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Zuschläge

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NovaTec Immundiagnostica GmbH

NovaLisa®
Cytomegalovirus (CMV) IgG ELISA
(CMVG0110)

Performance Characteristics

NovaTec Immundiagnostica GmbH

Table of Contents

1 Introduction

Cytomegalovirus (CMV) is a member of the herpesvirus group (Betasubfamily, DNA virus of 150-200 nm). These viruses share a characteristic ability to remain dormant within the body over a long period. Initial CMV infection, which may have few symptoms, is always followed by a prolonged, inapparent infection during which the virus resides in cells without causing detectable damage or clinical illness. Severe impairmant of the body´s immune system by medication or disease consistently reactivates the virus from the latent or dormant state.

CMV is found universally throughout all geographic locations and socioeconomic groups, and infects between 50% and 85% of adults. CMV infection is more widespread in developing countries and in areas of lower socioeconomic conditions. For the vast majority of people, CMV infection is not a serious problem, but it is to certain high-risk groups:

- to the unborn baby during pregnancy
- to immunocompromised persons, such as organ transplant recipients and persons infected with HIV.

Species	Disease	Symptoms e.g.	Transmission route
Cytomegalovirus (CMV)	Cytomegaly	In general asymptomatic. Complications in infants resulting from congenital CMV infection: hearing, mental or coordination problems	Transmission from person to person (intimate contact, saliva, urine, or other body fluids); Congenital infection; can also be transmitted via breast milk, transplanted organs, and rarely from blood transfusions

The presence of pathogen or infection may be identified by

- Microscopy:
- PCR
- Serology: e.g. by ELISA

2 Intended Use

The Cytomegalovirus (CMV) IgG ELISA is intended for the qualitative determination of IgG class antibodies against Cytomegalovirus (CMV) in human serum or plasma (citrate, heparin). CMV IgG avidity can be determined with assay Avidity Cytomegalovirus (CMV) IgG (Product code: ACMV7110).

3 Principle of the Assay

The qualitative immunoenzymatic determination of specific antibodies is based on the ELISA (Enzyme-linked Immunosorbent Assay) technique.
Microplates are coated with specific antigens to bind corresponding antibodies of the sample. After washing the wells to remove all unbound sample material a horseradish peroxidase (HRP) labelled conjugate is added. This conjugate binds to the captured antibodies. In a second washing step unbound conjugate is removed. The immune complex formed by the bound conjugate is visualized by adding Tetramethylbenzidine (TMB) substrate which gives a blue reaction product.
The intensity of this product is proportional to the amount of specific antibodies in the sample. Sulphuric acid is added to stop the reaction. This produces a yellow endpoint colour.
Absorbance at 450/620 nm is read using an ELISA microwell plate reader.

4 Performance Characteristics

4.1 Reproducibility (Precision)

Material

NovaLisa® Cytomegalovirus IgG — Lot: CMVG-080
Production date: 2015-11 — Expiry date: 2017-05-31

Positive and negative samples

Test Description

The reproducibility of the NovaLisa® CMV IgG ELISA kit was determined by comparing 24 replicates of 3 different samples in one assay (within-run) and by comparing 3 different samples assayed in 12 different runs (between-run).
Acceptance Criterion: CV < 15 %

Results

Within-run and between-run precision were estimated by analysis of variance and are presented in tables 1 and 2.

Table 1: Within-Run Precision (CMVG-080)

Sample	n	Mean (E)	CV [%]
#1	24	0,607	2,60
#2	24	1,359	10,63
#3	24	1,904	3,09

Table 2: Between-Run Precision (CMVG-080)

Sample	n	Mean (NTU)	CV [%]
#1	12	23,74	2,37
#2	12	32,82	5,57
#3	12	1,13	5,50

Conclusion

The acceptance criterion was met for all samples.

4.2 Analytical Specificity

4.2.1 Interference from Hemoglobin, Bilirubin and Triglycerides

Introduction

Increased concentrations of possible interference materials such as bilirubin, triglycerides and hemoglobin may interfere with immunoassays creating false-negative or false-positive results.
In order to investigate this topic a literature research in combination with investigation of nearly 100 parameters were performed.

Material and Test Condition

Different members of the NovaLisa® ELISA line were used including assays for the detection of different antibody isotypes (IgA, IgG, IgM, IgG + IgM) to bacteria, viruses, fungi, parasites and worms as well as an antigen ELISA for the detection of TSH.

Defined positive resp. negative or equivocal samples were used.

A certain amount of the potentially interfering substance was added to each sample. The final concentration of each substance was in a pathological range as also described by competitors (10 mg/ml hemoglobin, 0.5 mg/ml bilirubin and 5 mg/ml triglycerides). The results obtained with the sample with added “interfering substance” should be 60-140 % of the result of the untreated sample in order to fulfil the specifications.

Conclusion

The internal specifications of 60-140 % were always fulfilled.
Interferences with hemolytic, lipemic or icteric samples were not observed up to a concentration of 10 mg/ml hemoglobin, 0.5 mg/ml bilirubin and 5 mg/ml triglycerides.
These results are also in agreement with literature data.

