

Development and Improvement of Novel MAS™ Infectious Controls for Serology Diagnostic Tests

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Abstract

Background: Human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) remain major infections around the world. As not all viral infections are preventable, serological assays play a critical role in diagnoses, therapeutic monitoring, and treatment of these infections. The Thermo Scientific™ MAS™ Omni Infectious Controls are a family of controls containing single or multiple analytes in human plasma-based matrix designed to mimic patient samples in the assessment of serological assay performance. One of the greatest challenges within the field of Infectious Serology testing is method variation amongst the semi-quantitative assays. As an example, a result that is considered a low positive on one analyzer, may be considered a high positive on a different analyzer. Therefore, platform agnostic Quality Control material will provide evaluation among different methods. Quality Controls may also be developed to focus on certain platforms based on "fit-for-purpose" applications. We report here the development and performance evaluation of the MAS™ Omni Infectious Controls – For Use with Siemens Assays.

Methods: Two new MAS™ Omni Infectious Controls were developed and characterized to be added to the existing catalog of MAS™ Omni Infectious Control Products. MAS™ Omni Infectious BSI (Bloodstream Infections) Positive Control Panel – For Use with Siemens Assays* is a multi-constituent IVD quality control containing anti-HIV-1/2, anti-HBc, anti-HCV, and anti-HTLV I/II antibodies, as well as Hepatitis B surface antigen (HBsAg) that was developed for the Siemens Assays platform. The new product has been adapted from the existing BSI Positive Control Panel* by increasing the titer of HBsAg while decreasing the titer of anti-HBc and anti-HCV. MAS™ anti-HBs Positive Control – For Use with Siemens Assays* was developed for the assessment of assay performance detecting anti-HBs on the Siemens Assays Platform. The new product has been adapted from the existing anti-HBs Positive Control by increasing the titer of anti-HBs. Development and performance evaluations were performed on SIEMENS™ and non-SIEMENS™ platforms. Shelf life of the products are determined by accelerated, real-time stability, open vial, and in-use monitoring.

Results: Two new MAS™ Omni Infectious Controls were developed and evaluated to be specifically used on the Siemens Assays Platform. Both products demonstrated acceptable performance on the Siemens™ Centaur™ and Abbott™ Architect™. Stability studies demonstrated a minimum of 24- or 12-months shelf life, 30 or 60 days of open vial stability, and 8 hours of in-use stability when stored at 2-8°C, respectively. Additionally, the studies demonstrate a basic understanding of method variation within Infectious Serology test methods.

Conclusions: Two new MAS™ Omni Infectious Control products that mimic patient samples have been developed for the assessment of assay performance on the Siemens Assay Platform in the clinical laboratory for anti-HBc, anti-HCV, and Hepatitis B surface antigen (HBsAg). These reliable and stable control materials will better support the assessment of serological assay performance on the Siemens platforms.

*Availability of product in each country depends on local regulatory marketing authorization status

Introduction

The MAS™ Omni Infectious Controls – For Use with Siemens Assays introduce two new products to the MAS™ Omni Infectious Serological Controls Products. The MAS™ Omni Infectious BSI Positive Control Panel – For Use with Siemens Assays has been developed and introduced to optimize the performance of anti-HBc, anti-HCV, and HBsAg on the Siemens platforms. As the performance of anti-HTLV and anti-HIV have previously been proven to show adequate performance on the Siemens platforms, no adjustments have been made for these two analytes. Therefore, the focus of the work presented here is centered on anti-HBc, anti-HCV, and HBsAg. The MAS™ anti-HBs Positive Control – For Use with Siemens Assays has been developed and introduced to better optimize the performance of anti-HBs on the Siemens platforms.

Methods/Materials

The MAS™ Omni Infectious BSI Positive Control Panel – For Use with Siemens Assays has been evaluated on Abbott Architect (anti-HBc, anti-HCV, anti-HIV 1/2, and HBsAg), Siemens Advia Centaur (anti-HBc, anti-HCV, and HBsAg), and DiaSorin Murex (anti-HTLV I/II).

MAS™ Product Description	Analyte	Pack Size	Shelf Life @ 2-8 °C	Open Vial Stability @ 2-8 °C
Thermo Scientific™ MAS™ Omni Infectious BSI Positive Control Panel – For Use with Siemens Assays (10027480-U)	anti-HIV 1/2 anti-HTLV I/II HBsAg anti-HBc anti-HCV	5 X 5 mL	12 months	60 days
Thermo Scientific™ MAS™ anti-HBs Positive Control – For Use with Siemens Assays (10027482-U)	anti-HBs	5 X 1 mL	24 months	30 days

Table 1: MAS Omni Infectious Serological Controls

Results

Performance Screening:

MAS™ Product Description	Analyte	Abbott Architect Mean (S/CO)	Siemens Centaur Mean (S/CO)
Thermo Scientific™ MAS™ Omni Infectious BSI Positive Control Panel – For Use with Siemens Assays (10027480-U)	HBsAg	Positive	Positive
	anti-HIV	Positive	Not Tested
	anti-HTLV	Positive*	Not Tested
	anti-HBc	Positive	Positive
	anti-HCV	Positive	Positive
MAS™ Product Description	Analyte	Abbott Architect Mean (mIU/mL)	Siemens Centaur Mean (mIU/mL)
Thermo Scientific™ MAS™ anti-HBs Positive Control – For Use with Siemens Assays (10027482-U)	anti-HBs	Positive	Positive

Table 2: Performance of MAS™ Omni Infectious Controls on different assay platforms.

