

Measurement Services for Neutralization Antibody Titer

LSI Medience (hereinafter LSIM) is offering measurement services for neutralization antibody titer against viruses in specimen such as human serum.

LSIM is capable to perform customization of assay method, validation, measurement on diagnostic samples as well as clinical trial samples, and to support vaccine development, clinical trial, post-marketing surveillance, epidemiological survey and so on. LSIM performs the assay in accordance with ISO15189 and provides a final report and electronic data to meet the expectations by sponsor.

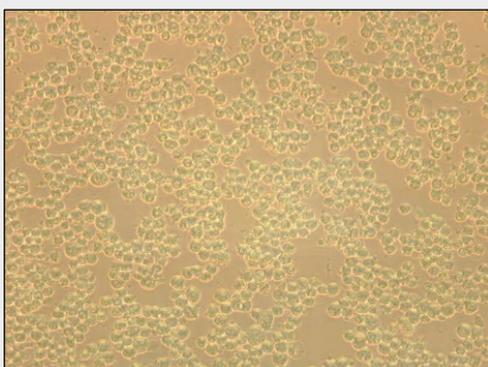
What is the "measurement for neutralization antibody titer"?

Once an antibody binds to a protein of virus, an infectivity of the virus particles will be lost. This method has very high specificity for measuring antibody titers. After serum and virus are mixed and allowed to undergo an antigen-antibody reaction, inoculate to the cells that are highly sensitive against the virus and cultured for a certain period of time to determine the presence of cytopathic effect (CPE). If CPE does not detected, an infection is suppressed and neutralization antibody titer is determined as positive, and an antibody titer is reported numerically.

An example of CPE



Normal Vero cells before infection by virus:
Culturing 3 days



CPE on Vero cells infected by Herpes virus:
5 days after virus inoculation

The instruments used



Microscope



Safety Cabinet: Class II

Usage

- **Immunogenicity assessment on vaccine**
Measuring antibody titer before and after vaccine inoculation is very practical for immunogenicity assessment and/or efficacy judgement on vaccine.
- **Judgement on immune possession against target virus**
Practicable for serum epidemiological investigation.

The list of viruses

- Adenovirus
- Herpes simplex virus type1, type2
- Picornavirus (Coxsackie virus · Echovirus, Enterovirus)
- Influenza virus
- Measles virus
- Mumps virus
- Respiratory syncytial virus (RSV)

Other measurement services except measurement for neutralization antibody titer

□ Influenza Virus

| Testing Method | Summary of Measurement |
|---|--|
| Virus Isolation / Culture | Isolate and culture influenza virus by using MDCK cells. |
| Virus Identification (Fluorescent Antibody Method) | Identify subtype by indirect fluorescent antibody method using monoclonal antibody. |
| Virus Identification (Hemagglutination Inhibition test) | Identify subtype by using hemagglutination inhibition antiserum. |
| Virus Titer Assay | Calculate TCID50 value by serial dilution of virus by using MDCK cells. |
| NA Inhibitory Activity Assay | Calculate concentration of 50% enzyme inhibitory activity against neuraminidase inhibitor. |
| Plaque Titer Assay | Calculate titer of virus by plaque method by using agar. |
| Plaque Drug Susceptibility Assay | Calculate 50% effective concentration of anti-influenza virus drug using plaque method. |
| Hemagglutination Inhibition Titer Assay | Calculate hemagglutination inhibition titer by hemagglutination inhibition test. |

□ Herpes Simplex Virus type-1, type-2 (HSV-1, HSV-2)

| Testing Method | Summary of Measurement |
|--|--|
| Virus Isolation / Culture | Isolate and culture Herpes Simplex Virus by using MRC-5 cells. |
| Virus Identification (Fluorescent Antibody Method) | Identify subtype by direct fluorescent antibody method using monoclonal antibody. |
| Shell Vial Culture method | Isolate and culture Herpes Simplex Virus and identify types of virus by using MRC-5 cells. |
| Plaque Titer Assay | Calculate titer of virus by plaque method by using methyl cellulose. |
| Plaque Drug Susceptibility Assay | Calculate 50% effective concentration of anti-Herpes Simplex Virus drug using plaque method. |

□ Varicella Zoster Virus (VZV)

| Testing Method | Summary of Measurement |
|--|--|
| Virus Isolation / Culture | Isolate and culture Varicella Zoster Virus by using MRC-5 cells. |
| Virus Identification (Fluorescent Antibody Method) | Identify subtype by direct fluorescent antibody method using monoclonal antibody. |
| Shell Vial Culture method | Isolate and culture Varicella Zoster Virus and identify types of virus by using MRC-5 cells. |
| Plaque Titer Assay | Calculate titer of virus by plaque method by using methyl cellulose. |
| Plaque Drug Susceptibility Assay | Calculate 50% effective concentration of anti-Herpes Simplex Virus drug using plaque method. |

● Contact

Drug Development Service Segment <http://www.medience.co.jp/English/index.html>

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LSI Medience Corporation

Number of samples from 2002 to 2019

| Virus name | | | Varicella Zoster Virus (VZV) | Herpes Simplex Virus type-1, type-2 (HSV-1, HSV-2) | Influenza Virus (Flu) |
|---|---|--|---------------------------------|--|--------------------------|
| Number of Sponsors | | | 2 | 2 | 12 |
| Number of tests on each item experienced at LSI Medience | Virus Culture test by using cell culture | Virus Culture | 2295 | 266 | 12668 |
| | | Virus isolation/ identification | 3330 | 2431 | 8044 |
| | | Virus Infectivity Titer (TCID ₅₀) | - | - | 30967 |
| | Drug Susceptibility test for Anti-viral drug | Plaque reduction method (EC ₅₀) | 471 | 777 | 407 |
| | | NA Inhibitory Activity | - | - | 13044 |
| | Antibody test for Vaccine | Neutralization antibody titer | - | - | 8088 |
| | | Hemagglutination inhibition antibody titer | - | - | 6816 |

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Viral Culture Team
Manual-based Viral Testing Group
Infectious Diseases Testing Department

Please contact us if you have questions for subtype of the listed viruses or any virus which is not written in this leaflet.

●Contact

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