

ADDENDUM VIII

Expected Distribution of Abbott Architect CEA Values						
		Percent (%)				
		0 – 3.0	3.1-5.0	5.1-10.0	>10	
		ng/mL	ng/mL	ng/mL	ng/mL	
Number of Subjects						
<b>Healthy Subjects</b>						
	Non-Smokers	149	83.2	11.4	5.4	0.0
	Smokers	159	74.2	18.2	6.9	0.6
	Total	308	78.6	14.9	6.2	0.3
<b>Malignant Disease</b>						
	Colorectal	150	24.0	10.7	10.7	54.7
	Gastric	37	68.2	5.4	10.8	21.6
	Pulmonary	110	47.3	19.1	9.1	24.5
	Mammary	117	62.4	11.1	10.3	16.2
	Ovarian	41	78.0	7.3	2.4	12.2
<b>Nonmalignant Disease</b>						
	Ulcerative Colitis	50	72.0	20.0	4.0	4.0
	Rectal Polyps	78	83.3	10.3	5.1	1.3
	Pulmonary	60	61.7	20.0	13.3	5.0
	Cirrhosis	110	47.3	30.0	15.5	7.3
	Hepatitis	60	70.0	16.7	11.7	1.7
	Renal	20	60.0	15.0	15.0	10.0

The distribution of CEA values determined in 1,141 specimens is shown in the table above. The distribution table for malignant disease is derived primarily from patients representing both active (clinical evidence of disease progression) and inactive (no clinical evidence of disease progression) disease states.