Performance Evaluation of the Aptima® HCV Quant Dx assay on the fully automated Panther system in comparison to cobas® HCV test for cobas® 6800/8800

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Background

Quantification of HCV RNA viral load plays a key role in management of HCV infected patients, before and during antiviral therapy.
In this study we compared the overall performance of the Hologic Aptima® HCV Quant Dx, a quantitative HCV assay based on real-time Transcription Mediated Amplification (TMA) technology, developed for the Panther system, with the Roche cobas® HCV assay for c6800/8800.

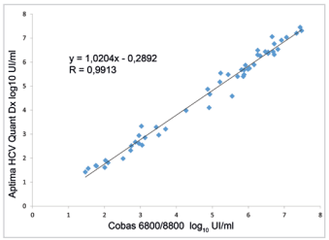
Assay performance

Method comparison

276 serum samples (84 fresh and 192 frozen) from HCV-infected patients were tested, using Aptima® HCV Quant Dx Assay, based on HCV viral load, as determined by routine testing using cobas® 6800/8800.

Prospective results

Fig 1. Comparison of Hologic and Roche assays (prospective, n=53)



- Deming regression was excellent between the 2 assays for quantifiable samples
- y = 1,02x-0,29, R = 0.991

Tab 1. Agreement between Hologic and Roche assays for detection and quantification of HCV RNA

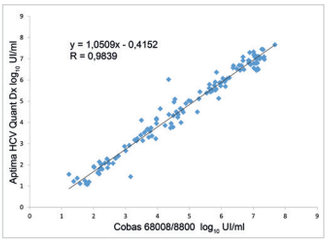
		Aptima HCV Quant Dx UI/ml			
TND: target not detected		TND	< 10	Quant	Total
Cobas 6800/8800 UI/ml	TND	**21**	0	0	**21**
	< 15	2	**4**	0	**6**
	Quant	1*	3**	**53**	**57**
	Total	**24**	**7**	**53**	**84**

* Roche 19UI/ml
** Threshold value between 16 and 40 UI/ml

- We observed a very good correlation between the 2 assays
- The overall percentage of agreement was 92,9%
- Kappa : 0.86

Retrospective results

Fig 2. Comparison of Hologic and Roche assays (retrospective, n=130)



- Deming regression was excellent between the 2 assays for quantifiable samples
- y = 1,05x-0,41, R = 0.984

Tab 2. Agreement between Hologic and Roche assays for detection and quantification of HCV RNA

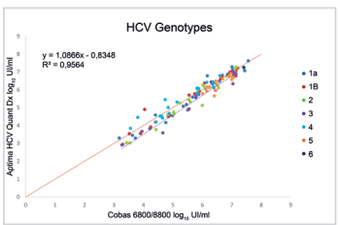
		Aptima HCV Quant Dx UI/ml			
TND: target not detected		TND	< 10	Quant	Total
Cobas 6800/8800 UI/ml	TND	**21**	0	0	**21**
	< 15	9	**13**	0	**22**
	Quant	1*	8**	**130**	**139**
	Total	**31**	**21**	**130**	**182**

* Roche 15 UI/ml ** Threshold value between 16 and 33 UI/ml

- We observed a good correlation between the 2 assays
- The overall percentage of agreement was 85,4%
- Kappa: 0.7
- Discrepant results were observed at very low viral load

Method comparison according to the genotype

Fig 3. Comparison of Hologic and Roche assays according to the genotype



- 111 retrospective samples from HCV-infected patients with a defined genotype (GT): (GT1a:19, GT1b:21, GT2:19, GT:18, GT4:19, GT5:14, GT6:1) were tested
- Excellent correlation was observed for all genotypes tested (GT 1 to 6) between the 2 assays

Analytic performance with reference panel

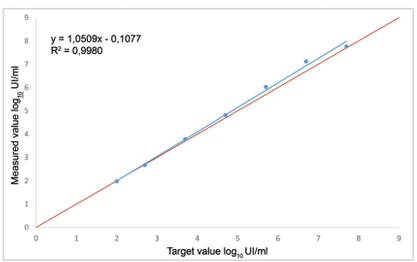
Serial dilution of Acrometrix panel (n=4 dilution per level) were used to assess repeatability and precision

