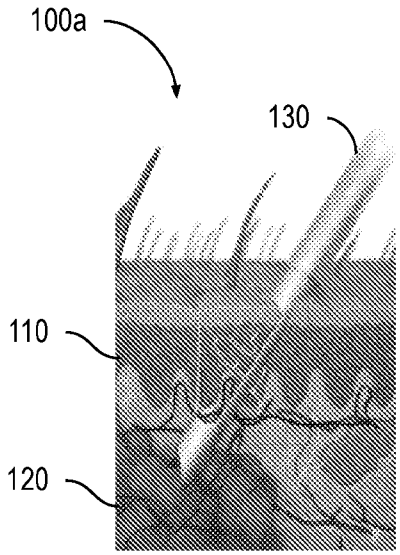


FIG. 1A
(PRIOR ART)

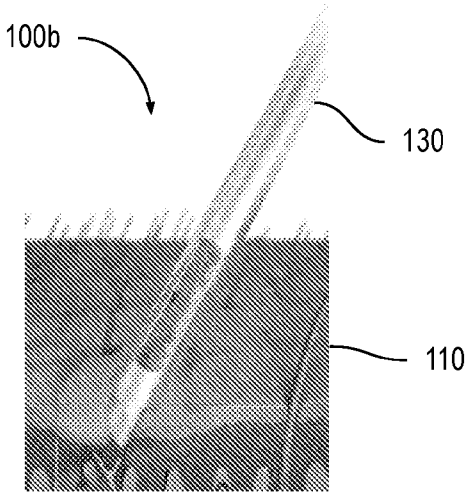


FIG. 1B
(PRIOR ART)

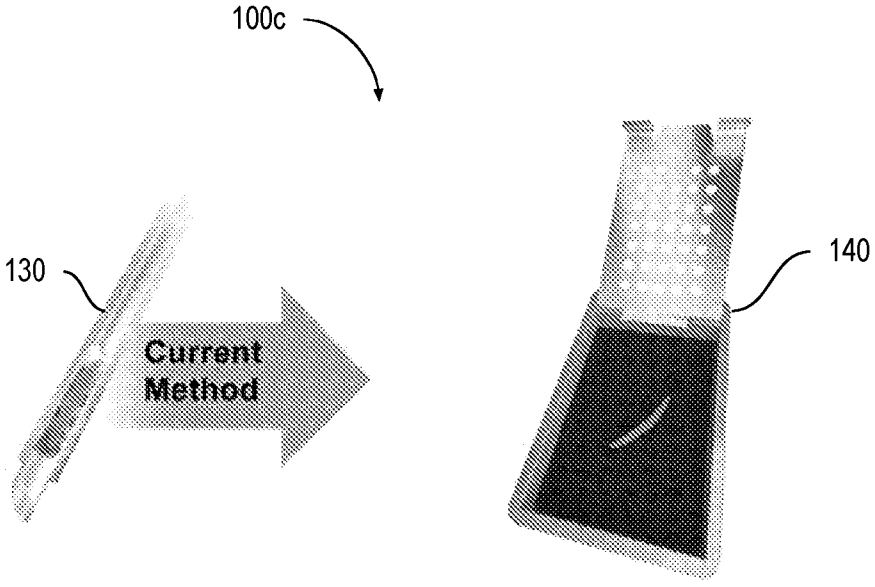


FIG. 1C
(PRIOR ART)

