

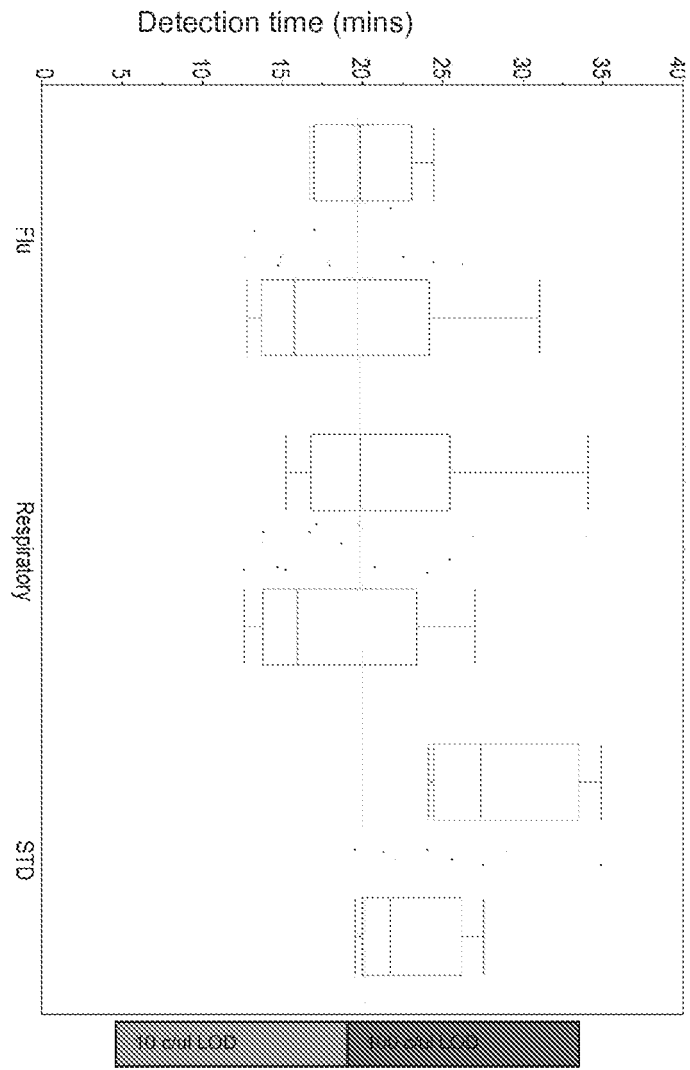


Fig. 1A

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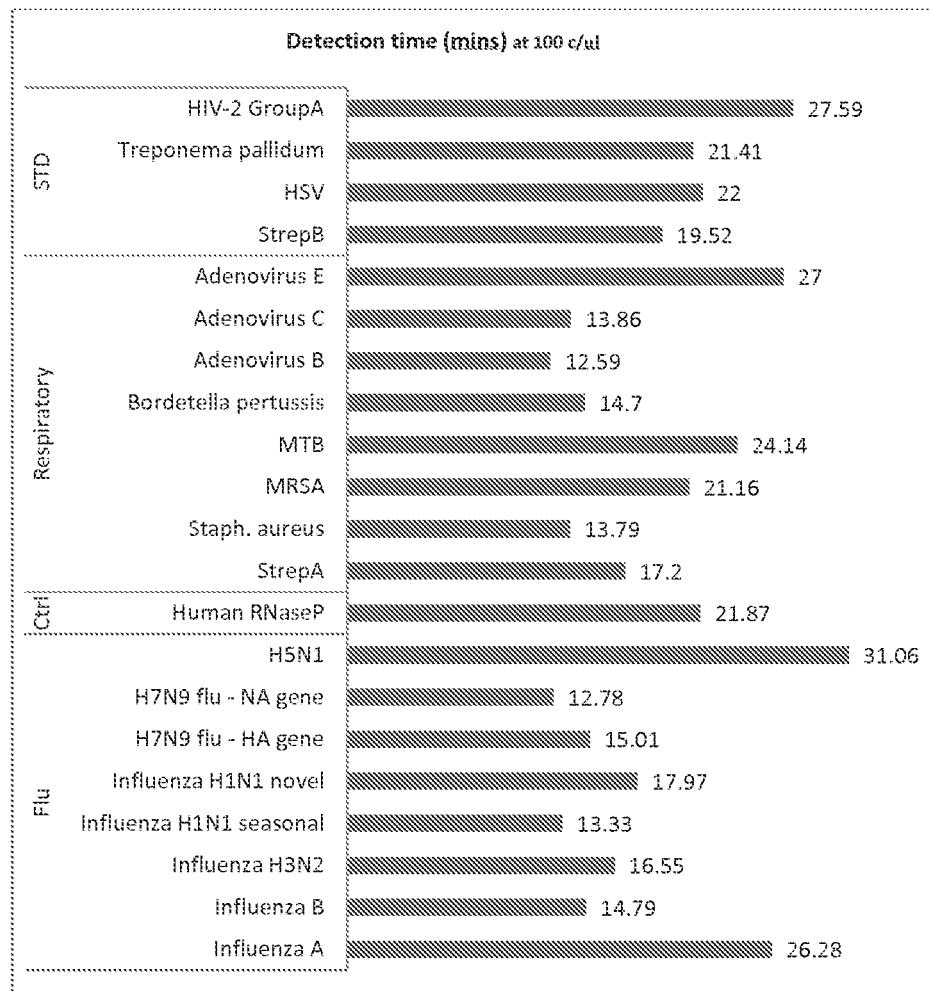


Fig. 1B

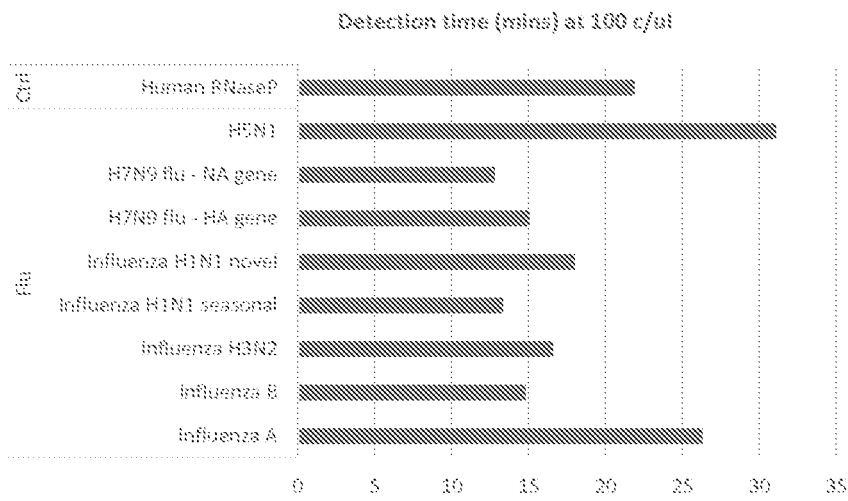


Fig. 1C

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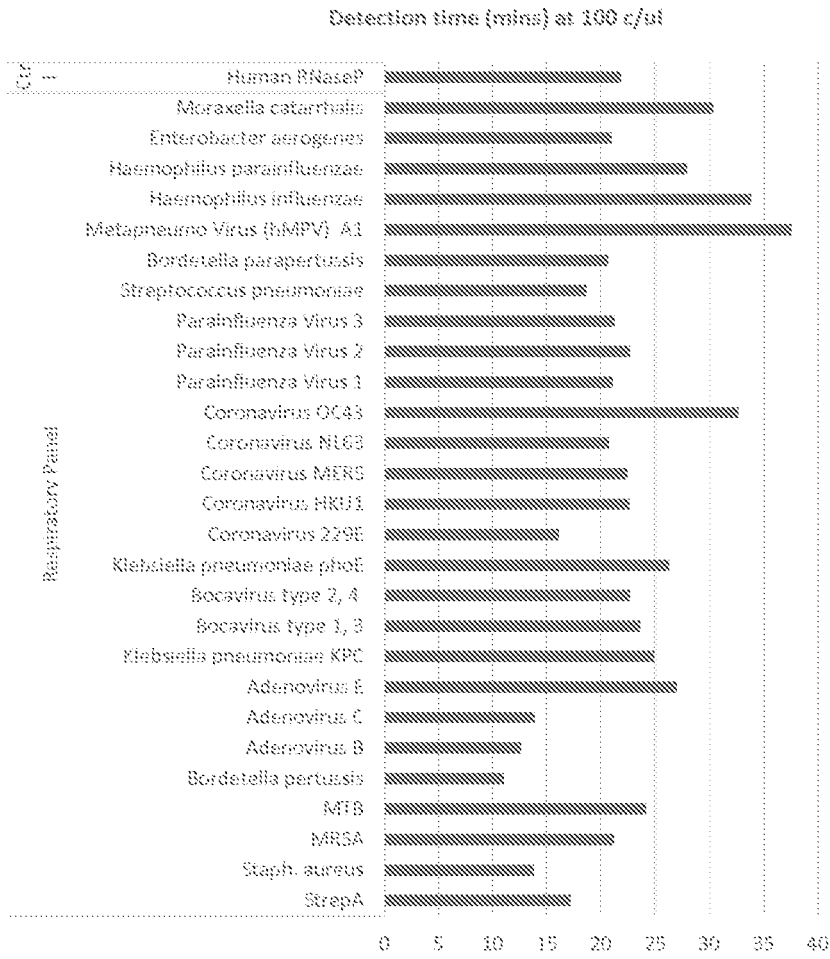


Fig. 1D

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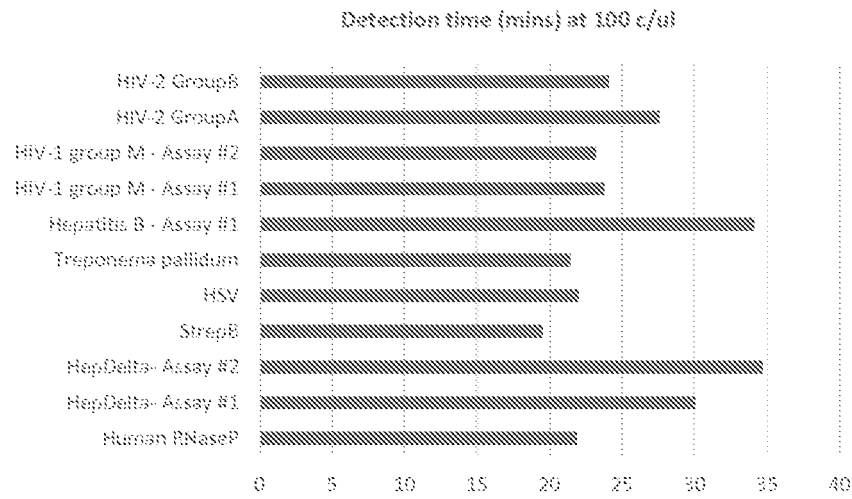


