

TVMGAIP TV/MG Implementation Kit Instructions for Use

Product Overview	
Name	TV/MG Implementation Kit
Part Number	TVMGAIP
Matrix	cobas® PCR Media
Analyte	<i>Trichomonas vaginalis</i> (TV) <i>Mycoplasma genitalium</i> (MG)
Fill Volume	1.1 mL
Number of vials	45 vials
Storage Temperature	-20°C or below
Shelf Life	18 months from date of manufacture
Regulatory Status	For In Vitro Diagnostic Use

Kit Composition		
Kit Components	Expected Result [†]	Qty/Kit
TV 3x LOD	TV Positive MG Negative	5 vials
TV 5x LOD	TV Positive MG Negative	5 vials
TV 10x LOD	TV Positive MG Negative	5 vials
MG 3x LOD	TV Negative MG Positive	5 vials
MG 5x LOD	TV Negative MG Positive	5 vials
MG 10x LOD	TV Negative MG Positive	5 vials
TV/MG 3x LOD	TV Positive MG Positive	5 vials
TV/MG 5x LOD	TV Positive MG Positive	5 vials
TV/MG 10x LOD	TV Positive MG Positive	5 vials
[†] Expected qualitative results must be established by the laboratory for the specific assay system in use. For kit configuration, refer to the layout shown below.		

Product Description

The TV/MG Implementation Kit contains whole, intact, heat-inactivated *Trichomonas vaginalis* and *Mycoplasma genitalium* organisms formulated in cobas® PCR Media. Control components are provided at relative levels corresponding to 3x, 5x, and 10x the analytically determined limit of detection (LOD) for each target analyte. The materials are intended to be processed in the same manner as patient specimens to evaluate the entire molecular diagnostic workflow, including nucleic acid extraction, amplification, and detection. The product contains non-infectious materials and is stable when stored under the recommended conditions. The product is unassayed and does not have assigned quantitative values. Each laboratory is responsible for establishing expected qualitative performance for its specific assay system.

Intended Use

The TV/MG Implementation Kit is an external, unassayed quality control panel intended for use with molecular diagnostic assays for the qualitative detection of *Trichomonas vaginalis* and *Mycoplasma genitalium*. The kit is designed for assay verification, validation, and workflow implementation activities in clinical, public health, and reference laboratories. This product is not a substitute for assay-specific controls provided by the assay manufacturer.

Principles of the Procedure

The TV/MG Implementation Kit contains whole, heat-inactivated *Trichomonas vaginalis* and *Mycoplasma genitalium* organisms formulated in cobas® PCR Media. Because the organisms are structurally intact, the control materials are designed to be processed in the same manner as patient specimens. When extracted and analyzed according to the assay manufacturer's instructions, the controls evaluate the full molecular diagnostic workflow, including nucleic acid extraction, amplification, and detection.

The kit is intended to support assay verification, workflow implementation, and laboratory validation activities. The materials are not intended to replace assay-specific internal or external controls provided by the assay manufacturer.

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Storage and Handling

The TV/MG Implementation Kit should be stored at -20°C or below. Thaw control components at room temperature. Mix each vial thoroughly prior to use. Once thawed, control materials are stable for up to 24 hours when stored at 2-8°C. Control components may be frozen and thawed a maximum of four (4) times for reuse. Additional freeze-thaws are not recommended.

Do not use TV/MG Implementation Kit beyond the expiration date. Do not dilute. Do not use the product if the kit carton or individual vials are damaged or show evidence of leakage. Discard affected materials in accordance with laboratory procedures.

Limitations

For in vitro diagnostic use. The TV/MG Implementation Kit is an unassayed external control. No quantitative values are assigned. Expected qualitative performance must be established by the laboratory for the specific assay system in use. The product is not intended to replace assay-specific internal or external controls provided by the assay manufacturer. Results obtained with these materials should be interpreted in conjunction with assay manufacturer instructions. Improper storage, handling, or use outside recommended conditions may affect performance.

Warnings and Precautions

The TV/MG Implementation Kit contains whole, heat-inactivated organisms. Although non-infectious, the product should be handled in accordance with universal precautions and standard laboratory biosafety practices. Use appropriate personal protective equipment (PPE), including gloves and laboratory coats, when handling this product.

Do not pipette by mouth. Avoid eating, drinking, or smoking in areas where specimens or controls are handled.

In the event of a spill, absorb the bulk material with appropriate absorbent material (e.g., paper towels) prior to application of disinfectant. Clean the affected area with an appropriate laboratory disinfectant (e.g., freshly prepared 0.5% sodium hypochlorite solution) and dispose of contaminated materials in accordance with institutional biohazard procedures. Dispose of all materials and waste in accordance with local, regional, and national regulations. For professional laboratory use only.

Symbols



Catalog Number



Lot Number



Expiration Date



Upper Limit of Temperature



Caution



For In Vitro Diagnostic Use



Positive Control



Instructions For Use



Manufacturer

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Kit Configuration										
	1	2	3	4	5	6	7	8	9	10
1	TV 3x LOD	TV 5x LOD	TV 10x LOD	MG 3x LOD	MG 5x LOD	MG 10x LOD	TV/MG 3x LOD	TV/MG 5x LOD	TV/MG 10x LOD	
2										
3	TV 3x LOD	TV 5x LOD	TV 10x LOD	MG 3x LOD	MG 5x LOD	MG 10x LOD	TV/MG 3x LOD	TV/MG 5x LOD	TV/MG 10x LOD	
4										
5	TV 3x LOD	TV 5x LOD	TV 10x LOD	MG 3x LOD	MG 5x LOD	MG 10x LOD	TV/MG 3x LOD	TV/MG 5x LOD	TV/MG 10x LOD	
6										
7	TV 3x LOD	TV 5x LOD	TV 10x LOD	MG 3x LOD	MG 5x LOD	MG 10x LOD	TV/MG 3x LOD	TV/MG 5x LOD	TV/MG 10x LOD	
8										
9	TV 3x LOD	TV 5x LOD	TV 10x LOD	MG 3x LOD	MG 5x LOD	MG 10x LOD	TV/MG 3x LOD	TV/MG 5x LOD	TV/MG 10x LOD	
10										