# **INFORMATION BULLETIN**

Understanding Access immunoassay reagent certificates of analysis (CoA)

Beckman Coulter prepares Access immunoassay reagents from biological components, such as antibodies or antigens, as opposed to the chemical components used to prepare chemistry testing reagents (tests for cholesterol or glucose, for example). Biological components, among other factors, contribute to the occasional lot-to-lot variability that immunoassay reagents can demonstrate. This variability can cause slight differences in test results that your laboratory may observe when comparing two or more Access immunoassay reagent lots.

A new Access immunoassay reagent lot goes through a rigorous testing protocol before it is released to our customers. This protocol includes testing of quality control and/or patient samples for performance evaluation. Results from this testing are included on an Access immunoassay reagent Certificate of Analysis (CoA). The CoA presents representative data that demonstrates an Access immunoassay reagent lot meets its specified acceptance criteria.

This information bulletin provides you with instructions for accessing a CoA from the Beckman Coulter website. The data provided on each CoA may help you evaluate any observed variance between two or more Access immunoassay reagent lots.



Move healthcare forward.

#### Accessing a CoA from the Beckman Coulter website

- 1. Open the Beckman Coulter website: http://www.beckmancoulter.com.
- 2. Select **Diagnostics**.
- 3. Find **RESOURCES** on the right side of screen. Select **Technical Documents**.



4. On the **Technical Documents** tab, select the **Search By Lot Number** option.

Technical Documents	My Technical Documents
Search By Pro	duct
Market Segment* Please select one	Product Line*
Document Category All Search Search Tips	Language English
• Search By Rea	agents/Calibrators/Controls
Search By Iter	m/REF/Document Number
Search By Lot	Number
Search By Ser	ial Number
💽 Search By Key	word

- Enter the current reagent lot number in the Lot Number field. Select Search. The search results are displayed underneath the Technical Document Search Results heading.
- 6. Find the **Document Name** column. Select the document name underlined in red.

First	Prev 1	Next	Last	
	Documen	t Name	Document Type	Line/Series/Product
	ACCESS	<u>hTSH</u>	Certificates of Analysis	

- 7. Select **Open** on the menu bar at the bottom of the screen to display the CoA.
- 8. Repeat steps 5 7 to access the CoA for another reagent lot.

### **Comparing CoA results**

The following certificates present the release testing information for two different lots of reagent.

