DIAGNOSTIC CAPACITY OF CYTOKERATIN 19 FRAGMENTS (CYFRA 21-1) IN LUNG CANCER:
Comparison of the Immunoassays on the Architect System and on the Elecsys System

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Aims

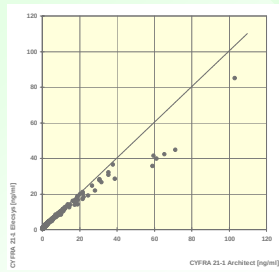
To compare CYFRA 21-1 in healthy individuals, benign and malignant lung diseases as measured on

- **the Architect system (Abbott Diagnostics) and**
- **the Elecsys system (Roche Diagnostics)**

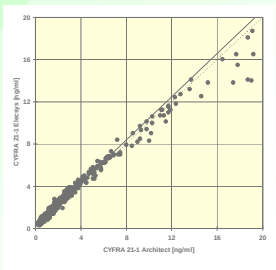
Sample

Diagnosis	Number	Men / Women
healthy individuals	69	34 / 35
benign lung diseases	278	180 / 98
lung cancer	267	200 / 67
Non small cell lung cancer	210	155 / 55
adenoid	81	
squamous cell	82	
large cell	37	
other histology	10	
Small cell lung cancer	57	45 / 12

Correlation
CYFRA 21-1 Architect vs. CYFRA 21-1 Elecsys

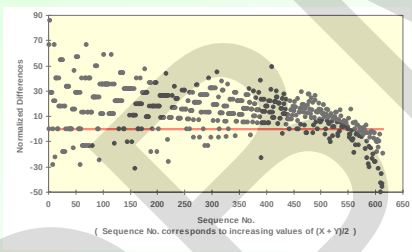


Correlation
CYFRA 21-1 Architect vs. CYFRA 21-1 Elecsys

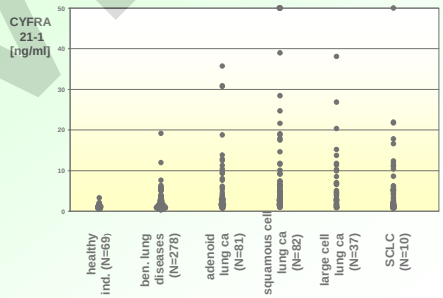


Values <20ng/mL
N=593

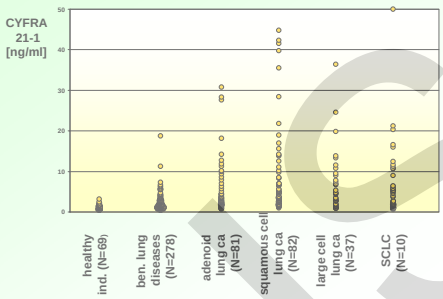
Difference Plot
CYFRA 21-1 Architect vs. CYFRA 21-1 Elecsys



Dot Plots CYFRA 21-1 Architect
Healthy Individuals, Benign Lung Diseases and Lung Cancer Patients



Dot Plots CYFRA 21-1 Elecsys
Healthy Individuals, Benign Lung Diseases and Lung Cancer Patients



Distribution of Values:
Healthy Individuals and Benign Lung Diseases

Group	N	Marker	Unit	Median	Range	95th Perc.
healthy individuals	69	CYFRA 21-1 A.	ng/mL	0.9	0.3 – 3.2	1.7
		CYFRA 21-1 El.	ng/mL	1.0	0.3 – 3.1	2.1
benign lung diseases	278	CYFRA 21-1 A.	ng/mL	1.1	0.2 – 19.1	3.8
		CYFRA 21-1 El.	ng/mL	1.3	0.4 – 18.7	4.3

Distribution of Values:
Lung Cancer Patients Depending on Histology

Group	N	Marker	Unit	Median	Range	95th Perc.
all lung cancer	267	CYFRA 21-1 A.	ng/mL	2.6	0.5 – 103	28.3
		CYFRA 21-1 El.	ng/mL	2.8	0.6 – 84.9	24.5
NSCLC	210	CYFRA 21-1 A.	ng/mL	2.8	0.6 - 71.2	30.8
		CYFRA 21-1 El.	ng/mL	3.1	0.7 - 44.7	27.6
SCLC	57	CYFRA 21-1 A.	ng/mL	1.7	0.5 - 103	21.7
		CYFRA 21-1 El.	ng/mL	2.0	0.6 - 84.9	20.2

