

National Institute of Biologicals

(Ministry of Health & Family Welfare)

A-32, Sector-62, NOIDA-201 309 (UP)

Acceptance Criteria for test and examination of Blood Glucose Test Strips (Imported & Manufactured in India) and shall be effective from 01.01.2016

CURRENT	Specifications	Reference
Criteria for acceptance	<p>95% of the individual Glucometer results shall fall within + 15mg/dL of the results of the 'Reference Method' at glucose concentrations <75mg/dL and within +20% at glucose concentrations >75mg/dL</p> <p>Maximum allowable deviation should be less than 15%</p>	<p>System Accuracy requirement: ISO15197:2003</p> <p>Who: Laboratory Diagnosis and Monitoring of Diabetes Mellitus, 2002</p>