



**Medical Devices Bureau, Ministry of Health Malaysia**  
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## Medical Device / Equipment RECALL

Date Issued : 28 April 2008

Ref:MDB/R/2008/004

<b>IMMEDIATE ACTION</b>	√
<b>ACTION</b>	
<b>UPDATE</b>	
<b>INFORMATION REQUEST</b>	

<b>PRODUCT</b>	<b>Clinitest® hCG Cassette Pregnancy Test Kit</b>
<b>CLASS</b>	IVD :- Class B
<b>USE</b>	<p>The Clinitest hCG pregnancy test kit is intended for professional use only in hospitals / clinics and is not sold in pharmacies for home use. The Clinitest hCG pregnancy test may be carried out to:</p> <ul style="list-style-type: none"> <li>• Determine pregnancy</li> <li>• As part of the investigation of certain patient symptoms</li> <li>• To rule out pregnancy before treatments or diagnostic x-rays / procedures that are contraindicated or should be avoided by pregnant women</li> </ul> <p><b>Siemens Medical Solutions Diagnostics are recalling lot 97552 and lot 97574 of Clinitest hCG pregnancy test kits following identification of a manufacturing defect.</b></p> <p>The manufacturer reports that the sensitivity of the reagent with Clinitest hCG lot 97552 and lot 97574 has decreased and that this decrease in sensitivity has the potential to generate false negative hCG results.</p> <p>The shelf life of lot 97552 and lot 97574 is impacted by the shift in sensitivity and can no longer</p>

	<p>guarantee.</p> <p>According to the published notification in the website, The Irish Medicines Board (IMB) has been advised by the Irish distributors that all public and private hospitals / clinics that have received the affected lot have been advised of this recall.</p>
<b>SOURCE OF MEDICAL DEVICE RECALL / ALERT</b>	Irish Medicines Board website, date issued: 15 <sup>th</sup> April 2008
<b>ALERTING / RECALLING FIRM</b>	<p><b>In Ireland (as reported through the IMB website):-</b></p> <p>Siemens Healthcare Diagnostics (Manufacturer) Allphar Services Limited (Distributor)</p> <p>Siemens Medical Solutions Diagnostics Europe Limited Chapel Lane Swords Co. Dublin</p> <p>Telephone: +33 1 49229905 Fax: +33 1 49223248 Email: <a href="mailto:sylvie.legledic@siemens.com">sylvie.legledic@siemens.com</a></p>
<b>REASON</b>	<b>Lot 97552 and lot 97574 of the Clinitest hCG pregnancy test kits <u>has been recalled</u></b> by the manufacturer due to the potential for false negative results i.e. a negative result obtained in pregnancy.
<b>SCENARIO IN MALAYSIA</b>	<b>No details available at this moment.</b> Please check whether the device is available and contact the distributor.
<b>ACTION</b>	<p><b><i>Action or Recommendations For Healthcare Professionals</i></b></p> <ul style="list-style-type: none"> <li>• Ensure that all relevant staff in your institution are informed of this recall</li> <li>• Determine if you have lot 97552 and lot 97574 of the above product</li> <li>• Locate and cease using product from lot 97552 and lot 97574</li> <li>• Determine how much of this product has been used</li> <li>• Follow the distributor / manufacturers</li> </ul>

	<p>recommendations for quarantine and disposal of product</p> <ul style="list-style-type: none"> <li>• Follow up patients as required</li> </ul> <p><b><i>Action or Recommendations For Patients</i></b></p> <ul style="list-style-type: none"> <li>• Patients who have had a recent pregnancy test in hospital but are concerned that the negative result received may be incorrect should contact or seek a retest from their GP, family planning clinic or pharmacist.</li> </ul>
<b>RECOMMENDATION</b>	<p>Users of the abovementioned device should contact the distributors/supplier of this device (if available) and <b>inform the Medical Devices Bureau, Ministry of Health</b> providing the following information:-</p> <ol style="list-style-type: none"> <li>a. Name of healthcare centre/hospital/clinic</li> <li>b. Contact person and contact number</li> <li>c. Numbers of units available</li> </ol>
<b>CONTACT/ENQUIRIES IN MALAYSIA</b>	Currently No Information Available
<b>REFERENCES</b>	<a href="http://www.imb.ie/EN/Safety--Quality/Advisory%20Warning--Recall-Notices/Medical-Devices/Clinitest-hCG-Cassette-Pregnancy-Test-Kit-.aspx?page=1&amp;noticetypeid=1&amp;year=-1">http://www.imb.ie/EN/Safety--Quality/Advisory Warning--Recall-Notices/Medical-Devices/Clinitest-hCG-Cassette-Pregnancy-Test-Kit-.aspx?page=1&amp;noticetypeid=1&amp;year=-1</a>