

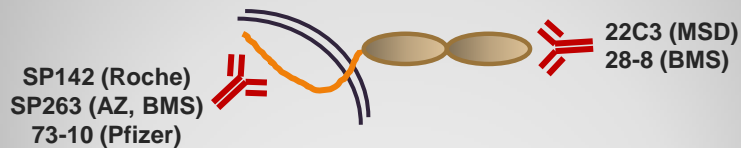
Московская Городская Онкологическая больница №62
Патологоанатомическое отделение

Гармонизация PD-L1 тестирования НМКРЛ

Савёлов Н.А.

2017

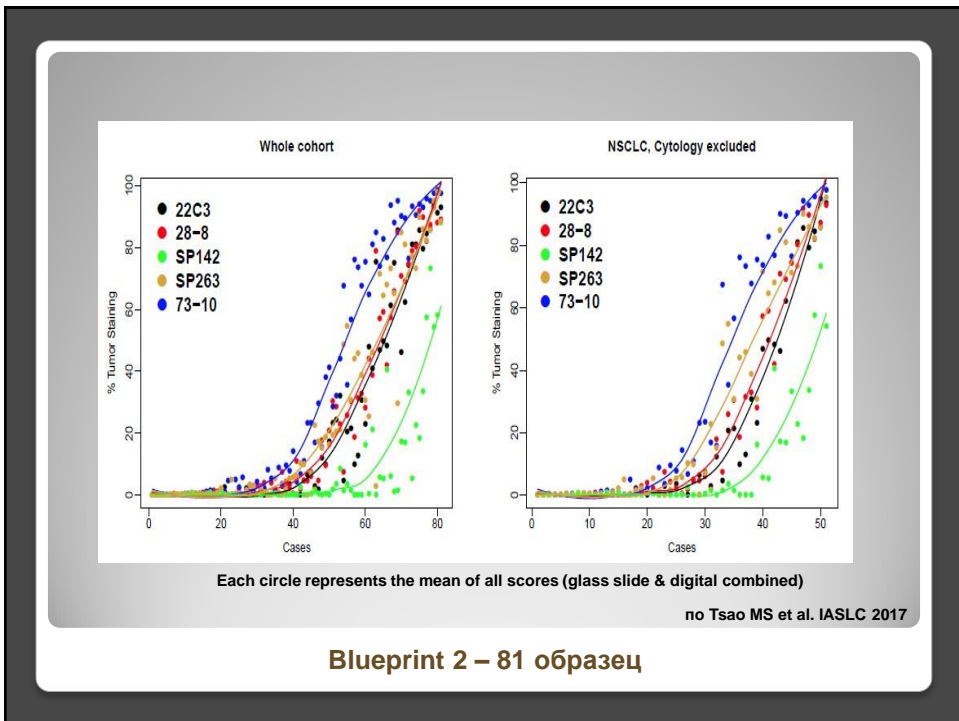
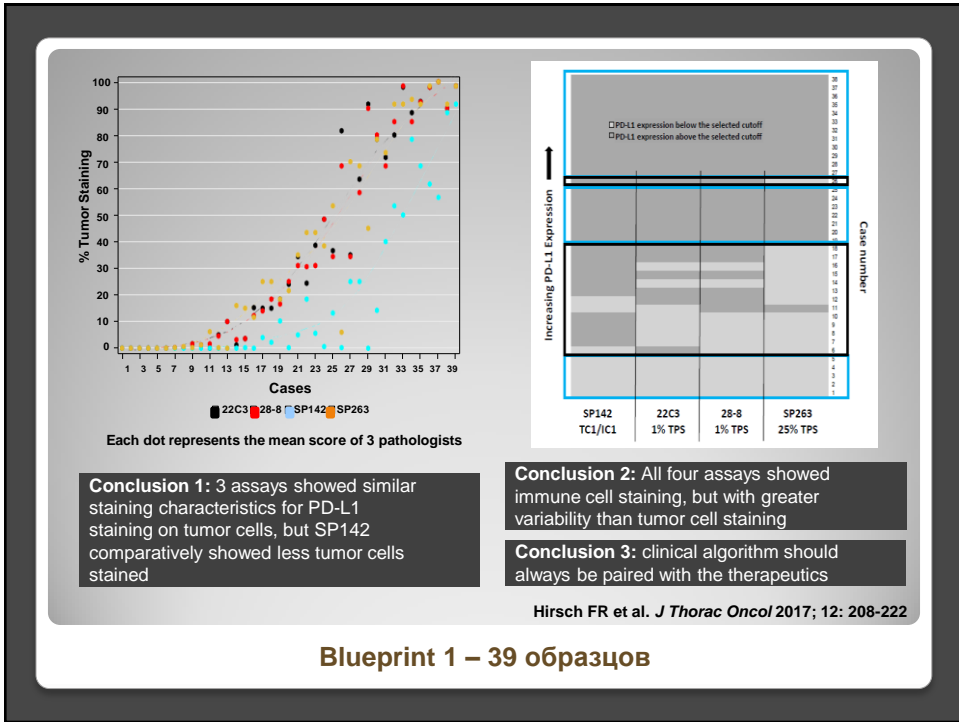
Агент	Платформа	Клон	Порог
Ниволумаб	Dako Link 48	28-8	$\geq 1\%$ TC
Пембролизумаб	Dako Link 48	22C3	$\geq 50\%$ TC и $\geq 1\%$ TC
Атезолизумаб*	Ventana	SP142	$\geq 1\%$ TC/IC
Дурвалумаб*	Ventana	SP263	$\geq 25\%$ TC
Авелумаб*	Dako-based	73-10	$\geq 1\%$ TC



