# Levonadifloxacin HiMIC™ Plate Kit (LND) (0.125 - 8 mcg/ml)

**MPK709**

Antimicrobial Susceptibility Testing
For *In Vitro* Diagnostic use

**Intended Use:**
Levonadifloxacin HiMIC™ Plate Kit is ready to use Minimum Inhibitory Concentration (MIC) determination kit by broth microdilution method, capable of showing MIC's of Levonadifloxacin against test organism in the range of 0.125 mcg/ml to 8 mcg/ml following specified incubation condition.

**Kit Contains:**

| No. | Content | 1 KT | 3KT |
|---|---|---|---|
| 1. | 96 Well HiMIC™ Plate | 1 No. | 3 No. |
| 2. | HiMIC™ Diluent Tubes | 12 No. | 36 No. |
| 3. | HiMIC™ Reading card | 1 No. | 3 No. |
| 4. | HiMIC™ Incubation Tray | 1 No. | 3 No. |

**Introduction:**
HiMIC™ Plate Kit is a broth microdilution method consisting of 96 well microtiter plate with detachable wells. It covers 7 two-fold dilutions in a single detachable well strip covering breakpoint scale which helps in reliable interpretation for Sensitive, Intermediate and Resistance detection with easy visual inspection, in compliance with CLSI and EUCAST guidelines. Detachable well strip is coated with gradient of antibiotics and growth medium which releases upon the rehydration. The detachable strip is coated with highest concentration in the top most well i.e. in "A" well and lowest concentration in the second last well i.e. "G" well whereas last well is a growth control i.e. "H" well. Each detachable well is given along with the antibiotic symbol at the top. HiMIC™ reading card is provided for easy interpretation of the MIC value by visible colour change.

**METHOD AND USE OF HiMIC™ Plate Kit**

- **Type of specimen**

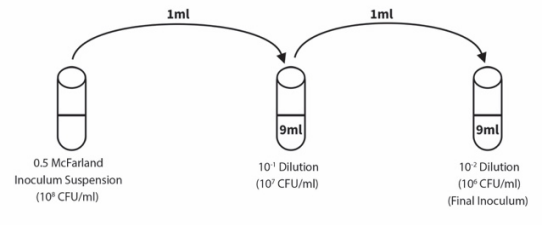
Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1,3).

- **Clinical specimen collection, handling and processing**

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1,3).

- **Preparation of Inoculum**

Use only pure cultures. Confirm by Gram-staining before starting susceptibility test. Transfer 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for 2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 620 nm).
Dilute the inoculum for further two dilutions to get final inoculum of $10^6$ cfu/ml.

