Performance of CMV QN assay from Altona Diagnostics S-28

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Introduction

The human Cytomegalovirus (CMV) is a member of the family Herpesviridae and belongs to the subfamily betaherpesvirinae. It consists an icosahedral capsid with a linear double-stranded DNA genome of approximately 230 kbp, a surrounding integument and an outer envelope. CMV has a worldwide distribution and infects humans of all ages, with no seasonal or epidemic patterns of transmission. The seroprevalence of CMV increases with age in all populations and ranges from 40 to 100%. Similar to infections with other herpesviruses, primary infection with CMV results in the establishment of a persistent or latent infection. Reactivation of the virus can occur in response to different stimuli, particularly immunosuppression. The vast majority of CMV infections are asymptomatic or subclinical, but congenital infections and infections in immunocompromised patients may be symptomatic and serious. In immunocompromised hosts, such as transplant recipients, HIV-infected or cancer patients, a CMV infection or reactivation may become a life-threatening disseminated disease.

Materials and Methods

Materials: One hundred eighty three, previously tested (urine, plasma and body fluids) clinical samples were extracted using Abbott m2000sp protocol

Methods:

Method 1. Laboratory-developed test (LDT) CMV quantitation assay based on Qiagen ASR real time qPCR and Acrometrix quantification standards run on Abbott m2000rt instrument.

Method 2. RealStar® CMV PCR Kit 1.0 assay based on quantitative real time PCR from Altona Diagnostics run on Roche LC480.

Analytical sensitivity and LOD were determined by run dilutions of the AcroMetrix® CMV Panel - Life Technologies and Altona standards provided in RealStar CMV kit.

Results

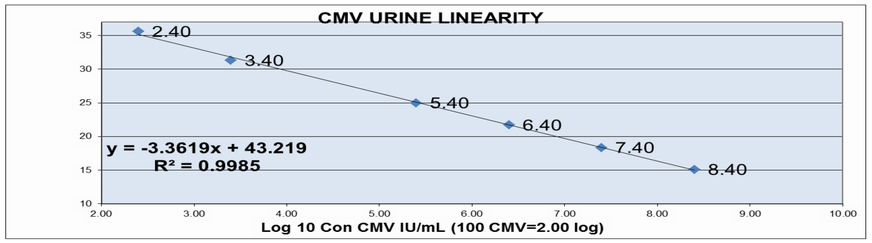
The RealStar® CMV PCR method demonstrated 100% agreement with the ASR CMV Qiagen assay: 114/114 positive samples were detected and 69/69 were not detected by each method. Of the 114 detectable samples, 5 were below the limit of quantification (LOQ) for each assay and thus correlated well. All detectable samples (N=114) were within tolerance +/- 0.5 log. Correlation regression was (R2=0.9441). Based on the Bland-Altman analysis, the mean difference (bias) between the two assays was -0.193, with 95% confidence intervals (-0.809 and 0.420). Analytical specificity was 100% when run against 47 different microbial and viral targets. RealStar CMV assay had the following characteristics: LOQ = 150 IU/mL; linear range 150-6,000,000 IU/mL; slope, -3.256; R 2 value=0.9987; PCR efficiency, 96%.

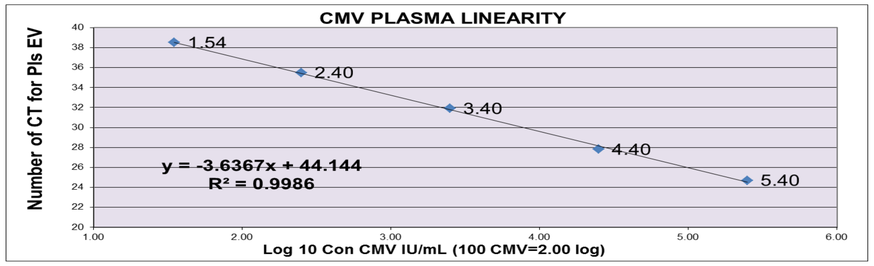
Instrumentation

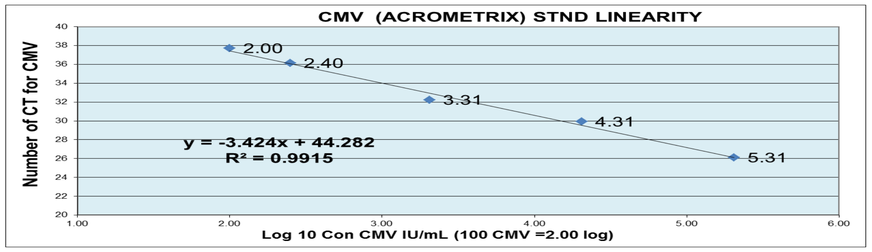
Abbott *m*2000sp

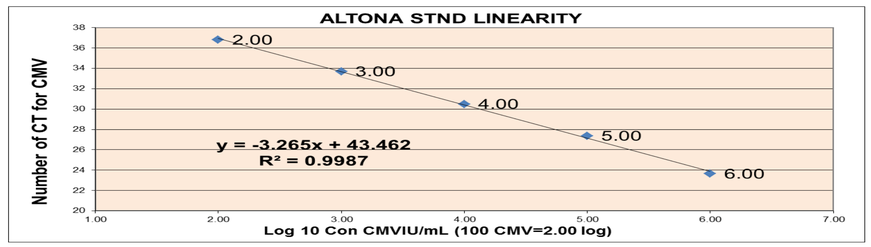
Roche LC480

Results Comparison









Results

		CMV QUANT ACL		
ALTONA		+	-	Total
CMV	+	53	0	
	-	0	69	
			Total	0

%	
100.0	Clinical Sensitivity = TP/(TP+FN)%
100.0	Clinical Specificity = TN/(FP+TN)%
100.0	Positive Predictive Value (PPV) = TP/(TP+FP)%
100.0	Negative Predicative Value (NPV) = TN/(FN+TN)%

