



# Performance of EBV QN assay from Altona Diagnostics S-27



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## Introduction

Epstein-Barr Virus (EBV) is a member of the family Herpesviridae. It has a doublestranded 172 kbp DNA which exists in a linear form in the mature virion and in a circular, episomal form in latently infected cells. EBV primarily infects lymphoid cells of the B lineage. EBV is unique among the herpesviruses in its ability to transform precursor and mature human B lymphocytes, converting them into lymphoblastoid lines capable of continuous proliferation. EBV is the etiologic agent of infectious mononucleosis. Virtually everyone becomes infected with the virus at some time during life. Childhood infections are mostly asymptomatic. EBV has been associated with some cancers, including Burkitt's lymphoma and nasopharyngeal carcinoma (NPC). The virus is also increasingly being recognized as an important viral agent in transplant recipients.

## Materials and Methods

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

### Methods:

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

**Method 2.** RealStar® EBV qPCR 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® EBV Panel from Life Technologies/ThermoFisher and Altona standards provided in RealStar® EBV kit.

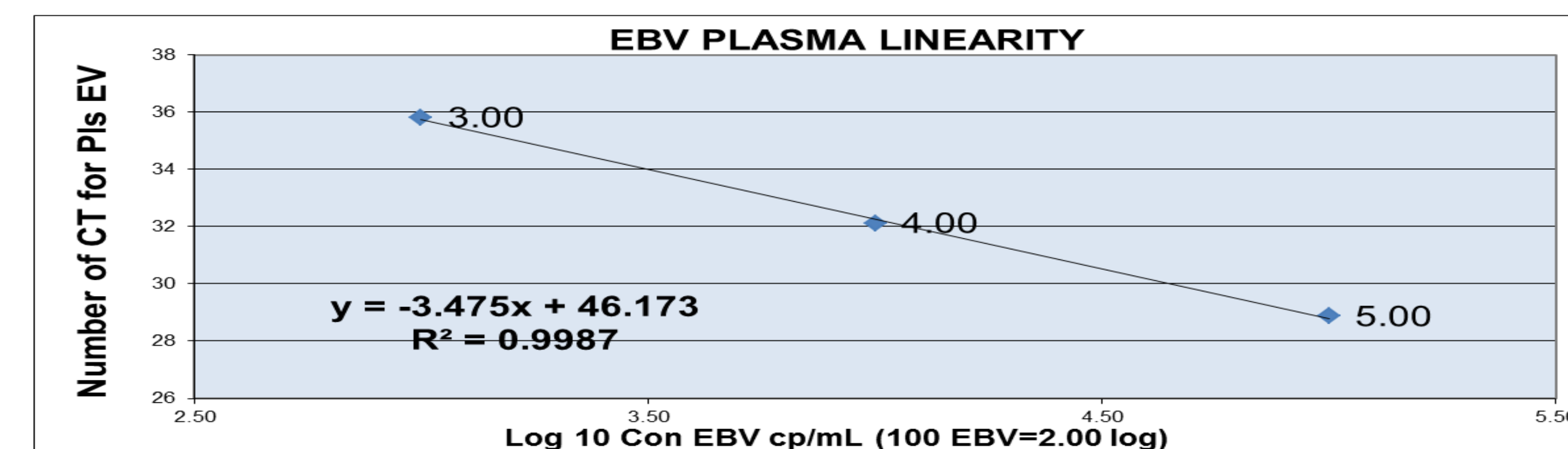
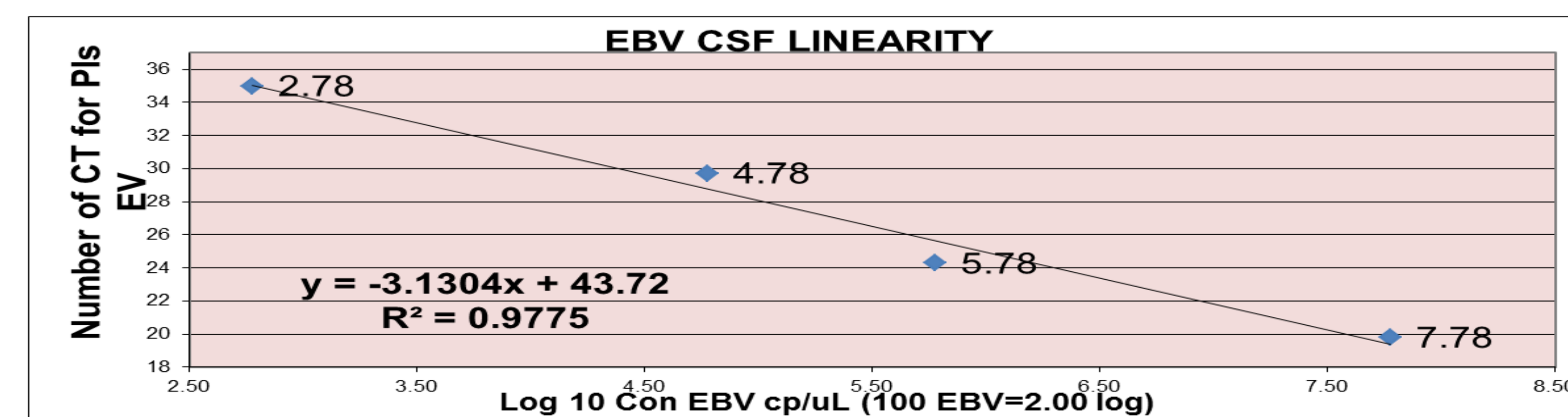
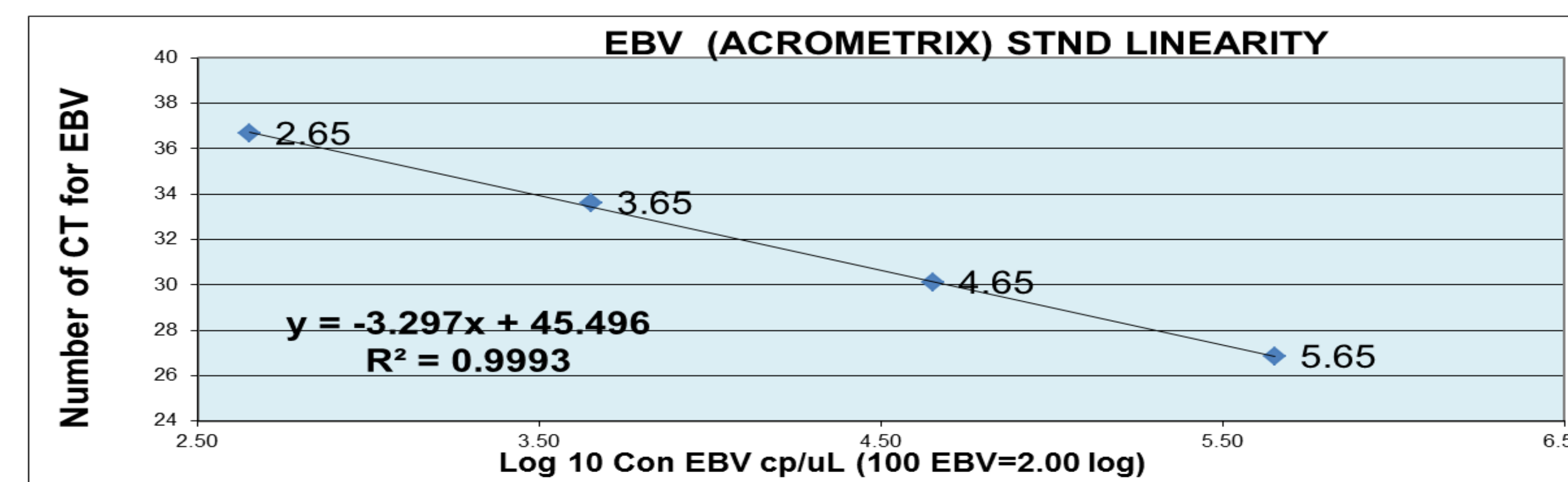
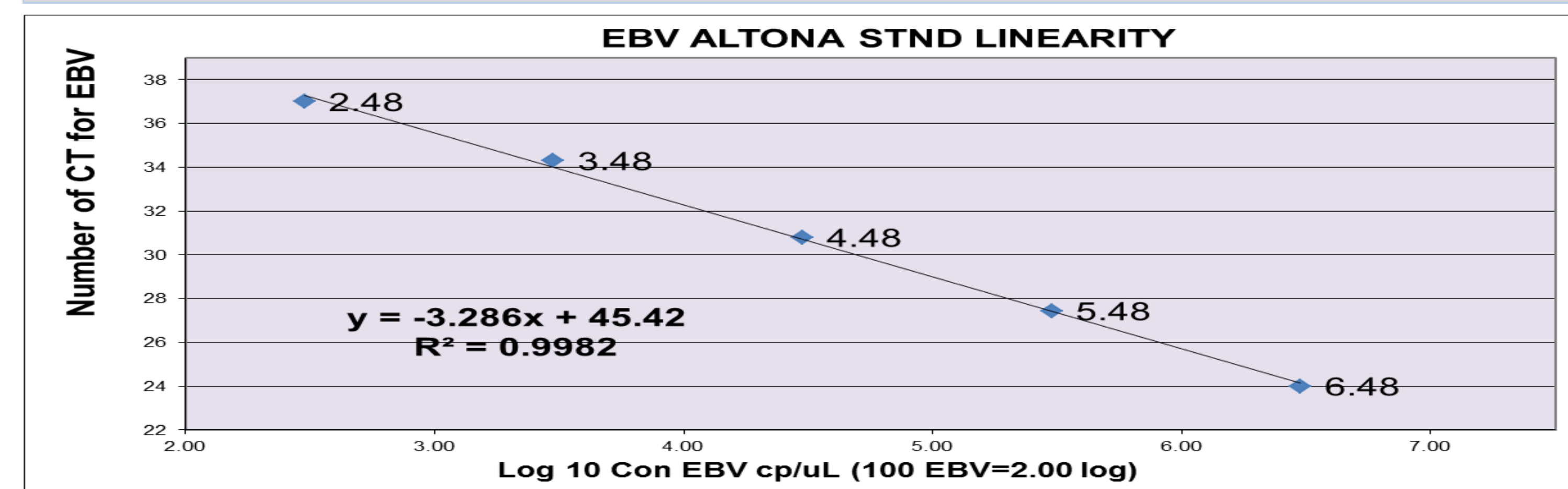
## Results