Distribution of Values:
Lung Cancer Patients Depending on Histology

Lung Cancer	N	Marker	Unit	Median	Range	95th Perc.
squamous cell	82	CYFRA 21-1 A.	ng/mL	3.5	0.8 – 71.2	59.1
		CYFRA 21-1 El.	ng/mL	3.6	1.0 – 44.7	35.5
adenoid	81	CYFRA 21-1 A.	ng/mL	2.0	0.6 – 35.6	13.7
		CYFRA 21-1 El.	ng/mL	2.4	0.7 – 30.7	14.1
large cell	37	CYFRA 21-1 A.	ng/mL	3.8	0.7 – 38.0	26.8
		CYFRA 21-1 El.	ng/mL	4.3	0.9 – 36.3	24.5
SCLC	57	CYFRA 21-1 A.	ng/mL	1.7	0.5 - 103	21.7
		CYFRA 21-1 El.	ng/mL	2.0	0.6 - 84.9	20.2
other	10	CYFRA 21-1 A.	ng/mL	3.6	0.7 – 35.4	35.4
		CYFRA 21-1 El.	ng/mL	4.2	1.0 – 32.1	32.1

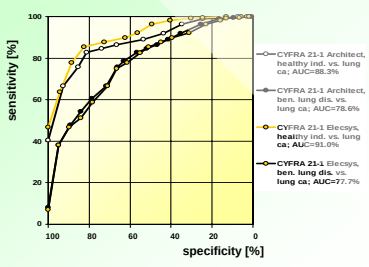
Sensitivity of CYFRA 21-1
Healthy Individuals vs. Lung Cancer Patients, Specificity 95%

Marker	Sensitivity [%]	AUC	Cut off
CYFRA 21-1 Architect	63 %	88.3 %	1.8 ng/ml
CYFRA 21-1 Elecsys	64 %	91.0 %	2.0 ng/ml

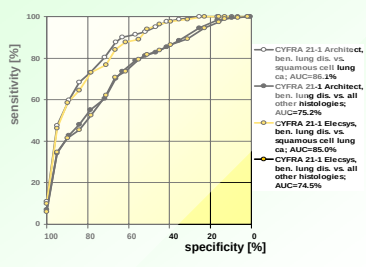
Sensitivity of CYFRA 21-1
Benign Lung Diseases vs. Lung Cancer Patients Depending on Histology, Specificity 95%

Marker	benign lung dis. vs.	Sensitivity [%]	AUC	cut off
CYFRA 21-1 Architect	all lung cancer (N=267)	38 %	78.6 %	3.7 ng/ml
	NSCLC (N=210)	39 %	80.9 %	
	adenoid (N=81)	24 %	75.8 %	
	squamous cell (N=82)	48 %	86.1 %	
	large cell (N=37)	51 %	81.6 %	
	SCLC (N=57)	35 %	70.0 %	
CYFRA 21-1 Elecsys	all lung cancer (N=267)	38 %	77.7 %	4.2 ng/ml
	NSCLC (N=210)	39 %	79.9 %	
	adenoid (N=81)	25 %	74.6 %	
	squamous cell (N=82)	46 %	85.0 %	
	large cell (N=37)	51 %	80.3 %	
	SCLC (N=57)	35 %	69.8 %	

ROC Curves of CYFRA 21-1 Architect vs. CYFRA 21-1 Elecsys
Healthy Individuals/ Benign Lung Diseases vs. Lung Cancer



ROC Curves of CYFRA 21-1 Architect vs. CYFRA 21-1 Elecsys
Benign Lung Diseases vs. Lung Cancer Depending on Histology



Conclusions

- **The well known diagnostic capacity of CYFRA 21-1 in lung cancer can be confirmed with both assays to the same extent.**
- **Although differences in values are small, measured values of the two tests can not be transfered and mixed.**