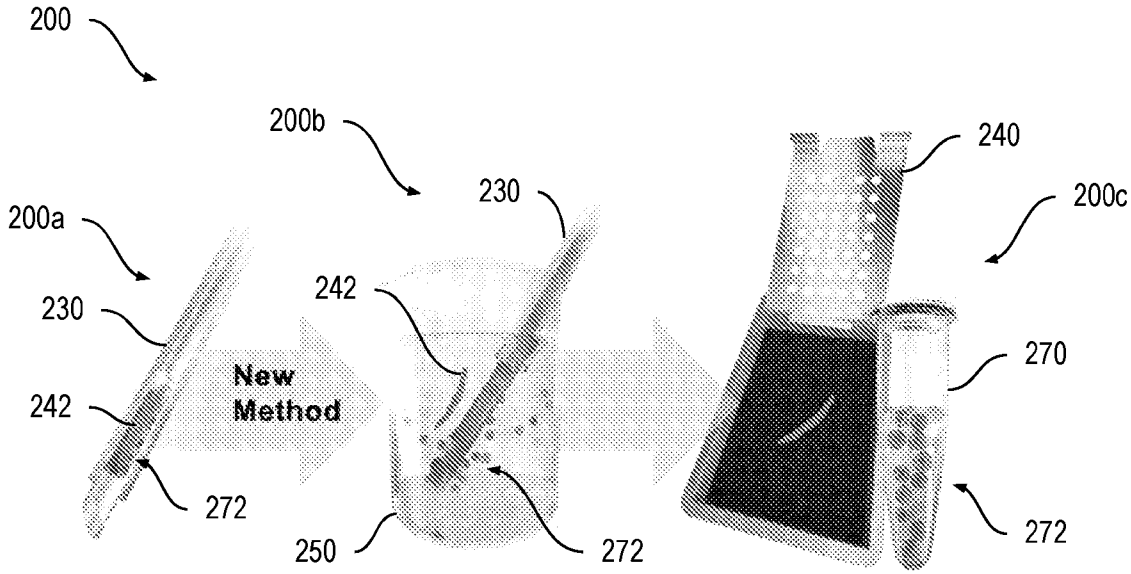

200
200b
230
240
200a
200c
230
242
New
Method
270
242
272
272
250
272

FIG. 2

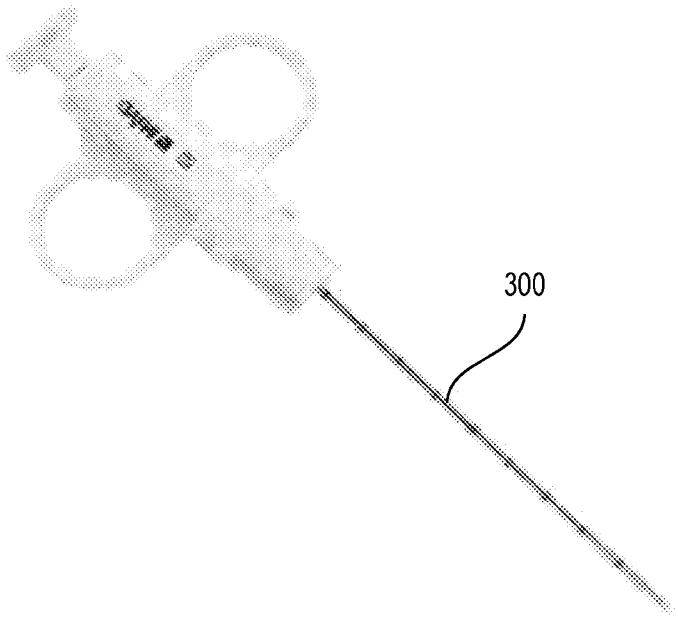

300

FIG. 3

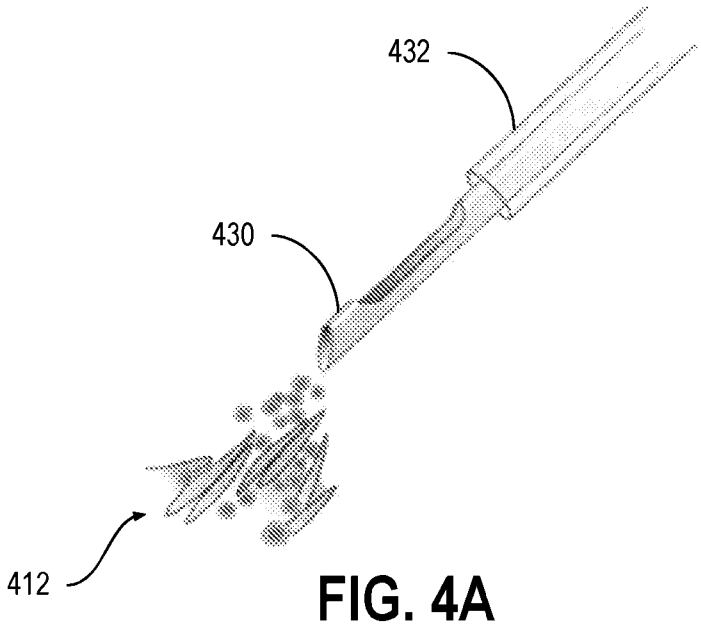


FIG. 4A

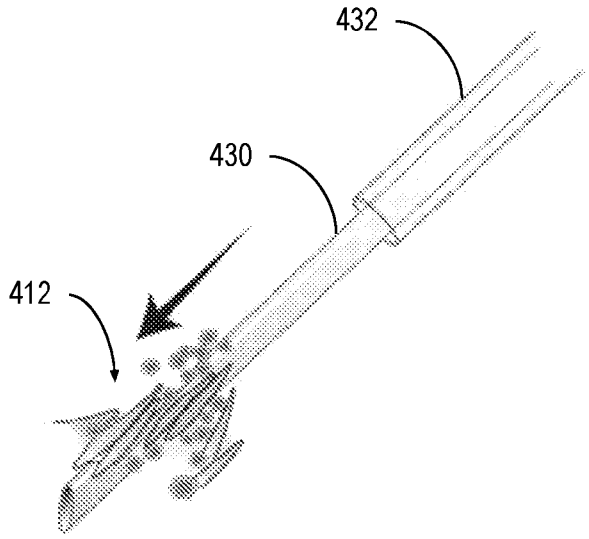


FIG. 4B

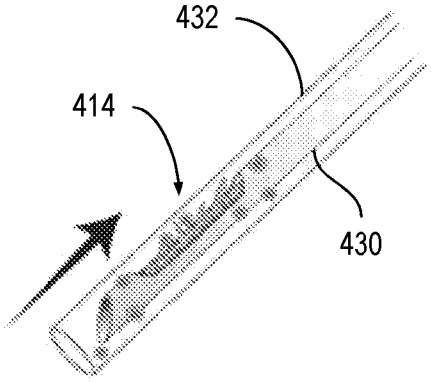


FIG. 4C

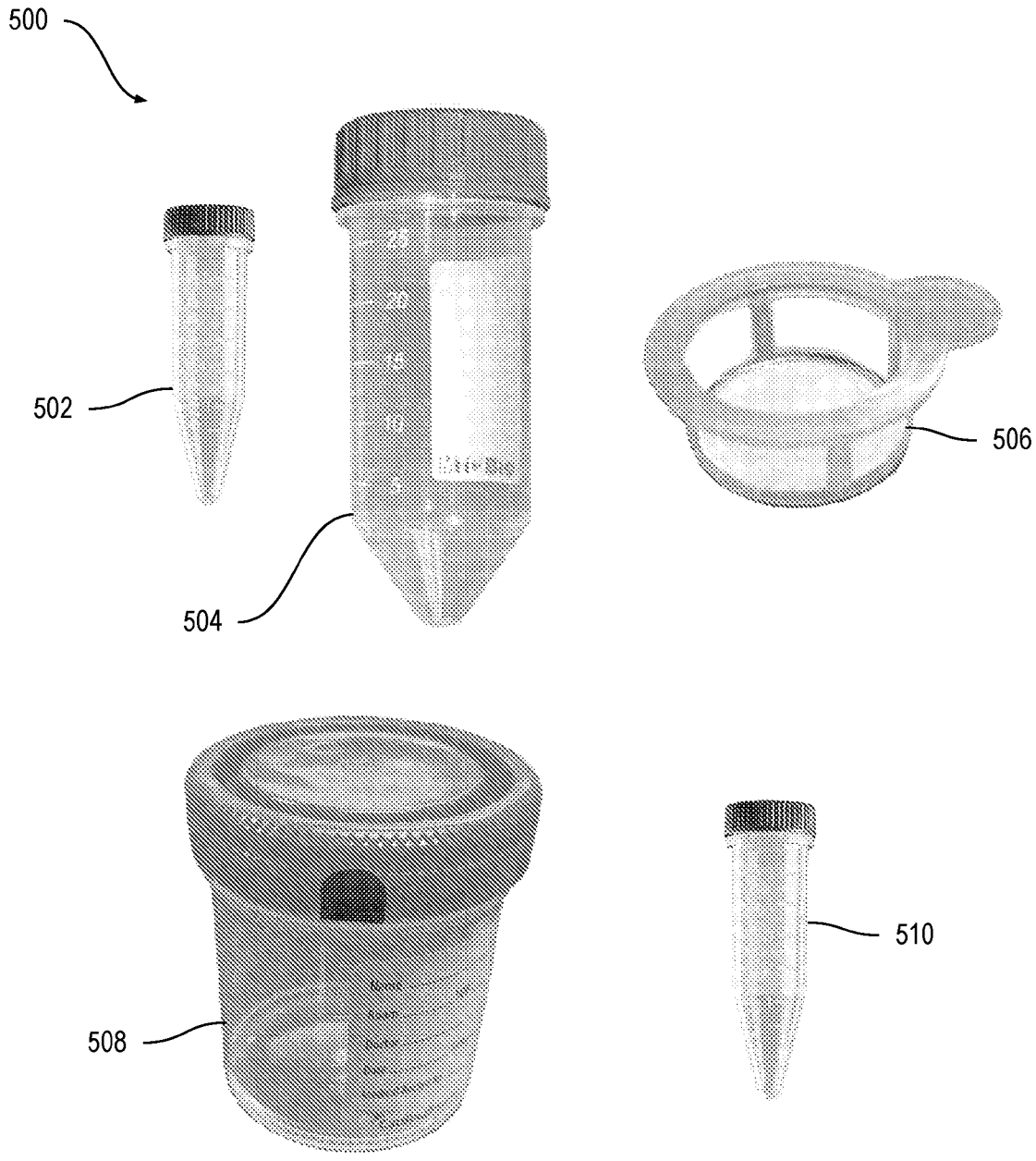


FIG. 5

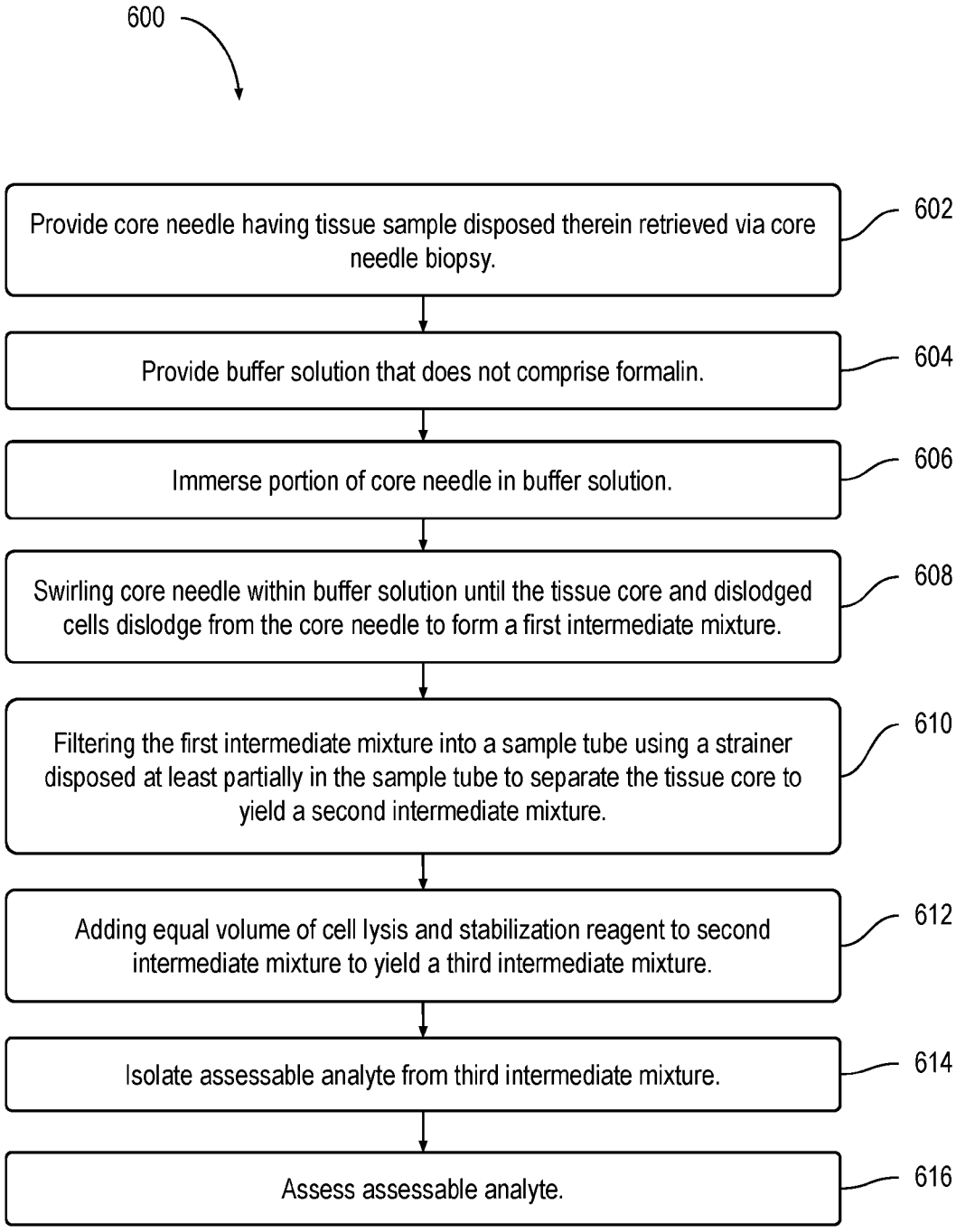

600
Provide core needle having tissue sample disposed therein retrieved via core needle biopsy.
602
Provide buffer solution that does not comprise formalin.
604
Immerse portion of core needle in buffer solution.
606
Swirling core needle within buffer solution until the tissue core and dislodged cells dislodge from the core needle to form a first intermediate mixture.
608
Filtering the first intermediate mixture into a sample tube using a strainer disposed at least partially in the sample tube to separate the tissue core to yield a second intermediate mixture.
610
Adding equal volume of cell lysis and stabilization reagent to second intermediate mixture to yield a third intermediate mixture.
612
Isolate assessable analyte from third intermediate mixture.
614
Assess assessable analyte.
616

FIG. 6



FIG. 7A

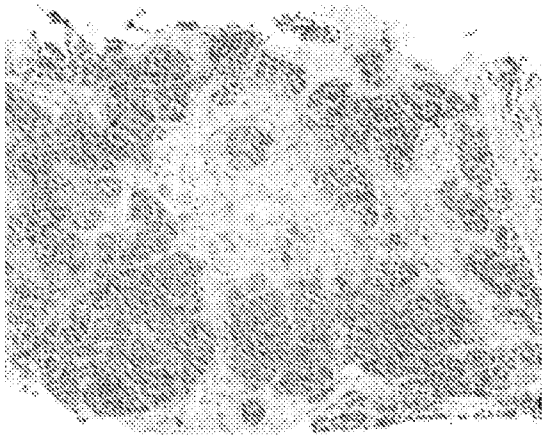


FIG. 7B

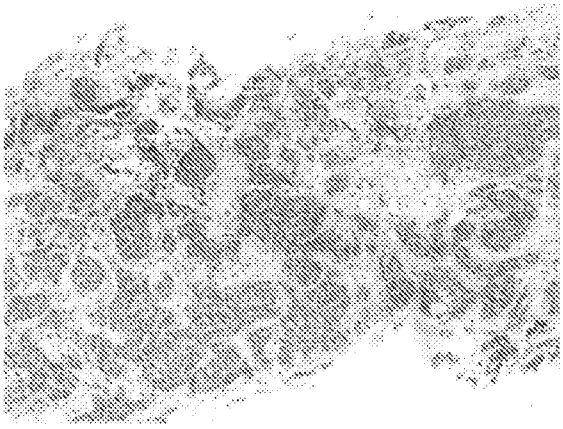


FIG. 7C



FIG. 8A

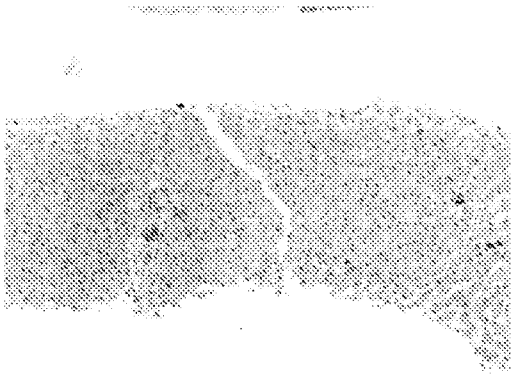


FIG. 8B



FIG. 8C



FIG. 9A

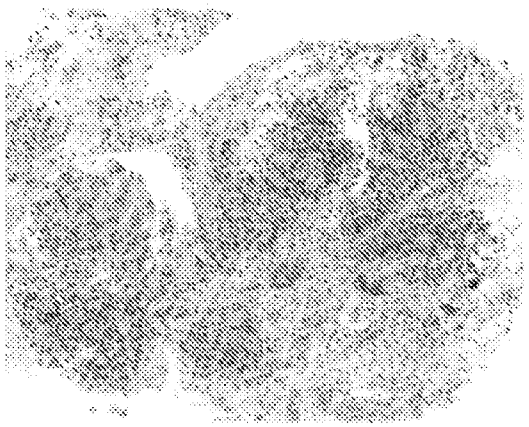


FIG. 9B

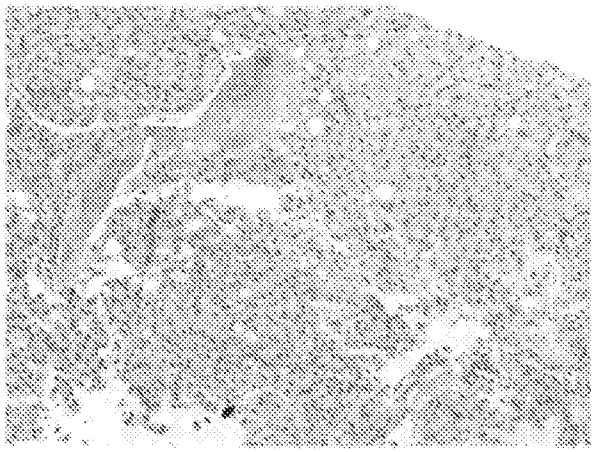


FIG. 9C



FIG. 10A

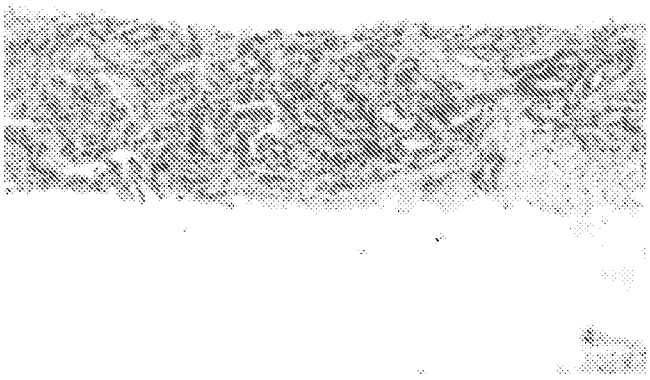


FIG. 10B



FIG. 11A

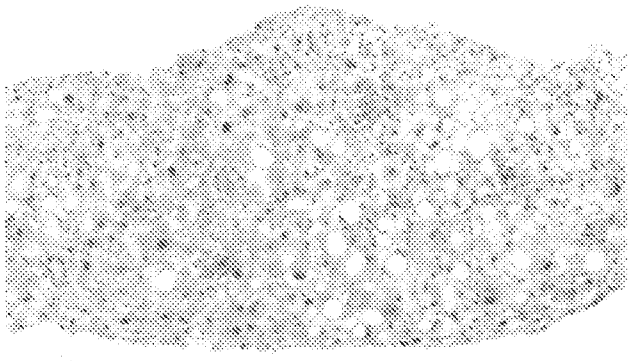


FIG. 11B

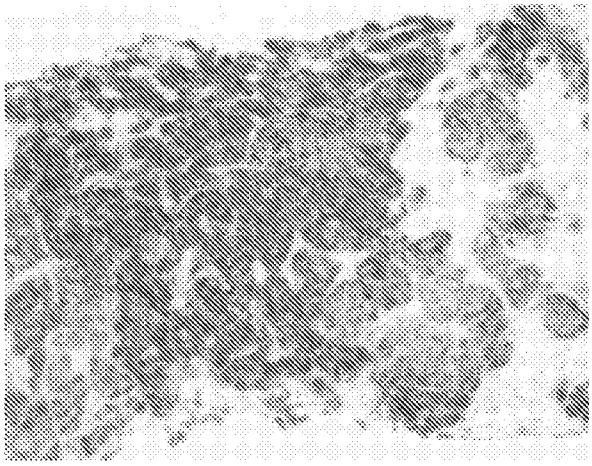


FIG. 12A

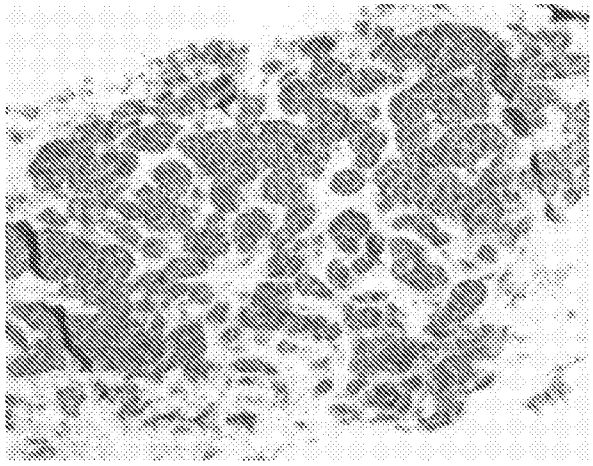


FIG. 12B

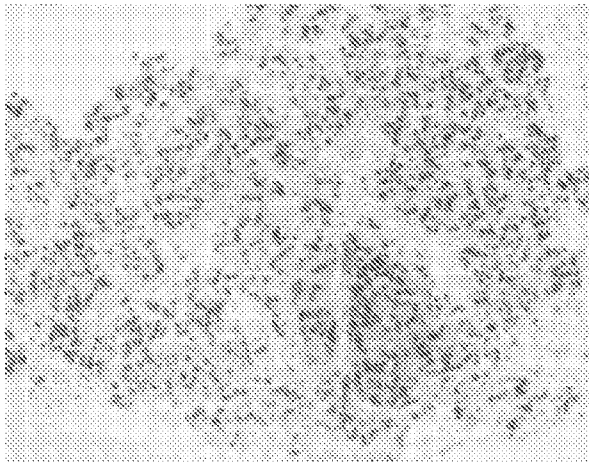


FIG. 12C

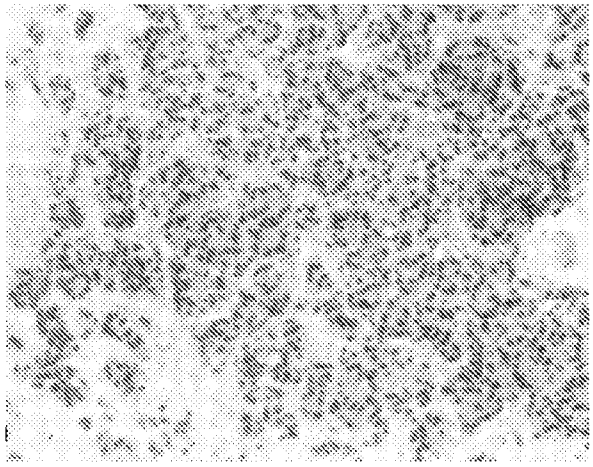


FIG. 12D

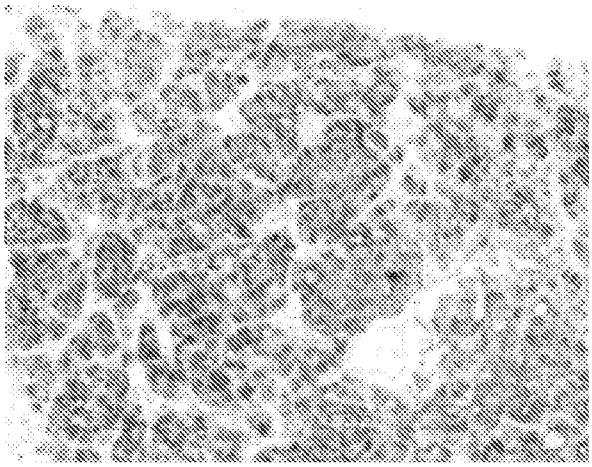


FIG. 12E

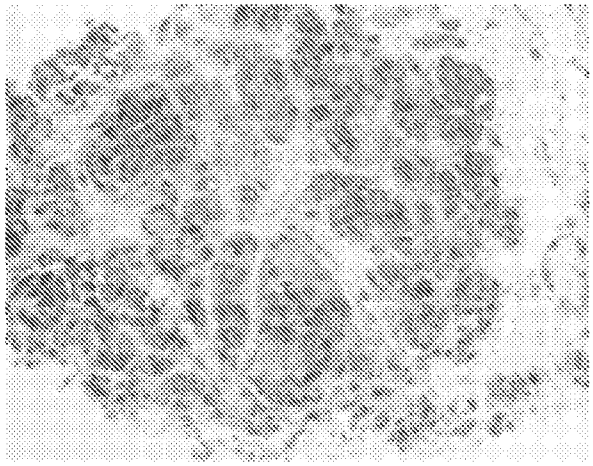


FIG. 12F

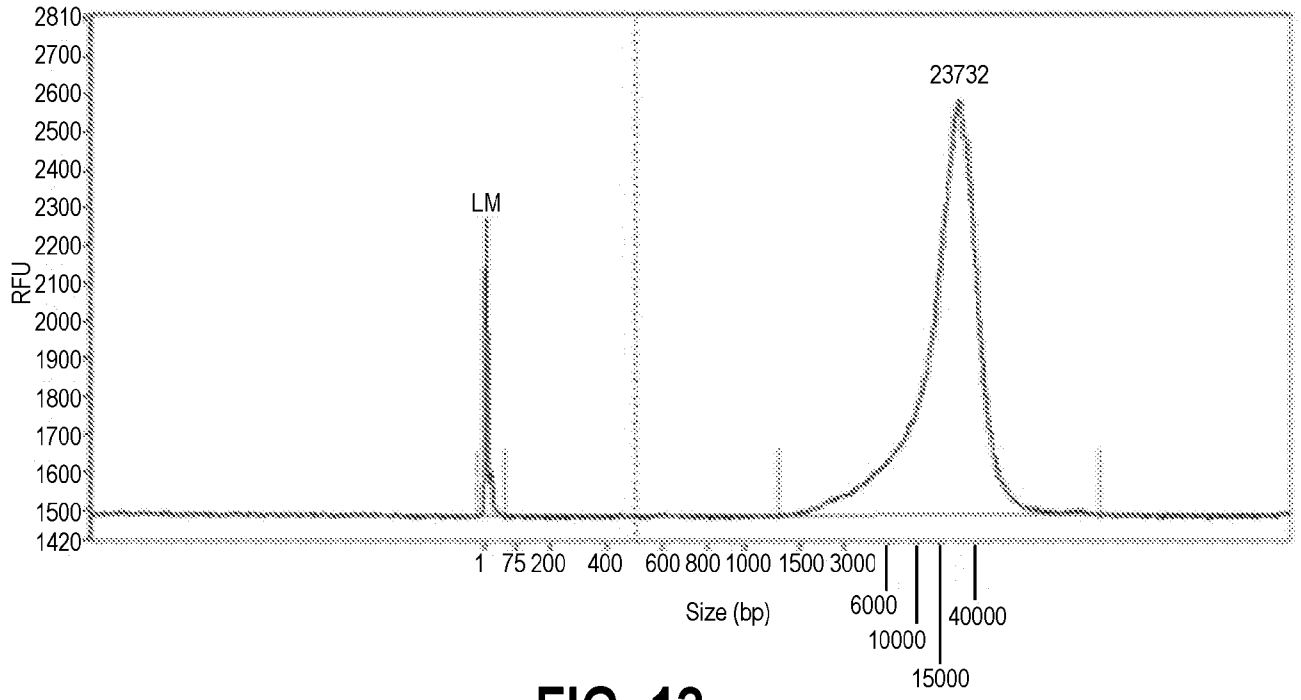

2810
2700
2600
2500
2400
2300
2200
2100
2000
1900
1800
1700
1600
1500
1420
RFU
LM
23732
1
75
200
400
600
800
1000
1500
3000
6000
10000
15000
40000
Size (bp)

