Evaluation of Commercially Available HPV Panels with the Alinity m HR HPV Investigational Use Only (IUO) Assay

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BACKGROUND

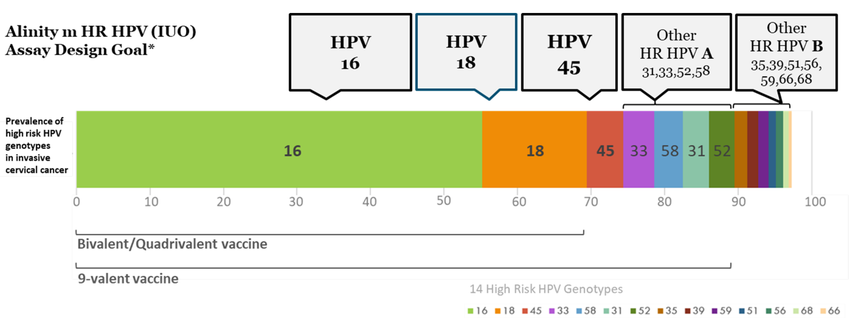
Human papillomavirus (HPV) infections are among the most common sexually transmitted infections that are responsible for almost all cervical cancers. HPV is a non-enveloped, double stranded DNA virus that replicates in the nucleus of squamous epithelial cells and induces hyperproliferative lesions. The Alinity m HR HPV Investigational Use Only (IUO) assay targets the conserved sequence within the L1 region of the HPV genome and was developed for robust detection of high-risk genotypes and partial genotyping for clinically relevant risk stratification where 16, 18, and 45 are individually reported and the remaining 11 targeted genotypes are aggregated into two groups A (31/33/52/58) and B (35/39/51/56/59/66/68). Here we evaluated the analytical performance of Alinity m HR HPV IUO assay with commercially available panels containing multiple HPV genotypes.

METHODS

This evaluation included three unique HPV panel sets that are commercially available from Microbix and included panels:

- VP-62-M1 (16/18/45),
- VP-62-M2 (31/33/66), and
- VP-62-M3 (39/51/52).

The panels were tested in triplicate over three days and standard deviation (SD) and coefficient of variation (CV) were calculated for each panel sets.



Dilution Protocol:

Panel VP-62-M1 (16/18/45)

1. Once material is at room temp and liquid, for 2 vials of VP-62-M1 (5.0mLs) and combine with 2.0mLs of neat ThinPrep in an Alinity m Transport Tube (total volume=10.0mL). Cap and mix gently.
2. Distribute 0.60mLs per tube to 3 Alinity m Transport Tubes.
3. Run 3 Alinity m Transport Tubes on Alinity m with Alinity m HR HPV (IUO)
4. Record Results and Interpretation for each system and include CNs for targets and cellular control. Alinity m CN/MR.
5. Repeat steps 1-4 over three days.

Panel VP-62-M2 (39/51/52)

1. Once material is at room temp and liquid, follow above for 3 vials of VP-62-M3.
2. Distribute entire volume (1.0mL) from each vial to 3 Alinity m Transport Tubes.
3. Run 3 Alinity m Transport Tubes.
4. Record Results and Interpretation for each system and include CNs for targets and cellular control.
5. Repeat steps 1-4 over three days.

Panel VP-62-M3 (39/51/52)

1. Once material is at room temp and liquid, follow above for 3 vials of VP-62-M3.
2. Distribute entire volume (1.0mL) from each vial to 3 Alinity m Transport Tubes.
3. Run 3 Alinity m Transport Tubes on Alinity m.
4. Record Results and Interpretation for each system and include CNs for targets and cellular control.
5. Repeat steps 1-4 over three days.

RESULTS

Table 1 Alinity m HR HPV IUO Precision

Microbix Panel		VP-62-M1 (16/18/45)				VP-62-M2 (31/33/66)			VP-62-M3 (39/51/52)		
HPV GT		16	18	45	CC	Group A 31 / 33	Group B 66	CC	Group A 52	Group B 39 / 51	CC
Day 1	Average CN	24.77	21.75	26.71	25.64	23.95	23.64	26.73	25.07	24.32	24.14
	SD	0.42	0.67	0.37	0.55	0.57	0.42	0.25	0.47	0.35	0.41
	%CV	1.70	3.08	1.40	2.14	2.37	1.79	0.92	1.89	1.43	1.72
Day 2	Average CN	24.18	21.40	26.09	24.99	24.05	23.46	26.66	24.43	23.56	22.97
	SD	0.19	0.26	0.17	0.15	0.23	0.28	0.17	0.41	0.35	1.14
	%CV	0.78	1.20	0.63	0.60	0.97	1.18	0.62	1.66	1.51	4.95
Day 3	Average CN	24.18	20.98	26.67	25.02	23.69	23.31	26.46	24.34	23.43	23.28
	SD	0.13	0.19	0.22	0.11	0.28	0.45	0.12	0.35	0.51	0.49
	%CV	0.53	0.91	0.83	0.44	1.19	1.95	0.46	1.42	2.17	2.11
Totals	Average CN	24.38	21.38	26.49	25.22	23.90	23.47	26.62	24.61	23.77	23.46
	SD	0.38	0.50	0.38	0.43	0.38	0.37	0.20	0.50	0.55	0.84
	%CV	1.56	2.34	1.43	1.71	1.57	1.56	0.76	2.02	2.30	3.56

- Panel member VP-62-M1 (16/18/45), the Alinity m HR HPV (IUO) average cycle number, SD, and %CV across nine replicates for HPV 16 was 24.38, 0.25, and 1.00%; for HPV 18 was 21.38, 0.37, 1.73%, for HPV 45 was 26.49, 0.25, and 0.95%.
- Panel VP-62-M2 (31/33/66), the Alinity m HR HPV (IUO) average cycle number, SD, and %CV across nine replicates for HPV 31/33 (Alinity m HR HPV (IUO) Group A) was 23.90, 0.36, and 1.51%; for HPV 66 (Alinity m HR HPV (IUO) Group B) was 23.47, 0.38, and 1.64%.
- Panel VP-62-M3 (39/51/52) the Alinity m HR HPV (IUO) average cycle number, SD, and %CV across nine replicates for HPV 39/51 (Alinity m HR HPV (IUO) Group B) was 23.77, 0.40, and 1.70%; for HPV 52 (Alinity m HR HPV (IUO) Group A) was 24.61, 0.41, and 1.66%.

CONCLUSIONS

Alinity m HR HPV (IUO) assay demonstrated 100% detection across the tested panels. The assay SD across the 3 panels was ≤0.40 and % CV was ≤1.73%.

DISCLOSURES

Josh Kostera and Danijela Lucic are employees of Molecular Diagnostics of Abbott (Des Plaines, IL, USA).

Alinity m HR HPV (IUO) reagents were provided by Molecular Diagnostics of Abbott (Des Plaines, IL, USA) for the completion of this study.