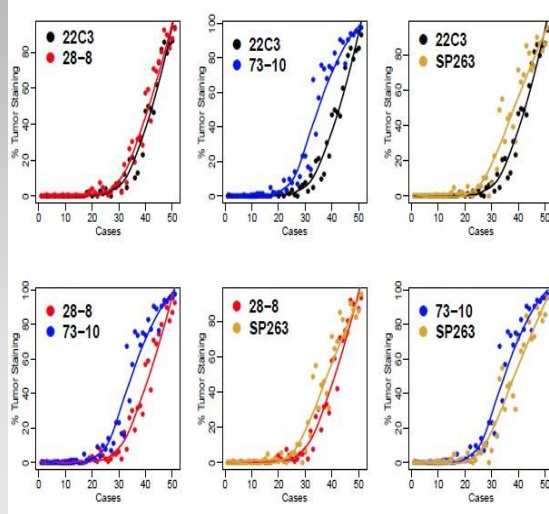
* препараты не зарегистрированы в России

по Kerr KM & Hirsch FR Arch Pathol Lab Med 2016

PD-L1 в НМКРЛ: антитела



Попарное сравнение между клонами 22C3, 28-8, SP263 и 73-10 (НМКРЛ)



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Blueprint 2 – 59 образцов

Распределение образцов на основании клинически значимого порога позитивности (только опухолевые клетки) для каждого метода