Fig. 1E

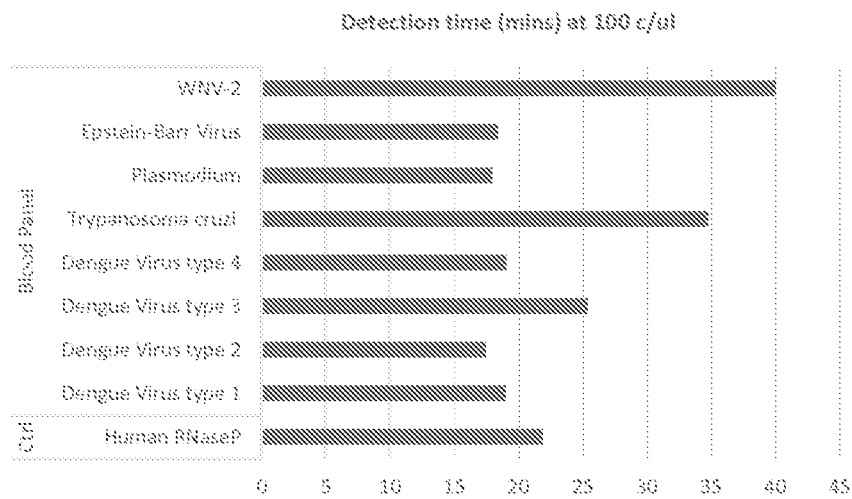


Fig. 1F

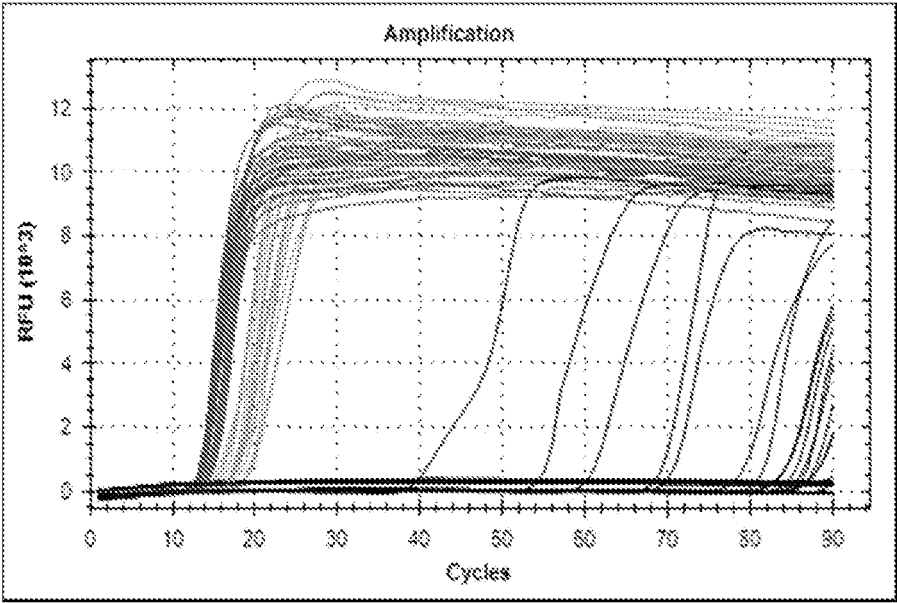


Fig. 2A

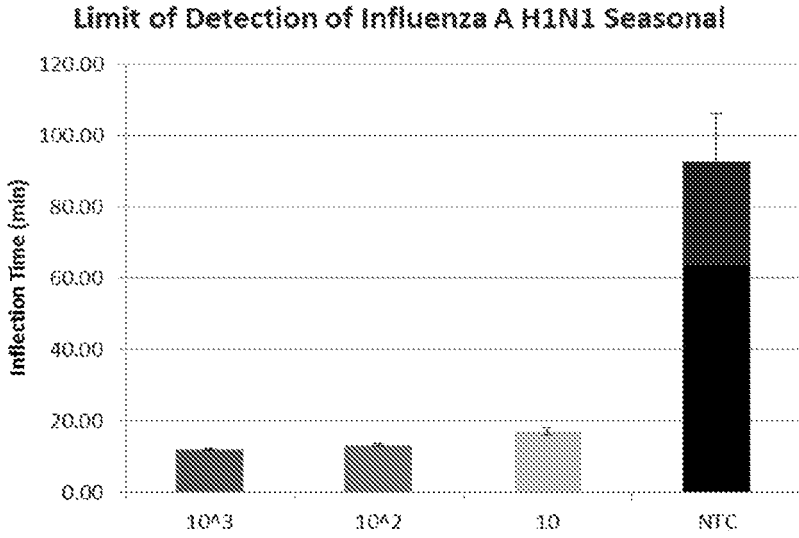


Fig. 2B

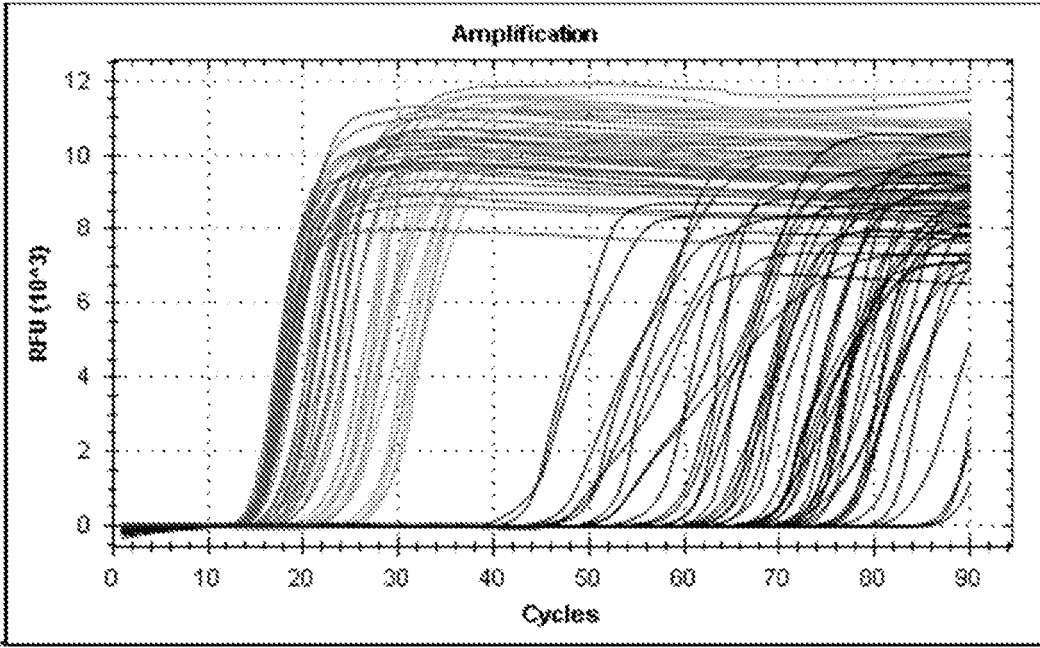


Fig. 3A

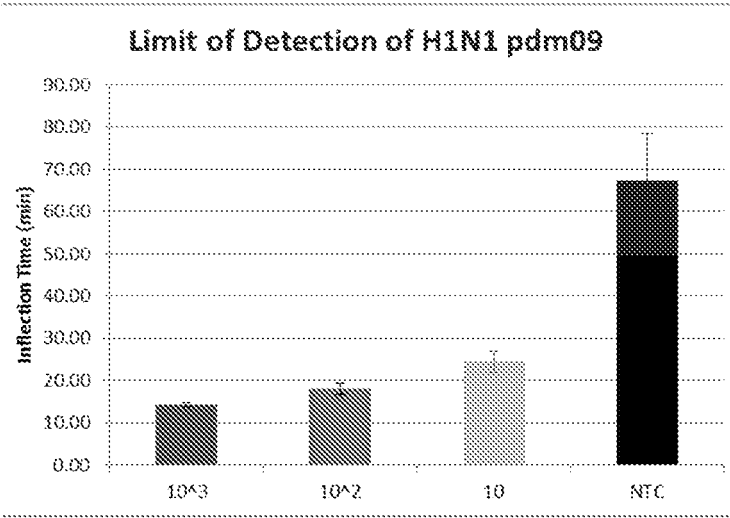


Fig. 3B

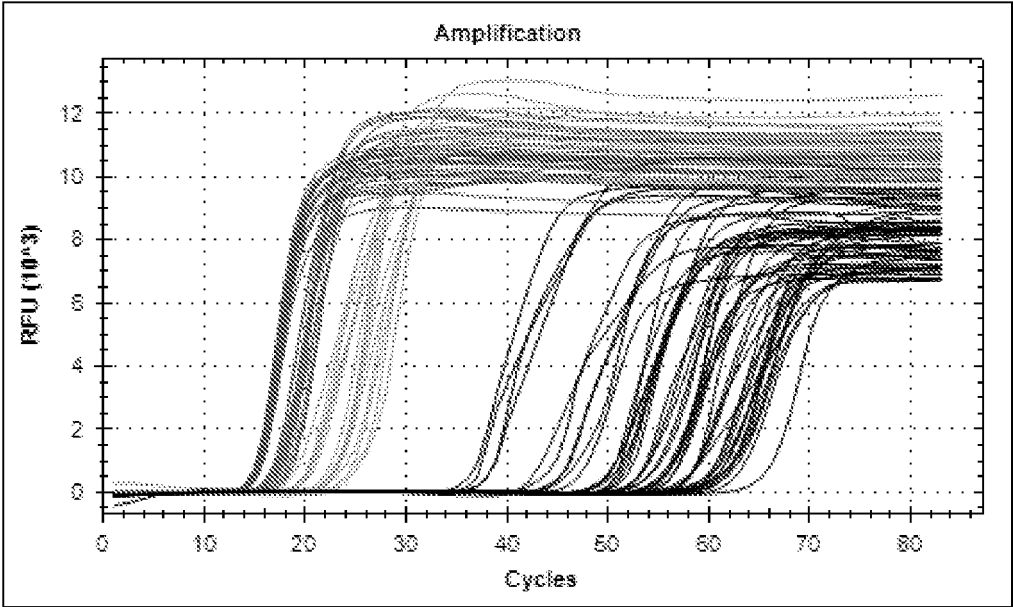


Fig. 4A

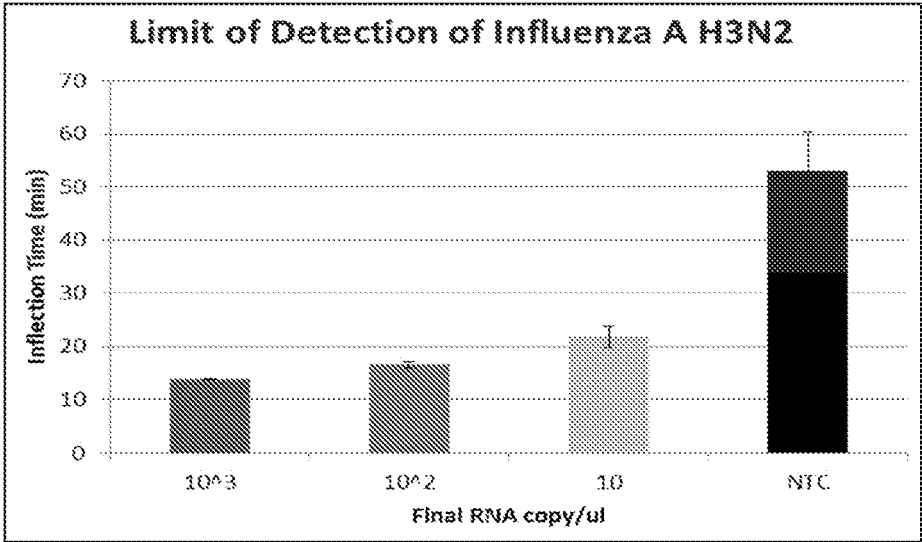


Fig. 4B

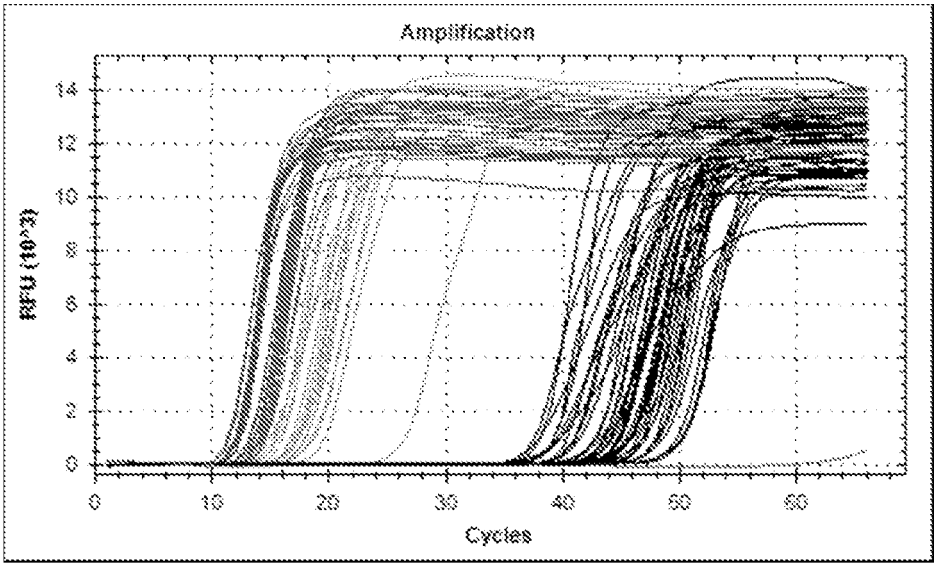


