

**Results:** All raw data reports can be found in the Alere Determine™ HIV – 1/2 Antibody Test validation binder.

1. Accuracy

Method being Validated	Diagnostic Accuracy Criteria (Results from Comparison Study)		Total
	Positive	Negative	
Positive	20	0	20
Negative	0	20	20
<b>Total</b>	<b>20</b>	<b>20</b>	<b>40</b>

1. Diagnostic Sensitivity =  $100 \times [TP/(TP+FN)]$
2. Diagnostic Specificity =  $100 \times [TN/(FP+TN)]$
3. Percent Positive Agreement (Positive Predictive Value)  
=  $100 \times TP/(TP+FP)$
4. Percent Negative Agreement (Negative Predictive Value)  
=  $100 \times TN/(TN+FN)$

	Manufacturer's Claims	Actual Results	Acceptability
Positive Agreement (Diagnostic Sensitivity)	<b>100%</b>	<b>100%</b>	<b>Acceptable</b>
Negative Agreement (Diagnostic Specificity)	<b>100%</b>	<b>100%</b>	<b>Acceptable</b>

## ABC LABORATORY DETERMINE ACCURACY STUDY

DATE 3-Aug-23  
LABTECH JANE DOE (JD)

		DETERMINE HIV 1/2 LOT 13373K106 EXP. 2023-08-08	ARCHITECT HIV 1/2 LOT 123456 EXP. 2024-04-08
1	35101146	REACTIVE	REACTIVE
2	35101147	REACTIVE	REACTIVE
3	35101148	REACTIVE	REACTIVE
4	35101149	REACTIVE	REACTIVE
5	35101150	REACTIVE	REACTIVE
6	35101151	REACTIVE	REACTIVE
7	35101152	REACTIVE	REACTIVE
8	35101153	REACTIVE	REACTIVE
9	35101154	REACTIVE	REACTIVE
10	35101155	REACTIVE	REACTIVE
11	35101156	REACTIVE	REACTIVE
12	35101157	REACTIVE	REACTIVE
13	35101158	REACTIVE	REACTIVE
14	35101159	REACTIVE	REACTIVE
15	35101160	REACTIVE	REACTIVE
16	35101161	REACTIVE	REACTIVE
17	35101162	REACTIVE	REACTIVE
18	35101163	REACTIVE	REACTIVE
19	35101164	REACTIVE	REACTIVE
20	35101165	REACTIVE	REACTIVE
21	621901078	NON REACTIVE	NON REACTIVE
22	621901079	NON REACTIVE	NON REACTIVE
23	621901080	NON REACTIVE	NON REACTIVE
24	621901081	NON REACTIVE	NON REACTIVE
25	621901082	NON REACTIVE	NON REACTIVE
26	621901083	NON REACTIVE	NON REACTIVE
27	621901084	NON REACTIVE	NON REACTIVE
28	621901085	NON REACTIVE	NON REACTIVE
29	621901086	NON REACTIVE	NON REACTIVE
30	621901087	NON REACTIVE	NON REACTIVE
31	621901088	NON REACTIVE	NON REACTIVE
32	621901089	NON REACTIVE	NON REACTIVE
33	621901090	NON REACTIVE	NON REACTIVE
34	621901091	NON REACTIVE	NON REACTIVE
35	621901092	NON REACTIVE	NON REACTIVE
36	621901093	NON REACTIVE	NON REACTIVE
37	621901094	NON REACTIVE	NON REACTIVE
38	621901095	NON REACTIVE	NON REACTIVE
39	RDLG	NON REACTIVE	NON REACTIVE
40	PBU	NON REACTIVE	NON REACTIVE
CONTROL VIROTROL I		REACTIVE	REACTIVE
CONTROL VIROCLEAR		NON REACTIVE	NON REACTIVE

REVIEWED BY: JOHN DOE

Date: 10 AUG 23