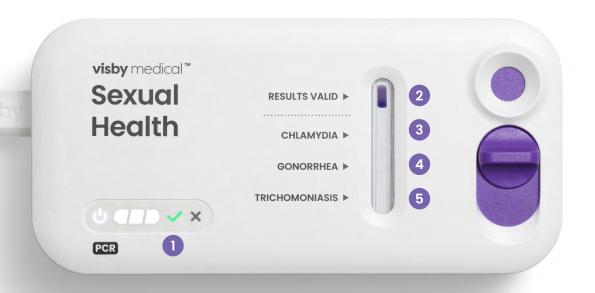
## **visby** medical™



Test a set of external controls with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures. An operator should confirm a valid test prior to interpreting results. A valid test is a green check mark present as well as the presence of a results valid purple spot. For more information, please review Instructions for Use and Quick Reference Guide.

**Note**: If the positive or negative external controls fail, repeat with a new Visby Medical Sexual Health Test. If the repeat test fails, please contact: Visby Medical Customer Support at 1-833-468-4729 (1-833-GoVisby).

	Device Information		Control Information		Internal Controls				External Controls		
Date	Lot#	Exp Date	Lot#	Exp Date	#1 Valid Electronic Control (Green Check Mark-Present or Absent)		#2- Results Valid Spot  (Spot Development- Present or Absent)		#3-5 Valid Positive Control?  (Spot development for all pathogens present)	#3-5- Valid Negative Control (No spot development for pathogens present)	Tech Initials
1 1		1 1		1 1	O Present	O Absent	O Present	O Absent	O Present	O Absent	
1 1		1 1		1 1	O Present	O Absent	O Present	O Absent	O Present	O Absent	
/ /		1 1		1 1	O Present	O Absent	O Present	O Absent	O Present	O Absent	
1 1		1 1		1 1	O Present	O Absent	O Present	O Absent	O Present	O Absent	
/ /		1 1		1 1	O Present	O Absent	O Present	O Absent	O Present	O Absent	



	Device Information		Control Information		Internal Controls				External Controls		
Date	Lot#	Exp Date	Lot#	Exp Date	#1 Valid E Control (Green Ch Mark-Pre Absent)	Valid Spot neck (Spot		#3-5 Valid Positive Control?  (Spot development for all pathogens present)	#3-5- Valid Negative Control (No spot development for pathogens present)	Tech Initials	
/ /		1 1		1 1	O Present	O Absent	O Present	O Absent	O Present	O Absent	
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1 1		1 1		1 1	O Present	O Absent	O Present	O Absent	O Present	O Absent	
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1 1		1 1		1 1	O Present	O Absent	O Present	O Absent	O Present	O Absent	
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Comments									