

## REGULATORY NOTES . . .

### STATE PROHIBITS CYTOTOXIC TESTING FOR FOOD ALLERGIES

Since June of 1984, the Bureau became aware of advertisements in the Philadelphia newspapers and elsewhere promoting cytotoxic testing in our state. These advertisements claim that for a small blood sample, consumers with any of a long list of medical problems could learn what foods to avoid in order to cure or alleviate these ailments.

These claims clearly offer the test to determine a state of health, contrary to previous representations made. We have also learned that physicians are solicited by these laboratories to order the test for their patients and in fact some physicians are using the results for diagnosis and treatment purposes. Accordingly, laboratories conducting the cytotoxic test come within the definition of a clinical laboratory subject to the Clinical Laboratory Act.

However, no license will be issued to any laboratory to perform cytotoxic testing because after extensive investigation, the Department has determined that the cytotoxic test is not an accepted procedure since it is an unproven diagnostic test lacking an acceptable scientific rationale, specificity, sensitivity and evidence of clinical effectiveness. The test is not supported by the scientific literature or well controlled studies and clinical trials as outlined in the Food and Drug Administration Guide No. 7124.27

In addition, the FDA Guide states that the only lawful, commercially marketed allergenic extracts are those licensed by the FDA and none have been approved for cytotoxic testing. It should be noted that allergenic extracts compounded within a laboratory itself as well as commercially marketed allergenic extracts are subject to the Pennsylvania Controlled Substances, Drug, Device and Cosmetic Act. Accordingly, this matter has been referred to the Department of Health, Division of Drugs, Devices and Cosmetics for possible action.

In view of the above, effective immediately, all facilities must cease and desist from offering and conducting the cytotoxic test for food allergies until the test can be validated. Cytotoxic testing poses a dangerous threat to the health and safety of individuals, especially those with serious health problems who may postpone seeking proper medical attention based upon the unsubstantiated claims made for cytotoxic testing.

Any laboratory presently licensed under the Clinical Laboratory Act to perform categories of tests currently acceptable to the department will lose its permit if the laboratory performs cytotoxic testing. Unlicensed facilities that continue to perform cytotoxic testing will be subject to legal action and the penalties under the Clinical Laboratory Act.

If you have any questions regarding this matter, contact this office.

Effective date of this policy is July 23, 1985

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