Dimeski, G. (2008) Interference Testing, Clin Biochem Rev 29, S43 – S48
Tate, J. and Ward, G. (2004) Interferences in Immunoassay, Clin Biochem Rev 25, 105 – 120

4.2.2 Cross-Reactivity

A panel of 20 specimens from patients with confirmed diseases other than Cytomegalovirus was tested to establish the analytical specificity of the NovaLisa® Cytomegalovirus IgG ELISA. The specimens were from patients infected with pathogens that may cause similar signs and symptoms to those observed for Cytomegalovirus or from individuals with diseases or conditions that have the potential for cross-reactivity.

Material

NovaLisa® Cytomegalovirus IgG Lot: CMVG-003
Production date: 2002-03 Expiry date: 2003-03
20 potentially cross-reactive samples

Results

Table 3: Results

Disease Type	Sample	NTU	Evaluation	Evaluation
Samples positive for:			NovaLisa	Enzygnost
HSV1+2/EBV/Measles/VZV IgG	1	3,3	neg	neg
EBV/Measles/VZV IgG	2	1,8	neg	neg
HSV1+2/EBV/Measles/VZV IgG	3	1,1	neg	neg
HSV1+2/EBV/Rubeola/VZV IgG	4	1,5	neg	neg
EBV/Rubeola/Measles/VZV IgG	5	3,3	neg	neg
HSV1+2/Rubeola/Measles/VZV IgG	6	4,3	neg	neg
EBV/Rubeola/Measles/VZV IgG	7	2,1	neg	neg
HSV1+2/EBV/Rubeola/Measles/VZV IgG	8	5,1	neg	neg
HSV1+2/EBV/Rubeola/Measles IgG	9	1,8	neg	neg
EBV/VZV IgG	10	10,1	eqv	neg
HSV1+2/EBV/Rubeola/Measles/VZV/CMV IgG	11	> 29,0	**POS**	**POS**
HSV1+2/EBV/Rubeola/CMV IgG	12	> 29,0	**POS**	**POS**
HSV1+2/EBV/Rubeola/Measles/VZV/CMV IgG	13	> 29,0	**POS**	**POS**
HSV1+2/EBV/Measles/VZV/CMV IgG	14	> 29,0	**POS**	**POS**
HSV1+2/EBV/Rubeola/Measles/VZV/CMV IgG	15	> 29,0	**POS**	**POS**
HSV1+2/Rubeola/Measles/VZV/CMV IgG	16	> 29,0	**POS**	**POS**
HSV1+2/Rubeola/Measles/VZV/CMV IgG	17	> 29,0	**POS**	**POS**
HSV1+2/EBV/Rubeola/VZV/CMV IgG	18	> 29,0	**POS**	**POS**
EBV/Rubeola/Measles/VZV/CMV IgG	19	> 29,0	**POS**	**POS**
HSV1+2/EBV/Rubeola/Measles/VZV/CMV IgG	20	> 29,0	**POS**	**POS**

Summary of the Results

Table 4: Summary of Results

Pathogen/Disease Type	Total Specimens	Positive Result	Positive Result
		NovaLisa	Enzygnost
HSV 1+2	15/20	9/20	10
EBV	17/20	8/20	10
Mumps	15/20	9/20	10
Measles	16/20	8/20	10
VZV	18/20	9/20	10
CMV	10/20	10/20	10
Total	20	Max.10/20	10

(Equivocal results were not included in the calculations. Sera with positive evaluation result (NovaLisa) contain IgG antibodies against Cytomegalovirus, which was confirmed in comparison to Enzygnost, see column evaluation Enzygnost)

Conclusion

Investigation of a specimen panel with antibody activities to potentially cross-reacting parameters (antibodies to several infectious agents) did not reveal evidence of false-positive results due to cross-reactions.
Sera determined with Enzygnost as positive for CMV show the expected positive result.

4.3 Diagnostic Sensitivity and Specificity

Introduction

The purpose of this study was to determine the efficiency of the assay to discriminate between positive and negative clinical samples.
To evaluate the diagnostic performance of the NovaLisa® CMV IgG ELISA, internal studies were conducted by NovaTec in comparison to an immunoassay already established on the market and in comparison to External Quality Control Schemes.

Materials

NovaTec CMV IgG
LOT: 003,011, 023, 028, 029, 034, 037, 040, 042, 045, 051, 056, 058, 062, 063, 069, 074, 077, 078, 080, 084
DiaSorin ETI-CMV IgG LOT: 680200
Reviewed by Paul Ehrlich Institute
Dade Behring Enzygnost

Total number of samples: 243

Results (Summary)

Table 5: Diagnostic Sensitivity and Specificity

		Target		
		positive	negative	**Σ**
NovaLisa® Cytomegalovirus (CMV) IgG	positive	132	1	**133**
	negative	1	109	**110**
	Σ	**133**	**110**	**243**

Diagnostic Sensitivity: 99.25% (95%-width of CI: 95.88% .. 99.98%)
Diagnostic Specificity: 99.09% (95%-width of CI: 95.04% .. 99.98%)
Agreement: 99.2 %

Conclusion

The acceptance criteria are met.