

1/22

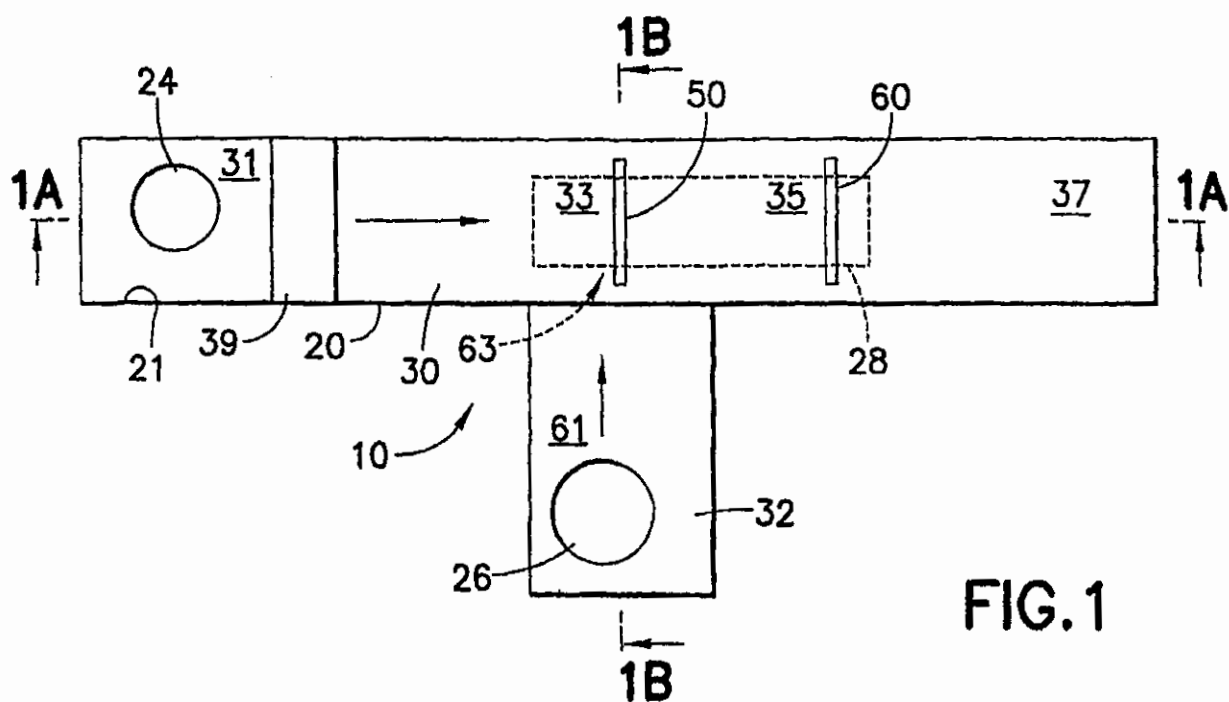


FIG. 1

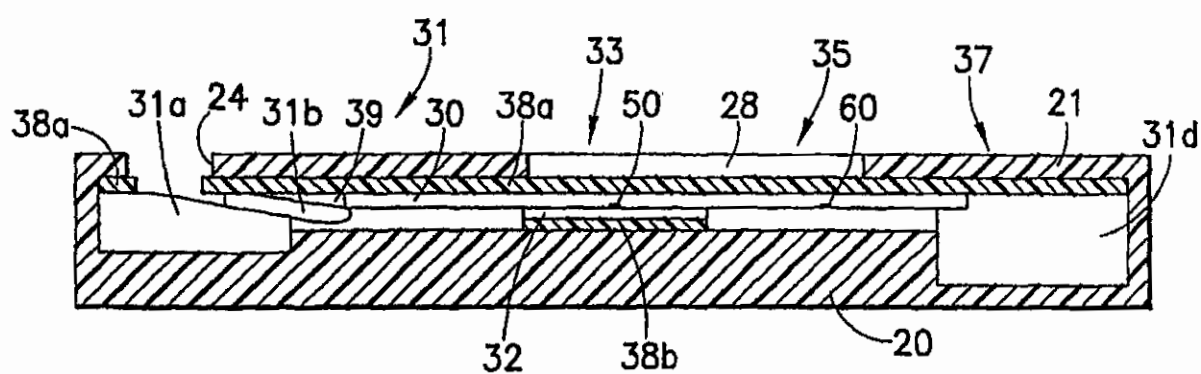


FIG. 1A

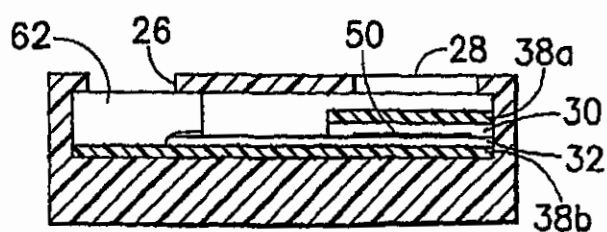


FIG. 1B

2/22

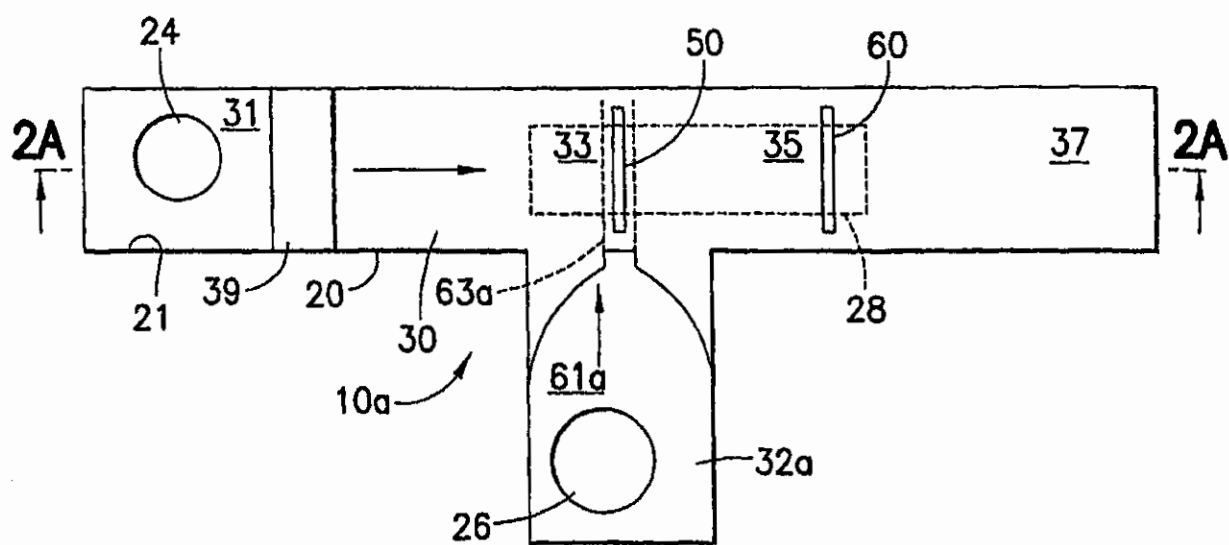


FIG.2

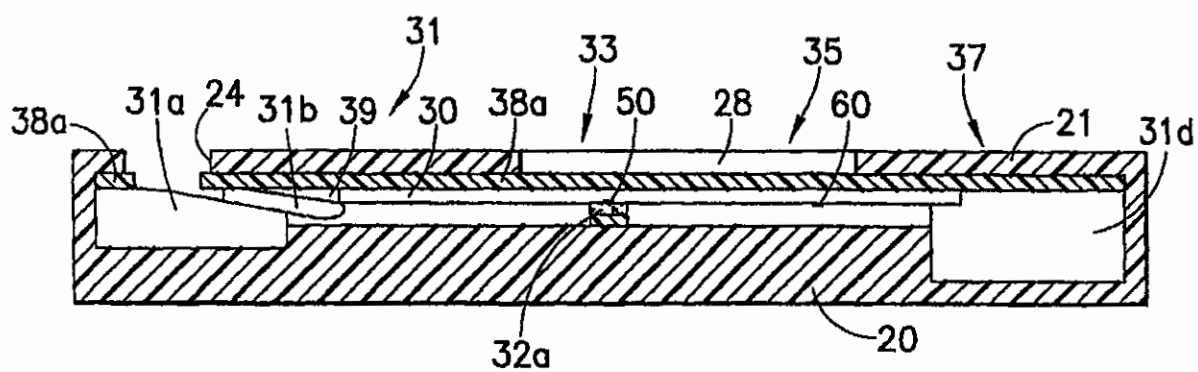


FIG. 2A

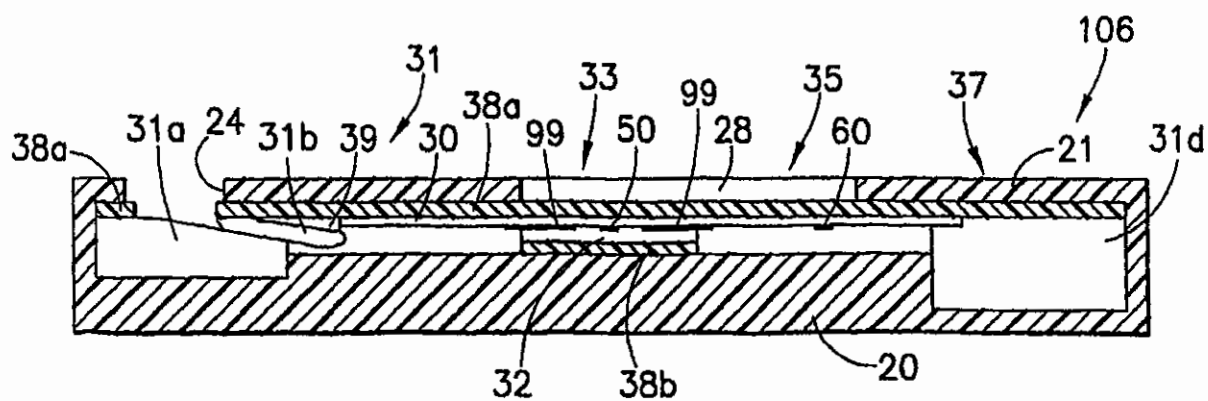


