

Table 1. Results illustrated are from this Study and were Obtained on the New Improved 2365 Membrane.
Values Indicated were Obtained by Averaging Results Across all Probes

Substance:	Concentration		GLUCOSE INTERFERING LEVEL		Concentration of Sub for Sample Error
	tested (mg/dl)	FORMULA WEIGHT	mg/dl	mmol/L	
Sodium Nitrite	1000	69.00	78.7453	11.4124	
✓ Ascorbic Acid	500	176.12	1004.6160	57.0416	
Uric Acid	5	168.11	166.6844	9.9152	
Isopropanol	1000	60.10	9955.3241	1656.4599	
Isopropanol	100	60.10	1504.4502	250.3245	
Hydrogen Peroxide	30	34.02	0.1548	0.0455	
Hydrogen Peroxide	3	34.02	0.1598	0.0470	
Acetylsalicylic Acid	100	180.16	607.7599	33.7345	
D-Penicillamine	1000	149.21	18586.3079	1245.6476	
Salicylamide	100	137.14	62.5750	4.5629	
Formaldehyde	2000	30.03	591.7247	197.0445	
Ethylene Glycol	1000	62.07	19245.1224	3100.5514	
Ethanol	2000	46.07	8158.9874	1770.9979	
Methanol	1000	32.04	-969.0182	-302.4401	
Potassium Iodide	1000	166.01	4410.2290	265.6604	
Acetaminophen (100)	100	151.17	653.4902	43.2288	
Acetaminophen (25)	25	151.17	564.4911	37.3415	
2,3 Dimercaptopropanol	20	124.22	42.8275	3.4477	
Guaiacol	20	124.14	12.5260	1.0090	
2-Thiouracil	20	128.15	153.6963	11.9935	
Thiourea	20	76.12	1.3911	0.1827	
Isoniazid	50	137.14	80.0057	5.8339	
P-Aminosalicylic Acid	100	153.14	32.6687	2.1333	
Hydroquinone	20	110.11	3.6752	0.3338	
✓ Pyridoxine HCl	200	205.64	-5991.2191	-291.3450	
Sodium Tetraborate	2000	381.37	-68529.7840	-1796.9369	
Sodium Oxalate	2000	134.00	68621.9136	5121.0383	
Potassium Cyanide	200	65.12	-1649.5553	-253.3101	
Sodium Azide	500	65.01	826.9253	127.1997	
Sodium Fluoride	1000	41.99	-53679.7840	-12783.9447	
Benzalkonium Chloride	200	396.11	415.7201	10.4951	
Cetylpyridinium Chloride	500	340.00	-1447.2222	-42.5654	
Thymol	5	150.22	54.9448	3.6576	
Methyl Paraben	200	152.15	690.5403	45.3855	
Salicylic Acid	200	160.11	-6390.8708	-399.1550	
Hydrazine Sulfate	20	130.12	28.0095	2.1526	
Hydroxylamine HCl	20	69.49	0.2564	0.0369	
o-Toluidine	20	107.16	8.3087	0.7754	
Phenol	20	94.11	4.7833	0.5083	
Sodium Sulfide	20	240.18	0.4111	0.0171	
2-Iodoacetamide	1000	184.97	5674.1858	306.7625	
Iodoacetic Acid	1000	207.90	50739.6091	2440.5776	
Potassium Thiocyanate	1000	97.18	339.7745	34.9634	
o-Tolidine Dihydrochloride	100	285.22	2777.5463	97.3826	
p-Phenylenediamine	20	181.07	13.6953	0.7564	
2-Mercaptoethanol	20	78.13	0.7990	0.1023	
Metaphosphoric Acid	1000		-3196.9136	#DIV/0!	

RESULTS

Table 1 illustrates the tabulated results obtained in this study on 2365 / Lamitec membranes. The values shown are the concentrations of the test substance required to give a glucose interference of 5 mg/dL. The values shown were obtained by averaging the results on all instruments whether or not they contained cell lysing agent in their respective buffers. Table 2 depicts the results obtained in this study on 2365 / Lamitec membranes and gives the average results obtained and the bias between the averages for instruments with and without 1515 cell lysing agent. In this table values shown are mg/dL concentrations of the test substance resulting in a 5 mg/dL error in the glucose reading. Table 3 shows the results obtained in this study when 2365AM membranes are compared directly to 2365 / Lamitec membranes on selected interfering substances. For Comparison purposes, Table 4 is a list of interferences and their effects on the 2365 AM membrane (without lamitec) as determined in the 2300 STAT 510 K (#K891480/A) submitted to FDA in mid 1989.

In these Tables, the severity of the interference is inversely related to the value indicated. That is the smaller the number indicated (whether positive or negative) for a particular substance the greater the interference observed. A positive number indicates a positive interference; glucose readings are elevated. A negative number indicates a negative interference; glucose readings are depressed.

CONCLUSIONS

After examining the results in Table 2, some general conclusions can be drawn around the effects of 1515 cell lysing agent on the interference rejecting capability of the 2365 / Lamitec membrane. First, there are some random variations in the observed bias of the average results obtained with and without 1515 present. The bias can be large in some cases and either positive or negative but tends to be smaller and less significant on the more severe interferences. Also, this bias is no worse than the differences observed, in the average response to any given interference, across probes without 1515 present (see the average results illustrated in Table 2). Therefore, there does not appear to be any significant difference between values obtained with and without 1515 cell lysing agent present.

If the results in Table 1 are compared to those in Table 4 it can be seen that in general the interference rejection capability of the improved 2365 membrane are much improved over those of the 2365AM membrane. This Conclusion is also supported by the results obtained in this study and depicted in Table 2.

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