PRECISION QC x 20 intra run

#	HPOS	HPOS	LPOS	LPOS	NEG CT	Neg ic
1	433000	5.64	29200	4.47	NOTD	30
2	455000	5.66	35200	4.55	NOTD	30
3	431000	5.63	26500	4.42	NOTD	30
4	477000	5.68	22300	4.35	NOTD	30
5	473000	5.67	27200	4.43	NOTD	27
6	431000	5.63	39100	4.59	NOTD	29
7	291000	5.46	23400	4.37	NOTD	28
8	381111	5.58	21900	4.34	NOTD	29
9	479000	5.68	43100	4.63	NOTD	27
20	204000	5.31	13100	4.12	NOTD	29
10	139000	5.14	13100	4.12	NOTD	29
11	137000	5.14	8100	3.91	NOTD	29
12	58700	4.77	3050	3.48	NOTD	28
13	70000	4.85	4310	3.63	NOTD	28
14	78000	4.89	2860	3.46	NOTD	28
15	57700	4.76	5070	3.71	NOTD	28
16	93600	4.97	5150	3.71	NOTD	29
17	35300	4.55	3750	3.57	NOTD	31
18	30900	4.49	17600	4.25	NOTD	31
19	38600	4.59	4040	3.61	NOTD	31
21	98800	4.99	6960	3.84	NOTD	27
22	65700	4.82	4320	3.64	NOTD	31
Ave		5.18		4.05		29.09
Stdn		0.427		0.402		1.229
%cv		8.3		9.9		4.2

ANALYTICAL SPECIFICITY 100%

	ACC	SOURCE	POS VIRUS	ALTONA	IC
1	H3299082	BRWA	MYCO	NOTD	27.7
2	F3186748	UTM	LEG	NOTD	27.3
3	R16701112	UTM	HSV P2	NOTD	27.4
4	R16738518	UTM	HSV P2	NOTD	27.3
5	H4048581	ESWAB	HSV P2	NOTD	27.4
6	R16679343	ESWAB	HSV P1	NOTD	27.3
7	R16685981	ESWAB	HSV P1	NOTD	27.4
8	T4144318	ESWAB	BP	NOTD	27.2
9	X3539456	ESWAB	E/R	NOTD	27.5
10	X3528760	ESWAB	RSV A	NOTD	28.3
11	S4088983	ESWAB	HMPV	NOTD	27.4
12	H4059235	BLA	HMPV	NOTD	27.7
13	R16709410	Plasma	HIV	NOTD	28.0
14	R16745842	Plasma	HIV	NOTD	26.7
15	F3943449	Plasma	HCV	NOTD	26.8
16	R16746964	Plasma	HCV	NOTD	27.3
17	R16733039	Plasma	HCV	NOTD	26.8
18	F3946335	Plasma	HCV	NOTD	27.3
19	R16690310	Plasma	BKV	NOTD	26.7
20	F3940156	Plasma	BKV	NOTD	27.4
21	H4045590	Plasma	HBV	NOTD	26.5
22	R16689237	Plasma	HBV	NOTD	27.4
23	R16713957	Plasma	HBV	NOTD	27.4
24	R17032992	UTM	VZV	NOTD	26.5
25	R17032992	UTM	VZV	NOTD	26.6
26	M3908512	ESWAB	CORONAVIRUS OC43	NOTD	27.3
27	X3549028	ESWAB	FLU A	NOTD	27.0
28	X3550355	ESWAB	FLU B	NOTD	26.5
29	X3546390	UTM	FLUB	NOTD	26.6
30	H3900187	UTM	RSV A	NOTD	26.0
31	X3553678	ESWAB	RSV B	NOTD	26.5
32	X3558159	ESWAB	RSV B	NOTD	26.6
33	X3545924	BLA	RSV B	NOTD	26.3
34	6258	ATCC	C. krusei	NOTD	27.8
35	34877	ATCC	C. albicans	NOTD	26.8
36	13047	ATCC	E. cloacea	NOTD	27.4
37	25238	ATCC	M. cattarrhalis	NOTD	27.4
38	700603	ATCC	K. pneumoniae	NOTD	27.5
39	49619	ATCC	S. pneumoniae	NOTD	27.5
40	25922	ATCC	E. coli	NOTD	27.3
41	34877	ATCC	C. neoformans	NOTD	28.7
42	22019	ATCC	C. parapsolisis	NOTD	26.4
43	10211	ATCC	H. influenzae	NOTD	26.3
44		ATCC	B. bronchisepta	NOTD	27.3
45	15480	ATCC	B. holmesii	NOTD	27.3
46	9797D	ATCC	B. pertussis	NOTD	26.8
47		ATCC	B. parapertussis	NOTD	26.6
					27.1

Conclusions

This study demonstrates that RealStar® CMV qPCR from Altona Diagnostics performs as well as Qiagen CMV ASR in-house assay. The performance characteristics are suitable for clinical diagnosis and monitoring of the transplant patient population.

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