FIG.3

3/22

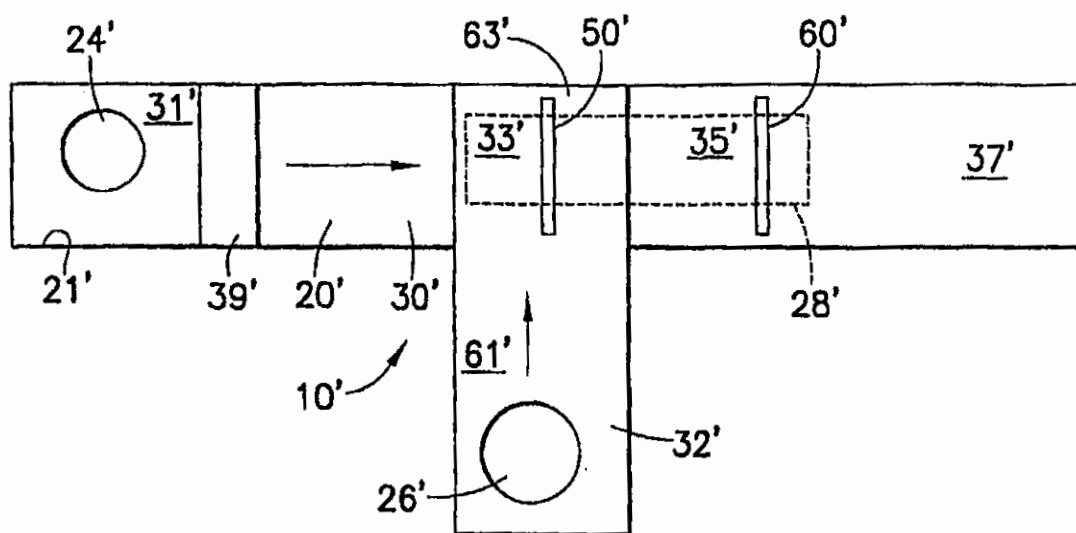


FIG. 4

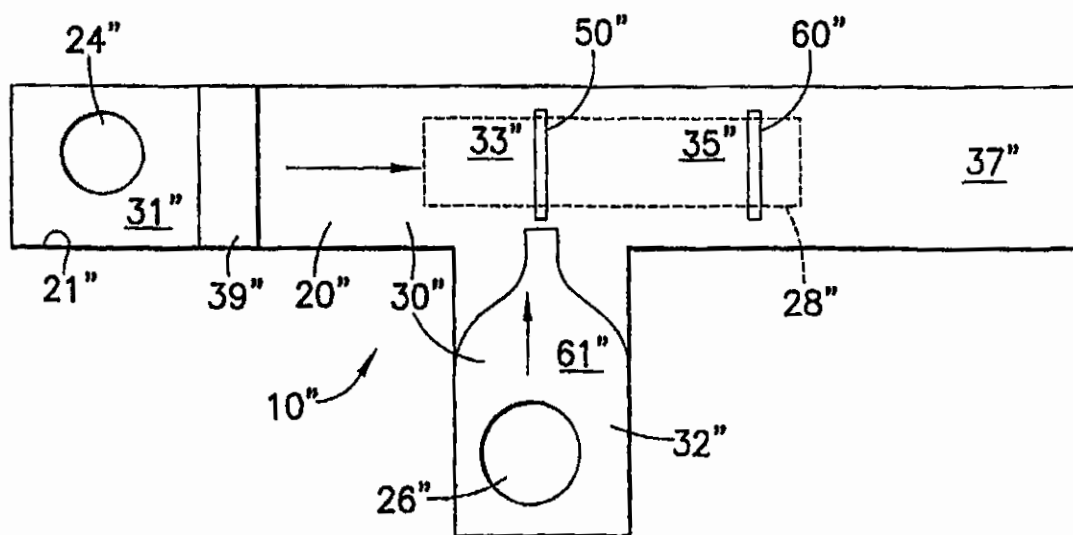


FIG. 5

4/22

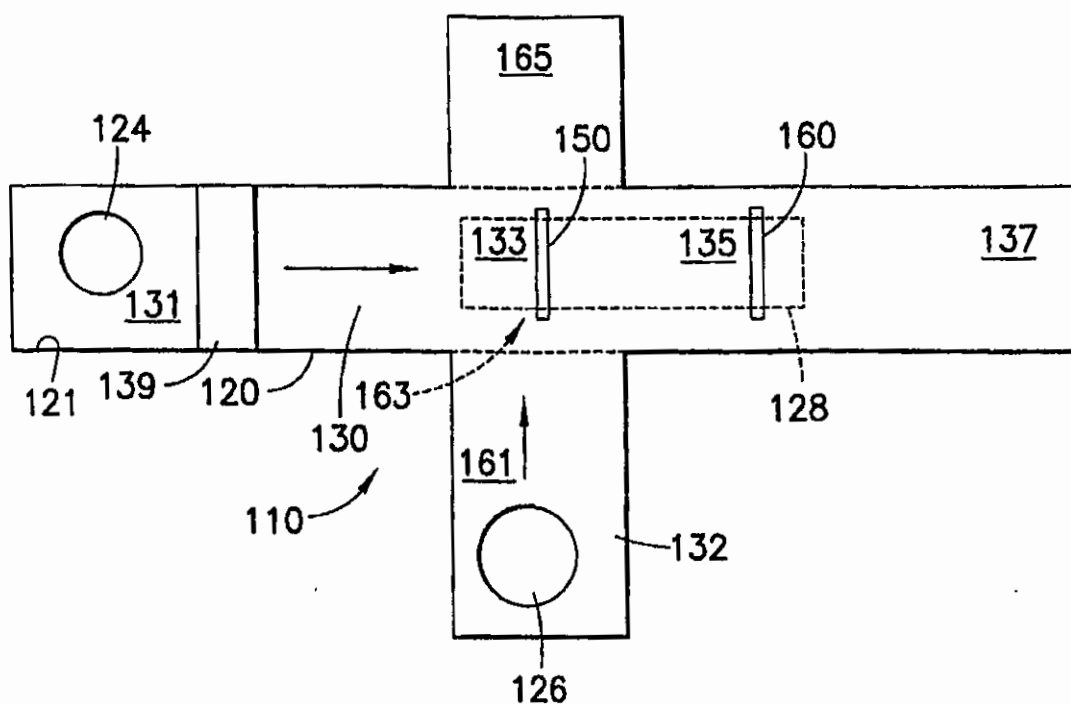


FIG. 6

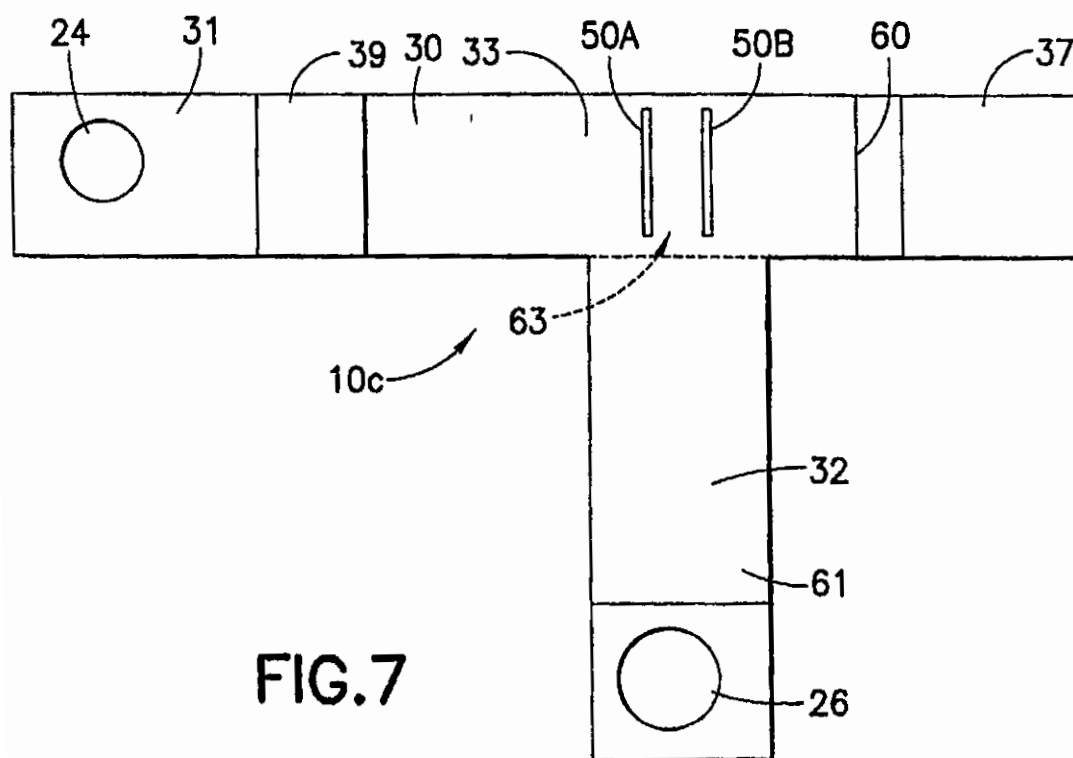
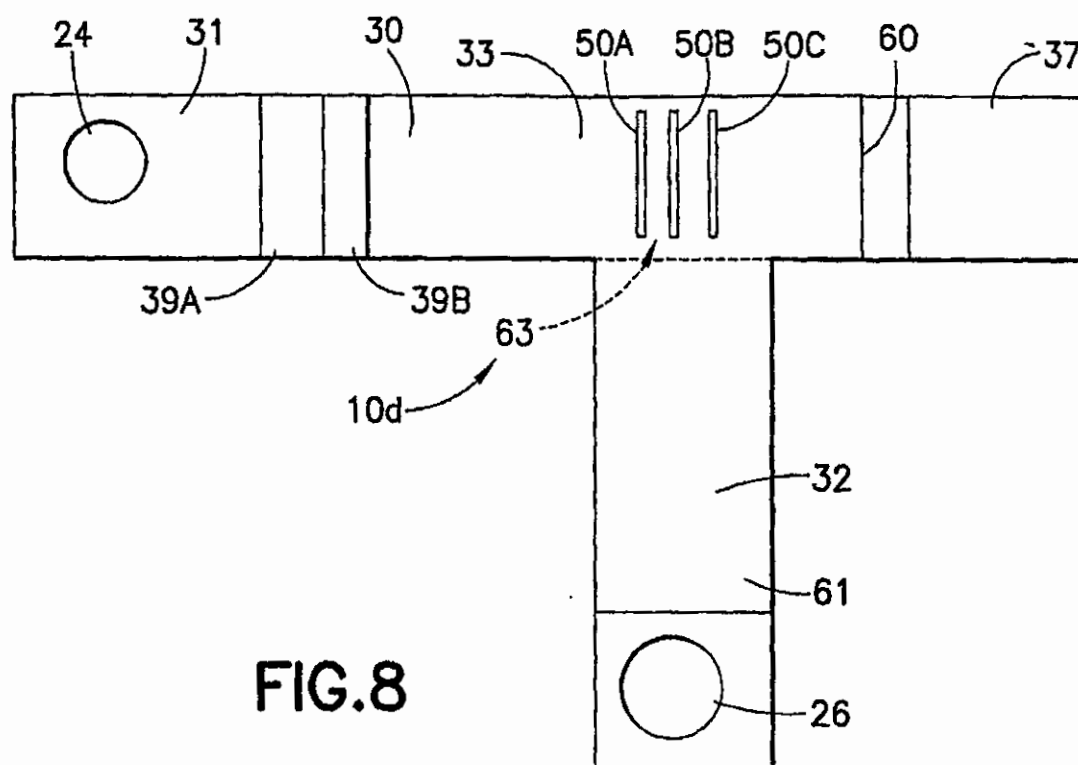
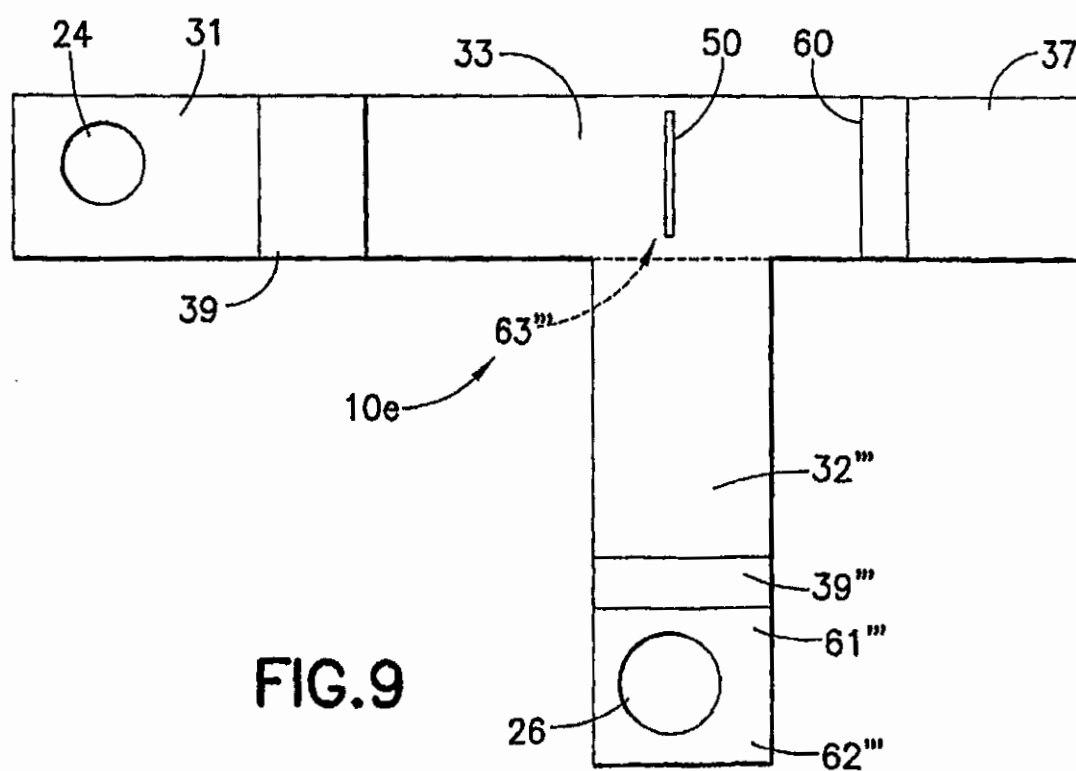