CERTIFICATE OF ANALYSIS Droduct: ACCESS* hTSHThis certificate is intended for use with COA: Hypersensitive TSH Reagent Pack Document No: 85-604184 MentificationThe following information describes this product tot.Manufacture33820 Mit Lot Number5308045 Expiration DateMit Pack Document No: 85-604184 Mit Lot NumberManufacture2016-02-08Mit Lot Number33820 Mit Lot NumberThe following table lists the control lots, stated ranges and results obtained during testing.The following table lists the control lots, stated range Mit Lot NumberManufacture2016-02-08The following table lists the control lots, stated range (ullimit) 1Mean (ullimit) Mean (ullimit) 1Manufacture2016-02Manufacture2017-07Manufacture2016-02 </th <th colspan="5">Current reagent lot number</th> <th colspan="5">New reagent lot number</th>	Current reagent lot number					New reagent lot number					
Itis certificate is intended for use with COA: Hypersensitive TSH Reagent Pack Document No: 95-004184         This certificate is intended for use with COA: Hypersensitive TSH Reagent Pack Document No: 95-004184           Identification         The following information describes this product bt.         This certificate is intended for use with COA: Hypersensitive TSH Reagent Pack Document No: 95-004184           Kit let Number         53820         Kit Lot Number         53824           Expiration Date         2017-01-31         Date of Manufacture         2016-02-06           The following table lists the control lots, stated ranges and results obtained during testing.         The following table lists the control lots, stated range and results obtained during testing.         The following table lists the control lots, stated range (jult 1         Mean (jult/mi)         Mean (jult/mi)         The following table lists the control lots, stated range (jult 1         Mean (jult/mi)         This certificate is intended for use with COA: Hypersensitive TSH Reagent Pack Add Pack Pack Pack Pack Pack Pack Pack Pack	CERTIFICATE OF ANALYSIS Product: ACCESS <sup>®</sup> hTSH					CERTIFICATE OF ANALYSIS Product: ACCESS <sup>®</sup> hTSH					
Identification         The following information describes this product lot.           Kit tern Number         33820           Kit tern Number         538845           Expiration Date         2017-01-31           Date of Manufacture         2018-02-08           The following table lists the control lots, stated ranges and results obtained during testing.           Level         QC Lot         Range (µUlmi)         Mean (µUlmi)           1         40291         0.43 - 0.59         0.44           2         40292         4.65 - 6.41         5.64           3         40293         2.84 + 39.32         34.45           Level         QC Lot         Range (µUlmi)         Mean (µUlmi)           1         40881         0.58 - 0.76         0.04           2         40882         2.22.7 - 30.75         2.7.77           Level         Patient Lot         Range (µUlmi)         Mean (µUlmi)           1         520015         0.45 - 0.61         0.53           2         520016         2.89 - 4.01         3.52           3         520017         12.89 - 1.7.81         16.29           4         520018         2.89 - 40.59         3.859           5         520019	This certifica	te is intended for use wit	h COA: Hypersensitive TSH Reagent Pa	ack Document No.: 95-904164	This certifica	This certificate is intended for use with COA: Hypersensitive TSH Reagent Pack Document No.: 95-904164					
Kit Item Number       33820         Kit Lem Number       538845         Expiration Date       2017-01-31         Date of Manufacture       2018-02-08         The following table lists the control lots, stated ranges and results obtained during testing.         Image: Colspan="2">Image: Colspan="2">The following table lists the control lots, stated ranges and results obtained during testing.         Image: Colspan="2">Image: Colspan="2">The following table lists the control lots, stated ranges and results obtained during testing.         Image: Colspan="2">Image: Colspan="2">The following table lists the control lots, stated ranges and results obtained during testing.         Image: Colspan="2">Image: Colspan="2">The following table lists the control lots, stated range: Colspan="2">Colspan="2">Stated range: Colspan="2">Colspan="2""Colspan="2""Colspan="2""Colspan=""2""Colspan=""2""Colspan=""2" <th>Identification</th> <th>The following informa</th> <th>tion describes this product lot.</th> <th></th> <th>Identification</th> <th colspan="5">Identification The following information describes this product lot.</th>	Identification	The following informa	tion describes this product lot.		Identification	Identification The following information describes this product lot.					
Initial Number     53645       Kit Lot Number     53645       Expiration Date     2017-01-31       Date of Manufacture     2016-02-06       Kit Lot Number       Status       The following table lists the control lots, stated ranges and results obtained during testing.       The following table lists the control lots, stated ranges and results obtained during testing.       Level     QC Lot     Range (µU(m))     Mean (µU(m))       1     40281     0.56 - 0.76     0.64       2     40282     4.65 - 0.41     5.64       3     40283     2.84 - 9.9.32     3.445       Level     QC Lot     Range (µU(m))     Mean (µU(m))       1     40081     0.56 - 0.76     0.64       2     40082     4.29 - 5.93     5.20       3     40283     2.24 - 2.9.2       3     40283     2.22 - 7.90       3     40283     2.22 - 5.93       3     40281     0.56 - 0.77       2     40882     2.29 - 5.93       3     40283     0.26 - 0.77       2     40882     2.29 - 5.93       3     40281     0.58 - 0.77       2     40882     2.29 - 5.93       3     2.20115     0.45 - 0.61 </th <th></th> <th>Kit Itom Num</th> <th>or 22020</th> <th></th> <th></th> <th>Kit Ite</th> <th>m Number</th> <th>33820</th> <th></th>		Kit Itom Num	or 22020			Kit Ite	m Number	33820			