The RealStar® EBV qPCR method demonstrated 97% agreement with the LDT assay: 110/113 clinical samples were detected and 61/62 were not detected by each method. Of the 113 detectable samples, 3 were close to the limit of quantification (LOQ) for each assay and were not detected. All detectable samples (N=110) were within tolerance +/- 0.6 log. Correlation regression was (R2=0.888). Based on the Bland-Altman analysis, the mean difference (bias) between the two assays was -0.338, with 95% confidence intervals (-1.200 and 0.527). Analytical specificity was 100% when run against 43 different microbial and viral targets. RealStar® EBV assay had the following characteristics: LOQ = 500cp/mL; linear range 500-10,000,000 cp/mL; slope, -3.286; R 2 value=0.9982; PCR efficiency, 97%.

## Instrumentation



## Results Comparison



## Results

		EBV ACL		
ALTONA		+	-	Total
EBV	+	52	1	53
	-	3	62	65
		Total		118
%				
94.5	Clinical Sensitivity = TP/(TP+FN)%			
98.4	Clinical Specificity = TN/(FP+TN)%			
98.1	Positive Predictive Value (PPV) = TP/(TP+FP)%			
95.4	Negative Predictive Value (NPV) = TN/(FN+TN)%			

ANALYTICAL SPECIFICITY					100%
ACC	SOURCE	POS VIRUS	ALTONA	IC	
1	H329082	UTM	MYCO	NOTD	26.8
2	F3186748	UTM	LEG	NOTD	26.5
3	R16701112	UTM	HSV P2	NOTD	26.5
4	R16738518	UTM	HSV P2	NOTD	26.6
5	H4048581	ESWAB	HSV P2	NOTD	26.8
6	R16679343	ESWAB	HSV P1	NOTD	26.4
7	R16685981	ESWAB	HSV P1	NOTD	26.6
8	T4144318	ESWAB	BP	NOTD	26.7
9	X3528760	ESWAB	RSV A	NOTD	26.7
10	S4088983	ESWAB	HMPV	NOTD	26.9
11	H4059235	BRW	HMPV	NOTD	27.3
12	R16709410	Plasma	HIV	NOTD	27.8
13	R16746964	Plasma	HCV	NOTD	26.8
14	R16733039	Plasma	HCV	NOTD	27.7
15	F3946335	Plasma	HCV	NOTD	28.7
16	R16756687	Plasma	BKV	NOTD	28.6
17	R16690310	Plasma	BKV	NOTD	30.8
18	F3940156	Plasma	BKV	NOTD	28.4
19	H4045590	Plasma	HBV	NOTD	27.0
20	R16689237	Plasma	HBV	NOTD	28.3
21	R16713957	Plasma	HBV	NOTD	26.7
22	R17035117	UTM	VZV	NOTD	28.2
23	R17032992	UTM	VZV	NOTD	27.6
24	M3908512	ESWAB	DRONAVIRUS OC	NOTD	28.1
25	X3549028	ESWAB	FLU A	NOTD	27.8
26	X3550355	ESWAB	FLU B	NOTD	27.9
27	H3900187	UTM	RSV A	NOTD	27.8
28	X3553678	ESWAB	RSV B	NOTD	27.8
29	X3545924	UTM	RSV B	NOTD	27.8
30	6258	ATCC	C. krusei	NOTD	26.9
31	34877	ATCC	C. albicans	NOTD	27.3
32	13047	ATCC	E. cloacea	NOTD	27.6
33	25238	ATCC	M. cattarrhalis	NOTD	29.3
34	700603	ATCC	K. pneumoniae	NOTD	27.6
35	49619	ATCC	S. pneumoniae	NOTD	27.3
36	25922	ATCC	E. coli	NOTD	27.3
37	34877	ATCC	C. neoformans	NOTD	27.4
38	22019	ATCC	C. parapsittosis	NOTD	26.6
39	10211	ATCC	H. influenzae	NOTD	26.7
40		ATCC	B. bronchisepta	NOTD	27.5
41	15480	ATCC	B. holmesii	NOTD	28.3
42	9797D	ATCC	B. pertussis	NOTD	26.4
43		ATCC	B. paraptussis	NOTD	26.8

PRECISION QC x 20 intra run					
	H POS	Log	LPOS	Log	IC
1	87400	4.94	5900	3.77	NOTD 30
2	124000	5.09	13600	4.13	NOTD 30
3	127000	5.10	6700	3.83	NOTD 30
4	126000	5.10	10700	4.03	NOTD 29
5	90200	4.96	6180	3.79	NOTD 28
6	85800	4.93	2490	3.40	NOTD 30
7	172000	5.24	17500	4.24	NOTD 28
8	220000	5.34	12800	4.11	NOTD 28
9	113000	5.05	7480	3.87	NOTD 31
10	28900	4.46	4150	3.62	NOTD 31
11	37800	4.58	2700	3.43	NOTD 31
12	32100	4.51	2540	3.40	NOTD 31
13	31000	4.49	2210	3.34	NOTD 31
14	37400	4.57	2290	3.36	NOTD 31
15	44400	4.65	3390	3.53	NOTD 31
16	97400	4.99	5900	3.77	NOTD 33
17	53100	4.73	3090	3.49	NOTD 26
18	67800	4.83	3890	3.59	NOTD 30
19	13100	4.12	660	2.82	NOTD 27
20	55700	4.75	4280	3.63	NOTD 29
Ave		4.82		3.66	29.86
Stdn		0.308		0.337	1.814
%cv		6.4		9.2	6.1

## Conclusions

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

## References

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