

Micral-Test Sensitivity

We feel a need to comment on the interpretation of results in a recent publication by Tiu et al. (1). There is an apparent error in Table 2. The last line in this table should read 50-2-0-0 instead of 33-3-2-1 as indicated. Nonetheless, Tiu et al. conclude that the Micral-Test was more specific yet less sensitive than the Microbumintest. This conclusion is based on a small true-positive population of $n = 12$. The question that really needs to be addressed is this: Was this a large enough true-positive population to draw such conclusions? We think not.

For example, if we assume the true sensitivity of Micral-Test to be $\geq 90\%$ (2,3), then how likely is it that one would observe a sensitivity of $\leq 75\%$ in repeated sampling as was observed in this study? With only 12 samples, a test with a true sensitivity of 90% will yield results equal to or worse than this study 11-12% of the time. And this assumes that the test was performed perfectly according to the manufacturer's packaging instructions. In other words, if 100 sites were to do the same identical experiment as performed in this study, obtaining only 12 positive samples and testing as indicated, one would expect that 11 or 12 of these sites would show results equal to or worse than this study.

Increasing the positive sample size from $n = 12$ to $n = 24$ dramatically lowers the chances of this scenario from 11-12 to 2-3%. If a sample size of $n = 60$ were attained, then this would drop to $< 0.1\%$. Therefore, one has to conclude that a sample size of $n = 12$ is not enough to give a clear indication of the true sensitivity, with high confidence, of either product. Furthermore, we do not recommend freezing and preserving the urine samples before testing, which was apparently part of the study design. This is indicated in the Micral-Test package insert.

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References

1. Tiu SC, Lee SS, Cheng MW: Comparison of six commercial techniques in the measurement of microalbuminuria in diabetic patients. *Diabetes Care* 16:616-20, 1993
2. Marshall SM, Shearing PA, Alberti KGMM: Micral-Test strips evaluated for screening for albuminuria. *Clin Chem* 38:588, 1992
3. Boehringer Mannheim Corporation: Micral-Test package insert, data on file

Response to Chmielewski and Miller

We would like to thank Steven A. Chmielewski and Earl E. Miller for pointing out the error in Table 2 of our study (1) and for their comments. The correct table appears here.

Fresh urine samples were used for both the Micral-Test and Microbumintest, as recommended in the package inserts of these tests. Samples were frozen and stored for the quantitative tests only after they were tested with these two tests.

We agree that the number of positive samples in our 75 samples was small. The same limitation in drawing conclusions on sensitivity applies to the Microbumintest also. It would be helpful to verify our conclusion in studies with larger positive sample sizes.

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References

1. Tiu SC, Lee SS, Cheng MW: Comparison of six commercial techniques in the mea-

Table 2—Micral-Test and Microbumintest testing of 75 urine samples, as compared with RIA

	Concentrations by RIA (mg/L)					
	0-10	10-20	20-30	30-50	50-80	80-130
Micral-Test (mg/L)						
100						
50			1		1	2
20	6	2	4	1		
10	15	4				
0	33	3	2	1		
Microbumintest (intensity of color change)						
++					1	2
+	4	7	7	2		
-	50	2				

Numbers indicate patients showing the particular result. From Tiu et al. (1).