

Unyvero LRT/Pneumonia Control Panel M404

Instructions for Use (Version for Unyvero LRT Application)

INTENDED USE:

Unyvero LRT/Pneumonia Control Panel M404 is intended for use as an external positive and negative quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of bacterial targets: *Acinetobacter* spp., *Chlamydia pneumoniae*, *Citrobacter freundii*, *Enterobacter cloacae* complex, *Enterobacter aerogenes*[†], *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Klebsiella variicola*, *Legionella pneumophila*, *Moraxella catarrhalis*, *Morganella morganii*, *Mycoplasma pneumoniae*, *Pneumocystis jirovecii*[†], *Proteus* spp., *Pseudomonas aeruginosa*, *Serratia marcescens*, *Staphylococcus aureus*, *Stenotrophomonas maltophilia*, *Streptococcus pneumoniae*, and antibiotic resistance markers; *ctx-M*, *imp^β*, *kpc*, *mecA*, *mecC*[†], *ermB*[†], *ndm*, *oxa-23*, *oxa-24*, *oxa-48*, *oxa-58*, *vim*, *tem*, *sul1*[†], *shv^β*, *gyrA83/87[†]* (*E.coli* and *P.aeruginosa*) by the Unyvero Lower Respiratory Tract (LRT) Application and Unyvero Hospitalized Pneumonia (HPN) Application performed on the Unyvero System. Unyvero LRT/Pneumonia Control Panel M404 is composed of synthetic DNA specifically designed for and intended to be used with the Unyvero LRT and Unyvero HPN Applications.

[†]Target detected with Unyvero HPN Application only, not available in U.S.

PRODUCT SUMMARY and PRINCIPLE:

Unyvero LRT/Pneumonia Control Panel M404 is composed of 3 controls, Unyvero LRT/Pneumonia Positive A, Unyvero LRT/Pneumonia Positive B and Unyvero LRT/Pneumonia Negative. Unyvero LRT/Pneumonia Positive A and Positive B contain surrogate control material composed of synthetic DNA corresponding to genome segments of pathogens and associated antibiotic resistance markers listed in Table 1 (page 1) and Table 2 (page 2). Unyvero LRT/Pneumonia Negative contains no DNA.

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 Unyvero LRT/Pneumonia Control Panel M404 is comprised of 12 tubes, 4 tubes of each Positive A and B, and 4 tubes of Negative control, 180µL each. Unyvero LRT/Pneumonia Positive controls contain synthetic DNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Unyvero LRT/Pneumonia Negative control contains buffers and preservatives. Tables 1 and 2 list the pathogens and antibiotic resistance markers that are monitored by the Unyvero LRT/Pneumonia Control Panel M404 when tested by Unyvero LRT (Table 1) and Unyvero HPN (Table 2) Application on the Unyvero System.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Do not dilute or transfer to another storage tube.
- This product is intended for *in vitro* analytical testing and is provided for Research Use Only (RUO).
- This product is for use with Unyvero LRT and Unyvero HPN Applications on Unyvero systems. It does not contain the entire genome of pathogens listed in Tables 1 and 2.
- This product is not intended for use as a substitute for the internal controls provided in the Unyvero LRT or Unyvero HPN Applications.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.
- Unyvero LRT/Pneumonia Control Panel M404 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

- Allow the control to be tested to come completely to room temperature (18° – 25°C).
- Use the control as provided. DO NOT DILUTE.
- Follow procedures listed in the Unyvero Instructions for Use provided by Curetis.
- Immediately before use, mix the control thoroughly by pulse-vortexing for 5-10 seconds. Gently tap the tube several times on the bench to remove any liquid caught in the cap before opening the tube.
- Remove the Transport Cap by gently pulling it upward and dispose of it. If necessary, use a new pipette tip to remove any bubbles on the surface of the Unyvero Sample Tube.
- Aspirate 180µL of the vortexed Control into the Sample Tube, and close it using the Unyvero Sample Tube Cap provided in the kit, align the small nodules on the neck of the Sample Tube with the openings on the Cap and press down to lock in place.
- Continue to process according to the Unyvero Instructions for Use.

