



REF:	Product/Trade Name:	Description:
70098-002	ThinPrep Pap Test PreservCyt Solution	250 x 20 ml Vials
ASY-05401		250 x 20 ml Vials
70406-002	ThinPrep PreservCyt Solution	4 x 946 ml Bottles
ASY-14753		100 x 20 ml Vials
ASY-15311	ThinPrep UroCyt PreservCyt Solution	100 x 20 ml Vials
ASY-14762	PreservCyt Collection Medium	100 x 20 ml Vials

**Basic UDI-DI: 54200455CYTSOLUTIONBP**

<b>Intended Purpose:</b>	<p><b>ThinPrep Pap Test PreservCyt Solution:</b> ThinPrep Pap Test PreservCyt Solution is a transport, preservative, and antibacterial medium for gynecologic samples and is used to prepare cytology slides using a ThinPrep processor as part of the ThinPrep System.</p> <p>ThinPrep Pap Test PreservCyt Solution is also a collection and transport medium for gynecologic samples for certain tests for Human Papilloma Virus (HPV) and other sexually transmitted infections. Refer to the manufacturer’s instructions for using PreservCyt Solution for collection, transport, and preparation of specimens for these tests. For professional use.</p> <p><b>ThinPrep PreservCyt Solution:</b> ThinPrep PreservCyt Solution is a transport, preservative, and antibacterial medium for non-gynecological samples and is used to prepare cytology slides using a ThinPrep processor as part of the ThinPrep System. For professional use.</p> <p><b>ThinPrep UroCyt PreservCyt Solution:</b> ThinPrep UroCyt PreservCyt Solution is a transport and preservative medium for urine samples and is used to prepare cytology slides using a ThinPrep processor as part of the ThinPrep System. For professional use.</p> <p><b>PreservCyt Collection Medium:</b> PreservCyt Collection Medium is a methanol-based reagent that serves as a transport, preservative, and antibacterial medium for molecular testing of gynecologic samples.</p> <p>Refer to the respective manufacturer’s package inserts for instructions for using PreservCyt Collection Medium for collection, transport, and preparation of specimens for use in their specific molecular tests. For professional use.</p>
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	Hologic, Inc. 250 Campus Drive Marlborough, MA 01752, USA 1 (800) 442-9892, +1 (508)-263-2900, www.hologic.com		
SRN:	US-MF-000001677		
<table border="1"> <tr> <td style="padding: 5px;">EC</td> <td style="padding: 5px;">REP</td> </tr> </table>	EC	REP	Hologic BV Da Vincilaan 5 1930 Zaventem, Belgium
EC	REP		
SRN:	BE-AR-000000127		
<p><b>We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:</b></p> <p>■ <b>Regulation (EU) 2017/746 on in vitro diagnostic medical devices</b></p> <p><b>Risk Class</b>                      A <input checked="" type="checkbox"/>    B <input type="checkbox"/>    C <input type="checkbox"/>    D <input type="checkbox"/></p> <p><b>Conformity Route:</b></p> <p style="border: 1px solid black; padding: 2px;">ANNEX I &amp; II+III (non sterile class A)</p>			

  
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*Signature*

Christine E Nichols  
 Director Regulatory Affairs, PRRC

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*Marlborough, MA 9/23/2022*  
 Issued in [place] & Date