

There are several tests available to detect a C. Diff infection and to determine if the strain that is present produces toxin. Some tests are very sensitive but take some days to complete, while other tests are rapid (several hours) but are not considered to be very sensitive or specific. The Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) have proposed a two-step testing process.

### The two-step process includes:

- Perform an initial screen on stool samples using a test for a *C. difficile* antigen called glutamate dehydrogenase (GDH). This test detects an antigen that is produced in high amounts by *C. difficile*, both toxin and non-toxin producing strains. It is considered to be very sensitive, but it is not very specific for toxin-producing *C. difficile*. This test indicates if *C. difficile* is present but not if the bacteria are producing toxins.
- **Positive GDH screening results should be** confirmed by any of the following confirmation assays and to detect the presence of toxins:
  - **Cell cytotoxicity test** is a tissue culture to detect the *C. difficile* toxin. Sensitive but requires 24 to 48 hours to get the test result.
  - **Toxigenic stool culture**, is a very sensitive test for *C. difficile*, but can take 2 to 3 days for results and cannot distinguish between *C. difficile* colonization and overgrowth/infection. Further testing for the toxin must be performed.
  - **PCR assays** are rapid and very sensitive methods to confirm the presence of *C. difficile* toxin. However, they are expensive. Some laboratories screen samples with the GDH test and confirm only the positive samples with the molecular assay. Not all laboratories have the capability of performing molecular testing.

**Note: Doctors Lab has the capability of performing molecular testing and uses the illumigene LAMP Nucleic Acid Amplification Test (NAAT) methodology that detects the presence or absence of all of the toxin producing strains of C. Difficile. It is highly Specific and Sensitive for toxigenic C. difficile.**

### Several things to know concerning the Doctors Lab C. Diff methodology:

1. **Sample Condition is Critical:** The American Society of Microbiology (ASM) sample guidelines state, "Testing for toxigenic C. Difficile should be limited to patients with > 3 non-formed (loose, watery, consistency of ketchup, takes on the shape of the container) stool specimens per 24-hour period, unless ileus (obstruction) is suspected."
2. **Doctors Lab's LAMP/NAAT C. Diff** test is considered to be a standalone diagnostic test for all toxigenic C. Difficile strains that does not need to be confirmed.
3. **Repeat Testing:**
  - a. Repeat testing following a Positive Test (test for cure) is not recommended since patients may carry toxigenic C. Difficile for months after clinical cure.
  - b. Repeat testing following a Positive Test is appropriate if the patient improves with therapy and relapses after completion of a treatment regimen (clinical relapse).
  - c. Repeat testing following a Negative test is Not typically recommended because nearly all Positive patients will be detected.