Int Lot Number     0.0649       Expiration Date     2017-01-31       Date of Manufacture     2016-02-08       The following table lists the control lots, stated ranges and results obtained during testing.       Image: Number of Manufacture     QC Lot     Range (aUM)       1     40291     0.43 - 0.59     0.49       2     40292     4.65 - 6.41     5.84       3     40203     22.4.65 - 6.41     5.84       1     40291     0.59 - 0.76     0.64       2     40882     4.29 - 5.93     5.20       3     40083     22.27 - 30.75     27.777       2     40882     2.29 - 5.93     5.20       3     40083     2.22 - 5.03     3.20       1     520015     0.45 - 0.61     0.58       2     520016     2.89 - 4.01     3.82       3     520017     1.82.97       4     520018     2.93.9 - 40.59     36.59       5     520019     52.90 - 73.00     0.56.2		Kit Let North				Kit Lot Number		536848			
Expiration Date     2017-01-31     Date of Manufacture     2016-02-06       Date of Manufacture     2016-02-06       The following table lists the control lots, stated ranges and results obtained during testing.       Level     QC Lot     Range (alUm)     Mean (alUm)       1     40291     0.43 - 0.59     0.49       2     40292     4.65 - 6.41     5.64       3     40293     28.48 - 9.9.2     34.45       Level     QC Lot     Range (alUm)       1     40881     0.56 - 0.76     0.64       2     40882     4.22 - 5.93     5.20       3     40882     2.22 7 - 30.75     2.77.77       Level     Patient Lot     Range (alUm)       1     520015     0.45 - 0.61       2     520016     2.89 - 4.01       3     520017     12.89 - 1.78       4     520018     20.39 - 40.59       5     520019     52.90 - 73.00		Kit Lot Numb	er 030840			Expiration Data		2017-03-31			
Level         QC Lot         Range (µUlmi)         Mean (µUlmi)         Mean (µUlmi)         Level         QC Lot         Range (µUlmi)         Range (µUlmi)		Expiration Da	te 2017-01-31			Expiration Date		2016-02-01			
The following table lists the control lots, stated ranges and results obtained during testing.         The following table lists the control lots, stated range           Level         QC Lot         Range (JUUni)         Mean (JUUni)         Mean (JUUni)         1         400201         0.43 - 0.59         0.49         1         400201         0.43 - 0.59         0.49         1         400201         0.43 - 0.59         0.49         1         400201         0.43 - 0.59         0.49         1         400201         0.43 - 0.59         0.49         1         2         400202         4.65 - 6.41         5.64         3         400203         28.48 - 39.32         3.445         3         400203         28.48 - 39.32         3.445         3         400203         28.48 - 39.32         20.445         3         400203         28.48 - 39.32         20.64         3         40081         0.56 - 0.7         2         40882         4.29 - 5.9         3         400883         0.22 - 7.07         2         40882         4.29 - 5.9         3         400883         0.22 - 7.07         2         40882         4.29 - 5.9         3         400883         2.22 - 7.03         3         400883         2.22 - 7.03         3         400883         2.22 - 7.03         3         2.20115		Date of Manufa	ture 2016-02-06			Date of	Manufacture	2010-03-18			
The following table lists the control lots, stated ranges and results obtained during testing.         The following table lists the control lots, stated range (all limit)           Level         QC Lot         Range (all limit)         Mean (all limit)         1         40291         0.43 - 0.59         0.49         1         40291         0.43 - 0.59         0.49         1         40291         0.43 - 0.59         0.49         1         40291         0.43 - 0.59         0.49         1         40291         0.43 - 0.59         0.49         2         40292         0.46 - 0.51         2         40291         0.48 - 0.59         2         40291         0.48 - 0.59         2         40291         0.48 - 0.59         2         40291         0.48 - 0.59         2         40291         0.48 - 0.59         2         40291         0.48 - 0.59         2         40291         0.48 - 0.59         2         40291         0.48 - 0.59         2         40291         0.48 - 0.59         2         40291         0.48 - 0.59         2         40291         0.48 - 0.59         2         40881         2.22 - 5.03         3         40883         2.22 - 5.03         3         40883         2.22 - 5.03         3         40883         2.22 - 5.03         3         40883         2.22 - 5.03											
Level         QC Lot         Range (µIUmi)         Mean (µIUmi)         Level         QC Lot         Range (µIU           1         40291         0.43 - 0.59         0.49         1         40291         0.43 - 0.5           2         40292         4.65 - 6.41         5.64         2         40292         4.66 - 6.4           3         40293         2.44 - 9.83         2         3.44 - 5         3         40292         2.68 - 9.76           Level         QC Lot         Range (µIUmi)         Mean (µIUmi)         1         40081         0.56 - 0.7           1         40881         0.56 - 0.76         0.64         1         40881         0.56 - 0.7           2         40882         4.29 - 5.63         5.20         3         40883         22.27 - 30.7           2         40882         2.27 - 30.75         27.77         3         40883         22.27 - 30.7           Level         Patient Lot         Range (µIUmi)         Mean (µIU/mi)         Level         Patient Lot         Range (µIU           1         520015         0.46 - 0.61         0.53         1         520015         0.46 - 0.6           2         520016         2.89 - 40.1         3.52         2		The following table list	s the control lots, stated ranges and res	ults obtained during testing.		The following	table lists the	e control lots, stated ranges and re	sults obtained during testing.		
