

**FIELD SAFETY NOTICE****Manual Immunoassay  
Active Renin IRMA Test Kit**

<b>Part Number</b>	<b>Lot Number</b>	<b>Expiration Date</b>
DSL25100	110919D	2011-11-18
	111017C	2011-12-16
	111017D	2011-12-16
	111114C	2012-01-16
	111212C	2012-02-10

Attention Active Renin IRMA Customer,

Beckman Coulter is initiating a voluntary recall for the product listed above. This letter contains important information that needs your immediate attention.

**ISSUE:**

- The Active Renin IRMA lots listed above may exhibit a decrease in stability of the coated tubes.
- As a result, quality control and patient sample results may be falsely elevated by up to 72%.

**IMPACT:**

- A falsely elevated renin result may result in failure to correctly diagnose the cause of hypertension.
- A falsely elevated renin result may also impact the aldosterone/renin ratio leading to a failure to correctly diagnose hypertension.

**ACTION:**

- Discontinue use of the Active Renin IRMA lots identified above and discard all remaining inventory.
- Review patient renin results for the lots listed above.
  - Failure of the test kits may be identified by control values out of range. If control values were out of range, patient results should not have been reported.
  - If control values were in range, but patient results do not match the clinical picture, consider repeating using an unaffected lot of Active Renin IRMA or an alternate vendor's product.

**RESOLUTION:**

- The Active Renin IRMA lots listed above have been removed from our inventory.
- A new lot of product will be available on January 9, 2012 for customers outside the United States.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product listed above to another laboratory, please provide a copy of the letter to them.



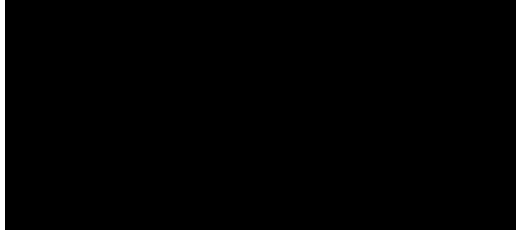
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center

- Via our website, <http://www.beckmancoulter.com>
- Via phone, call 1-800-854-3633 in Canada
- Outside the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for the inconvenience that this issue may have caused your laboratory.

Sincerely,



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