FIG. 7

5/22



6/22

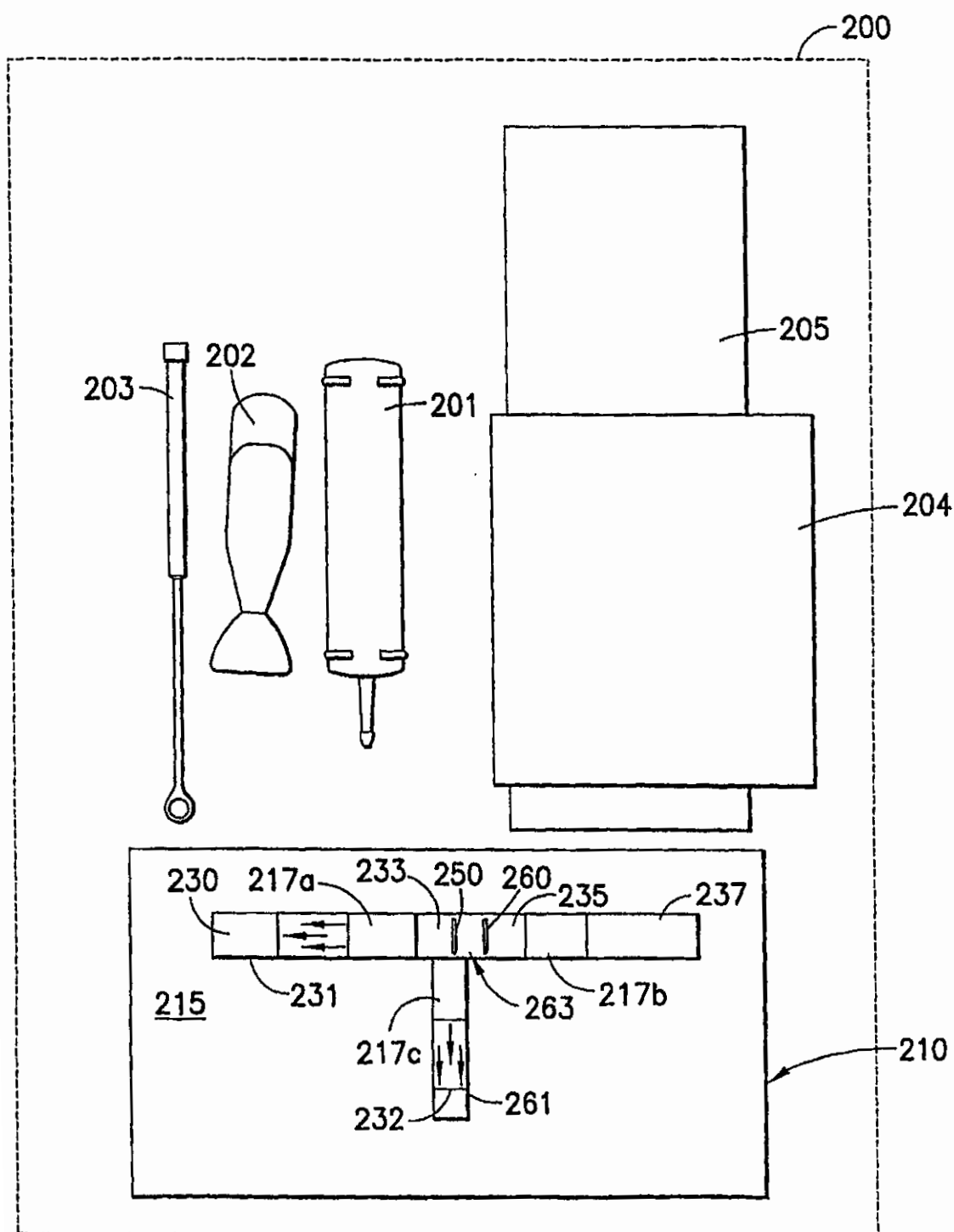


FIG. 10

7/22

TB STAT-PAK II vs. NEW GENERATION TB ASSAY

SAMPLES: TBGL CONTROLS

	TB STAT-PAK™ II	NEW GENERATION
32 U/ml	+++	+++
8 U/ml	++	++
2 U/ml	+/-	+
1 U/ml	-	+
1/2 U/ml	-	+
1/4 U/ml	-	+
1/8 U/ml	-	-
0 U/ml	-	-

