



**FUNGITELL ASSAY FOR (1,3)-B-D-GLUCANS
#91758**

EXPLANATION OF CHANGE: *Effective immediately*, Unit Code 91758, referred to Beacon Diagnostics Laboratory, will reflect the below changes.

<p>Current Always Message</p>	<p>Negative: Less than 60 pg/mL Indeterminate: 60-79 pg/mL Positive: Greater than or equal to 80 pg/mL</p> <p>Note: The Fungitell assay is indicated for presumptive diagnosis of fungal infection. It should be used in conjunction with other diagnostic procedures. The Fungitell assay does not detect certain fungal species such as the genus <i>Cryptococcus</i>, which produces very low levels of (1-3)-B-D-glucan. This assay also does not detect the Zygomycetes, such as <i>Absidia</i>, <i>Mucor</i>, and <i>Rhizopus</i> which are not known to produce (1-3)-B-D-glucan.</p>
<p>New Always Message</p>	<p>Negative: Less than 60 pg/mL Indeterminate: 60-79 pg/mL Positive: Greater than or equal to 80 pg/mL</p> <p>Note: The Fungitell assay is indicated for presumptive diagnosis of fungal infection. It should be used in conjunction with other diagnostic procedures. The Fungitell assay does not detect certain fungal species such as the genus <i>Cryptococcus</i>, which produces very low levels of (1-3)-B-D-Glucan. This assay also does not detect the Zygomycetes, such as <i>Absidia</i>, <i>Mucor</i>, and <i>Rhizopus</i> which are not known to produce (1-3)-B-D-Glucan.</p> <p>Serum glucan concentrations greater than or equal to 80 pg/mL are interpreted as a positive result. A positive result means that (1-3)-B-D-Glucan was detected in the serum sample submitted. A positive result does not define the presence of disease and should always be used in conjunction with other clinical findings to establish a diagnosis.</p> <p>The Fungitell assay detects (1-3)-B-D-Glucan regardless of its origin. Therapeutic interventions should be evaluated for their potential to contribute to serum burdens of (1-3)-B-D-Glucan. Special care should be taken in patient sample handling so as to avoid the introduction of contaminant (1-3)-B-D-Glucan. The presence in a patient sample of (1-3)-B-D-Glucan from a source other than fungal infection could cause a positive assay result that is inconsistent with the patient's clinical condition.</p>