FIG. 13

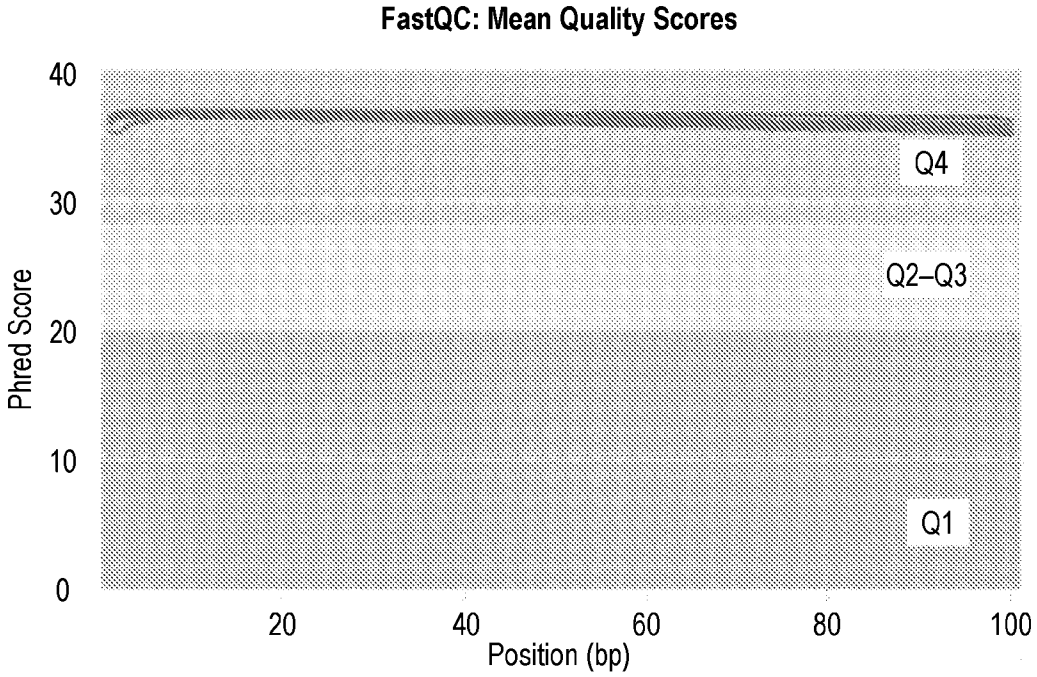

FastQC: Mean Quality Scores
Phred Score
40
30
20
10
0
Q4
Q2–Q3
Q1
20
40
60
80
100
Position (bp)

FIG. 14

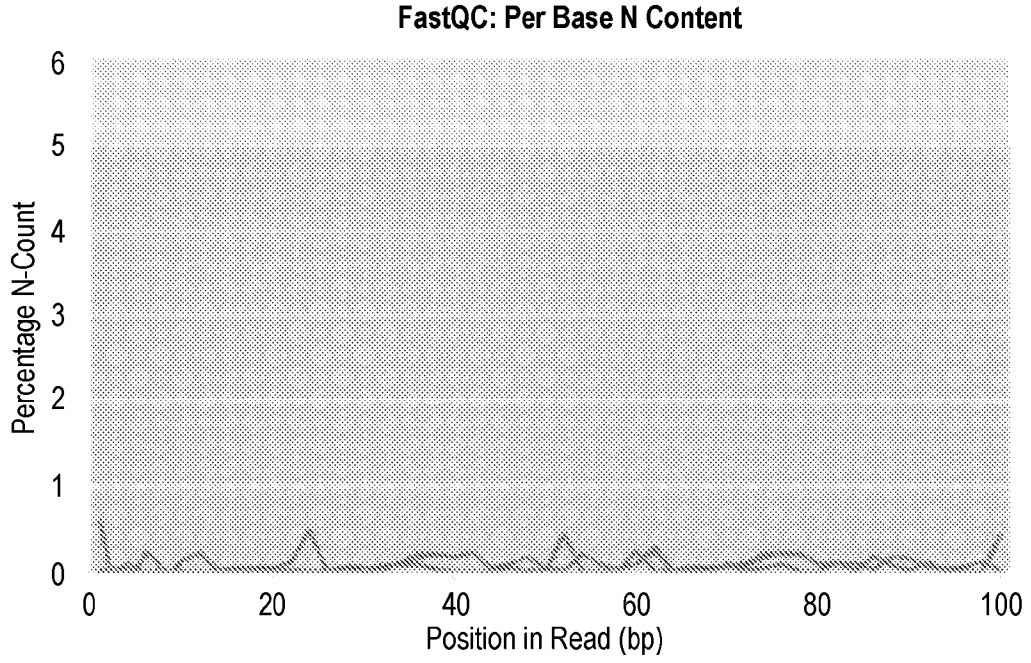

FastQC: Per Base N Content
Percentage N-Count
6
5
4
3
2
1
0
0
20
40
60
80
100
Position in Read (bp)

FIG. 15

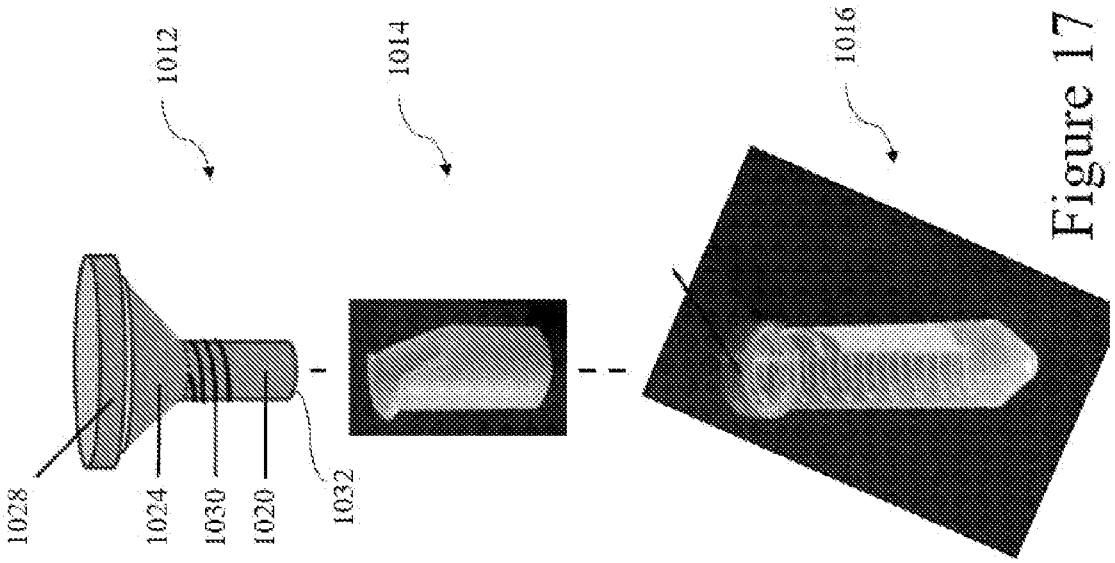


Figure 17

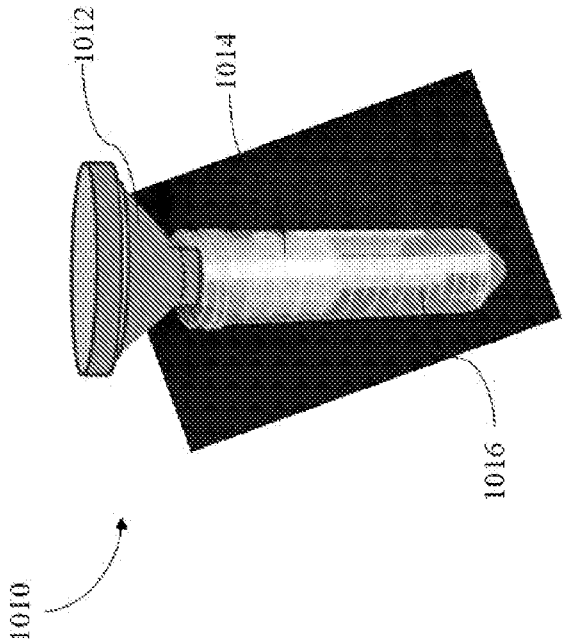


Figure 16

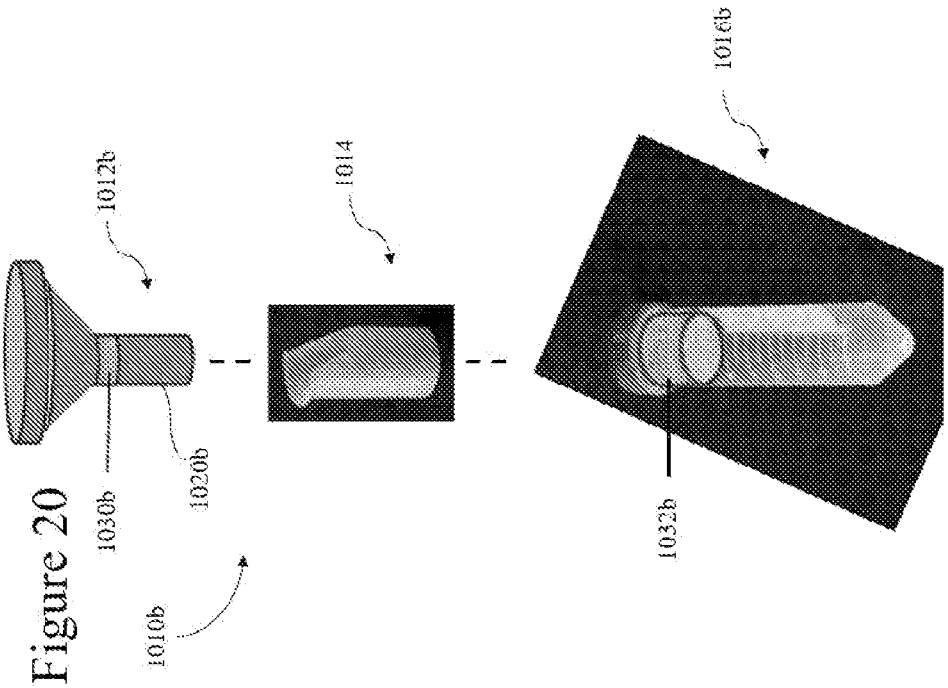


Figure 20

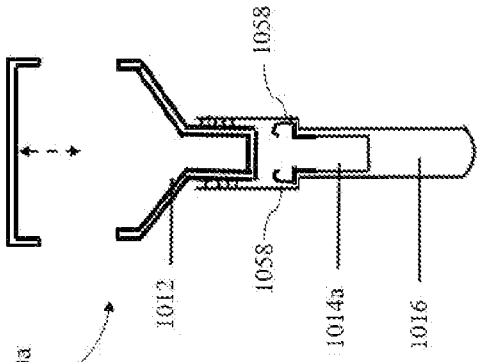


Figure 19

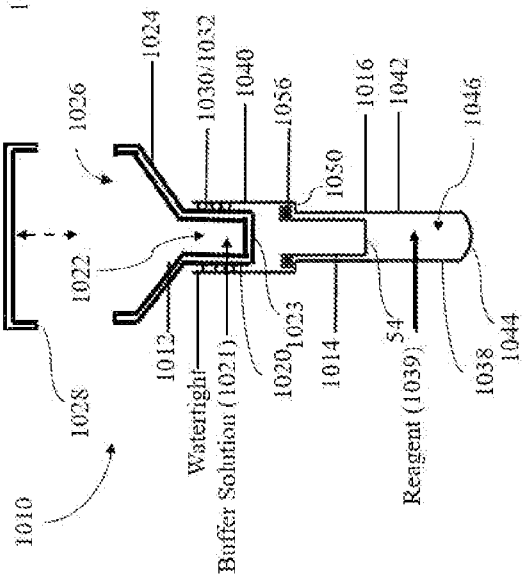


Figure 18

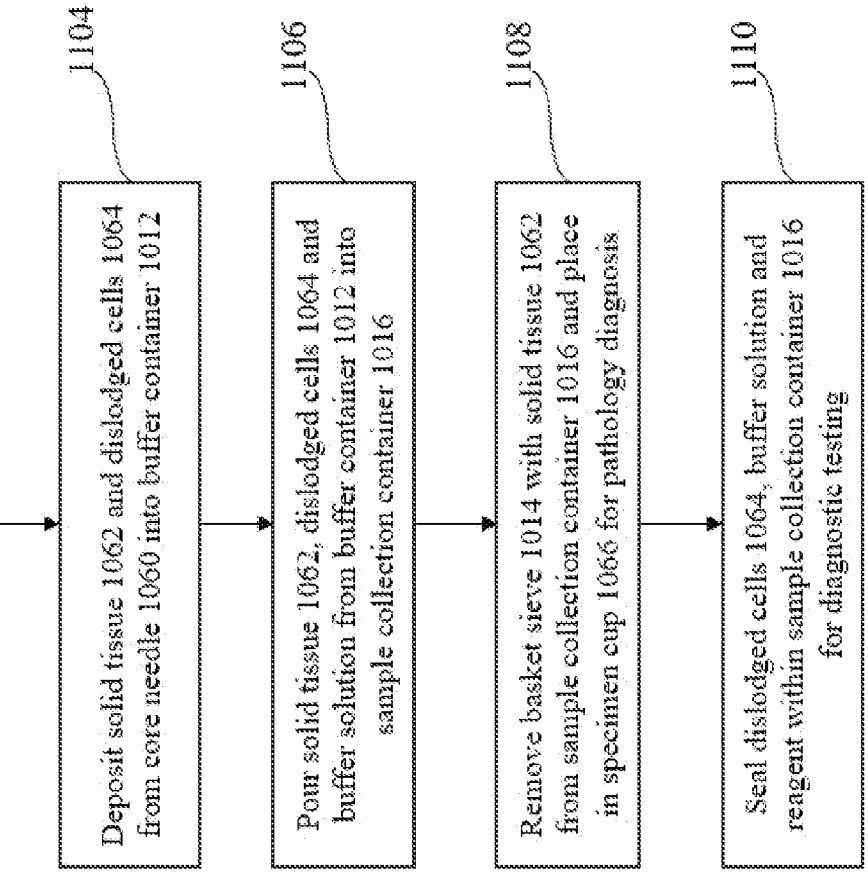

1100
1102
Perform biopsy using core needle 1060
1104
Deposit solid tissue 1062 and dislodged cells 1064 from core needle 1060 into buffer container 1012
1106
Pour solid tissue 1062, dislodged cells 1064 and buffer solution from buffer container 1012 into sample collection container 1016
1108
Remove basket sieve 1014 with solid tissue 1062 from sample collection container 1016 and place in specimen cup 1066 for pathology diagnosis
1110
Seal dislodged cells 1064, buffer solution and reagent within sample collection container 1016 for diagnostic testing

