

Customer Bulletin

January 04, 2013

**MULTIGENT[®] Benzodiazepines Assay
List Number 3L39-20
Notification of Sensitivity Change**

This letter contains important information regarding the MULTIGENT Benzodiazepines reagent, List Number 3L39-20. The following reagent lots have shown an increase in sensitivity to certain cross reactant benzodiazepine compounds, particularly Lorazepam and/or Lormetazepam, relative to the concentration values reported in the Specificity section of the reagent package insert:

Lot Number	Expiration Date
13434M500	31 May 2013
16082M500	31 Oct 2013
20167M500	31 Jan 2014
22147M500	31 Mar 2014

Please review the information below carefully and follow the necessary actions.

BACKGROUND:

Customers have reported an increase in the recovery of Bio-Rad Quality Control (QC) containing Lormetazepam when used with MULTIGENT Benzodiazepines lot 13434M500. Polyclonal antibody based immunoassays that measure class compounds such as benzodiazepines will exhibit lot to lot variation with regards to sensitivity to various compounds within the class. The release testing for the above lots includes verification that the assay detects all the appropriate non-glucuronide benzodiazepine class members at the package insert concentration. We are in the process of implementing additional modes of control for future lots.

Data:

Additional testing included in the table below lists the lowest concentrations of various benzodiazepines that yield positive qualitative results for the four relevant reagent lots.

Benzodiazepine Titration

Data

		Lot # 13434M500	Lot # 16082M500	Lot # 20167M500	Lot # 22147M500
Benzodiazepines	Package Insert Concentration ng/mL	Conc.ng/mL	Conc.ng/mL	Conc.ng/mL	Conc.ng/mL
Alprazolam	105	95	95	85	95
7-Aminoclonazepam	2500	2500	2500	2500	1500
Bromazepam	225	225	225	225	225
Clorazepate	120	110	110	110	110
Chlordiazepoxide	1100	1100	1100	1100	1100
Clobazam	145	145	145	145	145
Clonazepam	500	500	500	500	500
Delorazepam	110	80	110	100	110
Desmethyldiazepam	100	100	90	90	95
Diazepam	95	85	75	75	95
Flunitrazepam	175	175	175	175	175
Flurazepam	140	120	120	120	140
Lorazepam	1000	400	600	600	400
Lormetazepam	225	150	225	170	200
Medazepam	225	185	225	205	215
Nitrazepam	175	175	175	175	185
Norfludiazepam	115	105	115	115	115
Prazepam	110	110	110	100	110
Temazepam	125	125	125	125	125
Triazolam	125	125	125	100	125

IMPACT ON RESULTS:

Quality Control Values: QC material containing Lormetazepam, such as Bio-Rad Liquichek Urine Toxicology Controls, will generate elevated results when used in combination with MULTIGENT Benzodiazepines reagent lots 13434M500, 16082M500, 20167M500, and 22147M500. This may be observed as either low controls generating positive results above the cutoff value of 200 ng/mL, or elevated semiquantitative results. The following table shows the Bio-Rad control recoveries for the affected lots:

Lormetazepam Containing Controls	Control Conc. ng/mL	Reported Control Value for Lot # 13434M500	Reported Control Value for Lot # 16082M500	Reported Control Value for Lot # 20167M500	Reported Control Value for Lot # 22147M500
Bio-Rad S1E Low Ctl Lot # 71210	150	241	187	240	194
Bio-Rad S2E Positive Ctl Lot # 71540	375	582	418	495	456

Patient Samples: The increased cross-reactivity to Lorazepam or Lormetazepam can be observed in patient results, but presents no risk to patient management. This assay is intended for screening patient samples for benzodiazepines. Patient samples with Lorazepam or Lormetazepam present but below the published cross-reactivity concentrations may show positive results and/or elevated semiquantitative values may be observed. As stated in the package insert, results from this assay are considered only a preliminary screening result. An alternate method such as gas chromatography/mass spectrometry (GC/MS) should be used to obtain a confirmed analytical result.

NECESSARY ACTIONS:

Quality Control: Evaluate your QC ranges per your laboratory's procedures. Alternatively, you may use MULTIGENT DOA MC I Control Set, List Number 3L43-10, which contains Oxazepam instead of Lormetazepam and is validated for use with the MULTIGENT Benzodiazepines assay.

Retain a copy of this letter for your laboratory records. If you have forwarded MULTIGENT Benzodiazepines lots listed in this letter to another laboratory, please provide a copy of this letter to them.

CONTACTS:

If you have any questions regarding this information, please contact Abbott Customer Service for U.S. customers at 1-877-4ABBOTT. Customers outside the U.S. should contact their local customer service.

We regret any inconvenience this has caused.