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## Advisory Notice

For Users Of

Diazyme Direct Enzymatic HbA1c Assay, Calibrator and Controls  
Catalog Number(s): DZ168A, DZ168A-CAL and DZ168A-CON

### Subject

Diazyme Direct Enzymatic HbA1c Assay, Calibrator, and Controls update

### Background

In compliance with European REACH Regulation 1907/2006, an adjustment was made for control and 3<sup>rd</sup> party control matrix compatibility with Diazyme Direct Enzymatic HbA1c Assay reagents. Specific reagent, calibrator and control lot compatibility is necessary to meet product specification.

### Action

Users should use paired Reagent, Calibrator and Control lots as defined below.

Direct HbA1c (DZ168A) Previous Compatible Lots		
Direct Enzymatic HbA1c Reagents (DZ168A)	Calibrators DZ168A-CAL	Controls DZ168A-CON
HB003210	HBS002210	HBC001210
HB004210	HBS001220	HBC002210
HB001220	HBS002220	

Direct HbA1c (DZ168A) Recent Compatible Lots		
Direct Enzymatic HbA1c Reagents (DZ168A)	Calibrators DZ168A-CAL	Controls DZ168A-CON
HB005210	HBS003210	HBC003210
HB002220	HBS003220	HBC001220
HB003220		
HB004220		

\*Calibrator and control lots are exchangeable between the reagent lots listed in table.

### Notice

Reagent (DZ168A) lot **HB005210, HB002220, HB003220, HB004220**, Calibrator (DZ168A-CAL) lot **HBS003210, HBS003220** and Control (DZ168A-CON) lot **HBC003210, HBC001220** are paired for use together.

For the latest update on product related information, please contact Diazyme Technical Support at 858-455-4768 or by email [support@diazyme.com](mailto:support@diazyme.com).

ADV22002