

Order Name: C Diff An Test Number: 17262993 Revision Date: 04/03/2023

| TEST NAME                      |   | METHO              | METHODOLOGY                       |                       |
|--------------------------------|---|--------------------|-----------------------------------|-----------------------|
| Clostridium difficile Analyzer |   | Enzyme Immunoassay |                                   |                       |
| SPECIMEN REQUIREMENTS          |   |                    |                                   |                       |
| Specimen                       | Specimen Volume (min)   | Specimen Type      | Specimen Container                | Transport Environment |
| Preferred                      | 1mL or 1g   | Stool, Random      | Sterile Orange Screwtop Container | Refrigerated          |
| Alternate 1                    | 1mL or 1g   | Stool, Random      | ETM or Cary Blair container       | Refrigerated          |
| Instructions                   | Raw Soft or Liquid Stool in Sterile Screwtop Container. Stool collected ETM or Cary Blair Container also acceptable.<br>STABILITY: 3 days Refrigerated 2-8'C (Un-Preserved Stool only viable for 24hrs at RoomTemperature). If testing cannot begin within 3 days then<br>Freeze -20'C.<br>Note: Formed or Hard Specimens will be Rejected. |                    |                                   |                       |

| GENERAL INFORMATION |  |  |
|---------------------|--|--|
| Testing Schedule    | Sun-Sat  |  |
| Expected TAT        | 1-2 Days   |  |
| Clinical Use        | The C Diff Analyzer is a rapid membrane enzyme immunoassay for the simultaneous detection of <i>Clostridium difficile</i> glutamate dehydrogenase antigen and toxins A and B. The assay detects <i>C. difficile</i> antigen, glutamate dehydrogenase as a screen for the presence of <i>C. difficile</i> and confirms the presence of toxigenic <i>C. difficile</i> by detecting toxins A and B in fecal specimens from persons suspected of having <i>C. difficile</i> disease. |  |
| Notes               | Positive results are indicative of active infection while negative results effectively exclude infection.  |  |
| CPT Code(s)         | 87324, 87449   |  |
| Service Provided By | Oklahoma, Inc.   |  |