1         40201         0.43 - 0.59         0.49           2         40202         4.65 - 6.41         5.64         2         40202         4.65 - 6.4           3         40203         28.48 - 39.32         34.45         2         40202         4.65 - 6.4           4         0.49         3.445         2         40202         4.65 - 6.4         3           Level         QC Lot         Range (µIUm)         Mean (µUm)         Mean (µUm)         1         40881         0.56 - 0.7           2         40882         4.29 - 5.93         5.20         2         40883         0.22.7 - 30.75         27.77           2         40882         4.29 - 5.93         5.20         3         40883         0.22.27 - 30.75         27.77           Level         Patient Lot         Range (µUm)         Mean (µUm)         Mean (µUm)         Level         Patient Lot         Range (µU           1         520015         0.45 - 0.81         0.53         1         520015         0.45 - 0.8           2         520016         2.89 - 4.01         3.52         2         520017         12.89 - 17.81         16.29           3         520017         12.89 - 17.81         16.29         3 <th></th> <th>Level G</th> <th>C Lot Range (ulU/ml)</th> <th>Mean (ulU/ml)</th> <th></th> <th>Level</th> <th>QC Lo</th> <th>ot Range (µIU/mI)</th> <th>Mean (µlU/ml)</th>		Level G	C Lot Range (ulU/ml)	Mean (ulU/ml)		Level	QC Lo	ot Range (µIU/mI)	Mean (µlU/ml)		
2         40292         4.65 - 6.41         5.64           3         40293         28.48 - 39.32         34.45           Level         QC Lot         Range (ullum)         Mean (ullum)           1         40081         0.56 - 0.78         0.64           2         40082         42.9 - 5.93         5.20           2         40882         42.9 - 5.93         5.20           3         40083         22.7 - 30.75         2.777           Level         Patient Lot         Range (ullum)         Mean (ullum)           1         520015         0.45 - 0.61         0.53           2         520016         2.49 - 0.01         3.52           2         520016         2.89 - 4.01         3.52           2         520017         12.89 - 17.81         16.29           3         520019         52.90 - 73.00         65.62		1 4	0291 0.43 - 0.59	0.49		1	40291	1 0.43 - 0.59	0.49		
3         40293         28.48 - 39.32         34.45           Level         QC Lot         Range (µU)         Mean (µU/m)         Level         QC Lot         Range (µU/m)           1         40981         0.56 - 0.76         0.64         1         40981         0.56 - 0.78           2         40882         4.29 - 5.93         5.20         2         40982         4.29 - 5.9           3         40883         22.27 - 30.7         2.7777         3         3         40883         22.27 - 30.7           Level         Patient Lot         Range (µU/m)         Mean (µU/m)         Level         Patient Lot         Range (µU/m)           1         520015         0.45 - 0.61         0.53         2         2.82015         0.45 - 0.61           2         520016         2.89 - 4.01         3.62         2         520010         2.80 - 4.0           3         520017         12.89 - 1.78         16.29         3         520017         2.89.40           4         520018         2.939 - 40.59         36.59         5         520019         52.00 - 73.           5         520019         52.00 - 73.00         65.62         5         520019         52.00 - 73.		2 4	0292 4.65 - 6.41	5.64		2	40292	2 4.65 - 6.41	5.24		
Level         QC Lot         Range (µIUmi)         Mean (µIUmi)         Level         QC Lot         Range (µIU           1         40881         0.56 - 0.76         0.64         1         40881         0.56 - 0.7           2         40882         4.29 - 5.03         5.20         2         40883         22.27 - 30.7           2         40882         2.2.7 - 30.75         27.77         3         40883         22.27 - 30.7           Level         Patient Lot         Range (µIUmi)         Mean (µIUmi)         Level         Patient Lot         Range (µIU           1         520016         0.45 - 0.61         0.53         1         520015         0.46 - 0.6           2         5         520017         12.89 - 17.81         16.29         3         520017         12.89 - 17.81           4         520018         23.39 - 40.59         36.59         3         5         520019         52.90 - 73.00         55         520019         52.90 - 73.00         55.92         5         5         520019         52.90 - 73.00         5		3 4	0293 28.48 - 39.32	34.45		3	40293	3 28.48 - 39.32	32.04		
1         40881         0.56 - 0.76         0.64           2         40882         4.29 - 5.83         5.20           3         40882         2.2.7 - 30.75         2.7.77           Level         Patient Lot         Range (µUimi)         Mean (µUimi)           1         520015         0.45 - 0.61         0.53           2         520016         2.49 - 0.61         0.63           2         520016         2.89 - 4.01         3.52           2         520016         2.89 - 4.01         3.52           3         520017         12.89 - 1.7.81         16.29           4         520018         20.39 - 40.59         36.59           5         520019         52.90 - 73.00         05.62		Level G	C Lot Range (ulU/ml)	Mean (µIU/ml)		Level	QC Lo	ot Range (µIU/mI)	Mean (µlU/ml)		