NOTE: DILUTIONS ≤ 1 U/ml WERE MADE FROM 2 U/ml SAMPLE

FIG.11

8/22

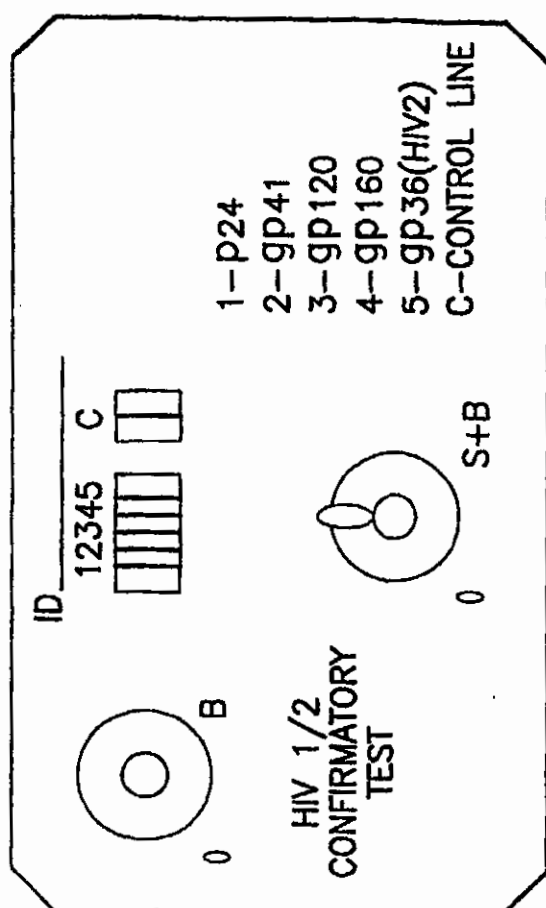
LABORATORY RESULT FOR THE NEW GENERATION HIV TEST

	DILUTION	NG HIV TEST	HIV STAT-PAK™
HIV-1	1:64	3	3
	1:128	3	2
	1:256	3	3
	1:512	2	2
	1:1024	1	1
	1:2048	1	N
	1:4096	1	N
	1:8192	N	N
HIV-2	1:4	3	3
	1:8	3	3
	1:16	3	2
	1:32	2	2
	1:64	2	1
	1:128	2	1
	1:256	2	N
	1:512	1	N
	1:1024	N	N
	1:2048	N	N

INTENSITY	RESULT
1 —	WEAK POS
2 —	MEDIUM POS
3 —	STRONG POS
N —	NEGATIVE

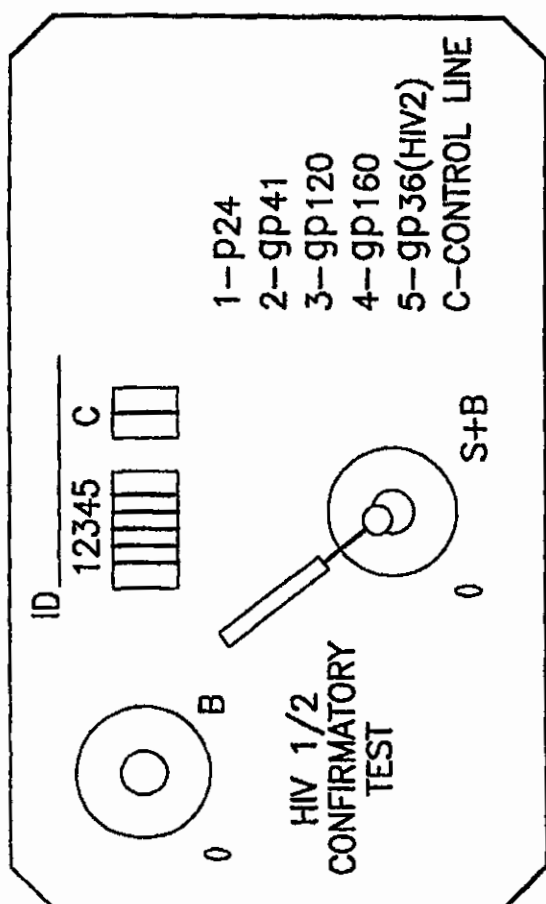
FIG.12

9/22



1. ADD 1 DROP (30 μ l) OF BUFFER TO THE SAMPLE WELL (S+B)

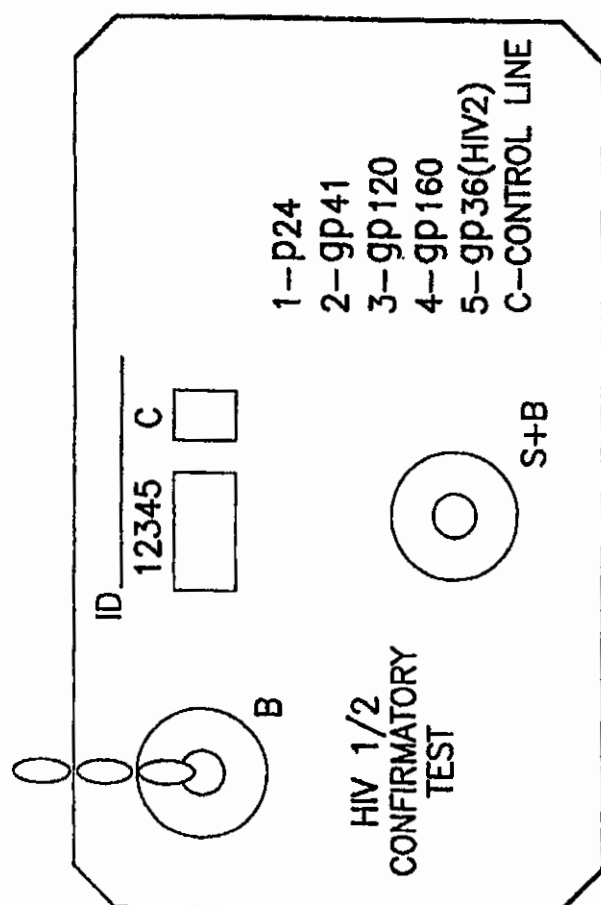
FIG. 13B



1. ADD 10 μ l OF SERUM/BLOOD TO THE SAMPLE WELL (S+B)

FIG. 13A

10/22



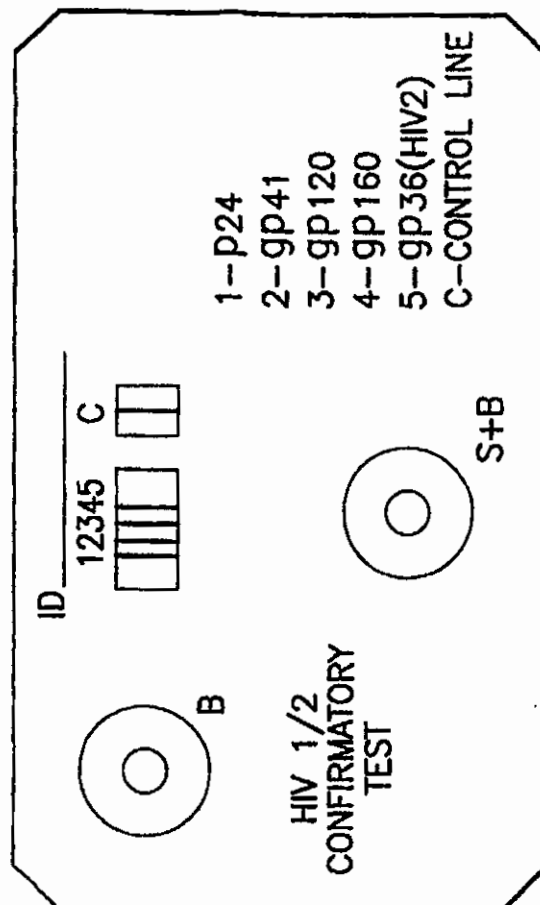
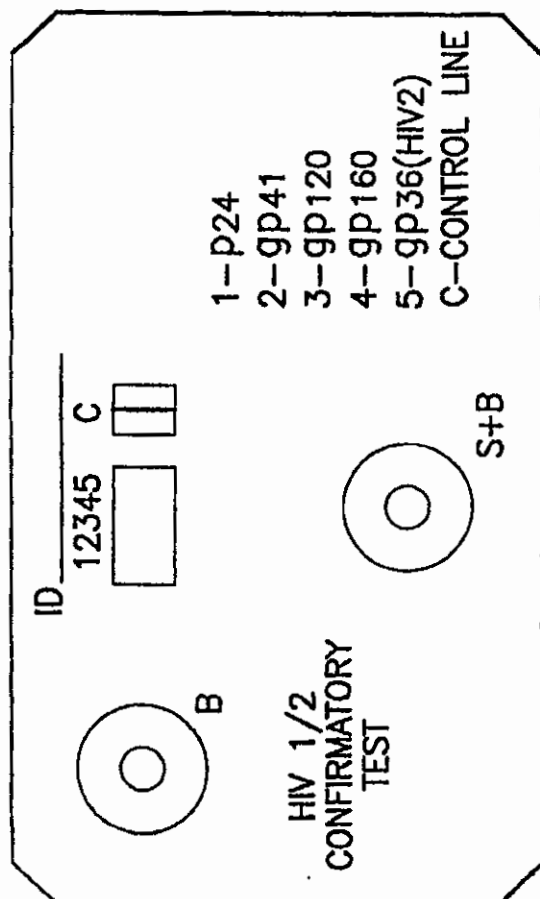
3. ADD 3 DROPS (90 μ l) OF BUFFER TO THE BUFFER WELL (B) WHEN THE COLORED LINES DISAPPEAR COMPLETELY

