

# 110P - Detection of HER2 overexpression in biliary tract cancers: comparison of AmoyDx<sup>®</sup> HER-2 (29D8) assay with Ventana PATHWAY anti-HER-2/neu (4B5) assay

Hui Dong<sup>1#</sup>, Wenqing Su<sup>2</sup>, Huangbin Lu<sup>3</sup>, Zhenna Liu<sup>3</sup>, Zhenghua Tang<sup>3</sup>, Zhan Huang<sup>2</sup>, Li Ruan<sup>4</sup>, Changbin Zhu<sup>2#</sup>

<sup>1</sup> Department of Pathology, Eastern Hepatobiliary Surgery Hospital, Shanghai 200438, People’s Republic of China; <sup>2</sup> Department of Translational Medicine, Amoy Diagnostics Co., Ltd., Xiamen, China; <sup>3</sup> Department of Research and Development, Amoy Diagnostics Co., Ltd., Xiamen, China; <sup>4</sup> Amoy Diagnostics Co., Ltd., Xiamen, China.

## BACKGROUND

- The human epidermal growth factor receptor 2 (HER2/neu), a member of epidermal growth factor receptor (EGFR) protein family, play a role as predictive and prognostic biomarkers in various tumor types, particularly biliary tract cancers (BTCs), a heterogeneous group of poor-prognosis solid tumors with limited treatment options.
- Accurate evaluating of HER2 overexpression is essential for selection and determination of eligible patients for HER2-directed therapy.
- Herein, we report the results of an immunohistochemistry (IHC) concordance study comparing the AmoyDx<sup>®</sup> HER-2(29D8) assay and the well-established Ventana PATHWAY anti-HER-2/neu (4B5) assay using a BTC cohort of 432 samples.

## METHODS

- Performance of the AmoyDx<sup>®</sup> HER-2 (29D8) assay was compared against the Ventana PATHWAY anti-HER-2/neu (4B5) assay using 432 pre-selected BTC samples.
- Further ISH testing was successfully performed in 134 of the samples to identify HER2-positive and HER2-negative samples according to standard criteria.

## RESULTS

- There was a high concordance between results from the AmoyDx 29D8 and PATHWAY 4B5 assays for HER2-negative (IHC 0, 1 +) and HER2-positive (IHC 2 + , 3 +) BTCs (98.38%, 425/432).

Table 1: Results of HER2 IHC assays

HER2 IHC Results		Ventana PATHWAY anti HER 2/neu (4B5)						
		0	1+	2+	3+	Total		
AmoyDx® HER-2 (29D8)	0	369	15	2	0	386		
	1+	7	9	1	0	17		
	2+	2	2	16	1	21		
	3+	0	0	2	6	8		
	Total	378	26	21	7	432		
Agreement	HER2-negative (IHC 0, 1 +)			99.01%				
	HER2-positive (IHC 2 + , 3 +)			89.29%				
	Overall			98.38%				
	All Types		Gallbladder		eCCA		iCCA	
	AmoyDx	PATHWAY	AmoyDx	PATHWAY	AmoyDx	PATHWAY	AmoyDx	PATHWAY
2+ (%)	4.86	4.86	5.42	5.42	3.23	3.23	4.03	4.03
3+ (%)	1.86	1.62	2.53	2.17	0.00	0.00	0.81	0.81

- When combined with the ISH results, the agreement was even increased to 99.29% (422/425).

Table 2: Comparison of HER2 scorings derived from the indicated assays

HER2 scorings		Ventana PATHWAY anti HER 2/neu (4B5)		
		Positive	Negative	Total
AmoyDx <sup>®</sup> HER-2 (29D8)	Positive	19	2	21
	Negative	1	403	404
	Total	20	405	425
Positive percent agreement		95.00% (95%CI: 75.13%, 99.87%)		
Negative percent agreement		99.51% (95%CI: 98.23%, 99.94%)		
Overall percent agreement		99.29% (95%CI: 97.95%, 99.85%)		

- In addition, the low concordance (34.63%, 9/26) between the two assays for IHC 1+ samples, indicating that the detection criteria for HER2 IHC 0 and 1+ still need further clarification, which reminds researchers to carefully select appropriate assays if they focus on BTC with HER2-low expression types.

## CONCLUSIONS

- Our data demonstrate that AmoyDx 29D8 exhibited high concordance with PATHWAY 4B5, and could provide critical information for the selection of HER2-targeted therapy for BTC patients.