
Urgent Field Safety Notice
PSA (ER-PR8) Mouse Monoclonal Antibody
19 June 2014
Return of Medical Device/Device Destruction

Date: 19 June 2014

Details on affected devices:

Product name: PSA (ER-PR8) Mouse Monoclonal Antibody
Product catalog #: 760-4271 (Roche #05269334001)
Product Lot #: 1226406B, 1226406C, 1226406D, 1309305B, 1309305C, 1330908B, 1330908C
Volume: 50 test
Expiration Date: 1226406B,C,D: 2014-08
 1309305B,C: 2015-03
 1330908B,C: 2015-10

Description of the problem:

PSA (ER-PR8), Cat # 760-4271, labeled as IVD was shipped to Roche/Ventana European distribution center in Mannheim. PSA is IVD Annex II listed and Cell Marque Corporation's quality system, though compliant to ISO13485:2003(E) has not been formally assessed to IVD Annex IV, so the product can only be sold as research use only (RUO) in Europe. Product has been distributed to end users in European countries.

No additional risk for the user is associated with the improper designation on the product labeling.

Advise on action to be taken by the user:

Cell Marque requests that any unused product be discarded by the user and that the Roche Diagnostics and their affiliated distributors contact their customers regarding this error. Roche Diagnostics affiliated distributors should contact Roche Diagnostics acknowledging receipt of this notice and for credit replacement to customers. Roche Diagnostics should contact Cell Marque directly for credit replacement to customers and affiliated distributors. Roche Diagnostics should contact Cell Marque directly acknowledging receipt of this notice and when receiving acknowledgement of receipt of this notice from affiliated distributors.

Product currently at Roche Diagnostics distribution center or at affiliated distributors should be returned to Cell Marque if the product still has at least 12 months of expiration dating remaining, otherwise product should be destroyed at the distribution site. If product is destroyed at Roche Diagnostics affiliated distributor sites, confirmation of the lot numbers and quantities of each lot destroyed should be forwarded to Roche Diagnostics. Roche Diagnostics to forward confirmation of product destruction received from affiliated distributors to Cell Marque and provide confirmation of lot numbers and quantities of any product destroyed at the Roche Diagnostics distribution center to Cell Marque.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Contact reference person:

Veronica Runyan/ VP, Regulatory and Quality Affairs
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Rocklin, CA. 95677 U.S.A.
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The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

Veronica Runyan/ VP, Regulatory and Quality Affairs

Date