North American Diagnostics Recalls Oral Rapid SARS-CoV-2 Rapid Antigen Test Kits That Are Not Authorized, Cleared, or Approved by the FDA

<table>
<thead>
<tr>
<th>Recall Date</th>
<th>Product Description</th>
<th>Recalling Firm</th>
<th>Recall Reason</th>
</tr>
</thead>
</table>
| 6/15/2022     | **Oral Rapid SARS CoV 2 rapid antigen test**  
packaged under the following brands:  
Oral Rapid Test  
Oral Rapid Antigen Test  
SML LDT Kits  
SML Brand Finished Kits  
SML Brand BT Test Kits  
SML Brand BT Antigen Test  
Kit LDT | North American Diagnostics  
Holly Hill, Florida | Various brands of SARS CoV 2 Antigen Rapid Test kits were offered for sale and distribution to consumers in the United States without marketing approval, clearance, or authorization from FDA. |

<table>
<thead>
<tr>
<th>Recall Class</th>
<th>Product Identification</th>
<th>Distribution</th>
<th>Affected Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Lot: FLUSA 1020-1, Batches 8, 10, and 12</td>
<td>122,366 units Nationwide including California</td>
<td>June 2022 and prior</td>
</tr>
</tbody>
</table>

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