Note: Unyvero is a registered trademark of Curetis GmbH, all rights reserved.

STORAGE and STABILITY:

The Unyvero LRT/Pneumonia Control Panel M404 should be stored refrigerated at 2-8°C. Unopened Unyvero LRT/Pneumonia Control Panel M404 material is stable through the expiration date printed on the kit label when consistently stored refrigerated. Unyvero LRT/Pneumonia Control Panel M404 components are for single use. Discard after use according to your local and federal regulations.

EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for Unyvero LRT/Pneumonia Control Panel M404 in demonstrating adequate system performance.

Expected results when controls are analyzed on the Unyvero System are listed in Table 1 for the Unyvero LRT Application and Table 2 for the Unyvero HPN Application.

Table 1. Expected Results of Unyvero LRT/Pneumonia Control Panel M404 with Unyvero LRT Application

Control name:	Unyvero LRT/Pneumonia POSITIVE A	Unyvero LRT/Pneumonia POSITIVE B	Unyvero LRT/Pneumonia NEGATIVE
Part number:	M40534	M40634	M40734
Microorganisms			
Enterobacteriaceae			
<i>Citrobacter freundii</i>	-	+	-
<i>Enterobacter cloacae</i> complex	+	-	-
<i>Escherichia coli</i>	+	-	-
<i>Klebsiella oxytoca</i>	+	-	-
<i>Klebsiella pneumoniae</i>	+	-	-
<i>Klebsiella variicola</i>	+	-	-
<i>Morganella morganii</i>	-	+	-
<i>Proteus</i> spp.	-	+	-
<i>Serratia marcescens</i>	+	-	-
Gram-positive			
<i>Staphylococcus aureus</i>	+	+	-
<i>Streptococcus pneumoniae</i>	-	+	-
Non-fermenting bacteria			
<i>Acinetobacter</i> spp.	-	+	-
<i>Pseudomonas aeruginosa</i>	+	-	-
<i>Stenotrophomonas maltophilia</i>	-	+	-
Other			
<i>Chlamydia pneumoniae</i>	-	+	-
<i>Haemophilus influenzae</i>	-	+	-
<i>Legionella pneumophila</i>	-	+	-
<i>Moraxella catarrhalis</i>	-	+	-
<i>Mycoplasma pneumoniae</i>	+	-	-
Resistance markers (pathogen association not shown)			
<i>ctx-M</i>	+	-	NA
<i>kpc</i>	+	-	NA
<i>ndm</i>	+	-	NA
<i>oxa-48</i>	+	-	NA
<i>vim</i>	+	-	NA
<i>mecA</i>	-	+	NA
<i>oxa-23</i>	NA	+	NA
<i>oxa-24</i>	NA	+	NA
<i>oxa-58</i>	NA	+	NA
<i>tem</i>	NA	+	NA

ORDERING INFORMATION:

Unyvero LRT/Pneumonia Control Panel M404

Part Number: M404

Kit Contains: 12 tubes x 180µL

4 each of Positive A, Positive B & Negative

Unyvero LRT/Pneumonia Control Panel M404

Instructions for Use (Version for Unyvero HPN Application)

INTENDED USE:

Unyvero LRT/Pneumonia Control Panel M404 is intended for use as an external positive and negative quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of bacterial targets; *Acinetobacter baumannii* complex, *Chlamydomydia pneumoniae*, *Citrobacter freundii*, *Enterobacter cloacae* complex, *Enterobacter aerogenes*[†], *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Klebsiella variicola*, *Legionella pneumophila*, *Moraxella catarrhalis*, *Morganella morganii*, *Mycoplasma pneumoniae*, *Pneumocystis jirovecii*[†], *Proteus* spp., *Pseudomonas aeruginosa*, *Serratia marcescens*, *Staphylococcus aureus*, *Stenotrophomonas maltophilia*, *Streptococcus pneumoniae*, and antibiotic resistance markers; *ctx-M*, *imp*[†], *kpc*, *mecA*, *mecC*[†], *ermB*[†], *ndm*, *oxa-23*, *oxa-24*, *oxa-48*, *oxa-58*, *vim*, *tem*, *sul1*[†], *shv*[†], *gyrA83/87*[†] (*E.coli* and *P.aeruginosa*) by the Unyvero Lower Respiratory Tract (LRT) Application and Unyvero Hospitalized Pneumonia (HPN) Application performed on the Unyvero System. Unyvero LRT/Pneumonia Control Panel M404 is composed of synthetic DNA specifically designed for and intended to be used with the Unyvero LRT and Unyvero HPN Applications.

