



# HIV-1/HIV-2 Antibody Test

## Product Specification Sheet



### INSTI® HIV-1/HIV-2 Antibody Test (50 individual tests with support materials)

### INSTI® HIV-1/HIV-2 Test Controls

<b>Product Code</b>	90-1019	90-1031
<b>List Price</b>	\$999.50	\$76.99
<b>CLIA Status</b>	CLIA Waived for fingerstick whole blood. Moderate Complexity for plasma and venous whole blood.	N/A
<b>Sample Type</b>	Fingerstick whole blood, venous whole blood, plasma	Human, plasma-based reagents or serum substitute
<b>Kit Contents</b>	<p>Materials: 50 individual tests per box</p> <hr/> <p>1 Single Test with Support Materials</p> <ul style="list-style-type: none"> <li>• 1 Membrane Unit</li> <li>• 1 Bottle 1, Sample Diluent (1.5ml)</li> <li>• 1 Bottle 2, Colour Developer (1.5ml)</li> <li>• 1 Bottle 3, Clarifying Solution (1.5ml)</li> <li>• 1 Single-Use Safety Lancet</li> <li>• 1 Capillary Test Pipette</li> <li>• 1 Alcohol Swab</li> <li>• 1 Package Insert</li> </ul> <p>1 Subject Information Brochure 1 Customer Letter</p> <hr/>	<p>Materials:</p> <hr/> <p>1 HIV-1 Positive Control (1.0ml) 1 HIV-2 Positive Control (1.0ml) 1 HIV Negative Control (1.0ml) 1 Package Insert 75 Disposable Bulb Control Pipettes</p> <hr/>
<b>Test Run Time</b>	1 minute	1 minute
<b>Shelf Life<sup>1</sup></b>	15 months	12 months
<b>QC Requirements</b>	<ul style="list-style-type: none"> <li>• For new INSTI operator verification prior to performing testing on patient specimens</li> <li>• When switching to a new lot number of INSTI test kits</li> <li>• Whenever a new shipment of kits is received</li> <li>• When temperature during storage of the kit falls outside of 2°-30°C (35.6°-86°F)</li> <li>• When the temperature of the test area falls outside of 15°-30°C (59°-86°F)</li> <li>• At regular intervals as determined by the user facility</li> </ul>	N/A
<b>Storage Conditions</b>	2°-30°C (35.6°-86°F) until expiration date	Store frozen at -20°C (-4°F) or refrigerate at 2°C (36°F) to 8°C (46°F) until expiration date

Performance <sup>2</sup>	Sample Type	Sensitivity	Specificity
	Venous Whole Blood	99.9%	100%
	Plasma	99.9%	100%
	Fingerstick Blood	99.8%	99.5%
	CLIA Fingerstick Blood <sup>2</sup>	100%	99.8%

<sup>1</sup>From date of manufacture <sup>2</sup>Based on US Clinical Trials of the INSTI HIV-1/HIV-2 Antibody Test.

Reimbursement of INSTI HIV Test	Type	Code	Additional Accessories (Sold Separately)	Code	Product	Price
	CPT & HCPCS Codes	86703 (CPT Code) G0433 (HCPCS Code)		10-1042	Lancets, 50 pack	\$23.00
	Modifiers	QW or 92		80-1087	Test Capillary Pipettes, 48 pack	\$24.95

**Head Office**  
bioLytical Laboratories Inc  
406-13251 Delf Place  
Richmond, BC, Canada V6V 2A2

**US Office**  
1465 Slater Road  
PO Box 5007  
Ferndale, WA, USA 98248

**Main 1 604 204 6784**  
**Toll-Free 1 866 674 6784**  
**Fax 1 604 244 8399**  
**Technical Support [customer@biolytical.com](mailto:customer@biolytical.com)**