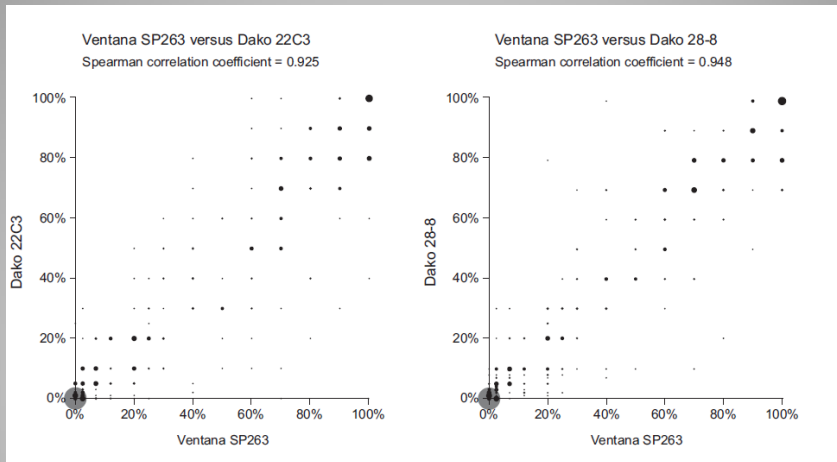
no Tsao MS et al. IASLC 2017

Blueprint 2 – 59 образцов

- 22C3, 28-8 and SP263 are comparable, SP142 detects less, while 73-10 stains more PD-L1 positive tumor cells
- PD-L1 scoring on digital images and glass slides show comparable reliability
- Scoring of tumor cell PD-L1 expression by pathologists on tissue samples shows strong reliability
- Scoring of immune cell PD-L1 expression remains challenging for pathologists, with poor reliability
- Scoring of PD-L1 expression on cytology samples may have moderate reliability; this requires further confirmation

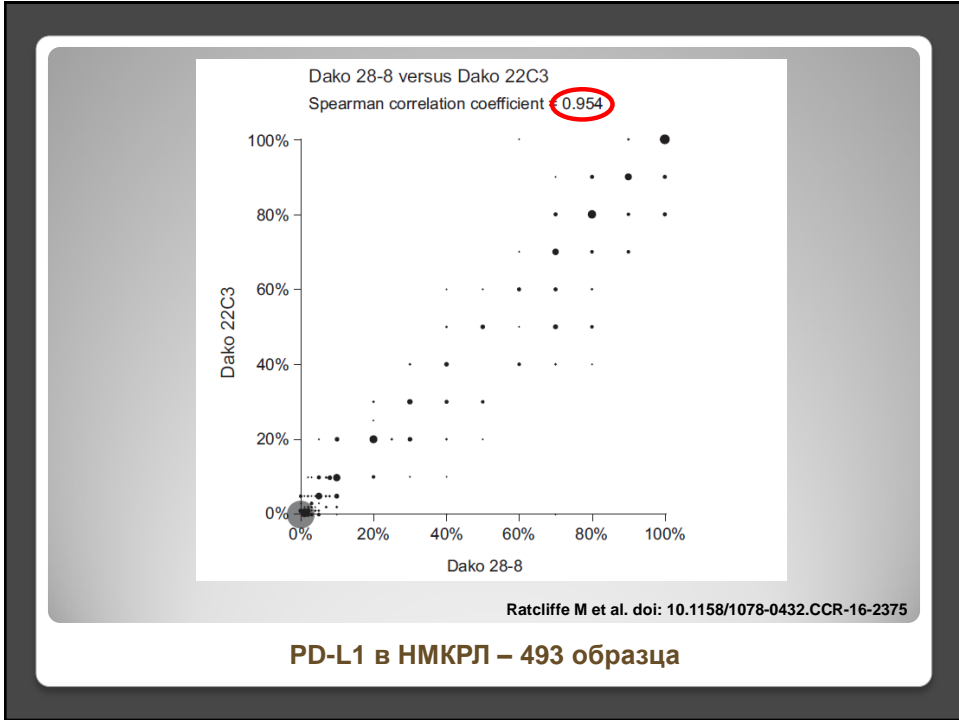
no Tsao MS et al. IASLC 2017

Blueprint 2 – 81 образец



Ratcliffe M et al. doi: 10.1158/1078-0432.CCR-16-2375

PD-L1 в НКРПЛ – 493 образца



		28-8		28-8		28-8	
		PD-L1 <1%	PD-L1 ≥1%	PD-L1 <25%	PD-L1 ≥25%	PD-L1 <50%	PD-L1 ≥50%
22C3	PD-L1 <1%	244	22	323	1	349	2
	PD-L1 ≥1%	24	130	40	56	32	37

	PD-L1 ≥1%	PD-L1 ≥25%	PD-L1 ≥50%
Positive Agreement	0.850	0.732	0.685
Positive by 22C3 vs 28-8 P-value	154 (36.7%) vs. 152 (36.2%) p=0.886	96 (22.9%) vs. 57 (13.6%) p=0.0005	69 (16.4%) vs. 39 (9.3%) p=0.002
Cohen's Kappa (95%CI)	0.763 (0.699 to 0.828)	0.677 (0.588 to 0.766)	0.643 (0.534 to 0.751)

no Saito T et al. IASLC 2017

PD-L1 в НМКРЛ – 420 образцов

