

# Clinical Performance Data



## Clinical Performance Data based on internal CE IVD validation study

Annex 4 Performance data

<b>Threshold scores</b>	
Indication for tumor	Score larger than 245
Verification via follow-up testing after 3 months	Score between 235 - 245
No indication of tumor	Score less than or equal to 235

<b>1. Sensitivity:</b>	
Number of patients	277
Thereof negative	270
Thereof positive	7
<b>Sensitivity</b>	<b>97.50%</b>

<b>2. Specificity</b>		
Number of patients	654+80=734	
Thereof positive	7	
Thereof negative	727	
Assumed cancer incidence	0.50%	Assumed incidence of 0.5%, because the share of test subjects below 40 years of age is high
Thus expected number of positive results	3.67	
Detectable positive results based on sensitivity of 97.5%	3.57	
false positive	3.42	
<b>Specificity</b>	<b>99.53%</b>	

<b>3. pos. predictive value</b>	<b>51%</b>
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