Harmonized System (GHS).</li> <li>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.</li> </ul> | <ul> <li>Innovative electronic technical document notifications tool.</li> <li>Centralized location complete with your customized preferences.</li> <li>Instant updates on document releases and changes.</li> </ul> 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<br>ssay Sheets   |  |              |            |   |                             |
| Search By Lot Number                                | C                  | E Declaration of C  | Conformity - Consur<br>Conformity - Hardwa |              |            |   |                             |
| Search By Serial Numb                               | er C               | ertificate of Comp<br>ertificates of Anal                 | liance<br>/sis                             | are          |            |   |                             |
| Search By Keyword                                   | C                  | onsumable IFU/C<br>onsumable Inform<br>ustomer Notificati | ation                                      |              |            |   |                             |
|   | In<br>N<br>O       | strument IFU/Mar  | ual<br>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<br>No.   | <u>Lot</u><br>No. | <u>Serial</u><br><u>No.</u> | <u>Release</u><br><u>Date</u> | Product<br>Use | Language |
|       | ALANINE AMINOTRANSFERASE (ALT) (AU US)<br>(.doc version) | Consumable<br>IFU CIS Setting<br>Sheet | AU Test Menu        | BAOSR6X0707  | <u>OSR6107</u>    |                   |                             | 12-19-<br>2016                | IVD            | English  |
|       | CALCIUM (ARSENAZO) (AU US)<br>(.doc version)             | Consumable<br>IFU CIS Setting<br>Sheet | AU Test Menu        | BAOSR6X11709 | <u>OSR60117</u> . |                   |                             | 12-21-<br>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<br>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.<br>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<br>quipment, and spill/leak procedures. |                                  |                              |                    |                             |   |  |  |  |  |
| arch By  | Search For<br>OSR                | Language<br>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<br>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<br>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<br>No.       | <u>Lot</u><br><u>No.</u> | <u>Serial</u><br><u>No.</u> | <u>Release</u><br><u>Date</u> | Product<br>Use | Language   |
| _ |       | ALANINE AMINOTRANSFERASE (ALT) (AU US)<br>(doc version)       | Consumable<br>IFU CIS Setting<br>Sheet | AU Test Menu        | BAOSR6X0707  | <u>OSR6107</u>        |                          |                             | 12-19-<br>2016                | IVD            | English    |
| _ | 9     | CALCIUM (ARSENAZO) (AU US)<br>(.doc version)                  | Consumable<br>IFU CIS Setting<br>Sheet | AU Test Menu        | BAOSR6X11709 | <u>OSR60117</u> .<br> |                          |                             | 12-21-<br>2016                | IVD            | English    |
| _ | 9     | ANTI-STREPTOLYSIN O (ASO)<br>(.doc version)                   | Consumable<br>IFU CIS Setting<br>Sheet | AU Test Menu        | BAOSR6X9404  | OSR6194               |                          |                             | 11-23-<br>2016                | IVD            | English    |
|   |       | ASPARTATE AMINOTRANSFERASE (AST) (AU<br>US)<br>(.doc version) | Consumable<br>IFU CIS Setting<br>Sheet | AU Test Menu        | BAOSR6X0905  | <u>OSR6109</u>        |                          |                             | 12-19-<br>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<br>IFU CIS Setting<br>Sheet | AU Test Menu          | BAOSR4D22902      | OSR4D229 |      | 04-29-<br>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<br>BLOS | ber Document Category Consumable IFU/CIS |  |                   |                             |  |  |  |  |  |
| Search Search Tips            |  | ।।<br>.ssay Sheets<br>E Declaration of Conformity - Consur                       | nable             |                             |  |  |  |  |  |
| Search By Lot                 | Number C                                 | E Declaration of Conformity - Hardwa<br>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<br>Other<br>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><br>Date | Product<br>Use | Language |
| Creatine Kinase (CK NAC)                     | Consumable<br>IFU CIS Setting<br>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<br>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.<br>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<br>equipment, and spill/leak procedures. |                                    |                               |                    |                             |   |
| Search By<br>Part Number/REF   | Search For<br>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<br>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<br>Save as<br>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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