### Universal Meditech Recalls Detec Hcg Pregnancy Urine Test Cassette Format For Inability To Continue Fulfilling Post-Market Responsibilities

<table>
<thead>
<tr>
<th>Recall Date</th>
<th>Product Description</th>
<th>Recalling Firm</th>
<th>Recall Reason</th>
</tr>
</thead>
</table>
| 11/1/2023   | Detec Hcg Pregnancy Urine Test Cassette Format  
REG Cat: 100-13 | UNIVERSAL MEDITECH INC. Reedley, California | Universal Meditech Inc. was violatively distributing PrestiBio" Breastmilk Alcohol Test Strip, 
DiagnosUSâŠ® SARS-CoV-2 Antibody (IgG/IgM) Test, HealthyWiser KetoFastâ" Ketone Test Strips and 
PrestiBio” Ketone Test Strips without marketing authorization. UMI is also recall their tests because they are going out of business and would not be able to continue fulfilling any post-market responsibilities of these distributed products. UMI claims to hold 510(k)s for the other devices, purchased the intellectual property in 2015 from the previous 510(k) holder, but FDA has been unable to verify this information. The devices may have unknown performance |
characteristics because the firm is unable to provide any documentation that the devices were manufactured in conformance with the Quality System regulation, including documentation (e.g., DHF) that the distributed devices had not been modified since original clearance in a way that could impact their safety and effectiveness, documentation of controlled storage temperature/humidity, and post-market surveillance documentation, such as complaints and adverse events.

<table>
<thead>
<tr>
<th>Recall Class</th>
<th>Product Identification</th>
<th>Distribution</th>
<th>Affected Dates</th>
</tr>
</thead>
</table>
| II           | **Detec Hcg Pregnancy Urine Test Cassette Format**  
Model Number: 100-13  
UDI-DI Code: None  
Lot Numbers: hCG-M5-2101-01 hCG-M5-2104-01 hCG-M5-2106-01 hCG-M5-2107-01 hCG-M5-2108-01 hCG-M5-2110-01 hCG-M5-2202-01 ... | 4103 Units Nationwide including California | 22 May 2023 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](https://www.fda.gov)

CDPH Food and Drug Branch  
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435  
(916) 650-6500 ● (916) 650-6650 FAX  
Internet Address: [www.cdph.ca.gov](http://www.cdph.ca.gov)