

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick whole blood, venipuncture whole blood and plasma specimens.

Feature	Benefit	
Detection equivalent to 3rd generation IgM	Detects recent HIV infections	
5 μL specimen collection loops provided	Sample size required is 10x less than some competing devices	
Built-in procedural control	Demonstrates assay validity	
External controls available	Ensures proper performance of the test	
Simple 3-step procedure	Minimal training required	
20 minute test read window	Conducive to batch testing and walk-away procedure	

Clinical specifications		
Time to results	20 minutes	
Test read window	20-40 minutes	
Sample type	Oral fluid, fingerstick whole blood, venipuncture whole blood and plasma	
CLIA complexity	Waived (moderate for plasma only)	
External controls	Positive HIV-1, positive HIV-2, negative (purchased separately)	
Built-in procedural control	IgG specific	
Storage requirements	2-27°C (36-80°F)	
Operating requirements	15-37°C (59-99°F)	
Method	Lateral flow	
Device shelf life	30 months from date of manufacture	
Kit size	25 count (Item no. 1001-0079) 100 count (Item no. 1001-0078)	
CPT code	86703 (CPT code)/G0435 (HCPCS)	
Additional items available	Visual Reference Panel (Item no. 1001-0505) Test Kit Control (Item no. 1001-0077)	

Performance	Sensitivity	Specificity
Oral fluid	99.3%	99.8%
Fingerstick whole blood	99.6%	100.0%
Venipuncture whole blood	99.6%	100.0%
Plasma	99.6%	99.9%

 $Please\ refer\ to\ the\ package\ insert\ for\ complete\ information\ on\ the\ OraQuick\ \textit{ADVANCE}{}^{\circ}\ HIV-1/2\ Antibody\ Test.$ 