2         40882         4.29-5.93         5.20         2         40882         4.29-5.93           3         40883         22.27-30.75         27.77         3         40883         22.27-30.75           Level         Patient Lot         Range (µIUmi)         Mean (µIUmi)         Level         Patient Lot         Range (µIUmi)           1         520015         0.45-0.61         0.63         2         520016         2.89-4.01           2         520017         12.89-17.81         16.29         2         520016         2.89-4.01           3         520017         12.89-17.81         16.29         3         520017         12.89-17.           4         520018         29.39-40.59         38.59         4         520018         20.93-40.7           5         520019         52.90-73.06         85.92         5         520019         52.00-73.7		1 4	0881 0.56 - 0.76	0.64		1	40881	1 0.56 - 0.76	0.65		
3         40883         22.27 - 30.75         27.77           Level         Patient Lot         Range (µU(m))         Mean (µU(m))         Mean (µU(m))         Level         Patient Lot         Range (µU           1         520015         0.45 - 0.61         0.53         1         520015         0.45 - 0.6         2         520016         2.89 - 401         3.52           3         520017         12.89 - 17.81         18.29         3         520017         12.89 - 17.           4         520018         29.39 - 40.59         36.59         3         520019         52.90 - 73.06         65.92		2 4	0882 4.29 - 5.93	5.20		2	40882	2 4.29 - 5.93	4.95		
Level         Patient Lot         Range (µIUmi)         Mean (µIUmi)         Level         Patient Lot         Range (µIU           1         552015         0.45 - 0.61         0.53         1         520015         0.45 - 0.61           2         520016         2.80 - 4.01         3.52         2         520016         2.89 - 4.01         3.52           3         520017         12.89 - 17.81         16.29         3         520017         12.89 - 17.41           4         550018         23.39 - 40.59         38.59         3         520018         22.93 - 40.59           5         520019         52.90 - 73.00         05.92         5         520019         52.90 - 73.00		3 4	0883 22.27 - 30.75	27.77		3	40883	3 22.27 - 30.75	26.51		
1         520015         0.44 - 0.61         0.53         1         520015         0.45 - 0.6           2         520016         2.89 - 4.01         3.52         3         520017         12.89 - 17.81         16.29         3         520017         12.89 - 17.81         16.29         3         520018         20.39 - 40.59         36.59         4         520018         20.39 - 40.59 <th></th> <th>Level Pat</th> <th>ent Lot Range (ulU/ml)</th> <th>Mean (µIU/ml)</th> <th></th> <th>Level</th> <th>Patient</th> <th>Lot Range (µIU/mI)</th> <th>Mean (µlU/ml)</th>		Level Pat	ent Lot Range (ulU/ml)	Mean (µIU/ml)		Level	Patient	Lot Range (µIU/mI)	Mean (µlU/ml)		
2         52016         2.89-4.01         3.52         2         520016         2.89-4.0           3         520017         12.89-17.81         18.29         3         522017         12.89-17.           4         520018         29.39-40.59         38.59         4         520018         29.39-40.           5         520019         52.90-73.06         85.92         -         5         520019         52.00-73.		1 5	9015 045-061	0.53		1	52901	5 0.45 - 0.61	0.51		
3         52017         12.89-17.81         18.29         3         52017         12.80-17.           4         52018         23.39-40.59         36.59         4         52018         23.39-40.59           5         52019         52.90-73.00         65.92         5         520019         52.90-73.00		2 5	29016 2.89 - 4.01	3.52		2	52901	6 2.89 - 4.01	3.44		
4         528018         29.39 - 40.59         36.59         4         528018         29.39 - 40.55           5         529019         52.90 - 73.06         65.92         5         529019         52.90 - 73.06		3 5	29017 12.89 - 17.81	16.29		3	52901	7 12.89 - 17.81	15.31		
5 529019 52.90 - 73.06 65.92 5 529019 52.90 - 73.06 -		4 5	29018 29.39 - 40.59	36.59		4	52901	8 29.39 - 40.59	34.35		
		5 5	9019 52.90 - 73.06	65.92		5	52901	9 52.90 - 73.06	64.29		
Other Results The following is a list of additional parameters tested for this product. Other Results The following is a list of additional parameters tested	Other Results	The following is a list	of additional parameters tested for this	product.	Other Results	The following	g is a list of a	dditional parameters tested for this	product.		
Parameter Specification Result Parameter Specificatio		Parameter	Specification	Result		Parameter		Specification	Result		
Analytical Sensitivity = 0.003 0.001 Analytical Sensitivity </= 0.003</td <td></td> <td>Analytical Sensitivity</td> <td><!--= 0.003</td--><td>0.001</td><th></th><td>Analytical Ser</td><td>nsitivity</td><td><!--= 0.003</td--><td>0.002</td></td></td>		Analytical Sensitivity	= 0.003</td <td>0.001</td> <th></th> <td>Analytical Ser</td> <td>nsitivity</td> <td><!--= 0.003</td--><td>0.002</td></td>	0.001		Analytical Ser	nsitivity	= 0.003</td <td>0.002</td>	0.002		
Label Information Correct ID and expiration is listed on Accept Label Information the product label		Label Information	Correct ID and expiration is listed o the product label	n Accept		Label Information Correct ID and exp the products		Correct ID and expiration is listed the product label	on Accept		