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COMPOSITION:

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- Remove the Transport Cap by gently pulling it upward and dispose of it. If necessary, use a new pipette tip to remove any bubbles on the surface of the Unyvero Sample Tube.
- Aspirate 180µL of vortexed Control into the Sample Tube, and close it using the Unyvero Sample Tube Cap provided in the kit, align the small nodules on the neck of the Sample Tube with the openings on the Cap and press down to lock in place.
- Continue to process according to Unyvero Instructions for Use.

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STORAGE and STABILITY:

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EXPECTED VALUES:

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Expected results when controls are analyzed on the Unyvero System are listed in Table 1 for the Unyvero LRT Application and Table 2 for the Unyvero HPN Application.

Table 2. Expected Results of Unyvero LRT/Pneumonia Control Panel M404 with Unyvero HPN Application

Control name:	Unyvero LRT/Pneumonia POSITIVE A	Unyvero LRT/Pneumonia POSITIVE B	Unyvero LRT/Pneumonia NEGATIVE
Part number:	M40534	M40634	M40734
Microorganisms			
Gram-positive			
<i>Staphylococcus aureus</i>	+	+	-
<i>Streptococcus pneumoniae</i>	-	+	-
Enterobacteriaceae			
<i>Escherichia coli</i>	+	-	-
<i>Enterobacter cloacae</i> complex	+	-	-
<i>Enterobacter aerogenes</i>	+	-	-
<i>Proteus</i> spp.	-	+	-
<i>Morganella morganii</i>	-	+	-
<i>Serratia marcescens</i>	+	-	-
<i>Citrobacter freundii</i>	-	+	-
<i>Klebsiella pneumoniae</i>	+	-	-
<i>Klebsiella oxytoca</i>	+	-	-
<i>Klebsiella variicola</i>	+	-	-
Non-fermenting bacteria			
<i>Pseudomonas aeruginosa</i>	+	-	-
<i>Acinetobacter baumannii</i> complex	-	+	-
<i>Legionella pneumophila</i>	-	+	-
<i>Moraxella catarrhalis</i>	-	+	-
<i>Stenotrophomonas maltophilia</i>	-	+	-
Other/Fungi			
<i>Haemophilus influenzae</i>	-	+	-
<i>Chlamydomydia pneumoniae</i>	-	+	-
<i>Pneumocystis jirovecii</i>	-	+	-
<i>Mycoplasma pneumoniae</i>	+	-	-
Resistance markers			
Resistance Gene			
<i>mecA</i>	-	+	-
<i>mecC</i>	+	-	-
<i>ermB</i>	-	+	-
<i>tem</i>	+	+	-
<i>shv</i>	+	-	-
<i>tem+shv</i>	+	-	-
<i>oxa-23</i>	-	+	-
<i>oxa-24</i>	-	+	-
<i>oxa-48</i>	+	-	-
<i>oxa-58</i>	-	+	-
<i>vim</i>	+	-	-
<i>imp</i>	+	-	-
<i>kpc</i>	+	-	-
<i>ndm</i>	+	-	-
<i>ctx-M</i>	+	-	-
<i>sul1</i>	+	-	-
Chromosomal Mutations			
<i>gyrA83 (E.coli)</i>	-	-	-
<i>gyrA87 (E.coli)</i>	-	-	-
<i>gyrA83 (P.aeruginosa)</i>	-	-	-
<i>gyrA87 (P.aeruginosa)</i>	-	-	-

ORDERING INFORMATION:

Unyvero LRT/Pneumonia Control Panel M404
Part Number: M404
Kit Contains: 12 tubes x 180µL
4 each of Positive A, Positive B & Negative