Figure 21

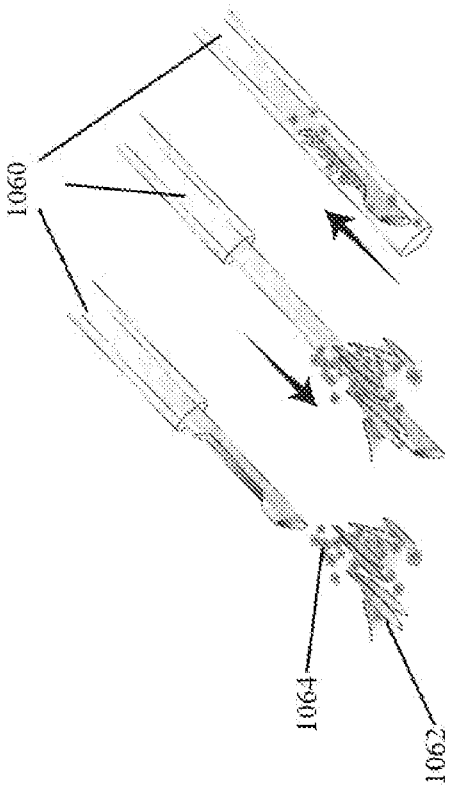


Figure 23

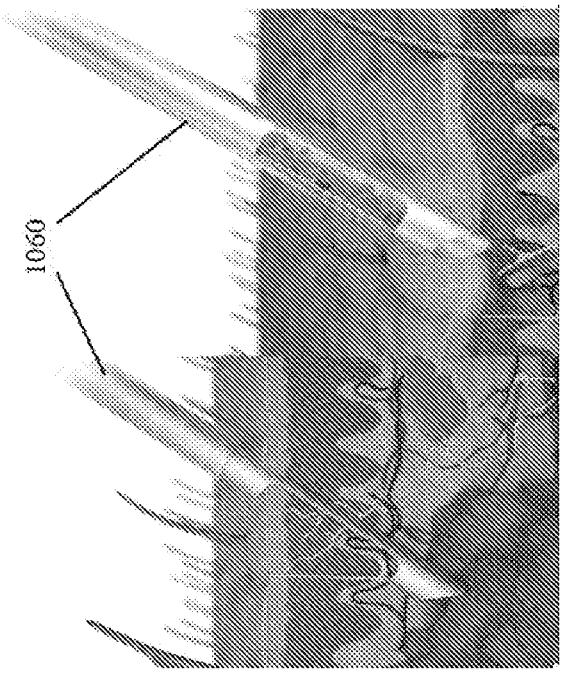


Figure 22

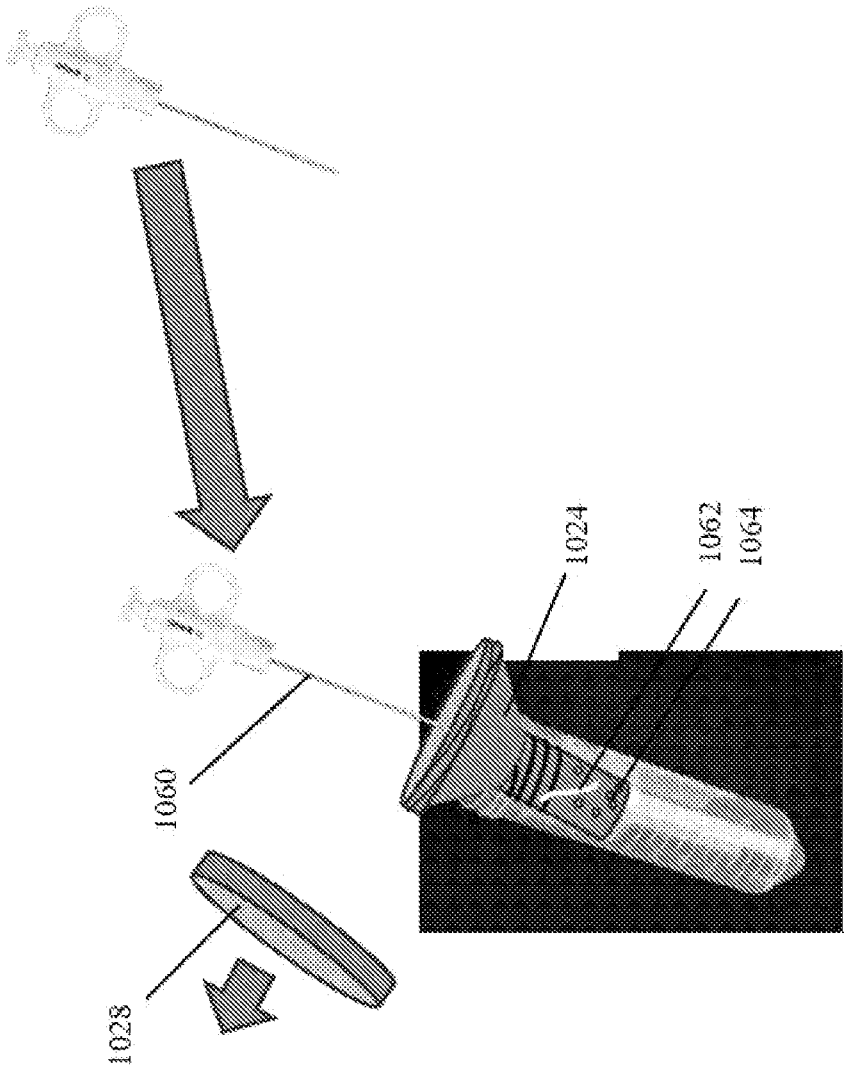


Figure 24

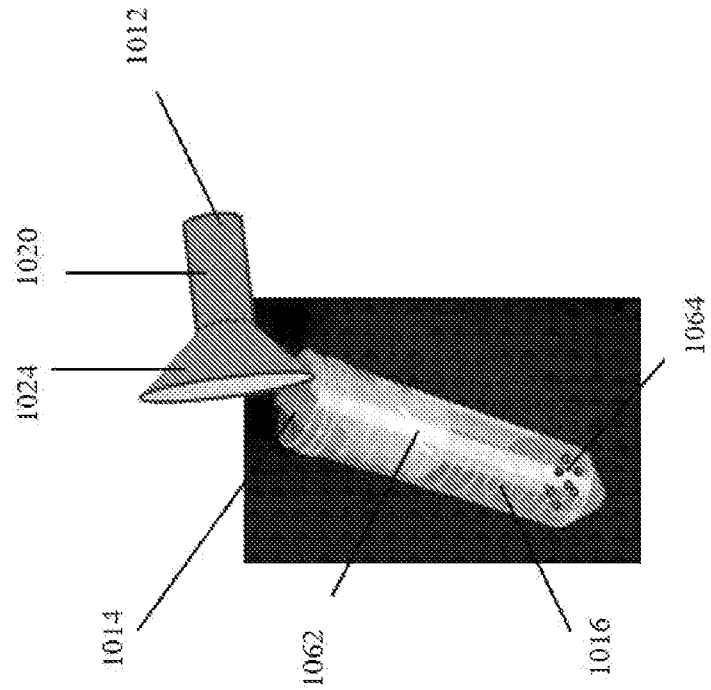


Figure 26

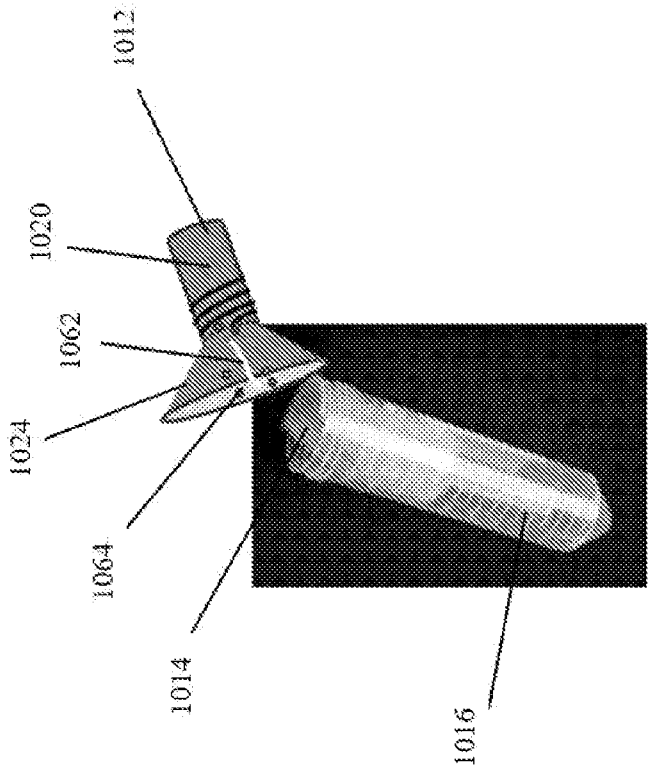


Figure 25

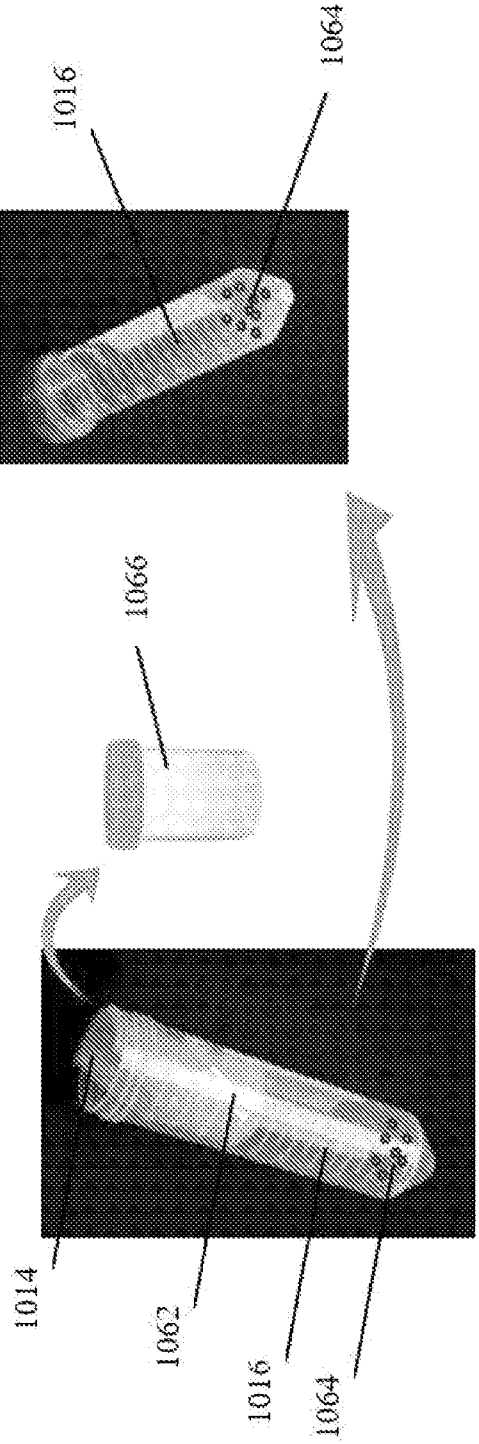


Figure 27

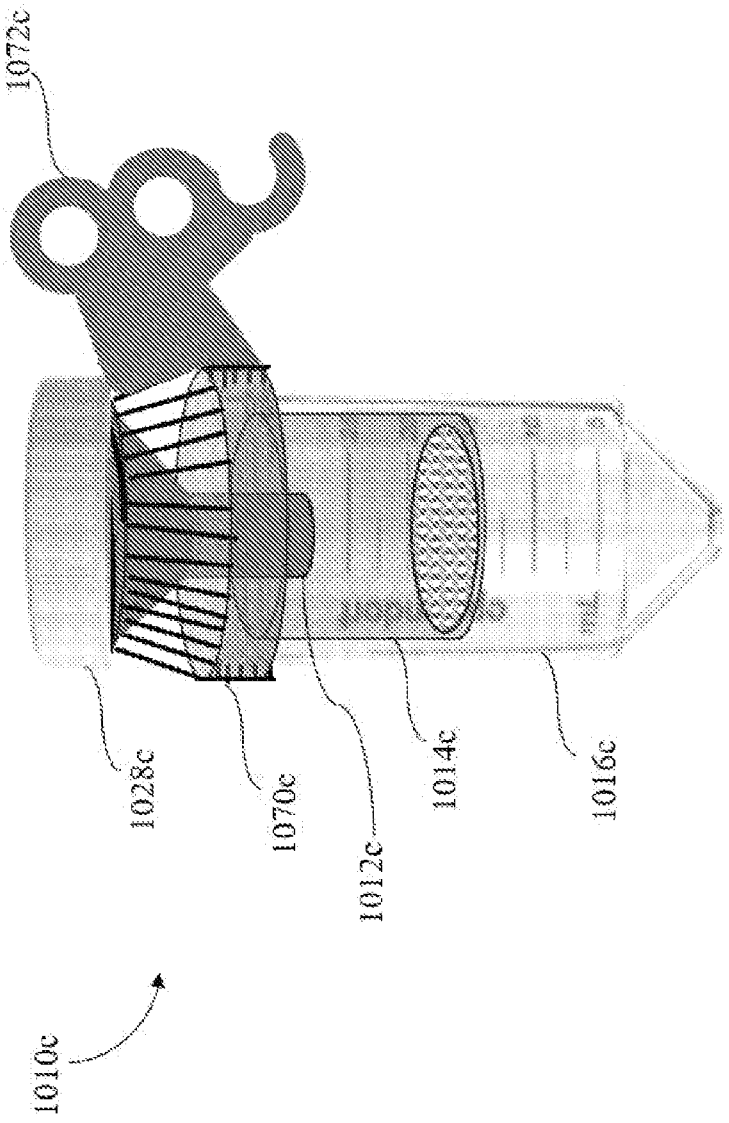


Figure 28

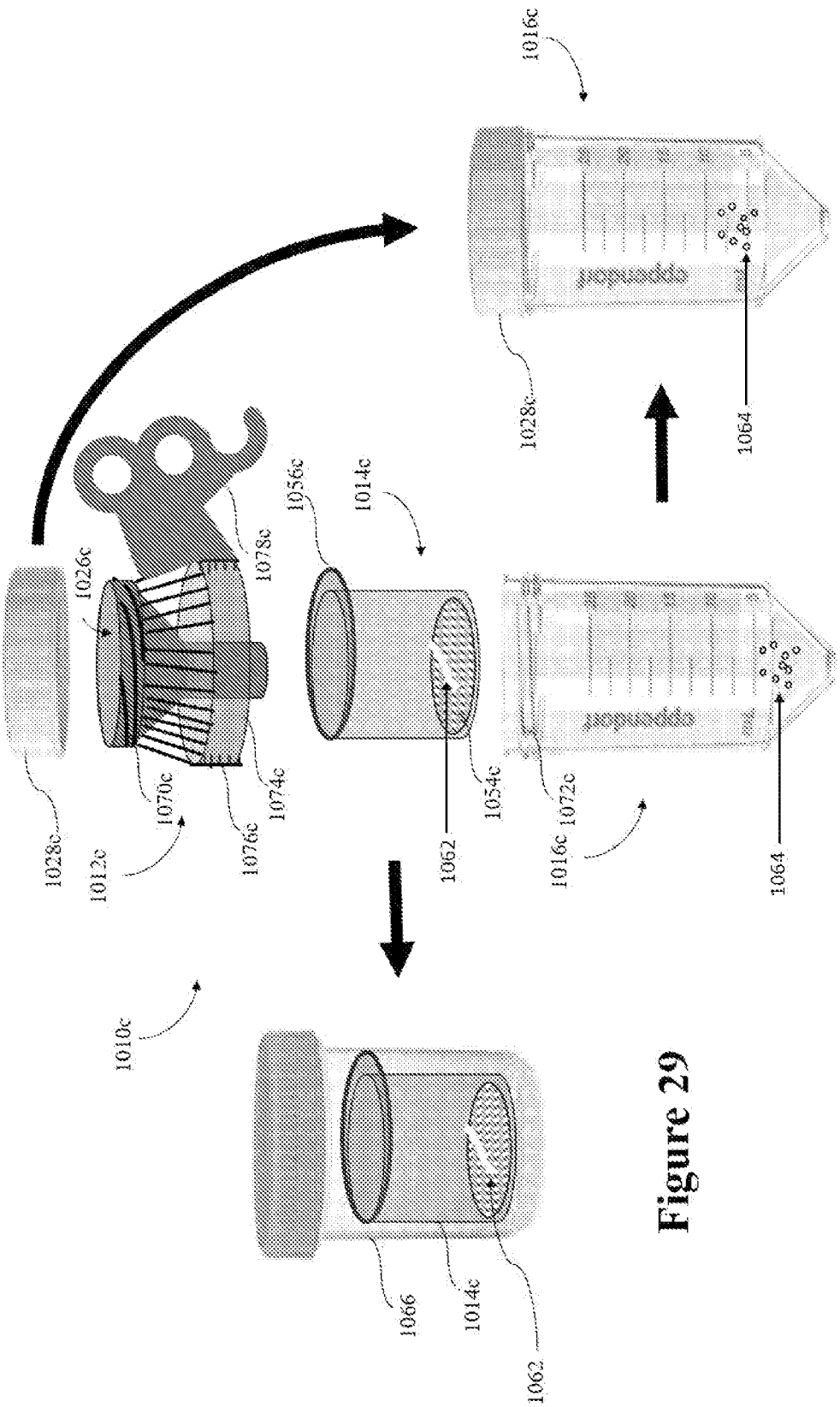

1016c
1028c
1064
1056c
1014c
1026c
1078c
1028c
1012c
1070c
1076c
1074c
1062
1054c
1072c
1016c
1064
1010c
1066
1014c
1062

Figure 29