Tab 3. Acrometrix HCV panel results

Samples	Target value log_{10} UI/ml	Result 1 log_{10} UI/ml	Result 2 log_{10} UI/ml	Result 3 log_{10} UI/ml	Result 4 log_{10} UI/ml	Mean log_{10} UI/ml	SD	Δ between expected and target
1	7,70	7,77	7,80	7,72	7,73	7,76	0,04	**0,06**
2	6,70	7,09	7,09	7,10	7,19	7,12	0,05	**0,42**
3	5,70	6,06	5,99	6,00	6,03	6,02	0,03	**0,32**
4	4,70	4,83	4,94	4,69	4,81	4,82	0,10	**0,12**
5	3,70	3,84	3,73	3,76	3,78	3,78	0,05	**0,08**
6	2,70	2,73	2,75	2,61	2,57	2,67	0,09	**-0,03**
7	2,00	1,90	1,99	1,88	2,13	1,98	0,11	**-0,02**

- Mean difference between measured and expected values was < 0.42 Log for serial dilution of Acrometrix panel tested 4 times per level.
- Repeatability was excellent with SD ranging from 0.11 to 0.03 Log.

Fig 4. Linearity with Acrometrix HCV panel



Analytic performance with serum samples

Tab 4. Reproducibility with serum samples from patients genotype 1a

Target value log_{10}/ml	Result 1 log_{10}/ml	Result 2 log_{10}/ml	Result 3 log_{10}/ml	Result 4 log_{10}/ml	Result 5 log_{10}/ml	Result 6 log_{10}/ml	Result 7 log_{10}/ml	Result 8 log_{10}/ml	Result 9 log_{10}/ml	Result 10 log_{10}/ml	Observed mean	SD	Δ between expected and target
3,08	2,86	2,89	2,86	2,94	2,95	2,83	3,02	2,85	3,02	2,99	2,92	0,07	**0,16**
2,08	1,95	2,09	1,74	1,95	1,88	1,85	2,11	1,91	1,8	1,83	1,91	0,12	**0,17**
1,48	1,3	1,49	1,45	1,27	1,35	1,35	1,42	1,29	1,33	1,38	1,36	0,07	**0,11**

Tab 5. Reproducibility with serum samples from patients genotype 4

Target value log_{10}/ml	Result 1 log_{10}/ml	Result 2 log_{10}/ml	Result 3 log_{10}/ml	Result 4 log_{10}/ml	Result 5 log_{10}/ml	Result 6 log_{10}/ml	Result 7 log_{10}/ml	Result 8 log_{10}/ml	Result 9 log_{10}/ml	Result 10 log_{10}/ml	Observed mean	SD	Δ between expected and target
3,01	3,08	3	3	3,05	3,01	3,07	3,03	3,02	3,04	3,15	3,05	0,05	**-0,04**
2,01	2,15	2,03	2,01	1,99	2,14	2,04	2,14	2,17	2,03	2,18	2,09	0,07	**-0,08**
1,40	1,74	1,38	1,53	1,47	1,33	1,73	1,33	1,5	1,34	1,58	1,49	0,15	**-0,10**

- Reproducibility assessed by testing serial dilutions (3 to 1.4 Log) of serum samples from patients (GT1a and GT4), N=10 per dilution level, was excellent for both genotypes, (SD's ranging from 0.05 to 0.15 Log).

Cross contamination

No cross contamination was observed when testing 5 consecutive runs using negative control and high positive control samples alternately.

Conclusion

The Hologic Aptima® HCV Quant Dx assay on the fully automated Panther system gave highly comparable performance to the cobas® 6800/8800 system for clinical samples. Reproducibility and repeatability using dilution series were excellent with commercially available panels or clinical samples. The Aptima assay, with just 0.5 ml sample input volume, was easy to use and could generate 120 test results in less than four hours. Overall the Hologic Aptima® quant Dx assay is highly suitable for use in the clinical laboratory setting.

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