*Anti-HTLV was tested using DiaSorin Murex HTLV I/II ELISA Kit.

MAS™ Product Description	Analyte	Abbott Architect Mean (S/CO)	Siemens Centaur Mean (S/CO)
Thermo Scientific™ MAS™ Omni Infectious BSI Positive Control Panel – For Use with Siemens Assays (10027480-U)	HBsAg	6.98	5.48
	anti-HIV	6.19	Not Tested
	anti-HTLV	5.05*	Not Tested
	anti-HBc	4.00	3.74
	anti-HCV	3.46	4.75
MAS™ Product Description	Analyte	Abbott Architect Mean (mIU/mL)	Siemens Centaur Mean (mIU/mL)
Thermo Scientific™ MAS™ anti-HBs Positive Control – For Use with Siemens Assays (10027482-U)	anti-HBs	36.9	15.93** 20.4**

Table 3: Comparison of Assay Performance of MAS™ Omni Infectious Controls on Abbott Architect and Siemens Advia Centaur.

*Anti-HTLV was tested using DiaSorin Murex HTLV I/II ELISA Kit.

**Controls were tested on two lots of Siemens reagents

Product Evaluation:

Siemens Reagent Lot	MAS™ anti-HBs Positive Control - For use with Siemens Assays					Within-Run (mIU/mL)	Within-Lot (mIU/mL)
	Sample ID	Rep 1 (mIU/mL)	Rep 2 (mIU/mL)	Rep 3 (mIU/mL)	Mean (mIU/mL)		
#144	AHBD23041V.1	.21	.21	.20	Mean: 20.4 %CV: 2.5	Mean: 18.2 %CV: 12.8	
	AHBD23041V.2	.20	.20	.20			
	AHBD23041V.3	.20	.21	.21			
	AHBD23041V.4	.21	.20	.20			
	AHBD23041V.5	.21	.20	.20			
#146	AHBD23041V.1	.16	.17	.16	Mean: 15.9 %CV: 2.9		
	AHBD23041V.2	.15	.15	.16			
	AHBD23041V.3	.16	.16	.16			
	AHBD23041V.4	.16	.16	.16			
	AHBD23041V.5	.16	.16	.16			

Table 4: Performance of MAS™ anti-HBs Positive Control – For use with Siemens Assays on the Siemens ADVIA Centaur analyzers

MAS™ Omni Infectious BSI Positive Control Panel - For Use with Siemens Assays						
Analyte	Siemens Centaur ID	107	108	206	207	
HBsAg	Within-Run Mean (S/CO)	5.67	5.30	5.67	5.27	
	Within-Run SD	0.14	0.18	0.13	0.12	
	Within-Run %CV	2.53	3.45	2.21	2.35	
Anti-HBc	Siemens Centaur ID	107	108	206	207	
	Within-Run Mean (S/CO)	3.70	3.63	3.81	3.81	
	Within-Run SD	0.16	0.16	0.22	0.12	
Anti-HCV	Within-Run %CV	4.43	4.51	5.68	3.12	
	Siemens Centaur ID	107	108	206	207	
	Within-Run Mean (S/CO)	4.64	4.95	4.60	4.83	
Anti-HIV	Within-Run SD	0.19	0.26	0.16	0.20	
	Within-Run %CV	4.06	5.32	3.57	4.21	

Table 5: Within-Run Performance of MAS™ Omni Infectious BSI Positive Control Panel – For use with Siemens Assays across four Siemens ADVIA Centaur Analyzers

MAS™ Omni Infectious BSI Positive Control Panel - For Use with Siemens Assays				
Analyte	Within-Lot Mean (S/CO)	Within-Lot SD	Within-Lot %CV	
HBsAg	5.48	0.24	4.40	
Anti-HBc	3.74	0.18	4.88	
Anti-HCV	4.75	0.25	5.22	

Table 6: Within-Lot Performance of MAS™ Omni Infectious BSI Positive Control Panel – For use with Siemens Assays across four Siemens ADVIA Centaur Analyzers

Conclusions

The MAS™ Omni Infectious BSI Positive Control Panel – For Use with Siemens Assays are stable and ready-to-use control materials that will better support the assessment of serological assay performance for anti-HBc, anti-HCV, and HBsAg on the Siemens platforms.

The MAS™ anti-HBs Positive Control – For Use with Siemens Assays are stable and ready-to-use control materials that will better support the assessment of serological assay performance for anti-HBs on the Siemens platforms.

The functional, physical, usability, performance, and reliability performance were assessed, verified, and validated. Upon evaluation, the MAS™ Omni Infectious Serological Controls – For Use with Siemens Assays demonstrated consistent performance to meet functional, physical, usability, performance, and reliability requirements during the verification and validation studies. The products have been launched in the US as IVD products.

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