FIG.13C

11/22

4. READ THE RESULTS AT 20 MINUTES
NEGATIVE RESULT: ONE LINE OR
POSITIVE RESULT INDICATES PRESENCE OF
ANTIGEN OR ANTIGENS (TWO--SIX LINES)

4. READ THE RESULTS AT 20 MINUTES
NEGATIVE RESULT: ONE LINE OR
POSITIVE RESULT INDICATES PRESENCE OF
ANTIGEN OR ANTIGENS (TWO--SIX LINES)



HIV1 POSITIVE RESULT
(AT LEAST TWO HIV1 ANTIGENS REACTIVE)

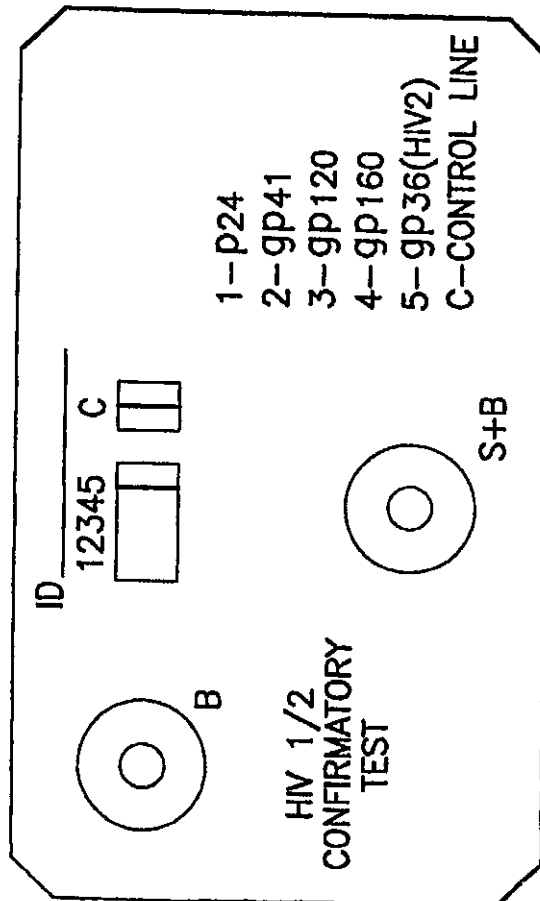
NEGATIVE RESULT

FIG.13E

FIG.13D

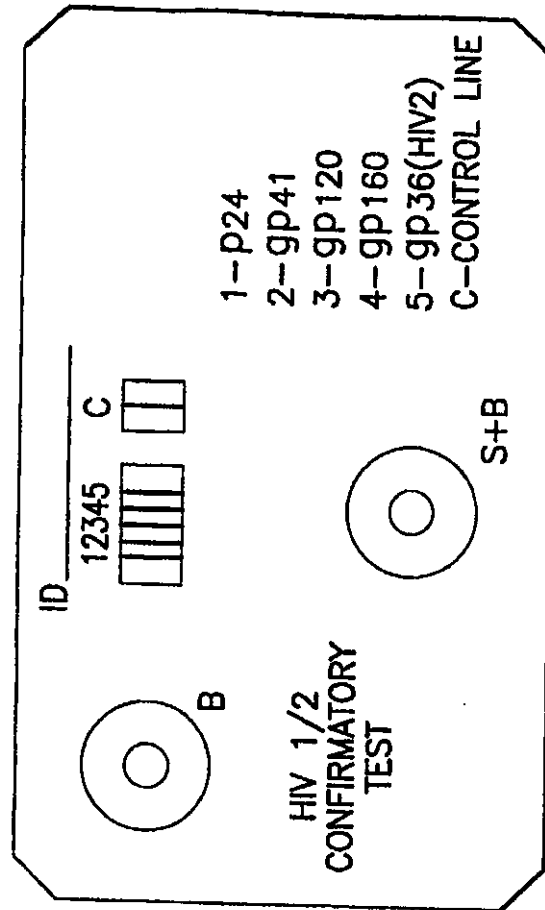
12/22

4. READ THE RESULTS AT 20 MINUTES
- NEGATIVE RESULT: ONE LINE OR POSITIVE RESULT INDICATES PRESENCE OF ANTIGEN OR ANTIGENS (TWO-SIX LINES)



HIV2 POSITIVE RESULT
(ONLY THE HIV2 ANTIGEN REACTIVE)

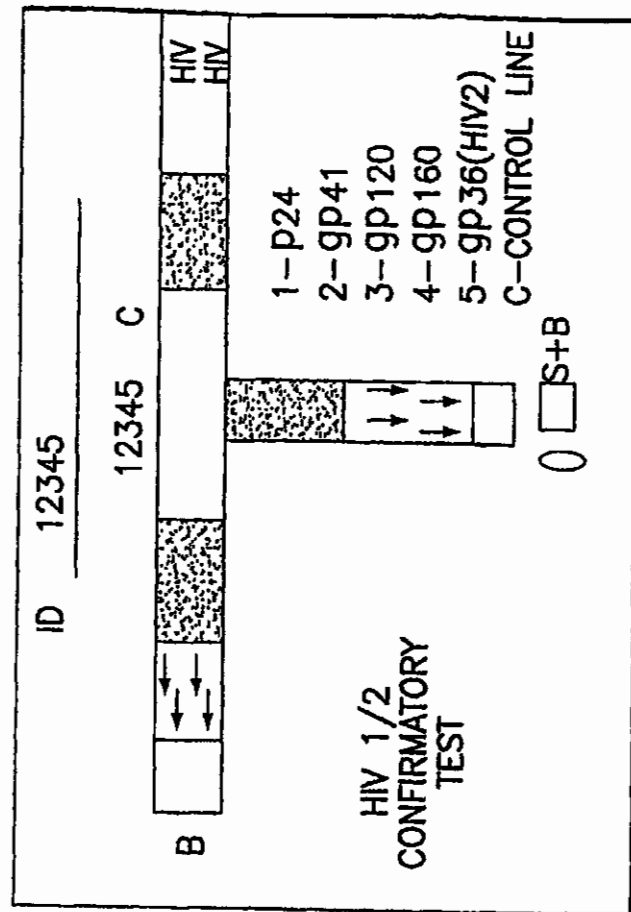
FIG.13F



HIV 1/2 POSITIVE RESULT
(AT LEAST TWO ANTIGENS FOR HIV1
AND THE HIV2 ANTIGEN ALL REACTIVE)