Fig. 5A

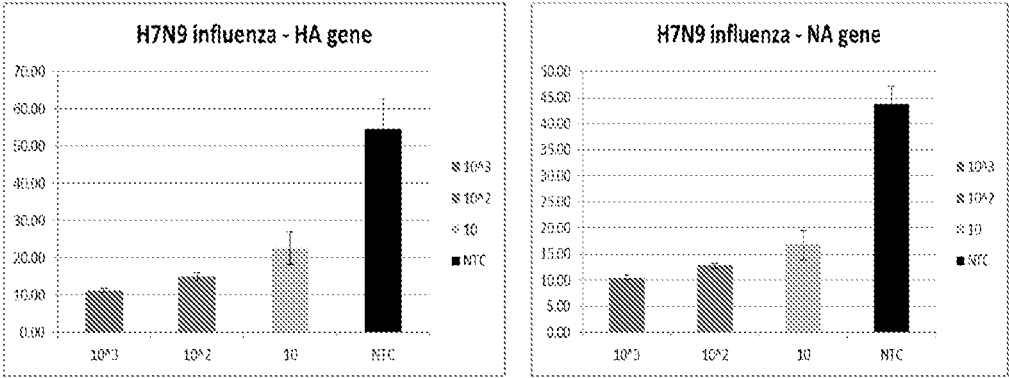


Fig. 5B

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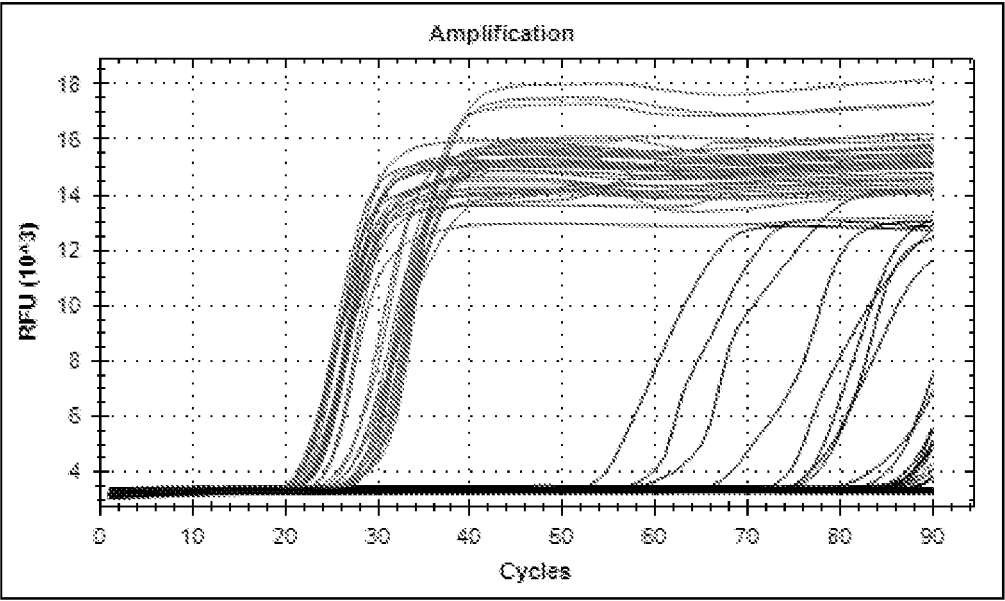


Fig. 6A

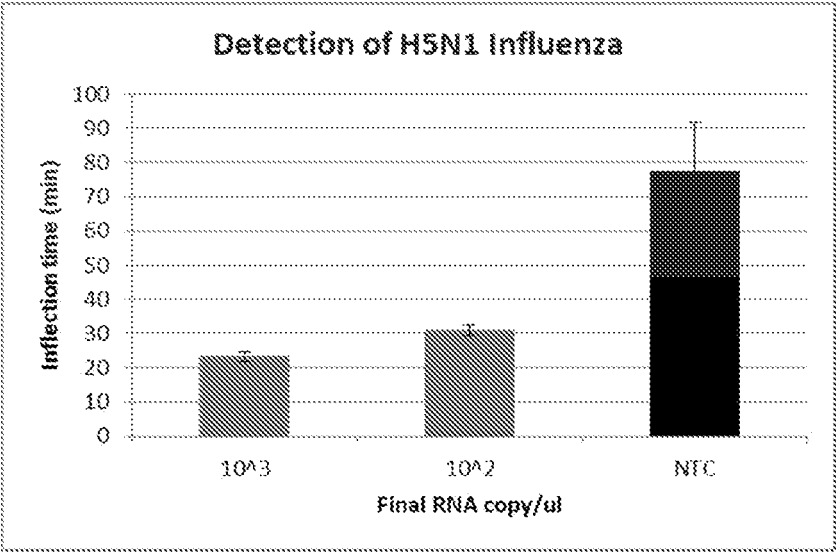


Fig. 6B

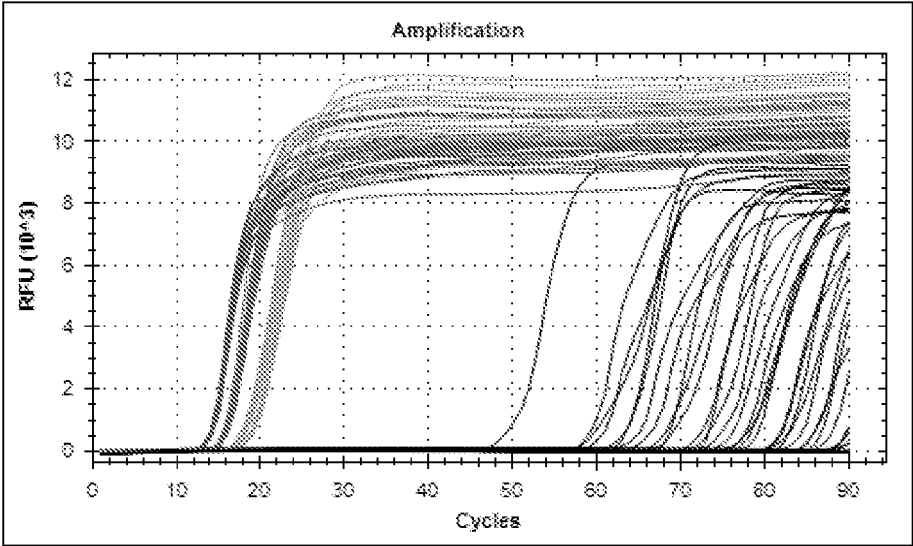


Fig. 7A

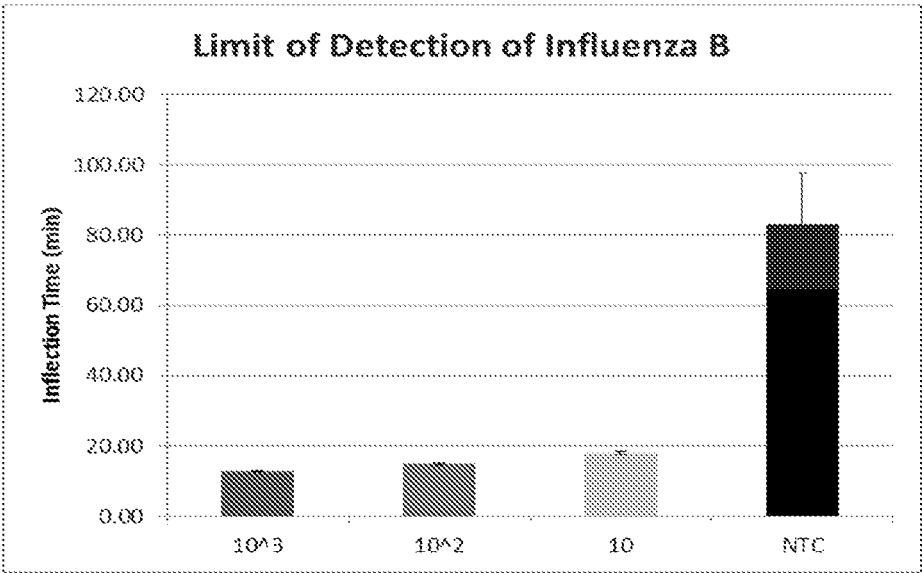


Fig. 7B

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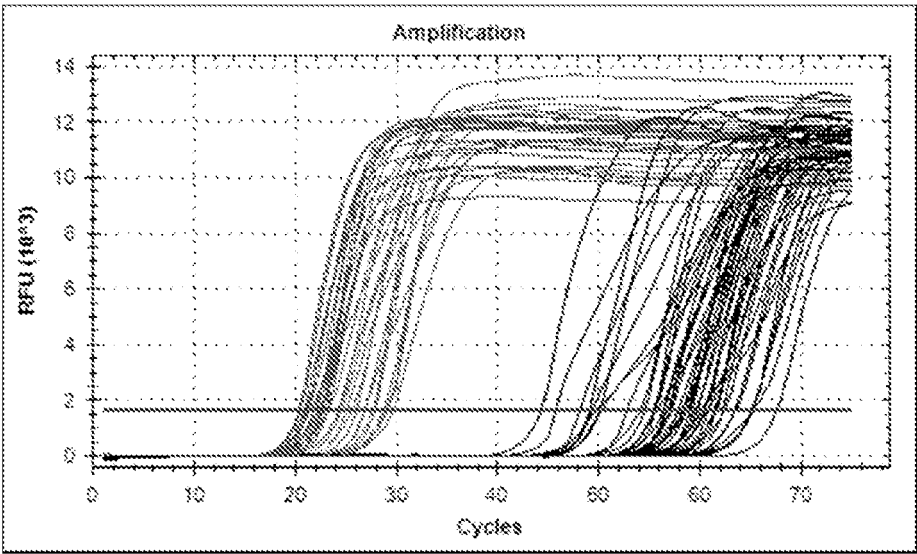


