



FROM YOUR LABORATORY SERVICES PROVIDER

Accurate and More Rapid Clostridium Difficile Testing Algorithm

Ann Robinson, Ph.D., DABMM, FAAM, Director of Microbiology and Virology

Clostridium difficile is the primary cause of hospital-acquired colitis in patients who receive antibiotics, chemotherapeutic agents, or other drugs that alter their normal flora. C. difficile is a major cost burden to our health care system, with hundreds of millions of dollars expended for hospital care. This situation has been intensified by the appearance of a new hyper-toxin producing strain of the organism that has become wide spread in the United States, Canada, and Europe during the past 5 years. This highly virulent strain is associated with significantly increased morbidity and mortality. It is a challenge for laboratories to provide accurate results that are both rapidly available and cost-effective.

To assist in the more rapid treatment and infection control management of patients with suspected C. difficile colitis, an EIA antigen test for glutamate dehydrogenase is offered in conjunction with the cell culture assay for cytotoxin. The EIA antigen test permits the rapid identification of the presence of C. difficile in stool samples in less than 24 hours but does not differentiate between toxin positive and toxin negative strains. Importantly, the EIA antigen test has a significantly greater sensitivity than the EIA assays that test for the presence of the A and B toxins of C. difficile. The negative predictive value of the EIA antigen test is >99%, permitting the reliable identification of patients who are not infected with C. difficile. Because the test cannot identify the toxin status of the organism and has a positive predictive value of only 50%, EIA antigen positive samples must reflex to the conventional cytotoxin assay for confirmation, requiring another 24-48 hours for a final result. The EIA antigen test is not available as a stand-alone assay. This two-step algorithm permits a more rapid and reliable identification of patients with C. difficile associated diarrhea than is possible with any single test modality currently available.

Test Information

DESCRIPTION C. DIFFICILE ANTIGEN REFLEX CULTURE

METHOD EIA & Cytotoxin neutralization in tissue culture

ORDER CODE CLTOXR

CPT CODE 87324

SAMPLE Walnut sized portion of fresh stool in a clean, leak proof, wax free container. Store and transport refrigerated. This test may reflex to additional tests. Additional fees may be added.

COMMENTS 1) Unacceptable conditions: stool stored at room temperature more than 2 hours. Stool received in transport media. 2) Stability: RT-2 hours, Refrigerated-24 is optimal but 72 hours is acceptable, Frozen-GT 72 hours (avoid repeat freeze/thaw cycles).

SCHEDULE Daily - day shift

TURNAROUND 1-3 days

RANGES None

Quick Facts

- ▶ Clostridium difficile is the primary cause of hospital-acquired colitis.
- ▶ To assist in the more rapid treatment and infection control management of patients with suspected C. difficile colitis, an EIA antigen test for glutamate dehydrogenase is offered in conjunction with the cell culture assay for cytotoxin.
- ▶ The negative predictive value of the EIA antigen test is >99%, permitting the reliable identification of patients who are not infected with C. difficile.
- ▶ EIA antigen positive samples must reflex to the conventional cytotoxin assay for confirmation
- ▶ This two-step algorithm permits a more rapid and reliable identification of patients with C. difficile associated diarrhea than is possible with any single test modality currently available.

For more information, please contact Client Services or see us on the Web at



Provided for the clients of

PATHOLOGY ASSOCIATES MEDICAL LABORATORIES • PACLAB NETWORK LABORATORIES
TRI-CITIES LABORATORY • TREASURE VALLEY LABORATORY • ALPHA MEDICAL LABORATORY

MAY 2007

For more information, please contact your local representative.