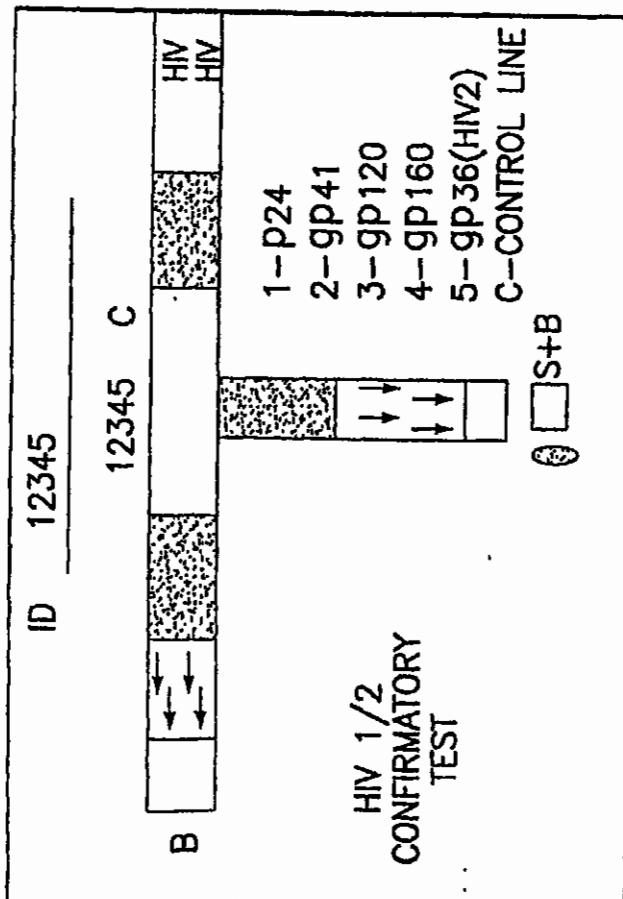
FIG.13G

13/22



2. ADD 1 DROP (30 μ l) OF BUFFER TO THE SAMPLE WELL (S+B)

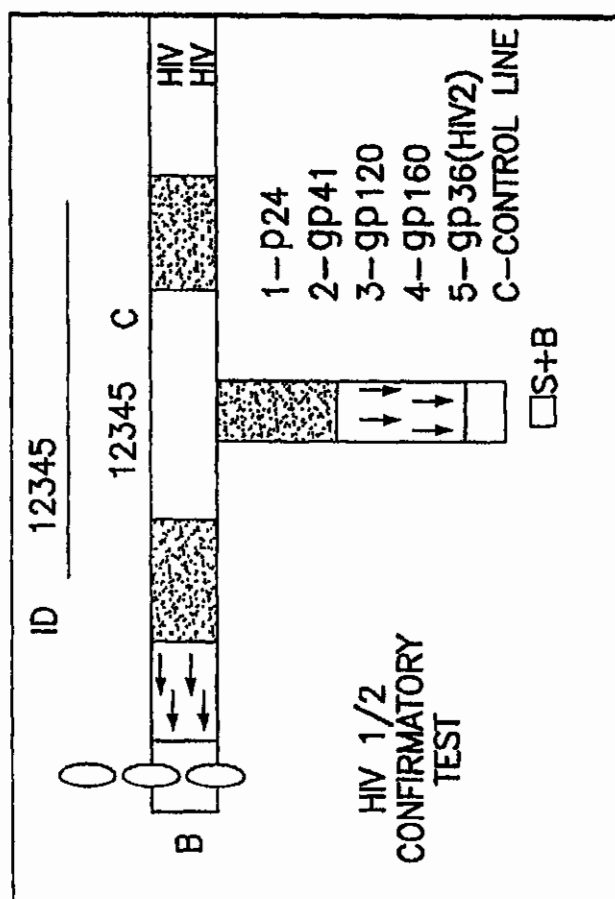
FIG.14B



1. ADD 10 μ l OF SERUM/BLOOD TO THE SAMPLE WELL (S+B)

FIG.14A

14/22

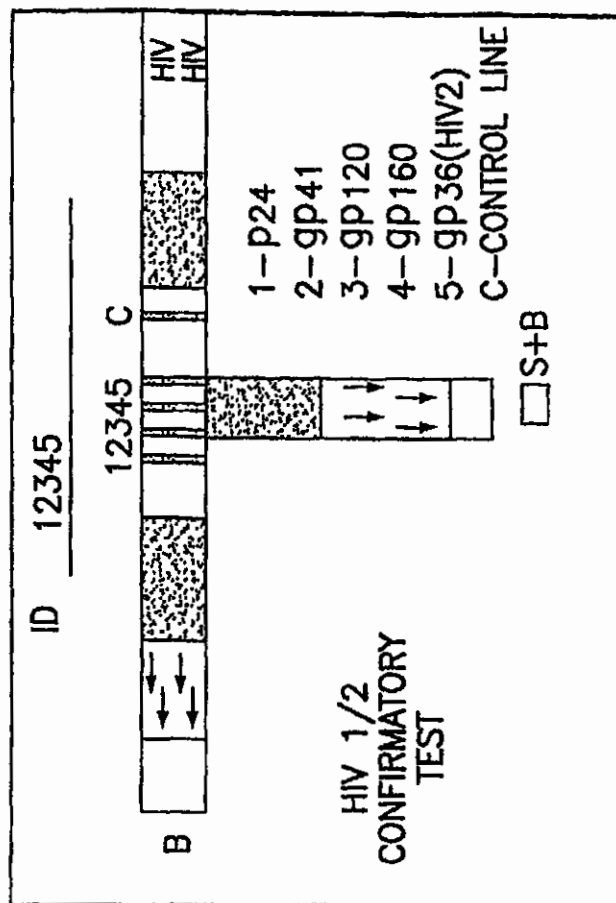


3. ADD 3 DROPS (90 μ l) OF BUFFER TO THE BUFFER WELL (B) WHEN THE COLORED LINES DISAPPEAR COMPLETELY

FIG.14C

15/22

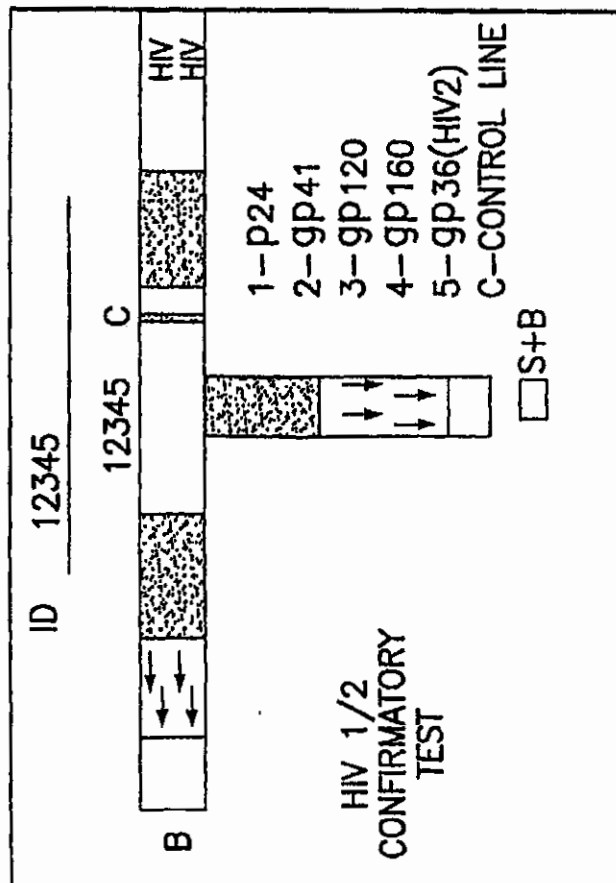
4. READ THE RESULTS AT 20 MINUTES
NEGATIVE RESULT: ONE LINE OR
POSITIVE RESULT INDICATES PRESENCE OF
ANTIGEN OR ANTIGENS (TWO-SIX LINES)



HIV1 POSITIVE RESULT
(AT LEAST TWO HIV1 ANTIGENS REACTIVE)

FIG.14E

4. READ THE RESULTS AT 20 MINUTES
NEGATIVE RESULT: ONE LINE OR
POSITIVE RESULT INDICATES PRESENCE OF
ANTIGEN OR ANTIGENS (TWO-SIX LINES)

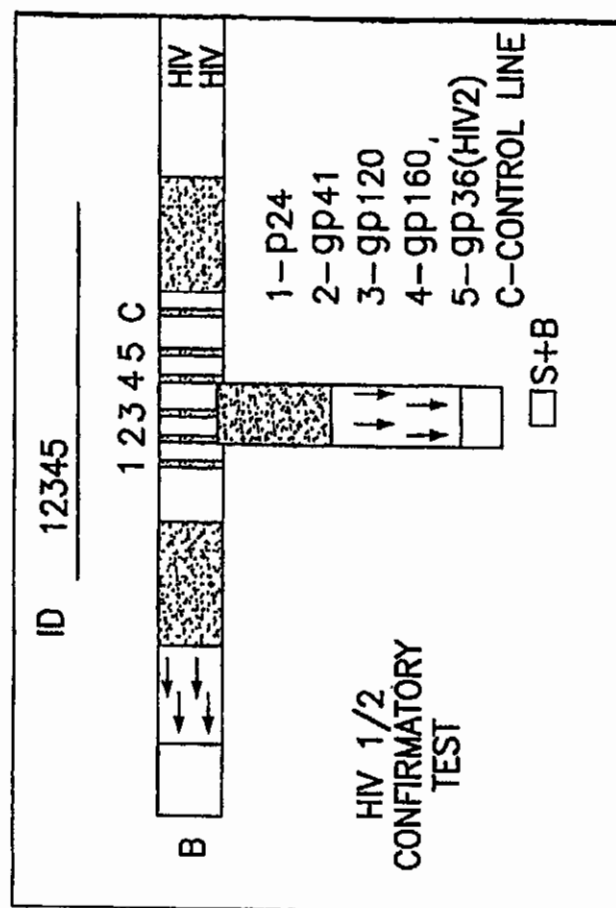


NEGATIVE RESULT

FIG.14D

16/22

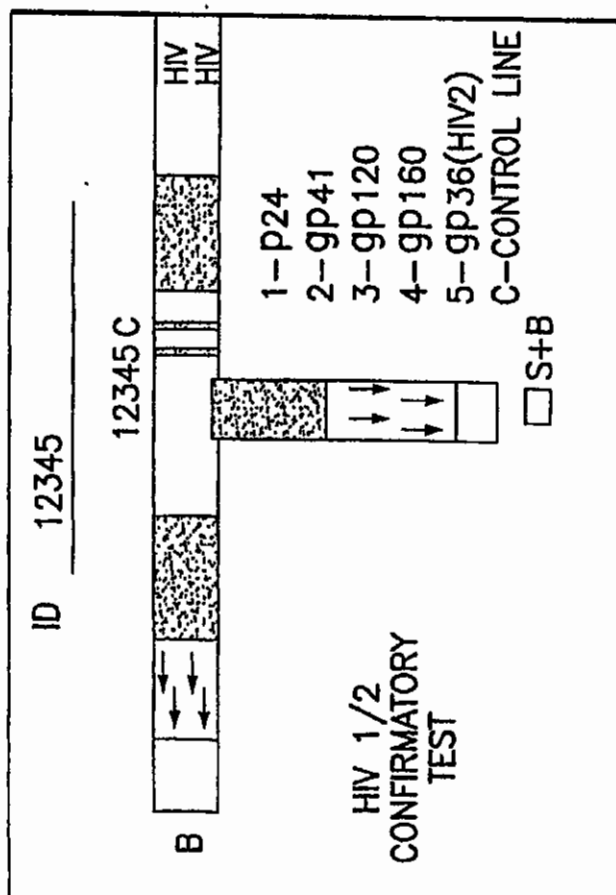
4. READ THE RESULTS AT 20 MINUTES
 NEGATIVE RESULT: ONE LINE OR
 POSITIVE RESULT INDICATES PRESENCE OF
 ANTIGEN OR ANTIGENS (THREE-SEVEN LINES)



HIV 1/2 POSITIVE RESULT
 (AT LEAST TWO ANTIGENS FOR HIV1
 AND THE HIV2 ANTIGEN ALL REACTIVE)