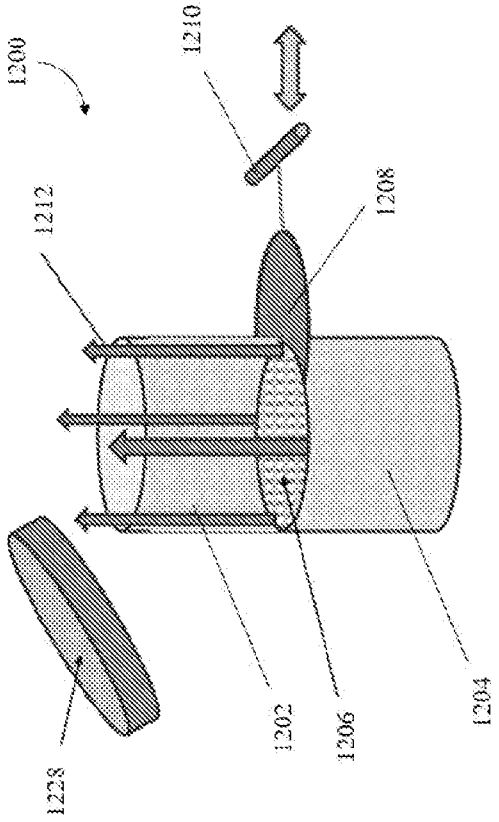


Figure 31

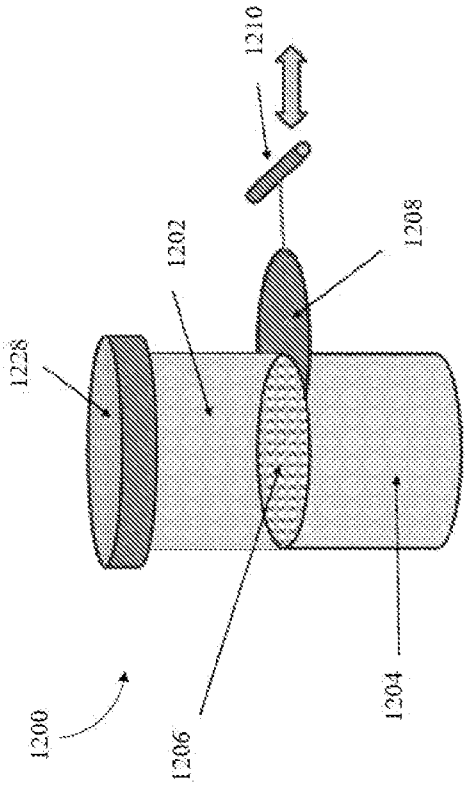


Figure 30

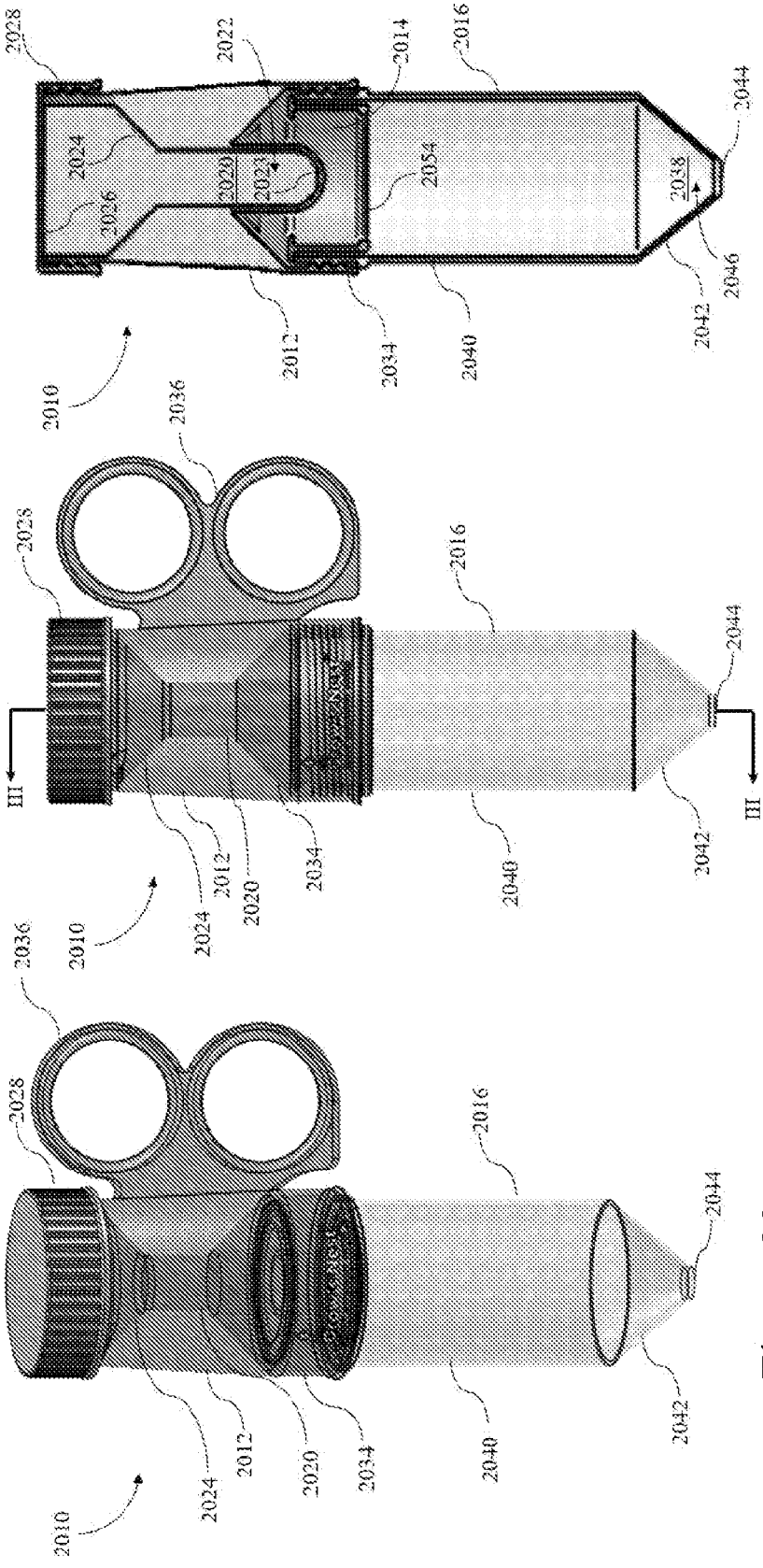


Figure 34

Figure 33

Figure 32

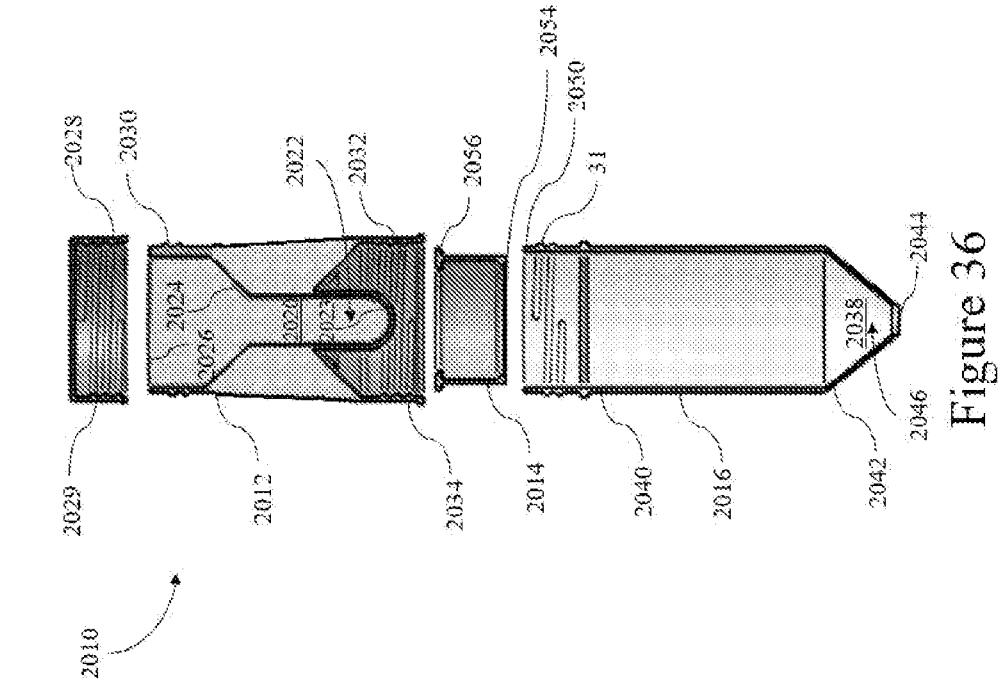


Figure 36

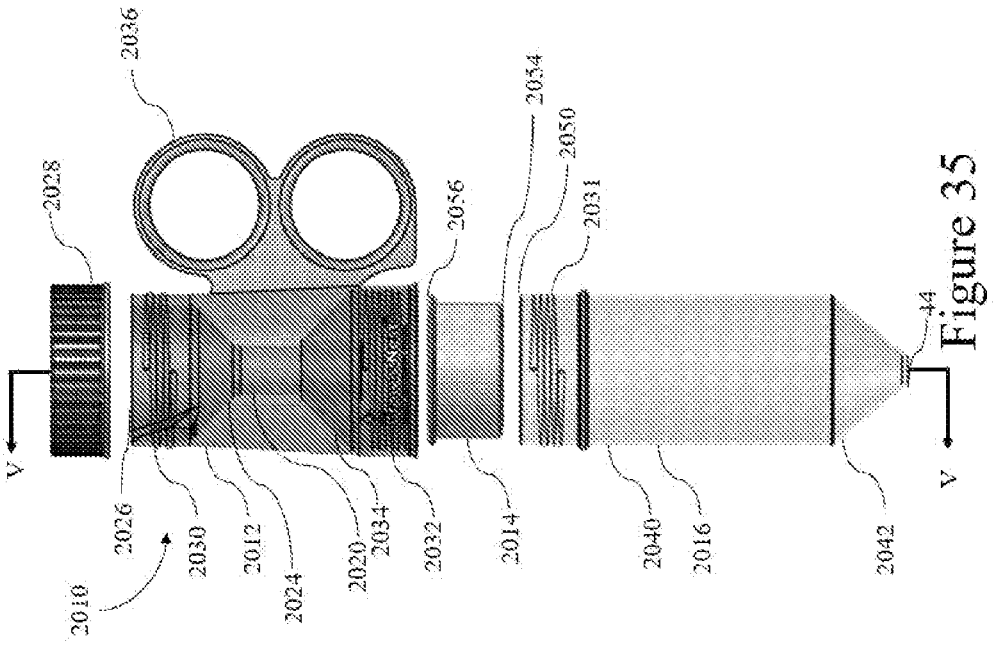


Figure 35

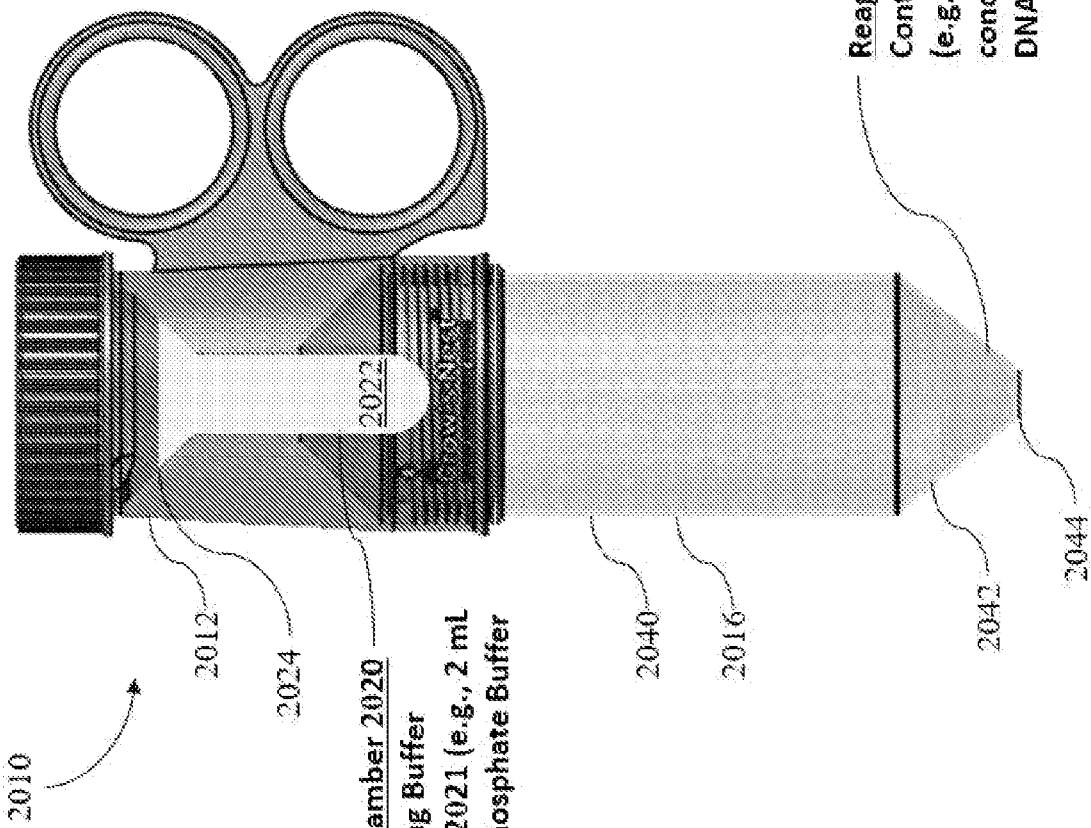

2010
2012
2024
Buffer Chamber 2020
Containing Buffer
Solution 2021 (e.g., 2 mL
Sterile Phosphate Buffer
Solution)
2022
2040
2016
Reagent Chamber 2038
Containing Reagent 2039
(e.g., 2 mL of 2x
concentration Cell Lysing and
DNA Preservation Solution)
2042
2044