Fig. 8A

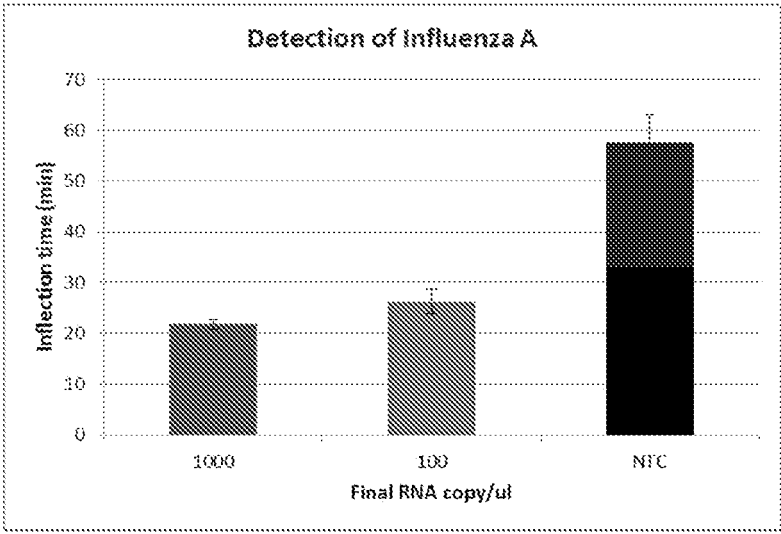


Fig. 8B

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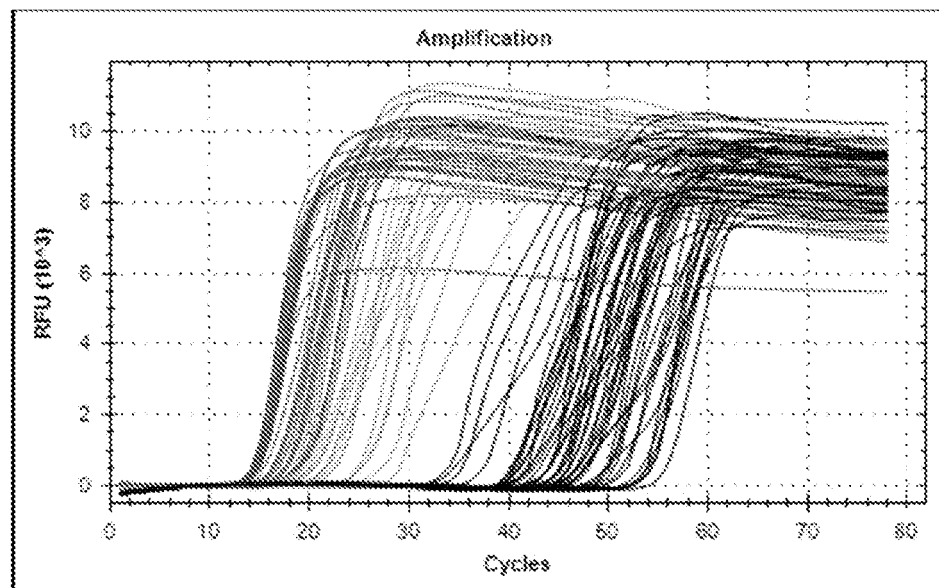


Fig. 9A

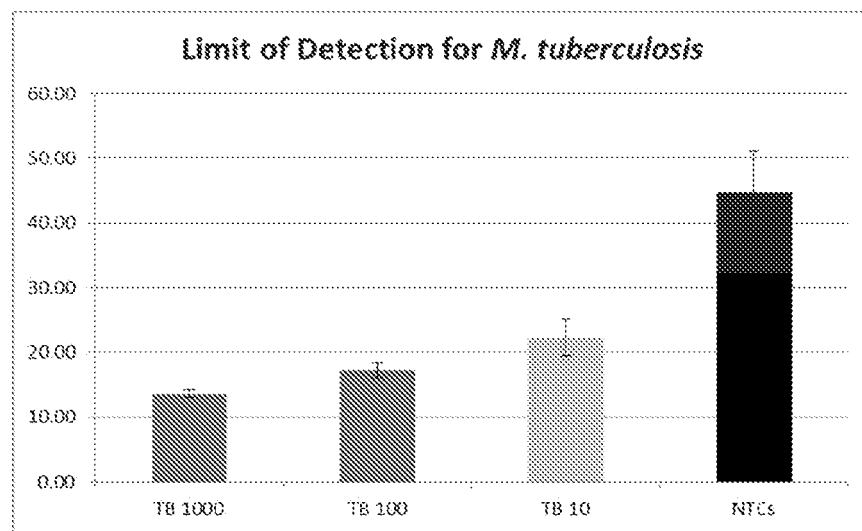


Fig. 9B

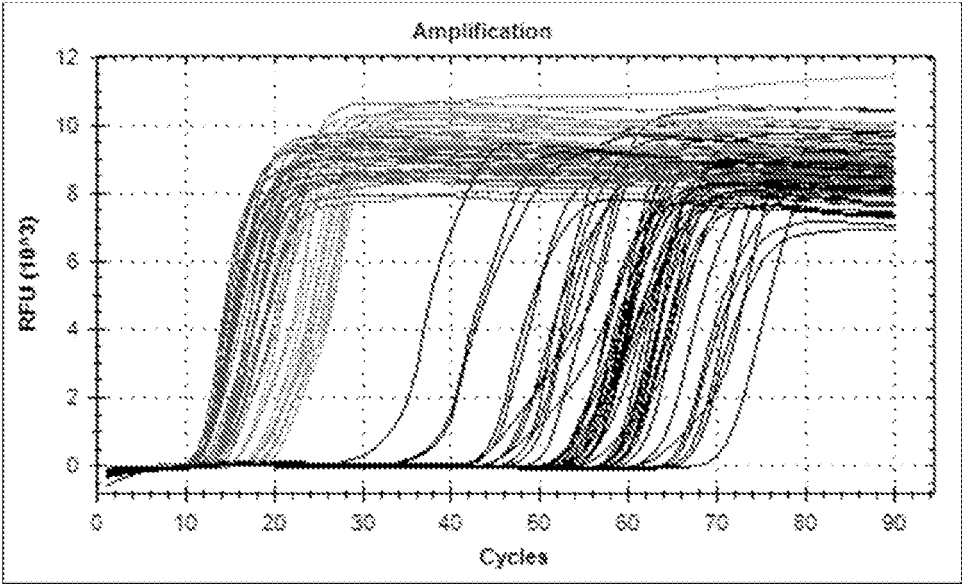


Fig. 10A

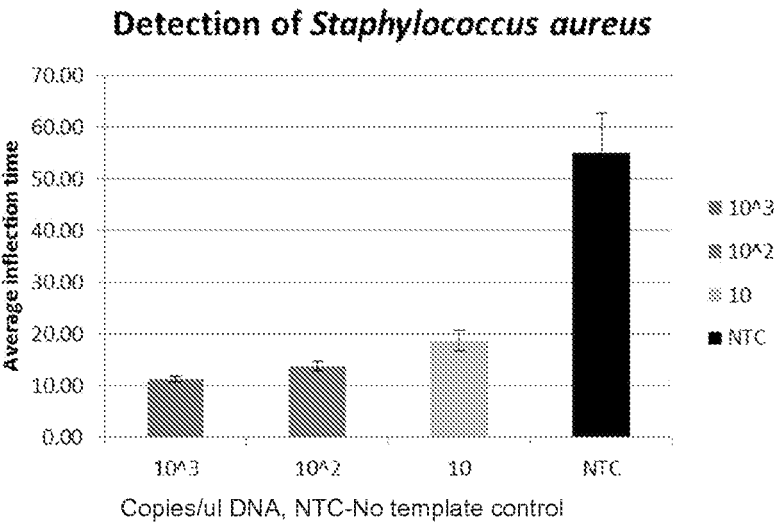


Fig. 10B

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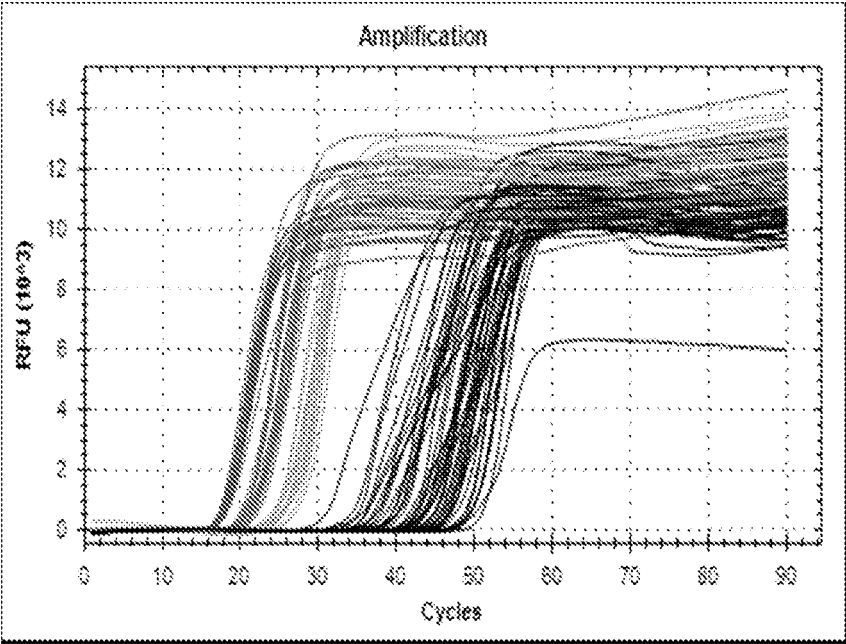