FIG.14G

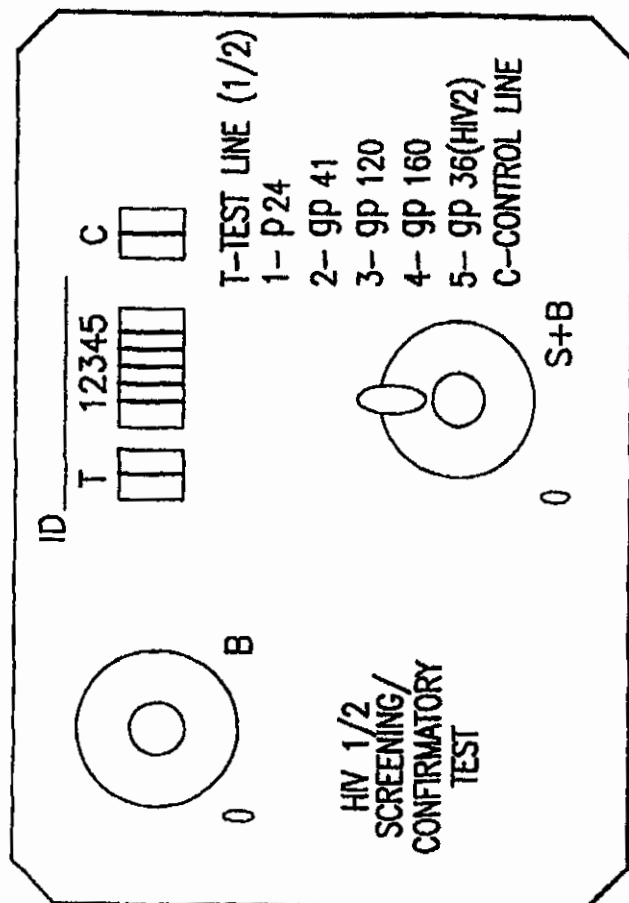
4. READ THE RESULTS AT 20 MINUTES
 NEGATIVE RESULT: ONE LINE OR
 POSITIVE RESULT INDICATES PRESENCE OF
 ANTIGEN OR ANTIGENS (THREE-SEVEN LINES)



HIV2 POSITIVE RESULT
 (ONLY THE HIV2 ANTIGEN REACTIVE)

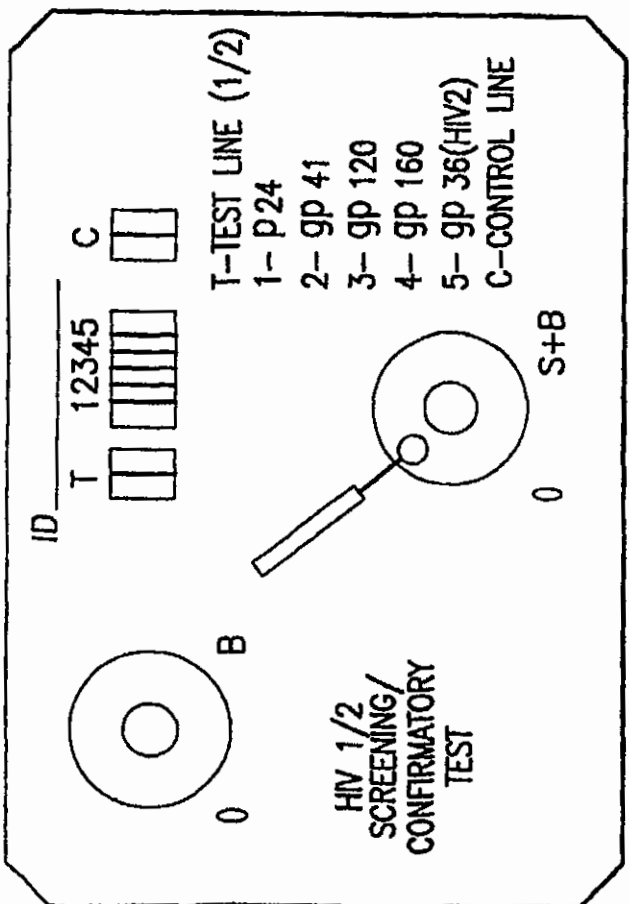
FIG.14F

17/22



1. ADD 1 DROP (30 μ l) OF BUFFER TO THE SAMPLE WELL (S+B)

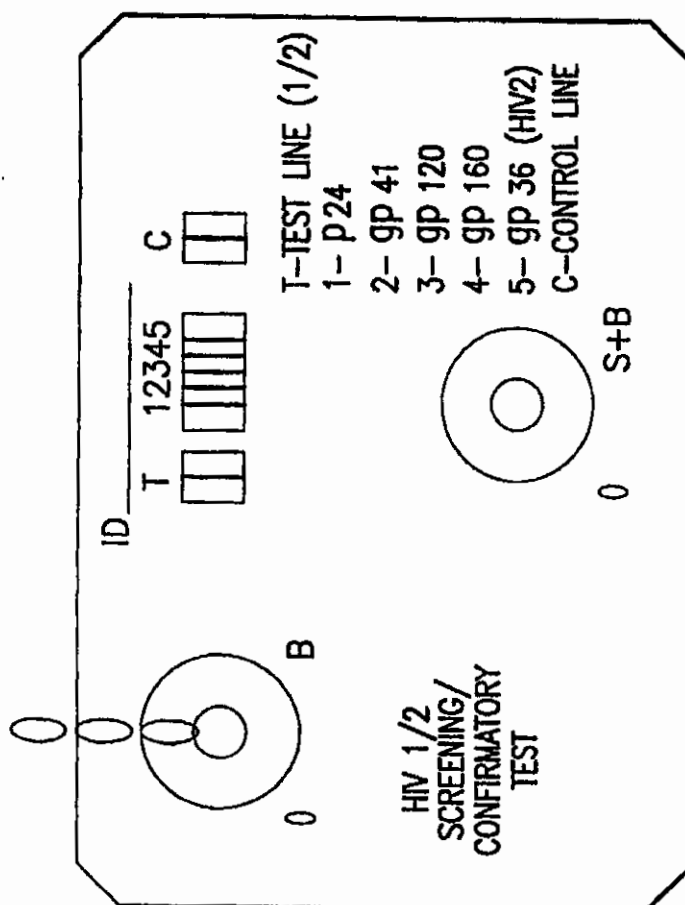
FIG.15B



1. ADD 10 μ l OF SERUM/BLOOD TO THE SAMPLE WELL (S+B)

FIG.15A

18/22

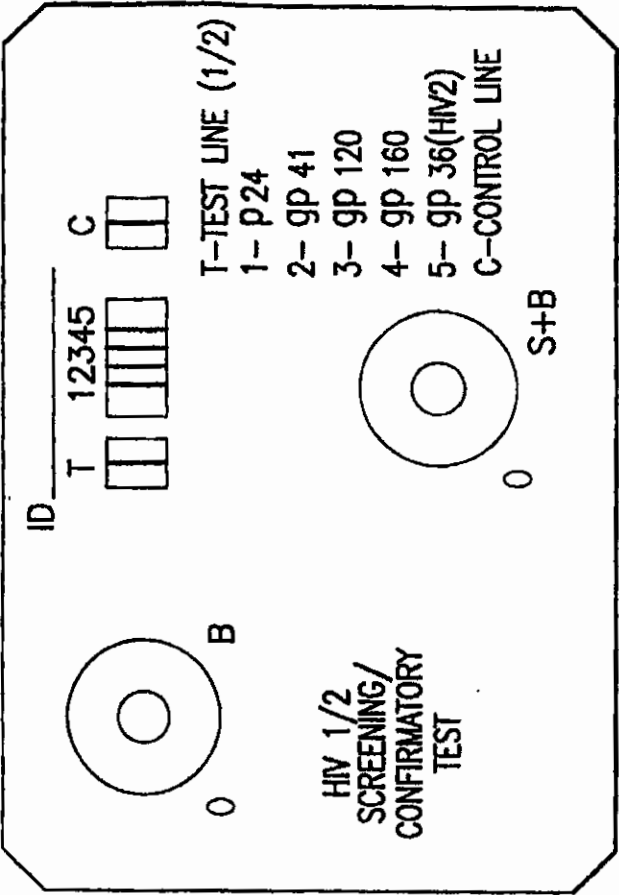


3. ADD 3 DROPS (90 μ l) OF BUFFER TO THE BUFFER WELL (B) WHEN THE COLORED LINES DISAPPEAR COMPLETELY

FIG.15C

19/22

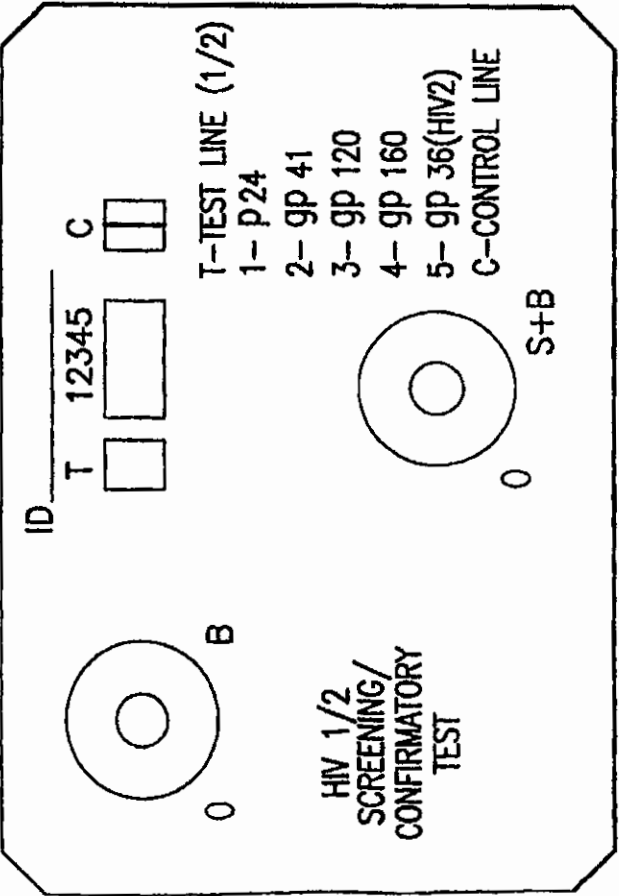
4. READ THE RESULTS AT 20 MINUTES
NEGATIVE RESULT: ONE LINE OR
POSITIVE RESULT INDICATES PRESENCE OF
ANTIGEN OR ANTIGENS (THREE--SEVEN LINES)