Figure 37

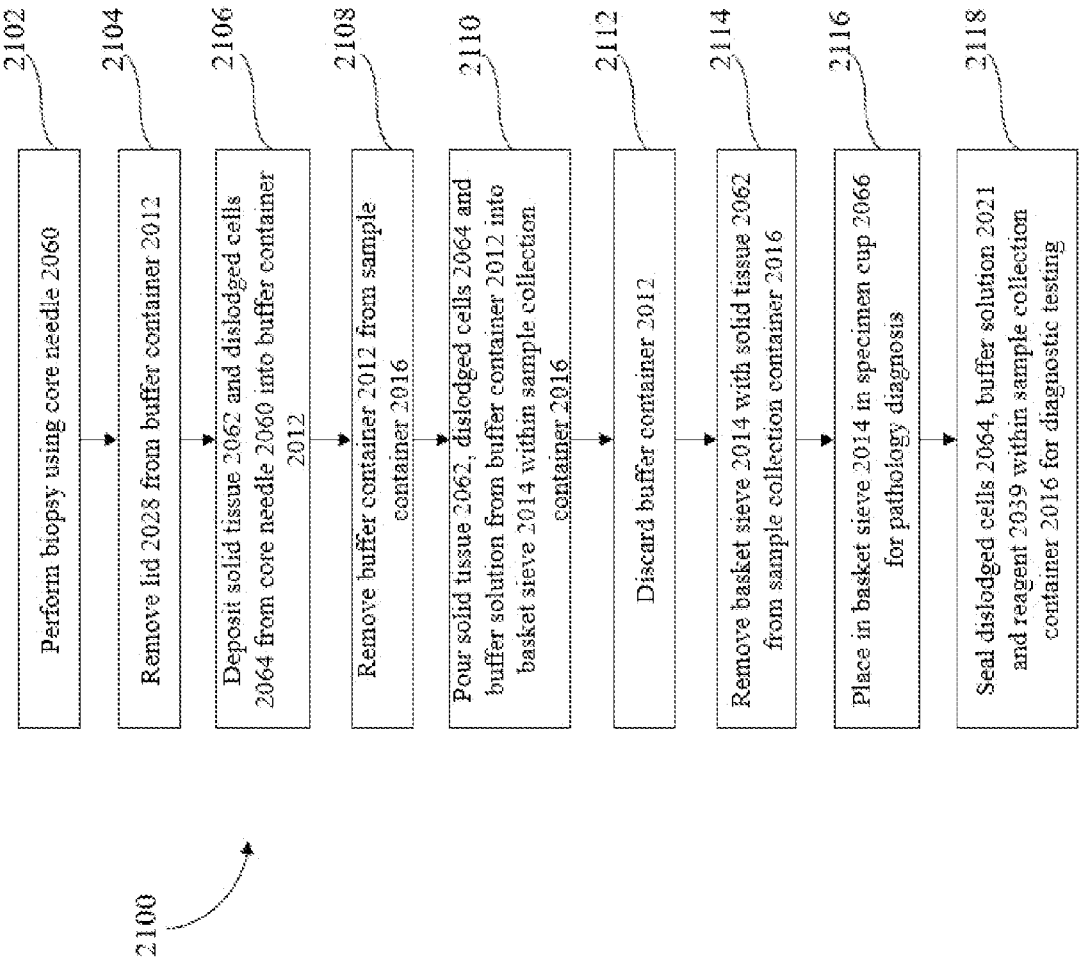

2100
2102
Perform biopsy using core needle 2060
2104
Remove lid 2028 from buffer container 2012
2106
Deposit solid tissue 2062 and dislodged cells 2064 from core needle 2060 into buffer container 2012
2108
Remove buffer container 2012 from sample container 2016
2110
Pour solid tissue 2062, dislodged cells 2064 and buffer solution from buffer container 2012 into basket sieve 2014 within sample collection container 2016
2112
Discard buffer container 2012
2114
Remove basket sieve 2014 with solid tissue 2062 from sample collection container 2016
2116
Place in basket sieve 2014 in specimen cup 2066 for pathology diagnosis
2118
Seal dislodged cells 2064, buffer solution 2021 and reagent 2039 within sample collection container 2016 for diagnostic testing

Figure 38

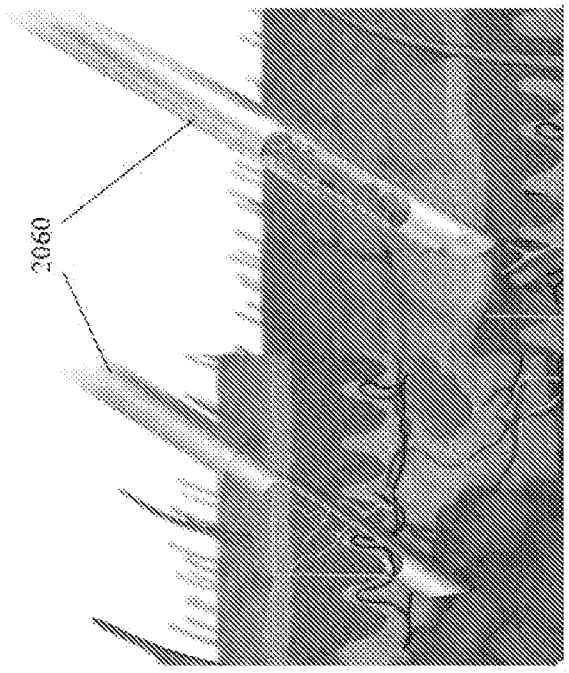


Figure 39

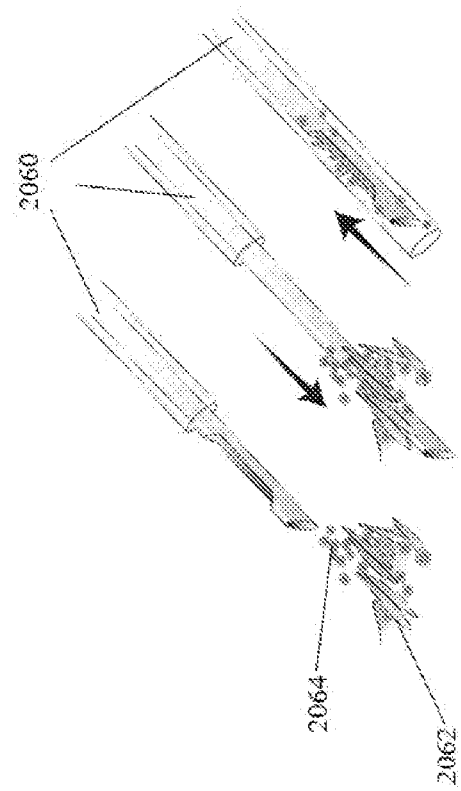
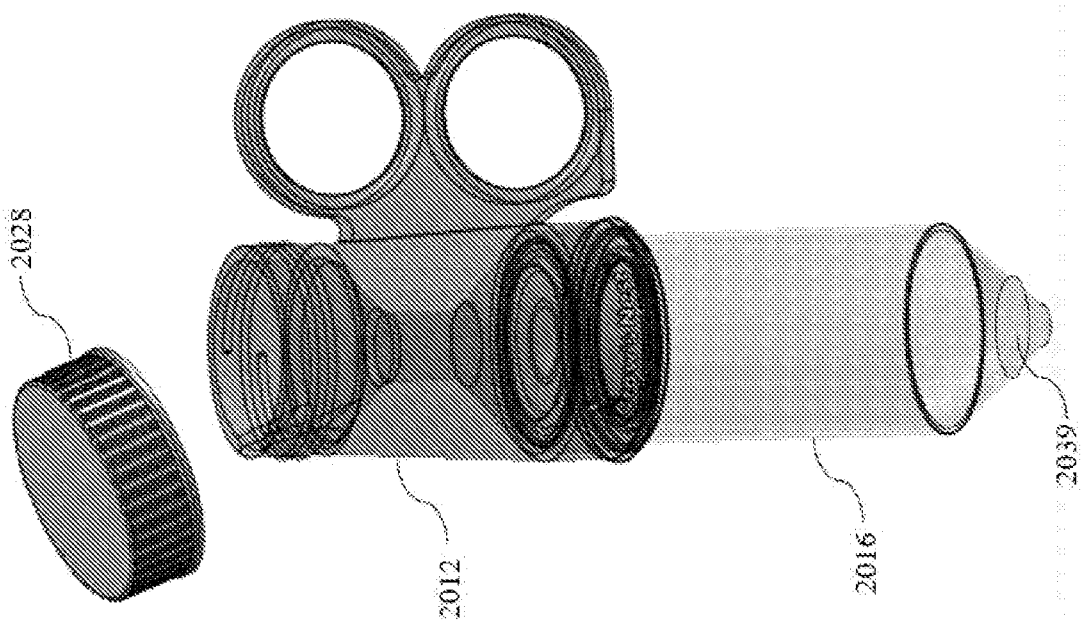