**QC lot:** this is a vendor lot of quality control material.

Patient lot: this is a Beckman Coulter lot of patient sample.

Range: this is the stated range for Beckman Coulter's control testing.

**Mean:** this is the mean of the observed values from Beckman Coulter's control testing.

**Note:** the lot numbers of quality controls and patient samples listed on the CoA occasionally change. If this occurs it is not possible to perform a lot-to-lot comparison for the controls or samples.

# Calculating the expected percent difference between a current and a new reagent lot

Use the following equation to calculate the percent (%) difference between two reagent lots:

New Lot Mean - Current Lot Meanx 100 = % Difference Between Two Reagent LotsCurrent Lot Mean

From the CoA example on page #3, the % difference for QC lot 40882 =

### Evaluating the percent difference between a current and a new reagent lot

An immunoassay reagent CoA certifies that the reagent lot meets its specified acceptance criteria. The results presented on each CoA are intended as guidelines for evaluating reagent lot-to-lot performance. **However, the percent difference between reagent lots that you observe in your laboratory may vary from the results reported by Beckman Coulter.** Slight differences are expected because of factors such as sample matrix, laboratory environment, and the immunoassay system in use.

For information about troubleshooting test results, consult the assay troubleshooting sections in your immunoassay system *Operator's Guide* and *Reference Manual*.

## **Contact information**

For more information or for any technical assistance, contact Beckman Coulter technical support.

- > From our website: http://www.beckmancoulter.com
- > By phone in the United States and Canada, call 1-800-854-3633; select option #1, then option #3
- > Outside the United States and Canada, contact your local Beckman Coulter representative

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