HIV1 POSITIVE RESULT
(T AND AT LEAST TWO HIV1 ANTIGENS
REACTIVE)

FIG.15E

4. READ THE RESULTS AT 20 MINUTES
NEGATIVE RESULT: ONE LINE OR
POSITIVE RESULT INDICATES PRESENCE OF
ANTIGEN OR ANTIGENS (THREE--SEVEN LINES)



NEGATIVE RESULT

FIG.15D

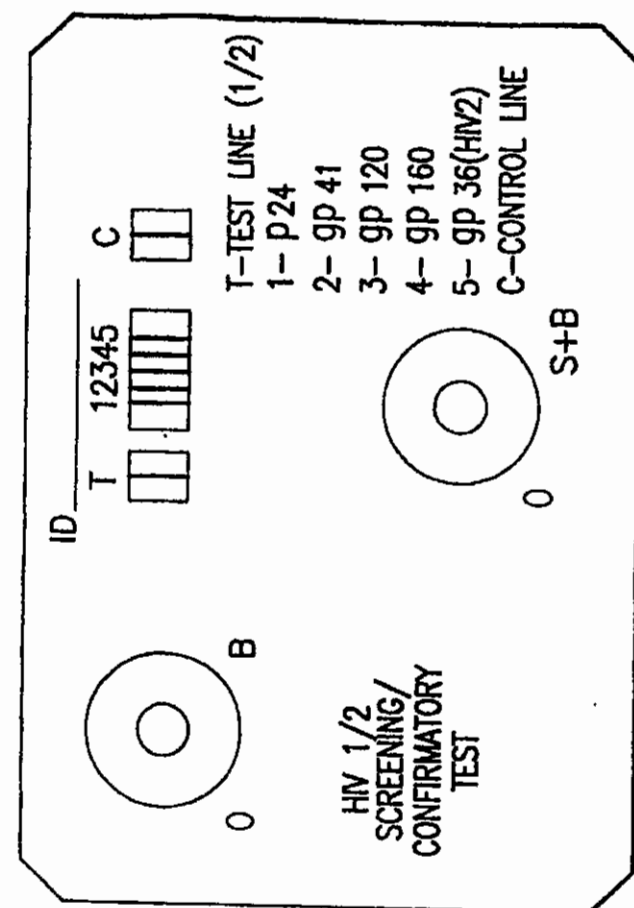
20/22

4. READ THE RESULTS AT 20 MINUTES

NEGATIVE RESULT: ONE LINE OR
POSITIVE RESULT INDICATES PRESENCE OF
ANTIGEN OR ANTIGENS (THREE-SEVEN LINES)

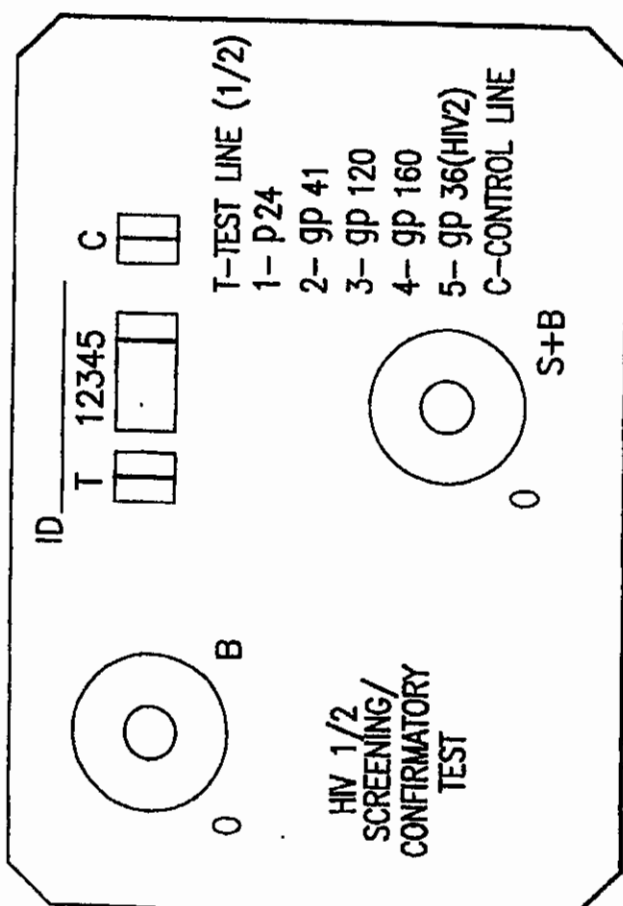
4. READ THE RESULTS AT 20 MINUTES

NEGATIVE RESULT: ONE LINE OR
POSITIVE RESULT INDICATES PRESENCE OF
ANTIGEN OR ANTIGENS (THREE-SEVEN LINES)



HIV 1/2 POSITIVE RESULT
(T AND AT LEAST TWO ANTIGENS FOR HIV1
AND THE HIV2 ANTIGEN ALL REACTIVE)

FIG.15G



HIV2 POSITIVE RESULT
(T AND ONLY THE HIV2 ANTIGEN REACTIVE)

FIG.15F

21/22

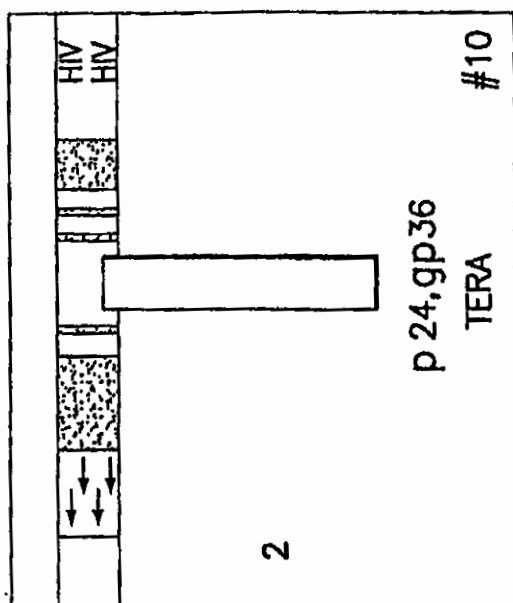


FIG. 16B

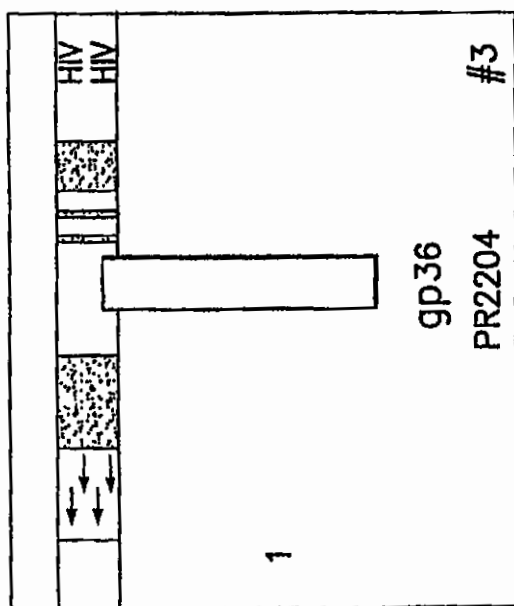


FIG. 16A

22/22

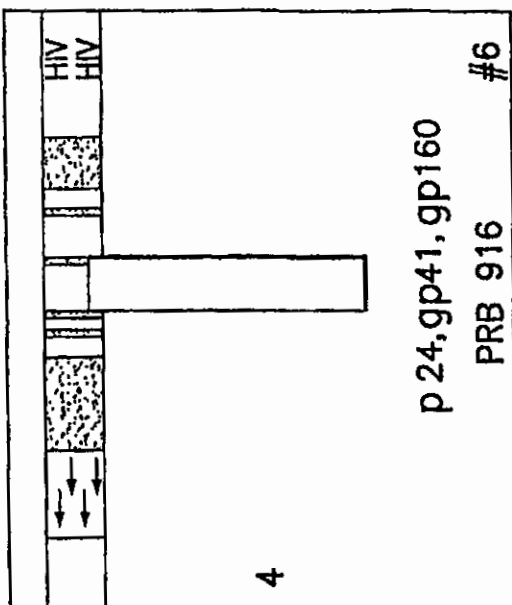


FIG. 16C

FIG. 16D

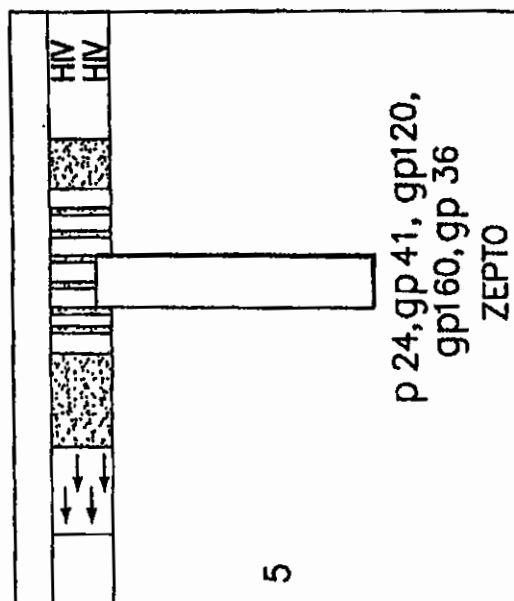


FIG. 16E