Figure 40



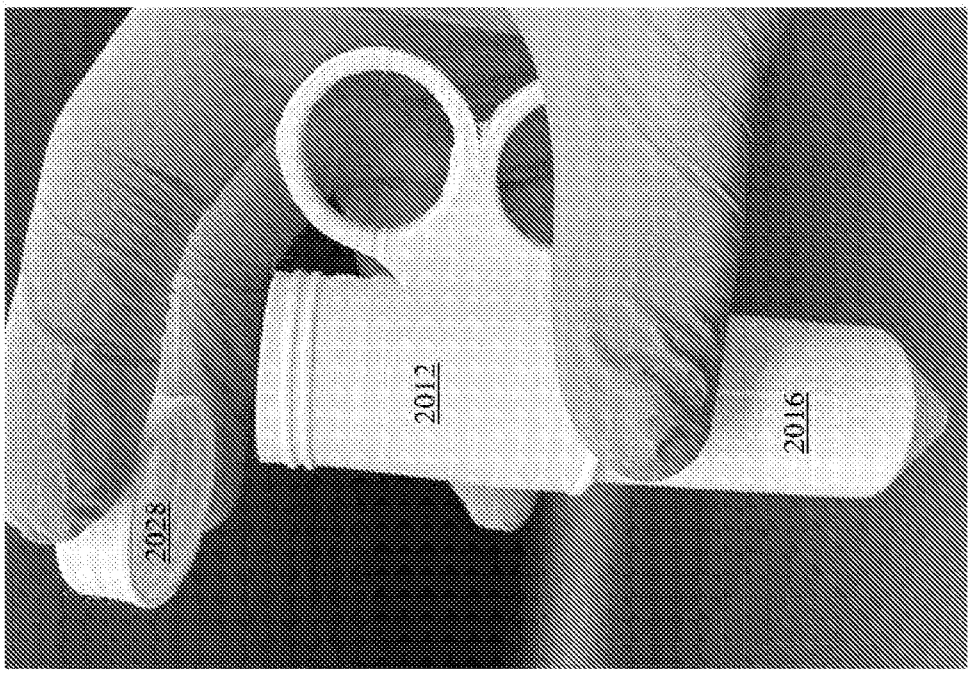


Figure 41

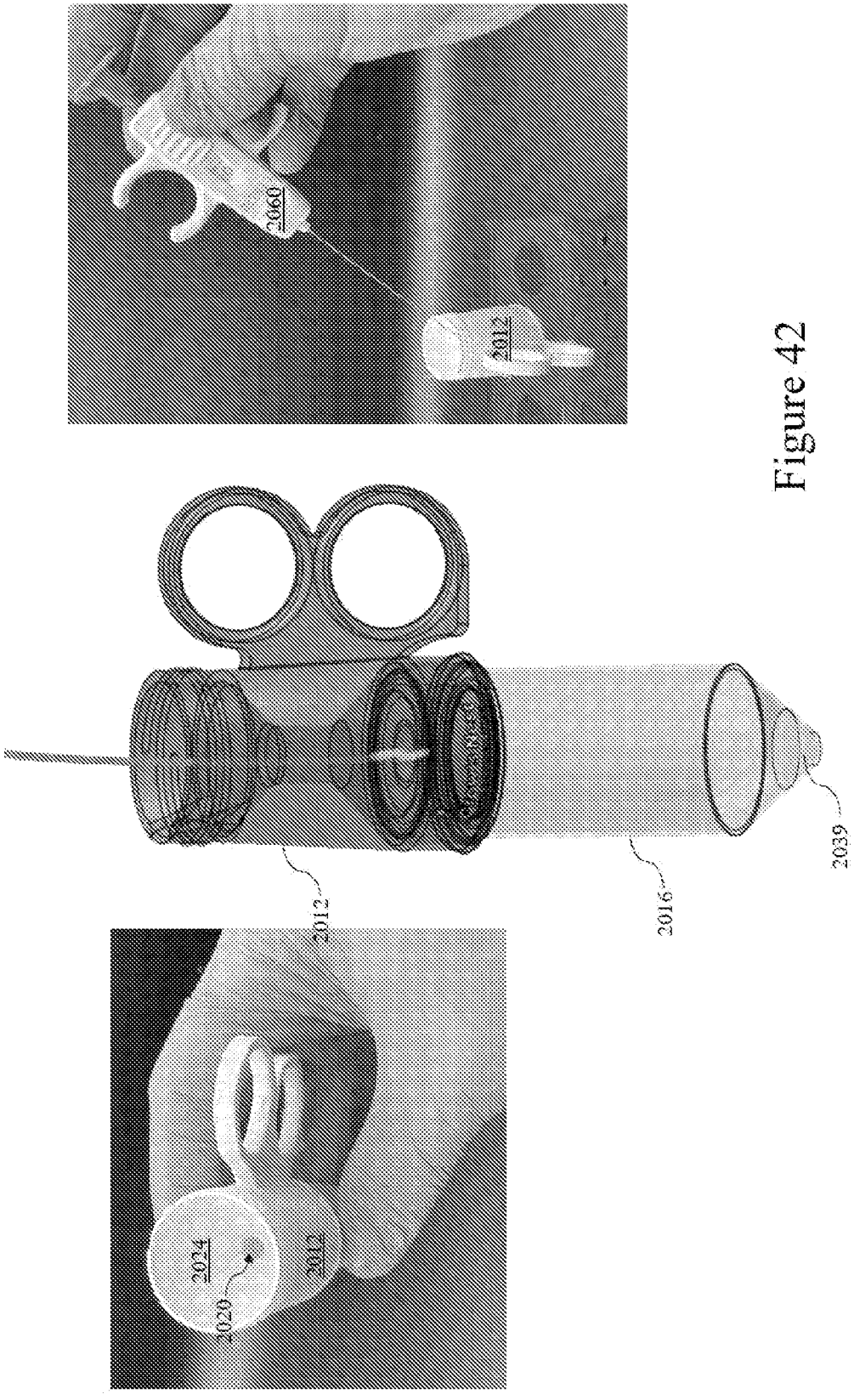


Figure 42

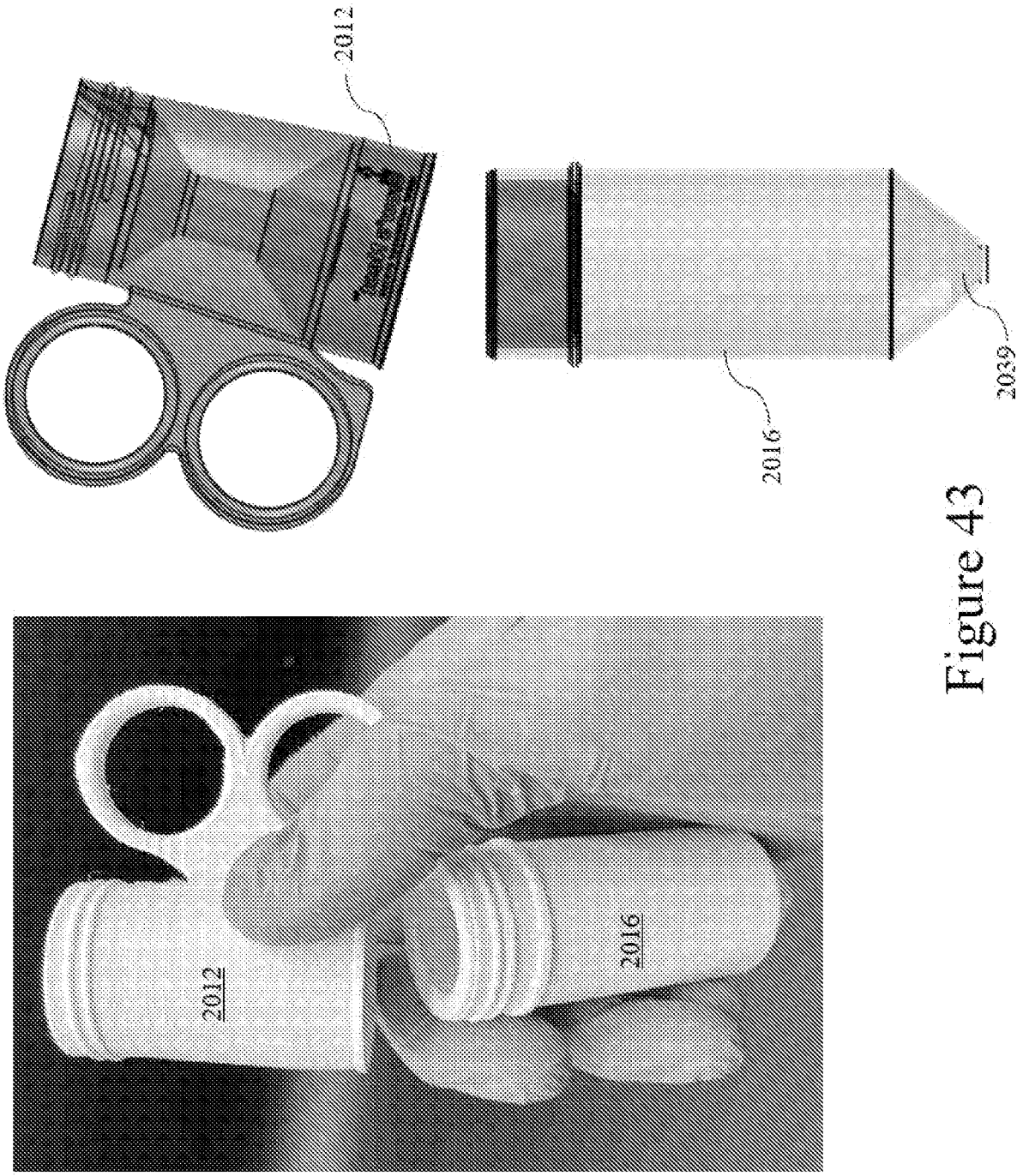
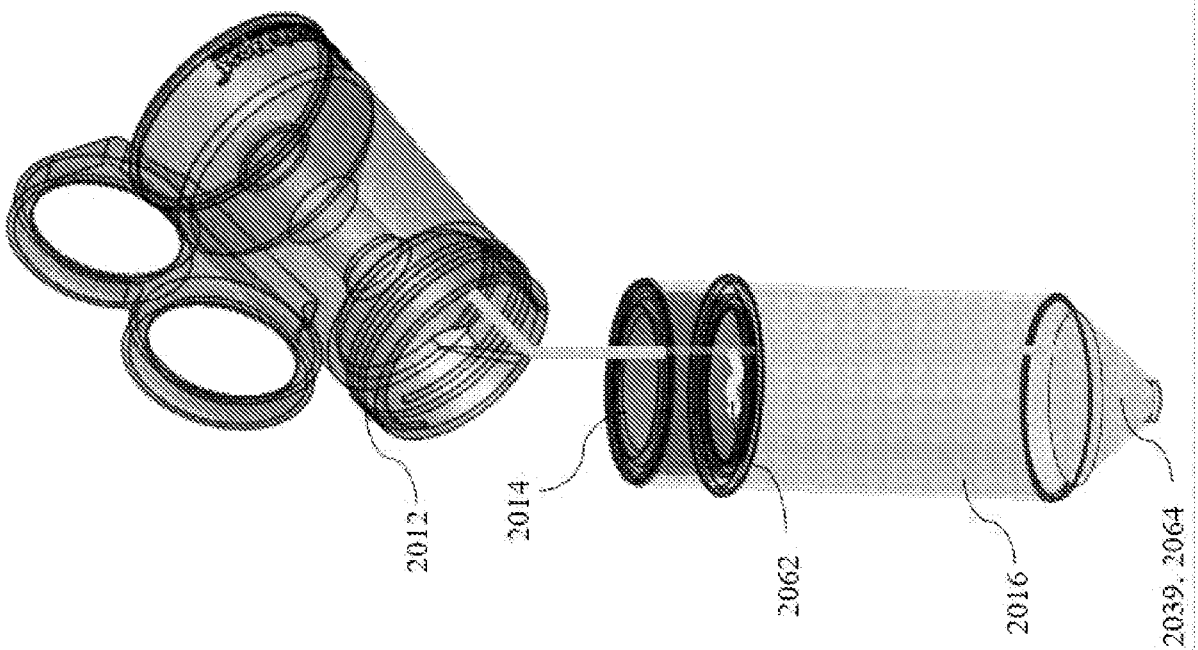


Figure 43



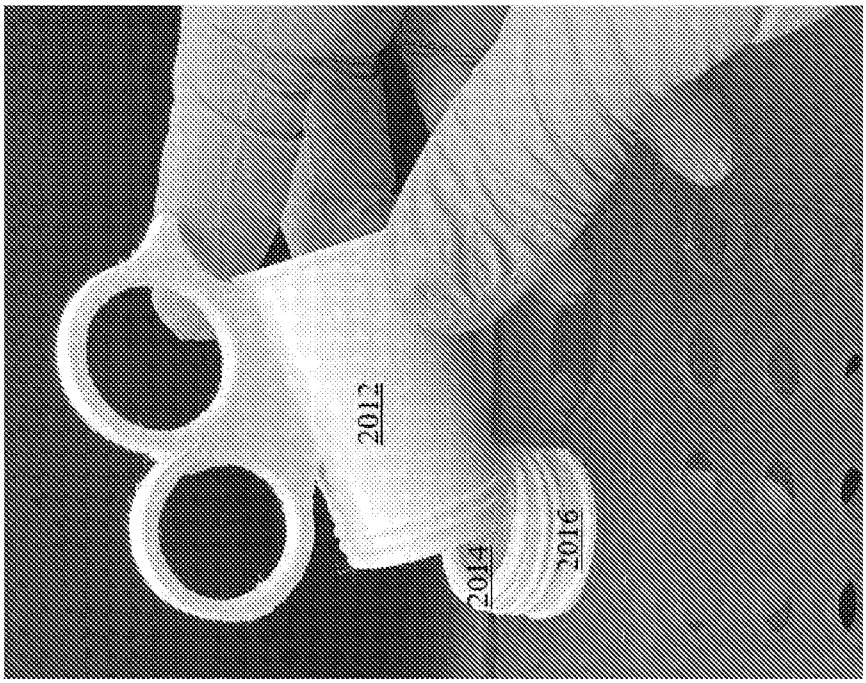
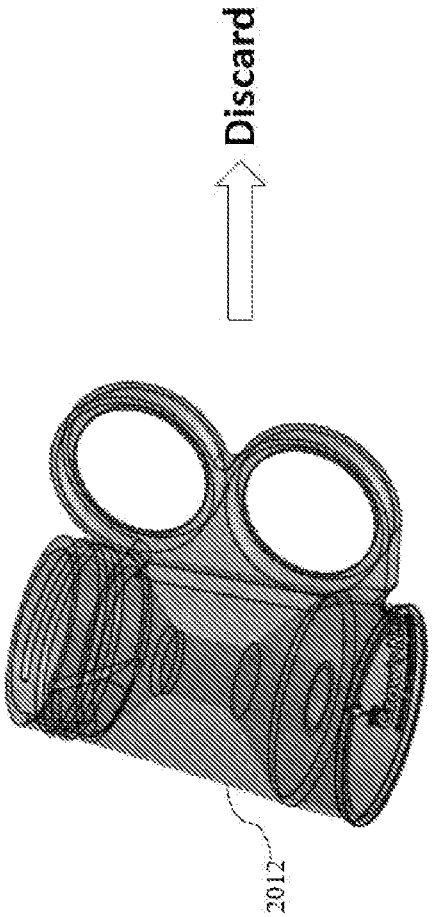


Figure 44



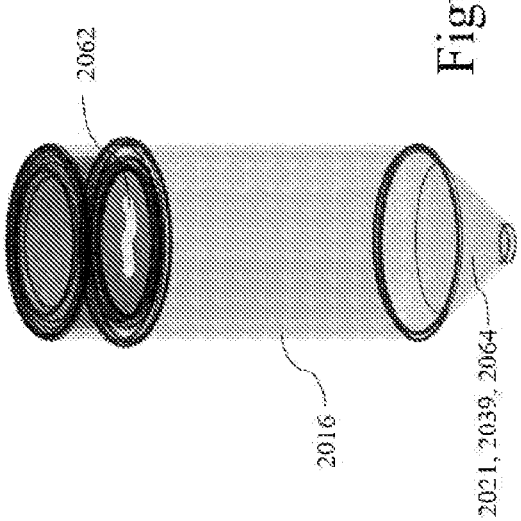
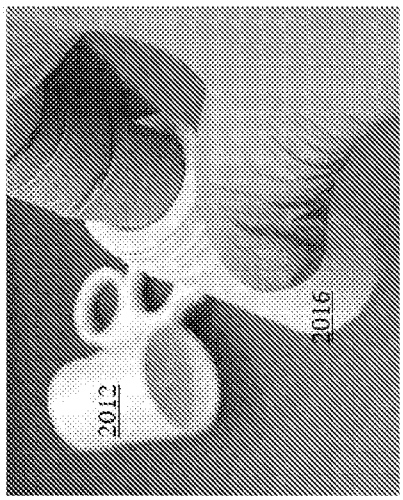


