

## INTROL<sup>®</sup> ME Control Panel M262

### INTENDED USE:

The INTROL<sup>®</sup> ME Control Panel M262 is intended for *in vitro* use as a quality control to monitor the amplification and detection of multiple cerebrospinal fluid pathogens. Detection of the bacteria, viruses, and yeast listed in Table 1 are an important aid to the diagnosis of meningitis and encephalitis. Meningitis (infection of meninges surrounding the brain and spinal cord) and encephalitis (infection of the brain) may be fatal depending on the infectious agent. Clinical symptoms caused by a wide variety of pathogens are often indistinguishable.<sup>1</sup> Therefore rapid laboratory diagnosis is critical to start and guide treatment.

INTROL<sup>®</sup> ME Control Panel M262 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

### PRODUCT SUMMARY and PRINCIPLE:

INTROL<sup>®</sup> ME Control Panel M262 is composed of 2 controls, INTROL<sup>®</sup> ME Positive M263 and INTROL<sup>®</sup> ME Negative M264. INTROL<sup>®</sup> ME Positive M263 contains synthetic RNA corresponding to genome segments of pathogens listed in Table 1. INTROL<sup>®</sup> ME Negative M264 contains non-target RNA.

Best practice is to establish a quality control program for every assay performed by the laboratory.<sup>2,3</sup> Routine use of quality controls that are consistent lot to lot assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents. Early investigation can prevent failed assay runs.

### COMPOSITION:

The INTROL<sup>®</sup> ME Control Panel M262 is comprised of 12 tubes, 200µL each, of synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. INTROL<sup>®</sup> ME Positive M263 contains nucleic acid segments of the bacteria, viruses, and yeast listed in Table 1.

### STORAGE and STABILITY:

INTROL<sup>®</sup> ME Control Panel M262 should be stored frozen (-25°C to -15°C). Unopened INTROL<sup>®</sup> ME Control Panel M262 is stable through the expiration date printed on the kit label when continuously stored frozen. INTROL<sup>®</sup> ME Positive M263 and INTROL<sup>®</sup> ME Negative M264 are for single use. Discard after use according to your local and federal regulations.

### INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come to room temperature (18° – 25°C).
2. Use the control as provided. **DO NOT DILUTE.**
3. Immediately before use, mix the control by briefly vortexing the tube for 3 – 5 seconds and then shake the tube down firmly to remove any droplets caught in the cap.
4. Analyze the control per the manufacturer instructions for use as a clinical sample.
5. Discard after use according to your local and federal regulations.

### PRECAUTIONS and WARNINGS:

- Do not dilute.
- This product does not contain any biological material and is not infectious. Universal Precautions are NOT required when handling this product.

Table 1:

INTROL <sup>®</sup> ME Positive M263	
<b>Bacteria</b>	
<i>Escherichia coli K1</i>	
<i>Haemophilus influenzae</i>	
<i>Listeria monocytogenes</i>	
<i>Neisseria meningitidis</i>	
<i>Streptococcus agalactiae</i>	
<i>Streptococcus pneumoniae</i>	
<b>Viruses</b>	
<i>Cytomegalovirus</i>	
<i>Enterovirus</i>	
<i>Herpes simplex virus 1</i>	
<i>Herpes simplex virus 2</i>	
<i>Human herpesvirus 6</i>	
<i>Human parechovirus</i>	
<i>Varicella zoster virus</i>	
<b>Yeast</b>	
<i>Cryptococcus neoformans/ gattii</i>	

### EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for INTROL<sup>®</sup> ME Control Panel M262 in demonstrating adequate system performance. Recoveries may vary depending on instrumentation, reagents and systematic or random errors.

### ORDERING INFORMATION:

INTROL<sup>®</sup> ME Control Panel M262

**Part Number: M262**

Kit Contains: 12 tubes x 200 µL  
6 each of Positive & Negative

1. Tunkel AR; Hartman BJ; Kaplan SL; et al. (November 2004). "Practice guidelines for the management of bacterial meningitis" (PDF). Clinical Infectious Diseases **39** (9): 1267–84. doi:10.1086/425368. PMID 15494903.
2. ISO 15189: Medical laboratories – Particular requirements for quality and competence.
3. CAP Molecular Pathology Checklist; Commission on Laboratory Accreditation, Laboratory Accreditation Program, Mol.20000