Fig. 11A

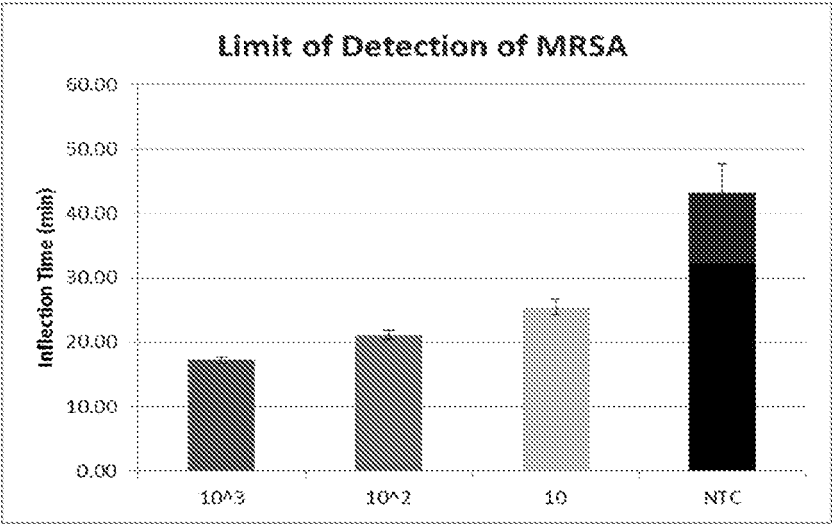


Fig. 11B

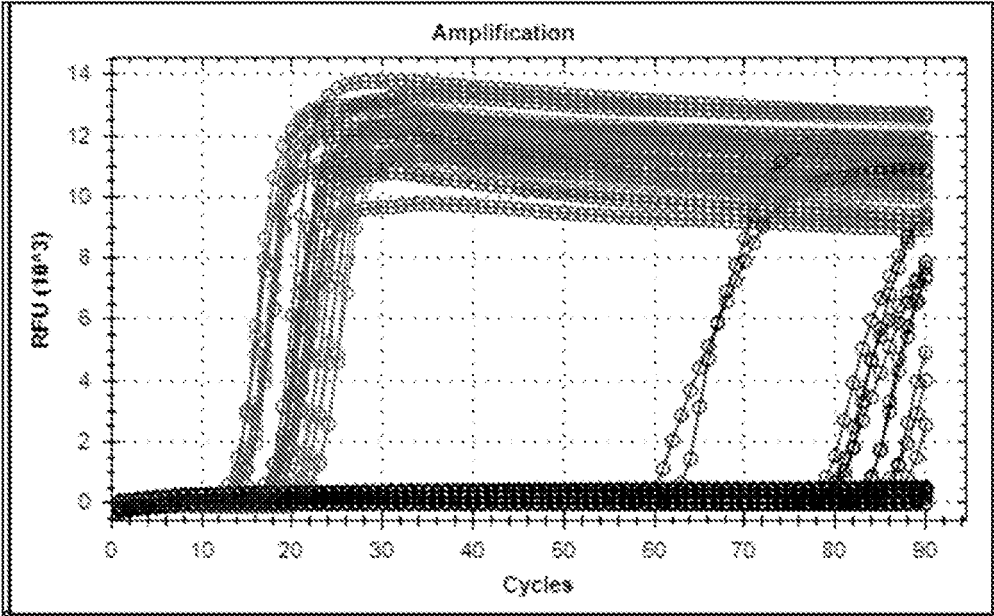


Fig. 12A

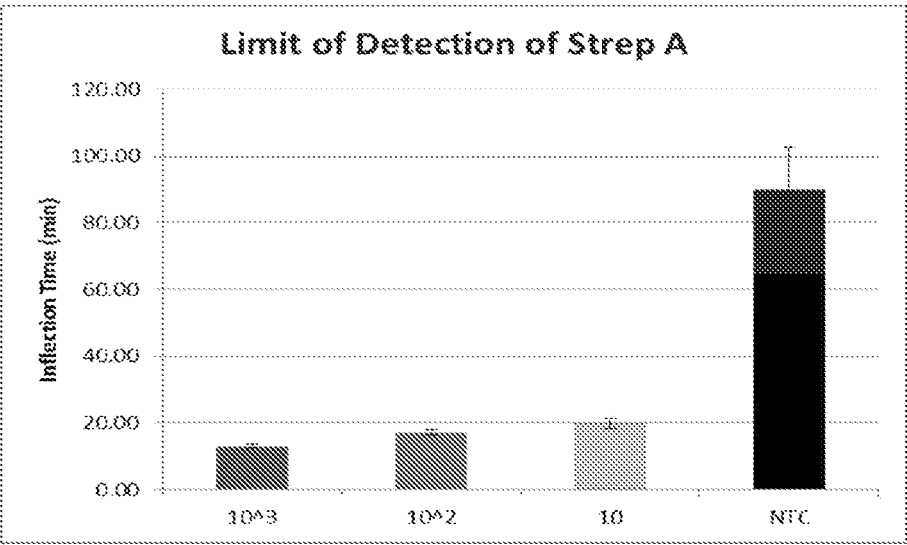


Fig. 12B

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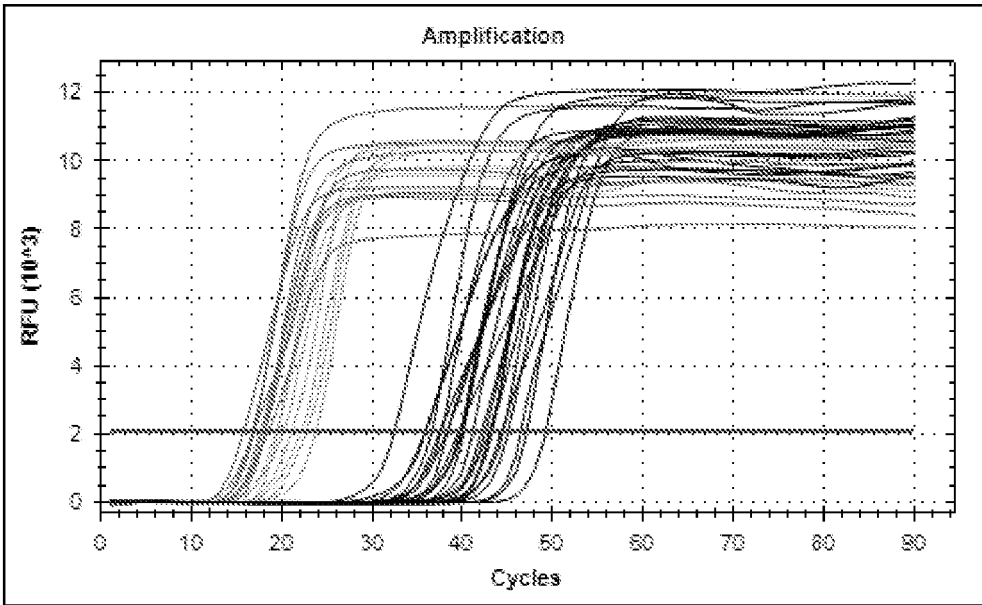


Fig. 13A

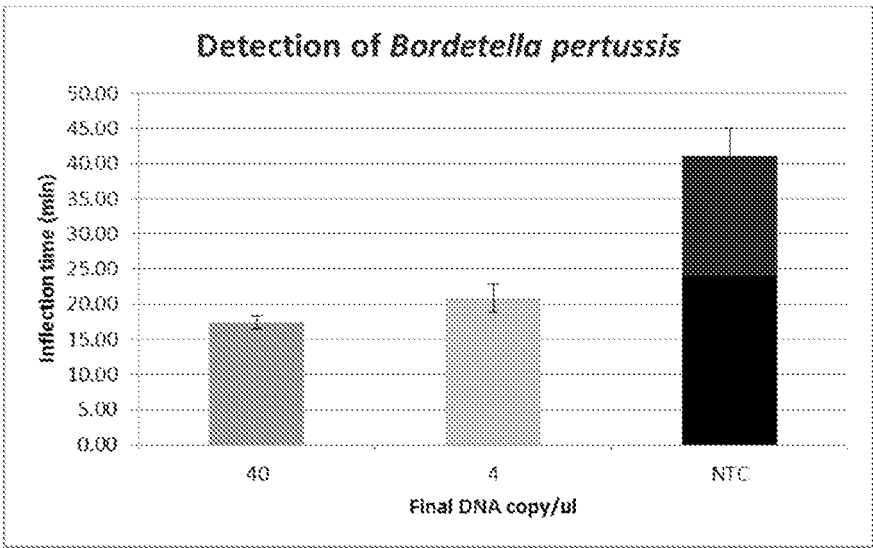


Fig. 13B

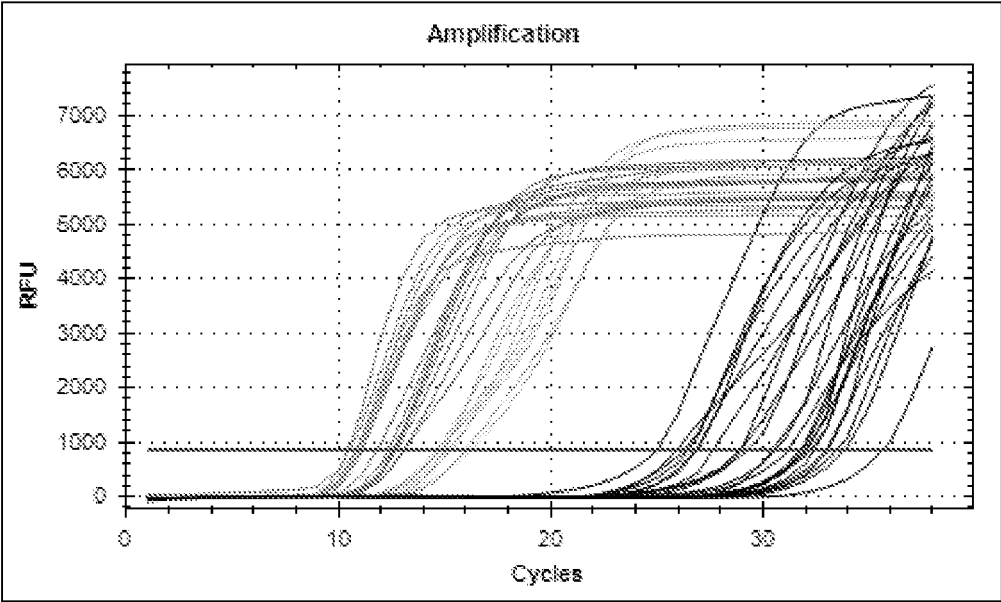


Fig. 14A

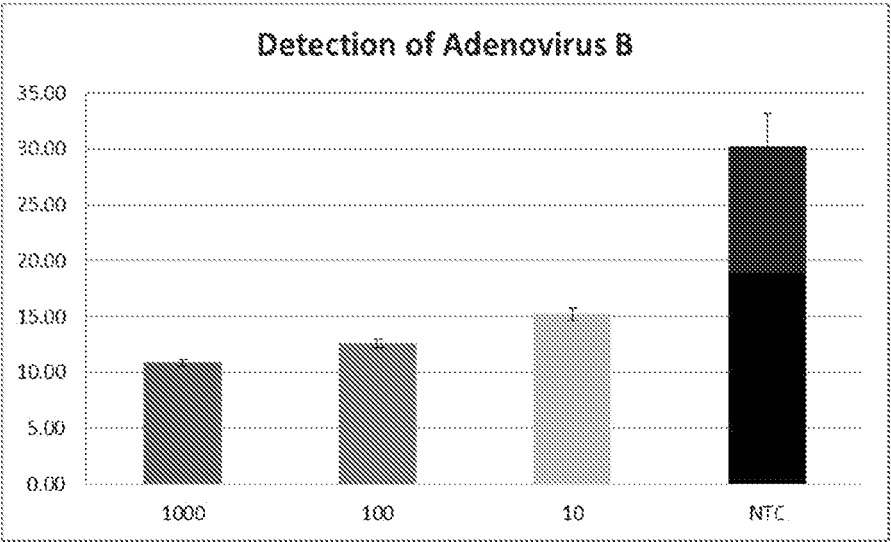


Fig. 14B

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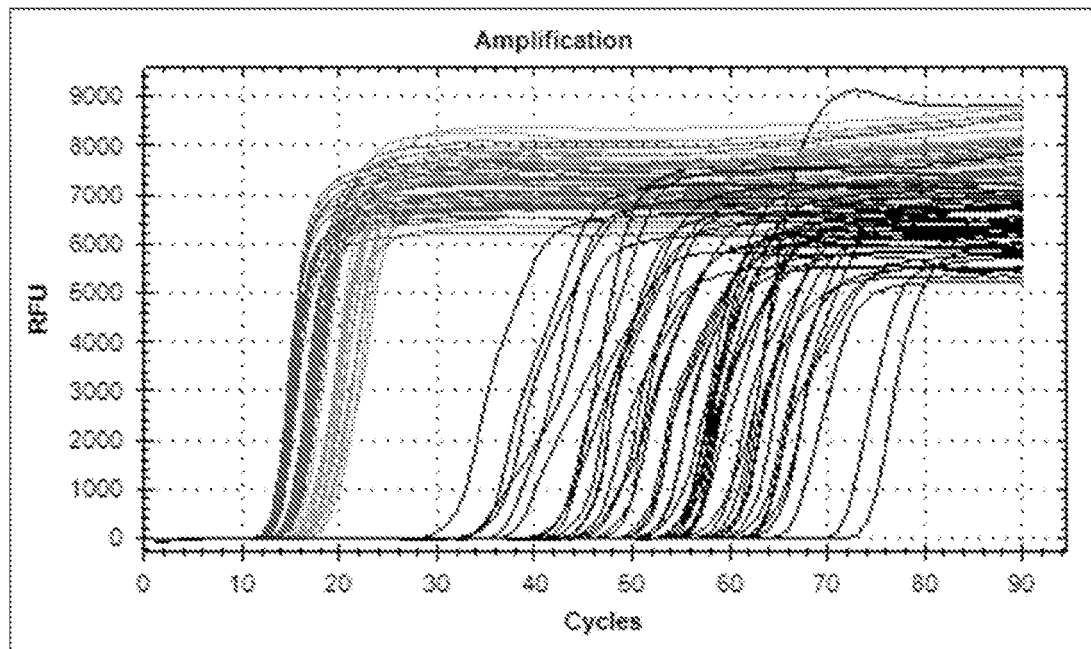