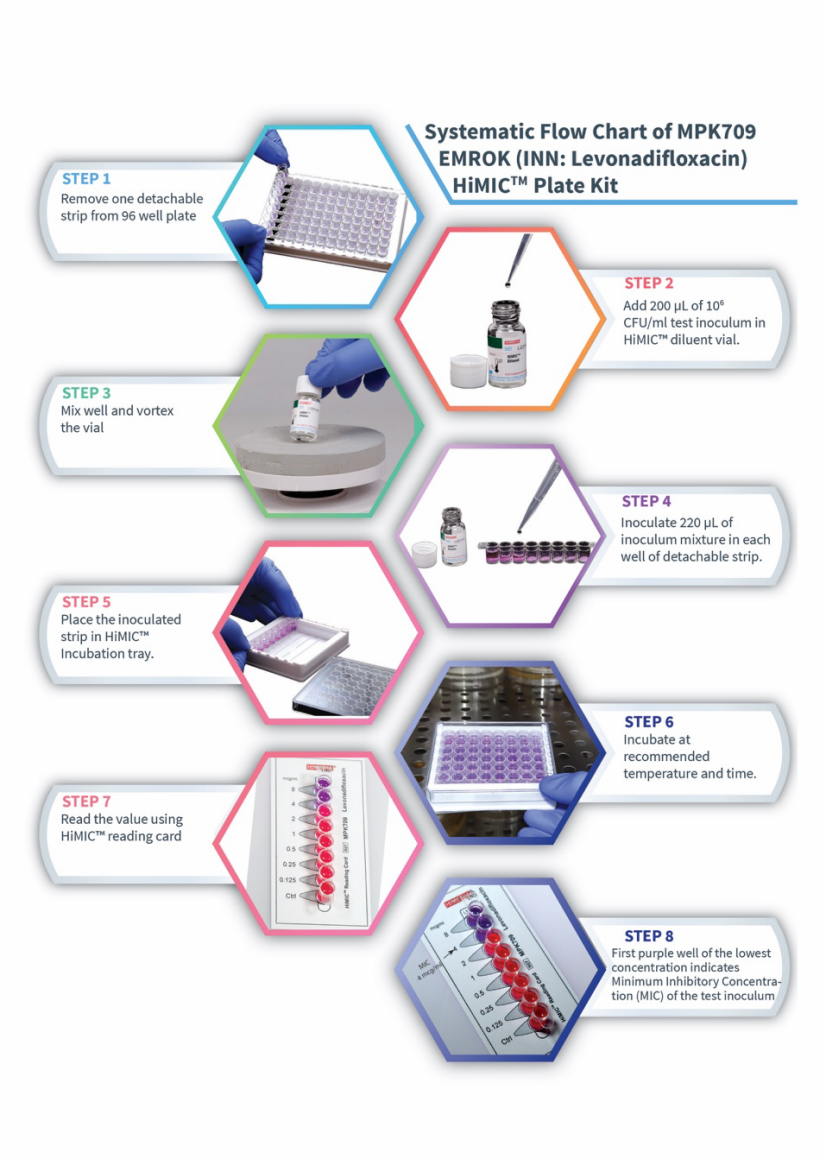


- **Test Procedure**

1. Remove the Levonadifloxacin HiMIC™ plate (HMP709) from Aluminum Zip Pouch.
2. Pick up the required number of detachable well strips and cover the remaining wells with the lid provided.
3. Inoculate 200 µL of $10^6$ CFU/ml inoculum into HiMIC™ diluent tube (LQ314II).
   (Note: Use one vial for single inoculum.)
   Mix well and vortex the tube
4. Inoculate 220 µL of inoculum mixture from above tube into the all 8 wells i.e. "A" to "H" wells
5. Gently shake the well strip and keep it in an incubator tray provided with the kit.
6. Transfer the tray in the incubator under appropriate conditions.

**MIC Reading:**

1. Read the wells when visible color change from purple to pink will be observed (or Read the wells after appropriate incubation.)
2. Remove the detachable well Strip from incubator tray.
3. Place it on the HiMIC™ reading card in the proper direction
4. Read the MIC where lowest concentration of the purple colored well is observed



**Warning and Precautions:**

1. HiMIC™ Plate Kit is intended for *In vitro* diagnostic use only.
2. Although based on simple procedure, HiMIC™ Plate Kit should only be used by at least semi-trained personnel.
3. HiMIC™ Plate Kit, should be used strictly according to procedures described herein.
4. Performance of HiMIC™ Plate Kit depends on use of proper inoculum and control cultures and proper storage temperature.
5. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
6. Place the unused strips back to recommended temperature.

## INTERPRETATION & QUALITY CONTROL (As per CLSI Guidelines) :

**Interpretation**

Use following interpretive criteria for susceptibility categorization as per CLSI.

| When testing | Incubation | Interpretative Criteria | | |
|---|---|---|---|---|
| | | ≤ S | I | ≥ R |
| *Staphylococcus aureus* (methicillin-resistant, methicillin-susceptible, _quinolone-resistant, quinolone-susceptible isolates) | 35-37°C for 18 hrs. | 2 | 4 | 8 |
| *Enterococcus faecalis* | 35-37°C for 18 hrs. | 8 | - | 16 |
| *Streptococcus pyogenes* | 35-37°C for 20-24hrs at 5% $CO_2$ | 1 | 2 | 4 |
| *Streptococcus dysgalactiae sp.* dysgalactiae | 35-37°C for 20-24hrs at 5% $CO_2$ | 0.25 | - | 0.5 |
| *Streptococcus agalactiae* | 35-37°C for 20-24hrs at 5% $CO_2$ | 0.5 | - | 1 |

**QUALITY CONTROL**

Quality control of Ezy MIC™ Strip is carried out by testing the strips with standard ATCC Cultures recommended by CLSI on suitable medium incubated appropriately.
Following are the reference MIC values (mcg/ml) range for Levonadifloxacin.

| Organism | Medium used | Incubation | Std. Quality Control limits (mcg/ml) |
|---|---|---|---|
| *P. aeruginosa* ATCC 27853 | Mueller Hinton Agar | 35-37°C for 18 hrs | 0.5 – 1.0 – 2.0 – 4.0 |

**Storage & Shelf Life:**

1. Once the consignment is received, store the HiMIC™ Plate Kit at -20°C to 8°C.
2. Use before expiry date on the label.
3. HiMIC™ Plate Kit left over from opened package must be kept dry.
4. Moisture should be prevented from penetrating into or forming within the package or storage container.
5. Check whether the batch number and expiry date are marked on the storage container.
6. Product performance is best within stated expiry period if correctly stored and handled.

**Disposal:**
After use, HiMIC™ Plate Kit and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

**Limitation of Test**

HiMIC™ Plate Kit provides *In vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

**References:**

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
3. Jorgensen, J. H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
4. Performance Standards of Antimicrobial Susceptibility Testing; 34th Edition. M100-Ed34, Vol.44, No.5, Jan-2024.

**Packing:**
Each Pack contains following material packed in a desired packing.
1) Levonadifloxacin HiMIC™ Plate Kit (1KT/3KT)
2) HiMIC™ Diluent tubes (12NO./36NO)
3) HiMIC™ Reading Card. (1NO / 3NO)
4) HiMIC™ Incubation Tray (1NO / 3NO)
5) Package Insert

**Layout of plate**
Product Code: MPK709
Product Name: Levonadifloxacin HiMIC™ Plate Kit
Concentration: 0.125 - 8 mcg/ml

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| **B** | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| **C** | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **D** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **E** | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| **F** | 0.25 | 0.25 | 0.25 | 0.25 | 0.25 | 0.25 | 0.25 | 0.25 | 0.25 | 0.25 | 0.25 | 0.25 |
| **G** | 0.125 | 0.125 | 0.125 | 0.125 | 0.125 | 0.125 | 0.125 | 0.125 | 0.125 | 0.125 | 0.125 | 0.125 |
| **H** | Growth Control | Growth Control | Growth Control | Growth Control | Growth Control | Growth Control | Growth Control | Growth Control | Growth Control | Growth Control | Growth Control | Growth Control |

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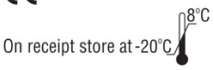


IVD In vitro diagnostic medical device

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Do not use if package is damaged

Indicates a single sterile barrier system with protective packaging outside

Do not re-use

Disclaimer :

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