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.

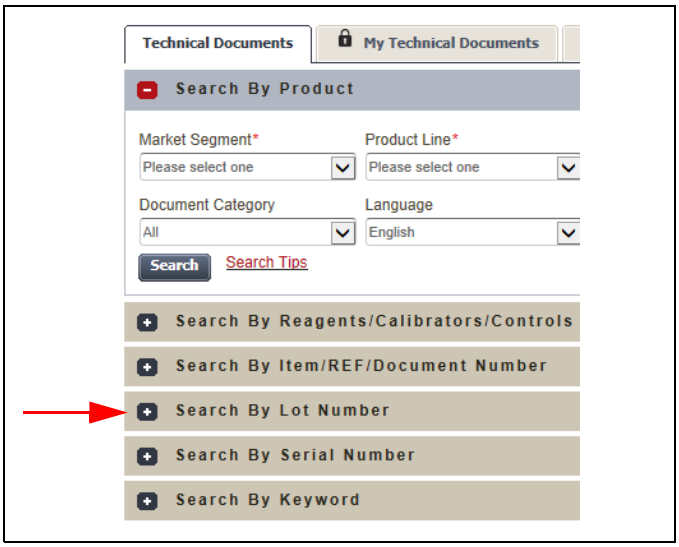
A new Access immunoassay reagent lot goes through a rigorous testing protocol before it is released to our customers. This protocol includes testing of quality control and/or patient samples for performance evaluation. Results from this testing are included on an Access immunoassay reagent Certificate 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.

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**.

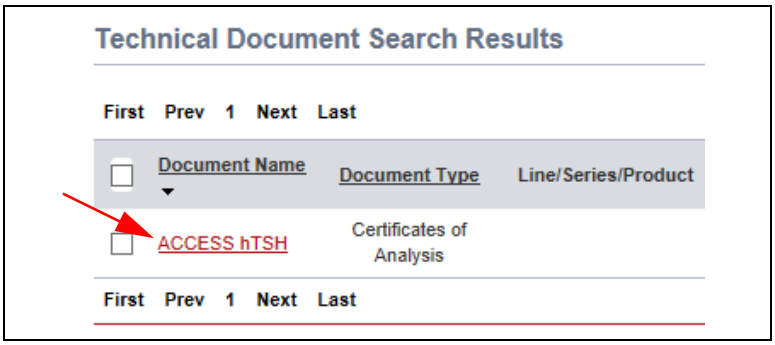
4. On the **Technical Documents** tab, select the **Search By Lot Number** option.



5. 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.



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.

Current reagent lot number

CERTIFICATE OF ANALYSIS
Product: ACCESS® hTSH

This certificate is intended for use with COA: Hypersensitive TSH Reagent Pack Document No.: 95-904164

Identification The following information describes this product lot.

Kit Item Number	33820
Kit Lot Number	536845
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.

Level	QC Lot	Range (µIU/ml)	Mean (µIU/ml)
1	40291	0.43 – 0.59	0.49
2	40292	4.65 – 6.41	5.64
3	40293	28.48 – 39.32	34.45
Level	**QC Lot**	**Range (µIU/ml)**	**Mean (µIU/ml)**
1	40881	0.56 – 0.76	0.64
2	40882	4.29 – 5.93	5.20
3	40883	22.27 – 30.75	27.77
Level	**Patient Lot**	**Range (µIU/ml)**	**Mean (µIU/ml)**
1	529015	0.45 – 0.61	0.53
2	529016	2.89 – 4.01	3.52
3	529017	12.89 – 17.81	16.29
4	529018	29.39 – 40.59	36.59
5	529019	52.90 – 73.06	65.92

Other Results The following is a list of additional parameters tested for this product.

Parameter	Specification	Result
Analytical Sensitivity	</= 0.003	0.001
Label Information	Correct ID and expiration is listed on the product label	Accept

New reagent lot number

CERTIFICATE OF ANALYSIS
Product: ACCESS® hTSH

This certificate is intended for use with COA: Hypersensitive TSH Reagent Pack Document No.: 95-904164

Identification The following information describes this product lot.

Kit Item Number	33820
Kit Lot Number	536848
Expiration Date	2017-03-31
Date of Manufacture	2016-03-19

The following table lists the control lots, stated ranges and results obtained during testing.

Level	QC Lot	Range (µIU/ml)	Mean (µIU/ml)
1	40291	0.43 - 0.59	0.49
2	40292	4.65 - 6.41	5.24
3	40293	28.48 - 39.32	32.04
Level	**QC Lot**	**Range (µIU/ml)**	**Mean (µIU/ml)**
1	40881	0.56 - 0.76	0.65
2	40882	4.29 - 5.93	4.95
3	40883	22.27 - 30.75	26.51
Level	**Patient Lot**	**Range (µIU/ml)**	**Mean (µIU/ml)**
1	529015	0.45 - 0.61	0.51
2	529016	2.89 - 4.01	3.44
3	529017	12.89 - 17.81	15.31
4	529018	29.39 - 40.59	34.35
5	529019	52.90 - 73.06	64.29

Other Results The following is a list of additional parameters tested for this product.

Parameter	Specification	Result
Analytical Sensitivity	</= 0.003	0.002
Label Information	Correct ID and expiration is listed on the product label	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:

$$\frac{\text{New Lot Mean - Current Lot Mean}}{\text{Current Lot Mean}} \times 100 = \% \text{ Difference Between Two Reagent Lots}$$

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

$$\frac{4.95 - 5.20}{5.20} \times 100 = -4.81\%$$

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

For Beckman Coulter's worldwide office locations and phone numbers, please visit www.beckmancoulter.com/contact

2016-2506