Fig. 15A

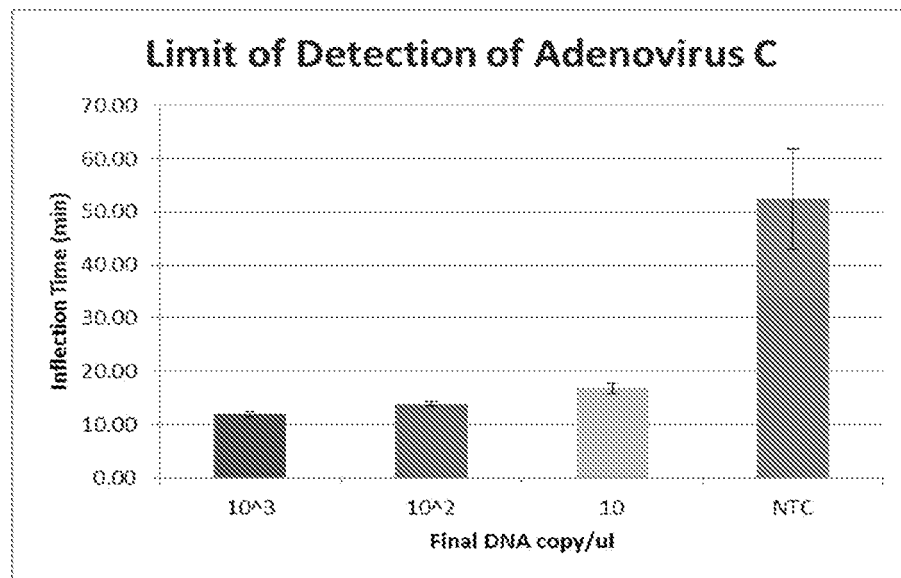


Fig. 15B

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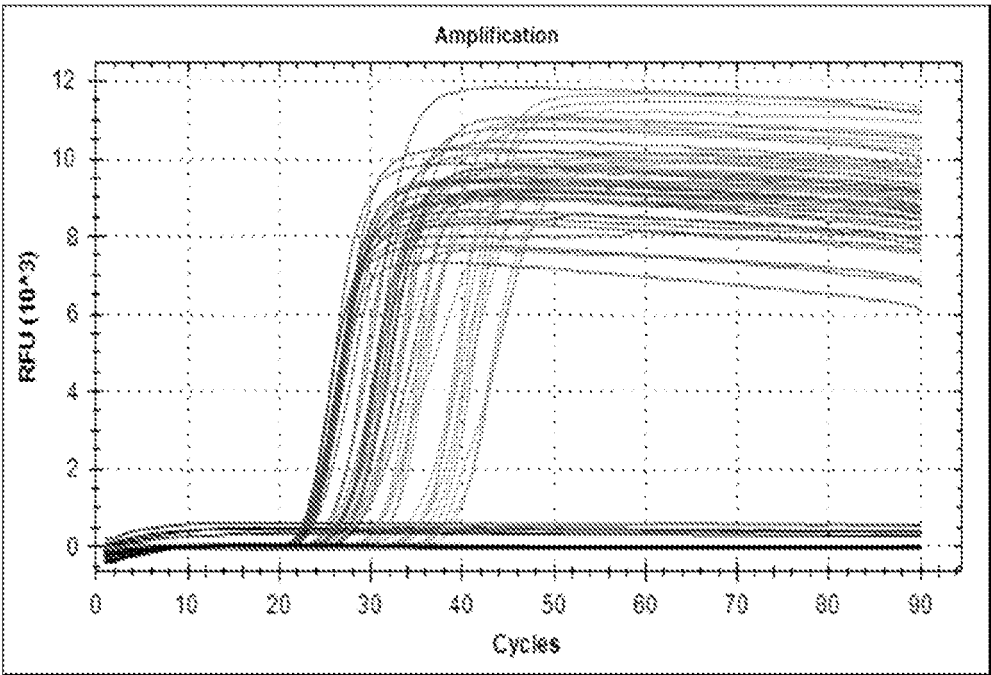


Fig. 16A

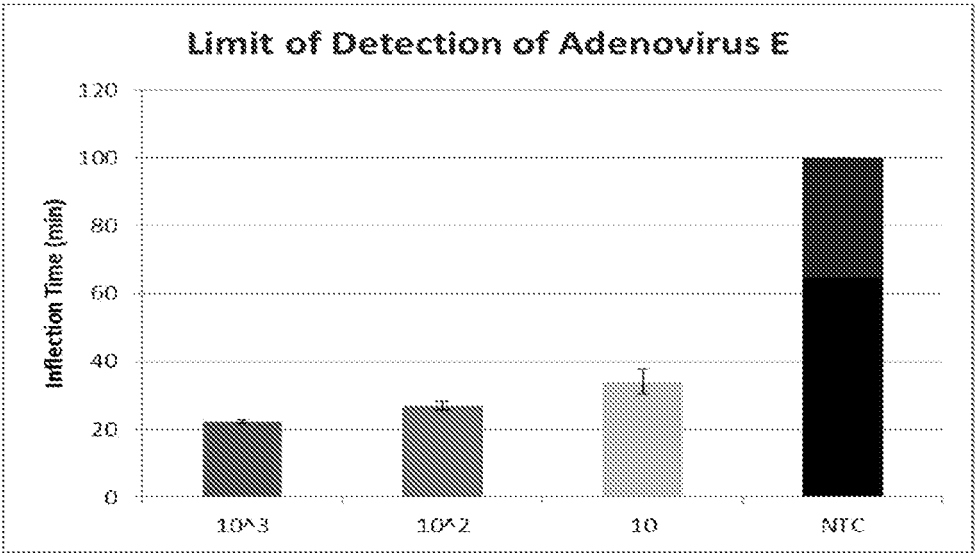


Fig. 16B

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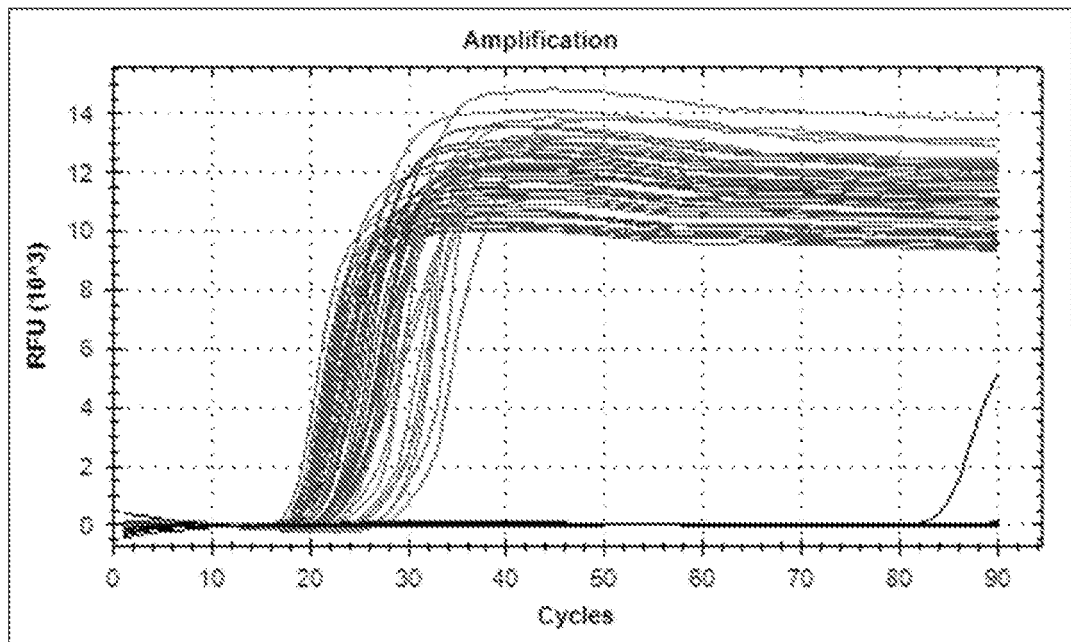