Figure 45



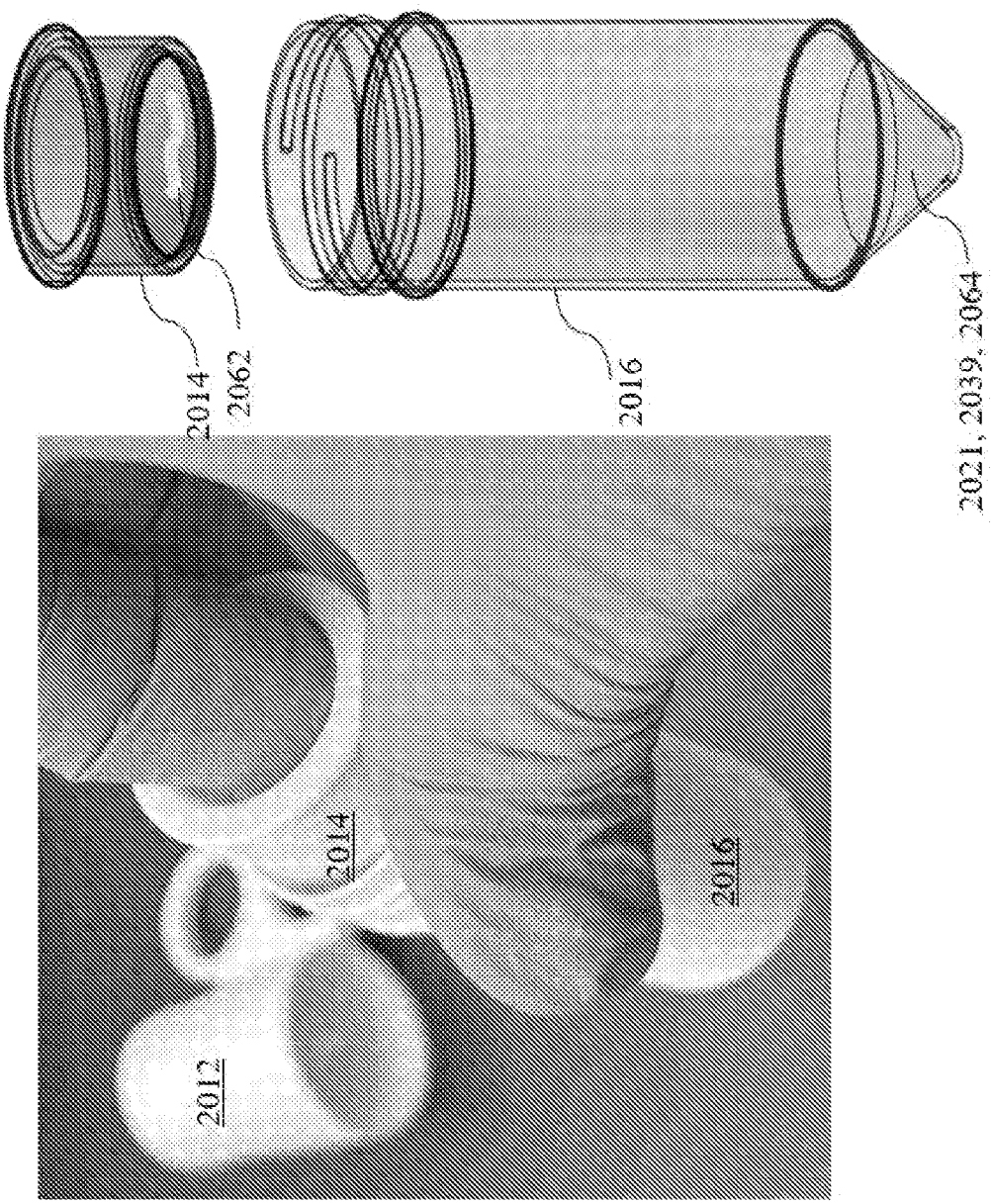


Figure 46

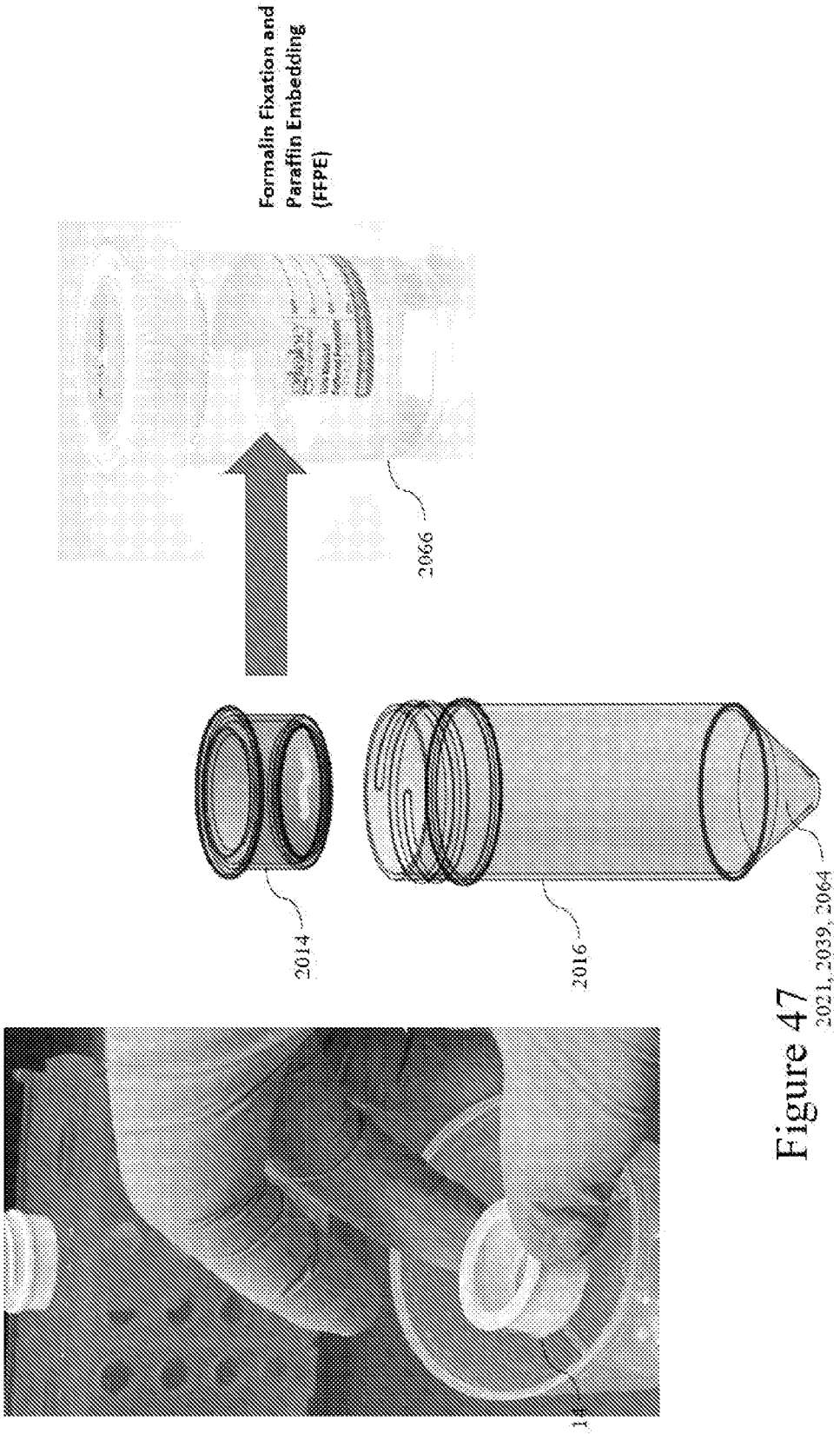

Formalin Fixation and Paraffin Embedding (FFPE)
2066
2014
2016
2021, 2039, 2064

Figure 47

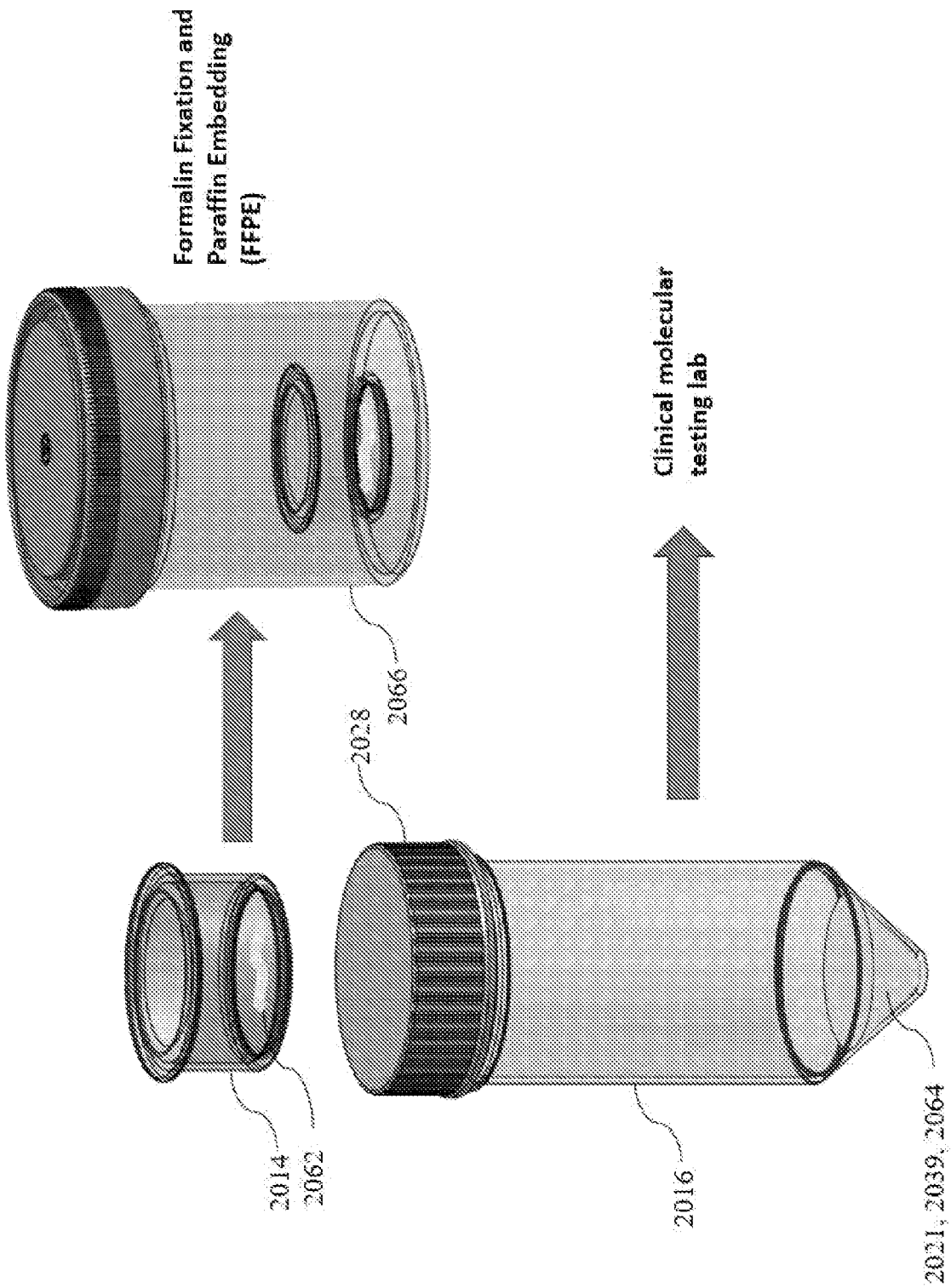

Formalin Fixation and Paraffin Embedding (FFPE)
Clinical molecular testing lab
2014
2062
2028
2066
2016
2021, 2039, 2064

Figure 48

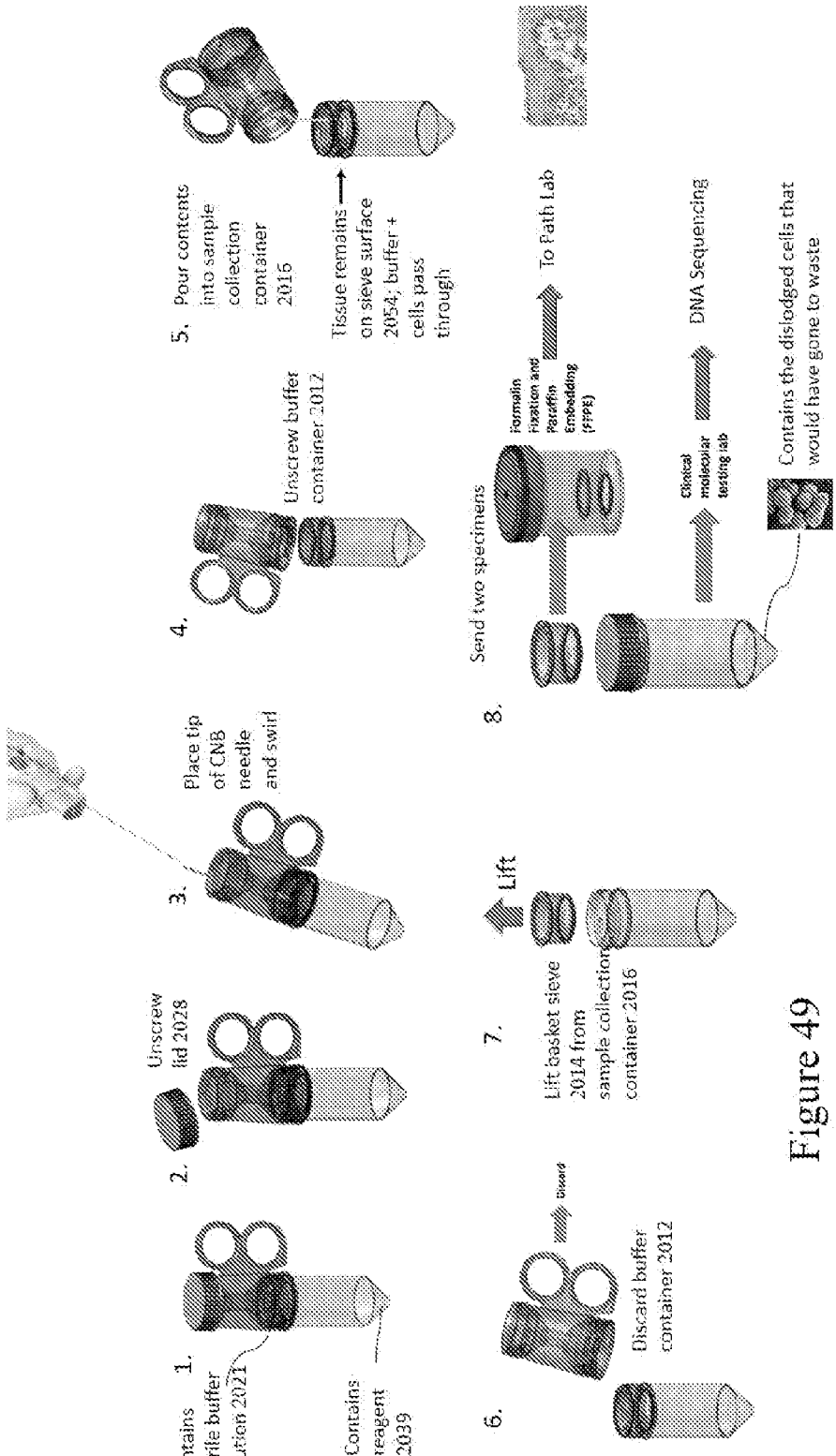

1.
Contains sterile buffer solution 2021
Contains reagent 2039
2.
Unscrew lid 2028
3.
Place tip of CNB needle and swirl
4.
Unscrew buffer container 2012
5.
Pour contents into sample collection container 2016
Tissue remains on sieve surface 2054; buffer + cells pass through
6.
Discard
Discard buffer container 2012
7.
Lift
Lift basket sieve 2014 from sample collection container 2016
8.
Send two specimens
Formalin Fixation and Paraffin Embedding (FFPE)
To Path Lab
Clinical molecular testing lab
DNA Sequencing
Contains the dislodged cells that would have gone to waste

Figure 49

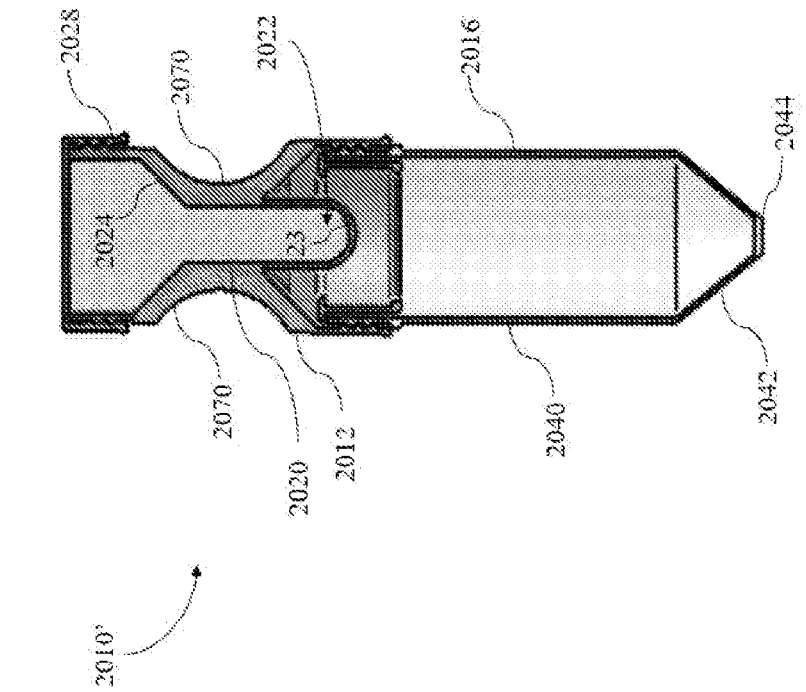


Figure 51

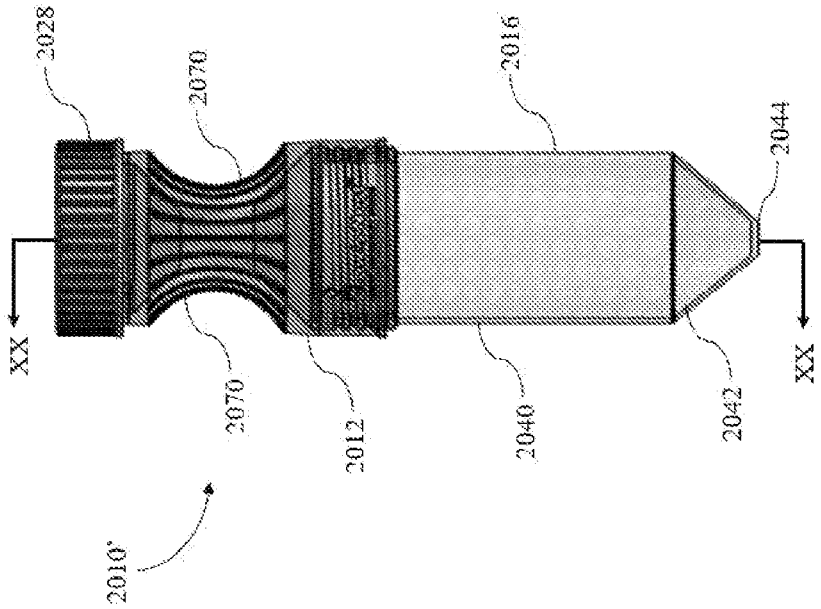


Figure 50