



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
Office of Health Care Quality

Spring Grove Center • Bland Bryant Building

55 Wade Avenue • Catonsville, Maryland 21228-4663

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D.,
Secretary

Procedure for Requesting Additional Tests for Health Awareness

Providers or other interested parties may submit a request in writing for the approval of additional tests to the Department of Health and Mental Hygiene, Office of Health Care Quality. The request should include a rationale for why it is in the interest of public health, and the testing device or analyzer that would be used.

A copy of the request should be forwarded to the Laboratory Administration for review.

The staff of the Laboratory Administration and the Office of Health Care Quality would review the proposed test to determine if:

- **The tests would benefit public health;**
- **The test is done on a CLIA waived analyzer;**
- **The test will be used for screening and not diagnostic or for management of a medical condition;**
- **The test can be easily performed in a health fair setting;**
- **The quality controls are available to insure the quality of the results.**

If additional information is required regarding the proposed test, additional research may be required which may include contacting the manufacturer of the test device, analyzer, reagents quality controls or other information or reviewing additional literature.

After review, the proposed test would be presented to the Laboratory Advisory Committee for additional input.

Upon completion of the review, the joint recommendation of the Laboratory Administration and the Office of Health Care Quality should be submitted in writing to the Secretary or designee for review and approval. The written approval or disapproval should be provided to the Office of Health Care Quality and the Laboratory Administration

The Office of Health Care Quality will provide the results of the review in writing to the group that requested the review.

The Office of Health Care Quality will provide an e-mail transmittal to all laboratories that perform health awareness testing indicating a new test has been approved. The new test will be added to the list posted on the OHCQ website.

Toll Free 1-877-4MD-DHMH – TTY/Maryland Relay Service 1-800-735-2258

Web Site: www.dhmh.state.md.us