Fig. 17A

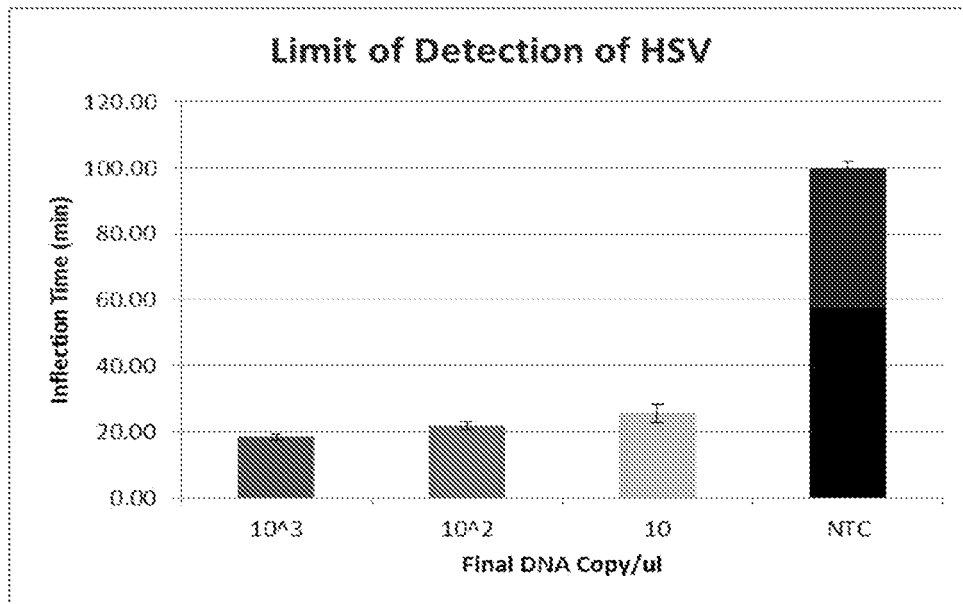


Fig. 17B

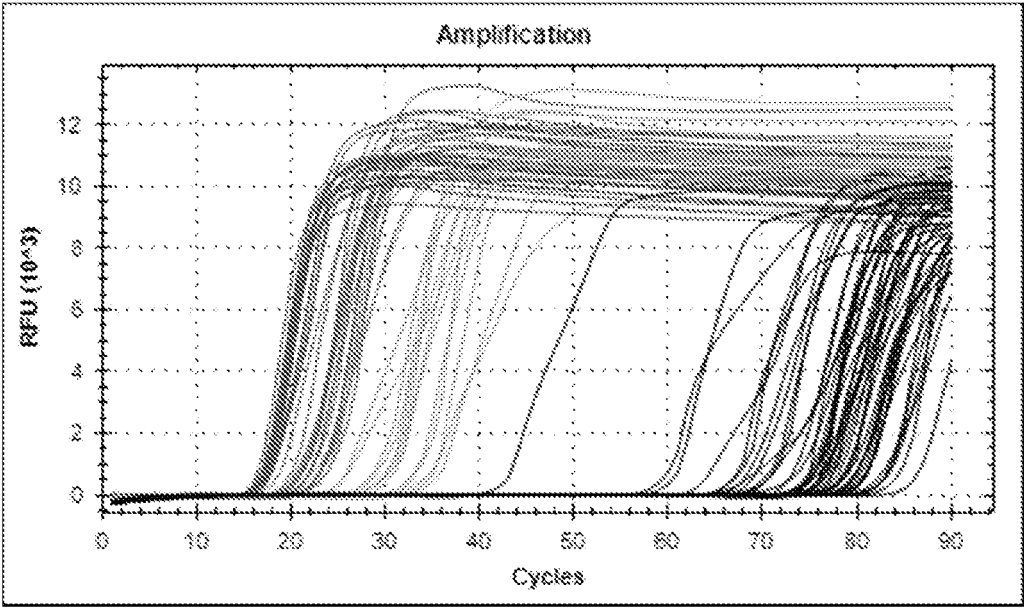


Fig. 18A

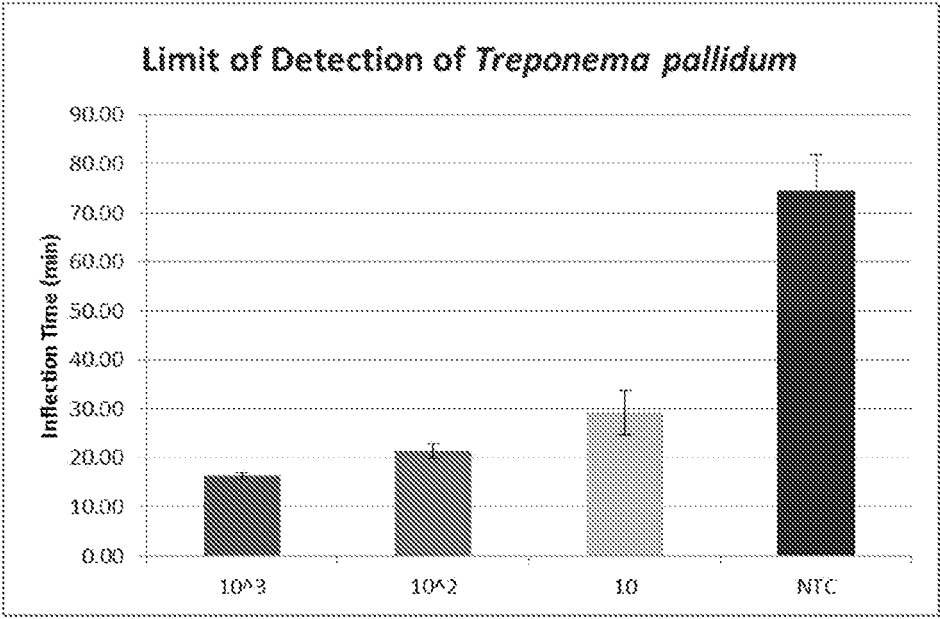


Fig. 18B

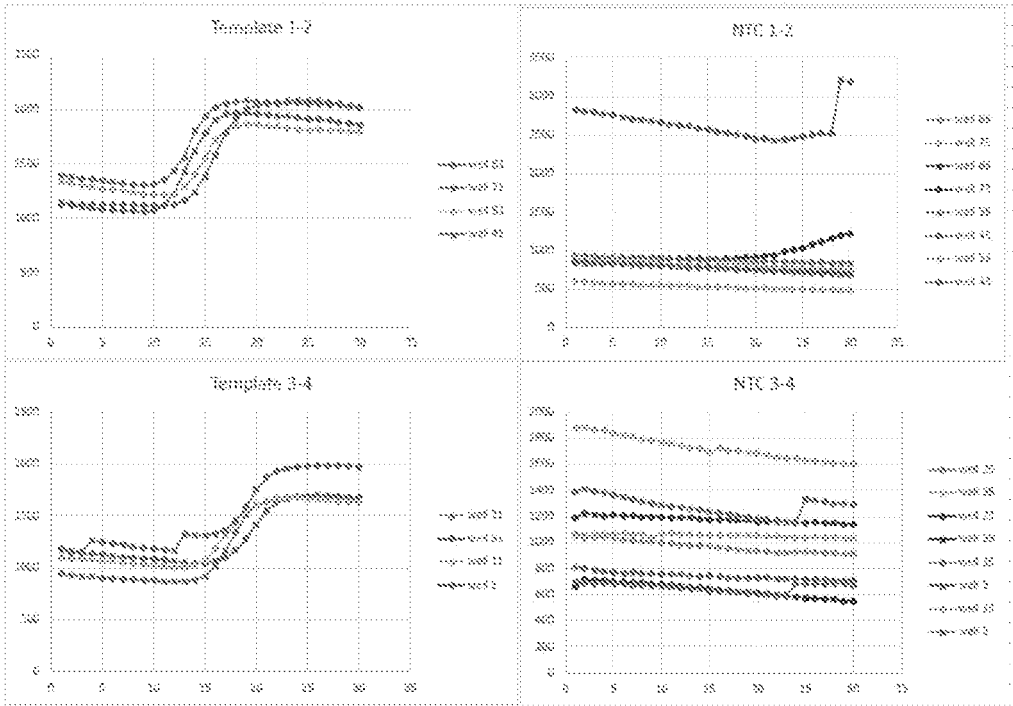


Fig. 19A

Fig. 19B

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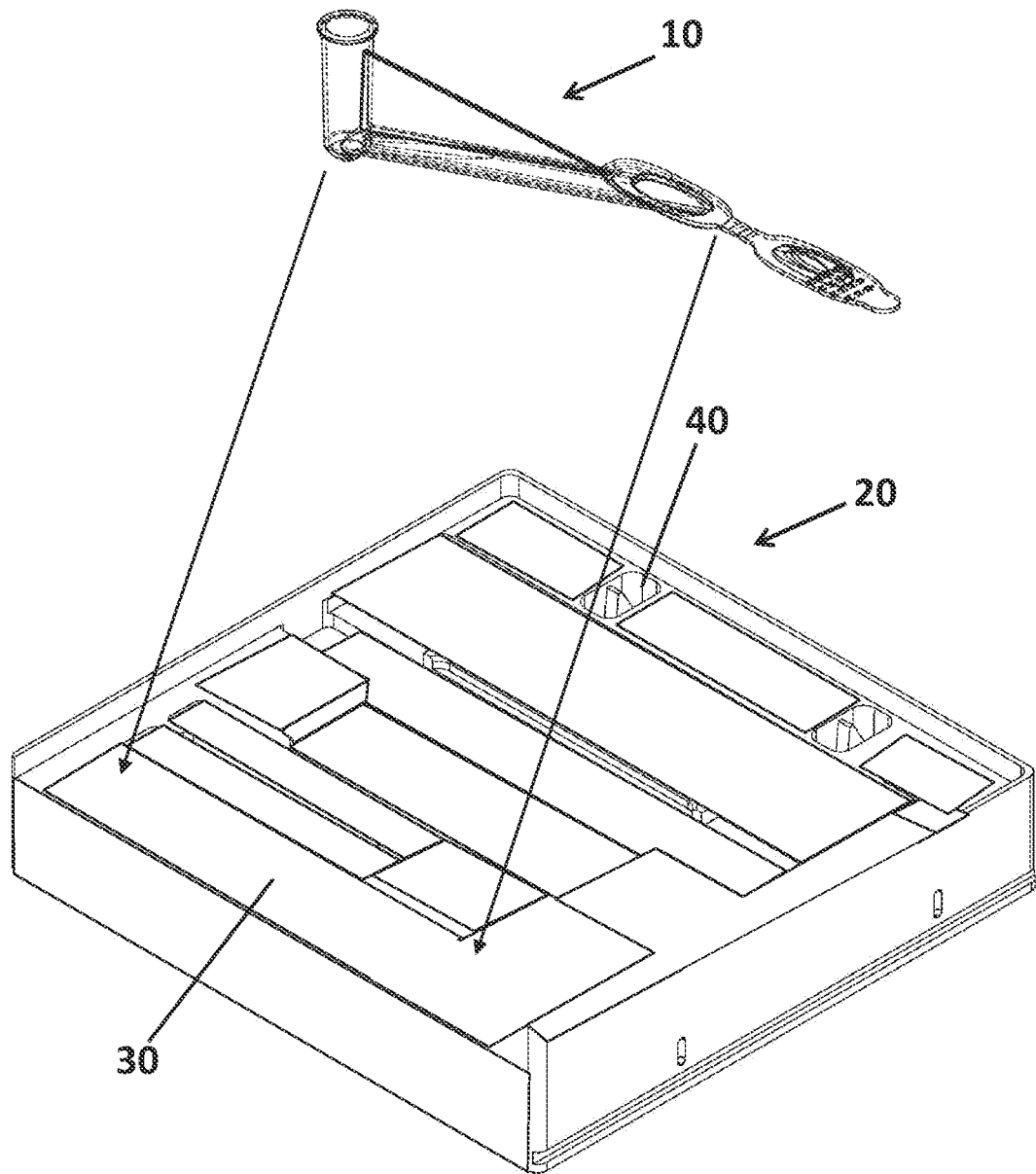


FIG. 20A

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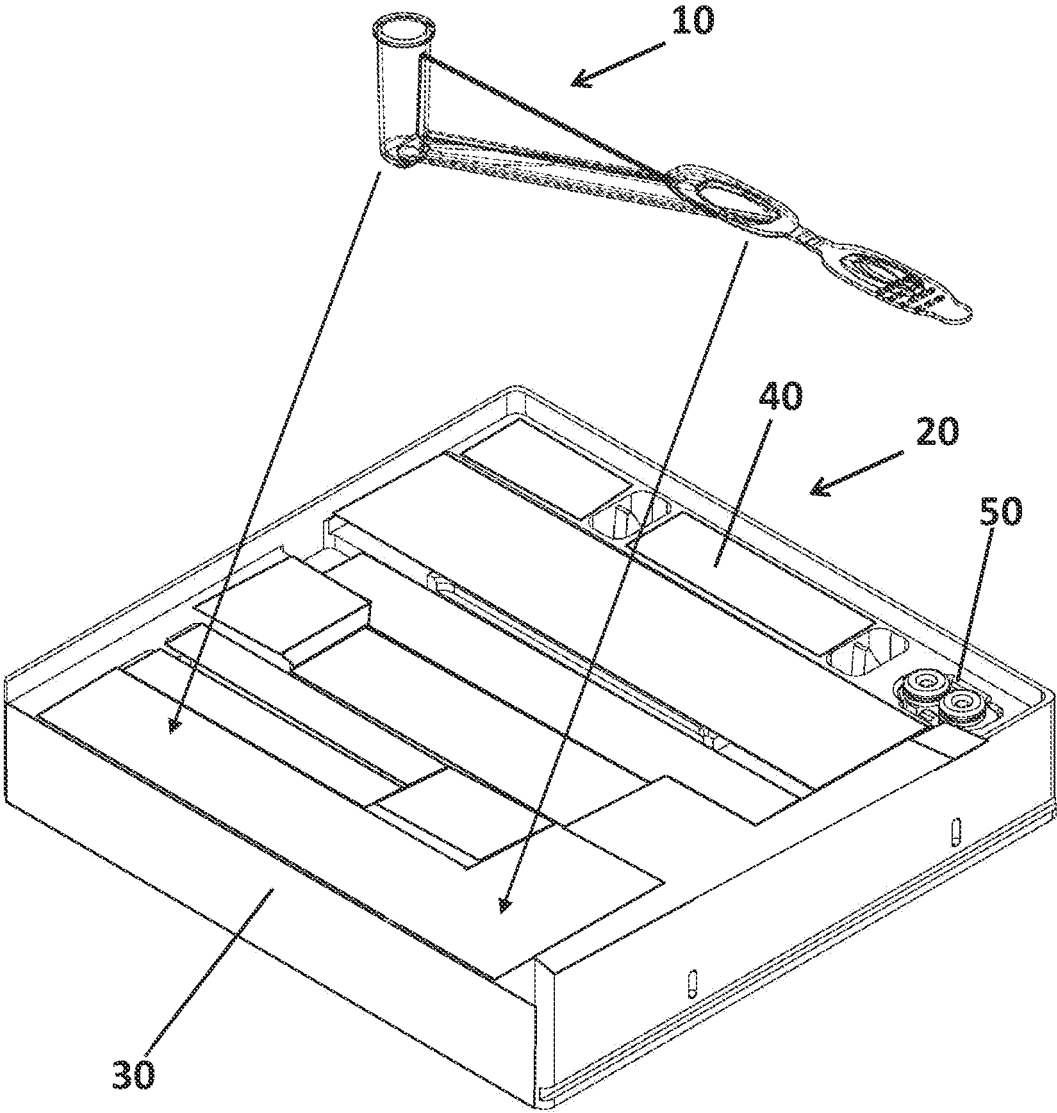


FIG. 20B

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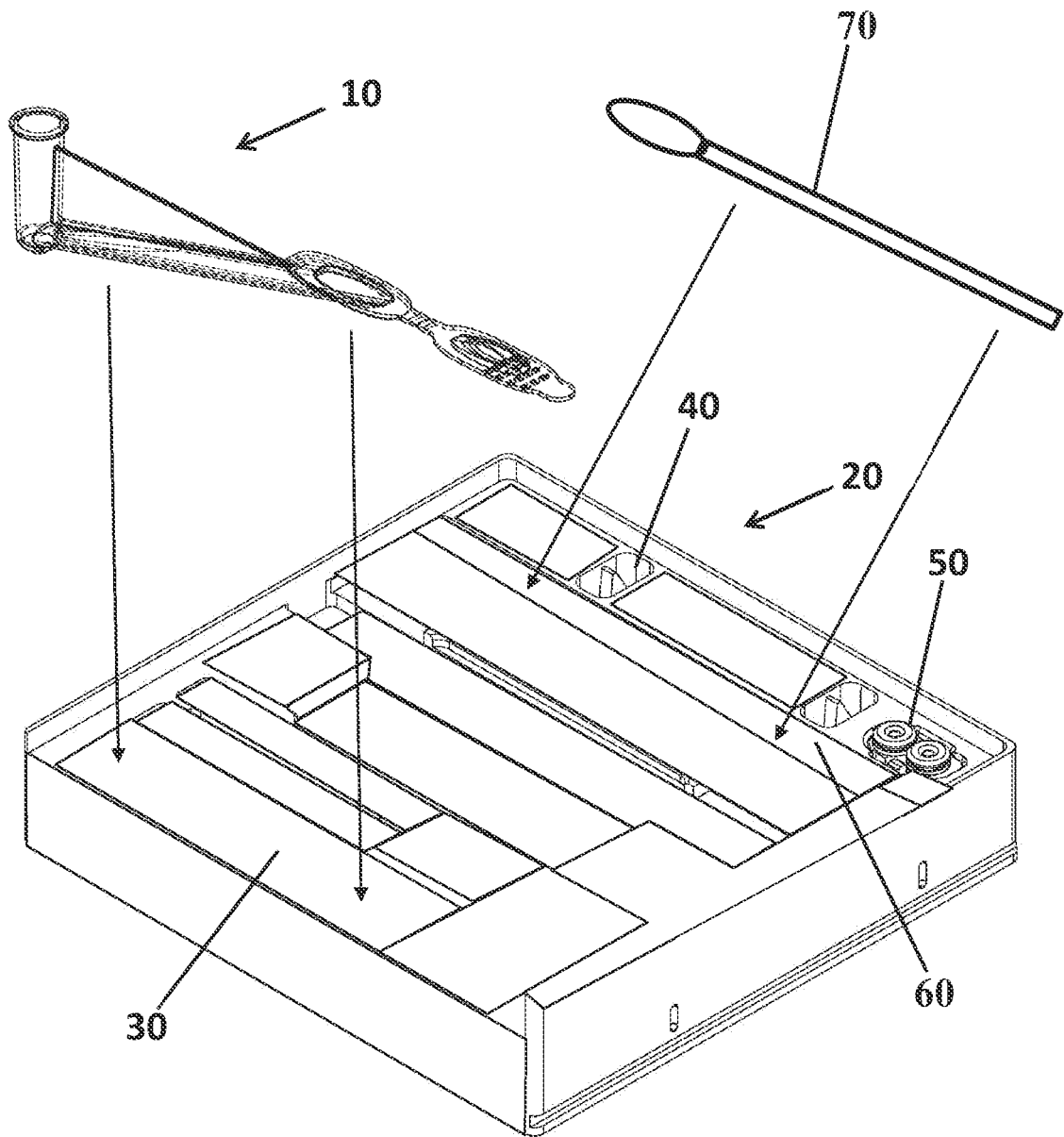


FIG. 20C

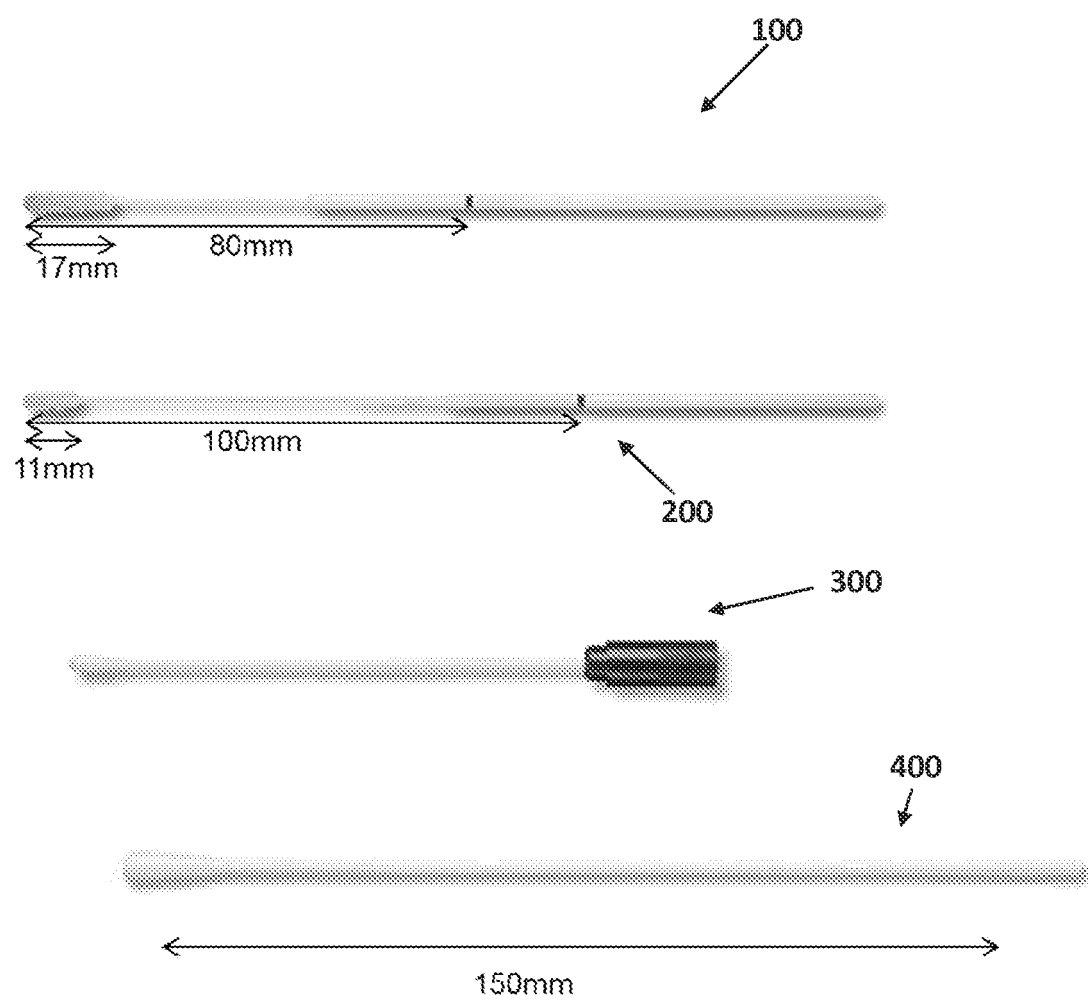


FIG. 21

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| Nosocomial Panel (HAI)                                   |                                   |                                                          |                                           |
|----------------------------------------------------------|-----------------------------------|----------------------------------------------------------|-------------------------------------------|
| <i>Acinetobacter baumannii</i>                           | Adenovirus B                      | Influenza H7N9 - HA gene                                 | <i>Candida albicans</i>                   |
| blaROB resistance gene                                   | Adenovirus C                      | Influenza H7N9 - NA gene                                 | <i>Chlamydia trachomatis</i>              |
| blaTEM resistance gene                                   | Adenovirus E                      | <i>Klebsiella pneumoniae</i>                             | HPV 16                                    |
| <i>Bordetella holmesii</i>                               | blaROB resistance gene            | KPC resistance gene                                      | HPV 18                                    |
| <i>Burkholderia cepacia</i>                              | blaTEM resistance gene            | <i>Legionella pneumophila</i>                            | HSV-1/2                                   |
| <i>Candida albicans</i>                                  | Bocavirus 1 + 3                   | Measles virus                                            | <i>Mycoplasma genitalium</i>              |
| <i>Clostridium difficile</i>                             | Bocavirus 2 + 4                   | mecA resistance gene                                     | <i>Neisseria gonorrhoeae</i>              |
| <i>Clostridium sordellii</i>                             | <i>Bordetella holmesii</i>        | mecC resistance gene                                     | <i>Streptococcus agalactiae</i> (Strep B) |
| <i>Enterobacter aerogenes</i>                            | <i>Bordetella parapertussis</i>   | Mumps virus                                              | <i>Treponema pallidum</i> (syphilis)      |
| <i>Enterobacter cloacae</i>                              | <i>Bordetella pertussis</i>       | <i>Mycobacterium tuberculosis</i>                        | <i>Trichomonas vaginalis</i>              |
| <i>Enterococcus faecalis</i>                             | <i>Chlamydia pneumoniae</i>       | <i>Mycoplasma pneumoniae</i>                             | Varicella-zoster virus                    |
| <i>Enterococcus faecium</i>                              | <i>Clostridium sordellii</i>      | Parainfluenza 1                                          |                                           |
| <i>Escherichia coli</i>                                  | Coronavirus 229E                  | Parainfluenza 2                                          |                                           |
| <i>Klebsiella pneumoniae</i>                             | Coronavirus HKU1                  | Parainfluenza 3                                          |                                           |
| KPC resistance gene                                      | Coronavirus MERS                  | Parainfluenza 4a                                         |                                           |
| <i>Legionella pneumophila</i>                            | Coronavirus NL63                  | Parainfluenza 4b                                         |                                           |
| mecA resistance gene                                     | Coronavirus OC43                  | Respiratory syncytial virus A (RSV A)                    |                                           |
| mecC resistance gene                                     | <i>Haemophilus influenzae</i>     | Respiratory syncytial virus B (RSV B)                    |                                           |
| <i>Moraxella catarrhalis</i>                             | <i>Haemophilus parainfluenzae</i> | Rhinovirus A                                             |                                           |
| <i>Mycobacterium abscessus</i>                           | Human metapneumovirus A           | Rhinovirus B                                             |                                           |
| <i>Pseudomonas aeruginosa</i>                            | Human metapneumovirus B           | Rhinovirus C                                             |                                           |
| <i>Serratia marcescens</i>                               | Influenza A - MP                  | Rubella virus                                            |                                           |
| Spike-in control                                         | Influenza B - MP                  | <i>Staphylococcus aureus</i>                             |                                           |
| <i>Staphylococcus aureus</i>                             | Influenza H1N1 - novel (2009)     | <i>Staphylococcus aureus</i> (Vancomycin-resistant) VRSA |                                           |
| <i>Staphylococcus aureus</i> (Vancomycin-resistant) VRSA | Influenza H1N1 - Seasonal         | <i>Streptococcus pneumoniae</i>                          |                                           |
| <i>Streptococcus agalactiae</i> (Strep B)                | Influenza H3N2                    | <i>Streptococcus pneumoniae</i> (penicillin-sensitive)   |                                           |
| <i>Streptococcus pneumoniae</i>                          | Influenza H5N1                    | <i>Streptococcus pyogenes</i>                            |                                           |
| <i>Streptococcus pneumoniae</i> (penicillin-sensitive)   |                                   |                                                          |                                           |
| <i>Streptococcus pyogenes</i>                            |                                   |                                                          |                                           |
| vanA resistance gene                                     |                                   |                                                          |                                           |
| vanB resistance gene                                     |                                   |                                                          |                                           |
| Controls                                                 |                                   |                                                          |                                           |
| Human RnaseP                                             |                                   |                                                          |                                           |
| Spike-in control                                         |                                   |                                                          |                                           |
| Additional Assays                                        |                                   |                                                          |                                           |
| <i>Bacillus anthracis</i>                                |                                   |                                                          |                                           |
| <i>Yersinia pestis</i>                                   |                                   |                                                          |                                           |
| Infectious Disease Panel                                 |                                   | Enteric/Respiratory Panel                                |                                           |
| Dengue Virus 1                                           |                                   | <i>Clostridium difficile</i>                             |                                           |
| Dengue Virus 2                                           |                                   | <i>Escherichia coli</i>                                  |                                           |
| Dengue Virus 3                                           |                                   | Hepatitis A                                              |                                           |
| Dengue Virus 4                                           |                                   | <i>Listeria monocytogenes</i>                            |                                           |
| <i>Plasmodium</i>                                        |                                   | Norovirus lineage I                                      |                                           |
| <i>Trypanosoma cruzi</i> (chagas)                        |                                   | Norovirus lineage II                                     |                                           |
| West Nile Virus 1                                        |                                   |                                                          |                                           |
| West Nile Virus 2                                        |                                   |                                                          |                                           |
|                                                          |                                   | STD Panel (blood)                                        |                                           |
|                                                          |                                   | Epstein-Barr Virus                                       |                                           |
|                                                          |                                   | Hepatitis A                                              |                                           |
|                                                          |                                   | Hepatitis B assay                                        |                                           |
|                                                          |                                   | Hepatitis C                                              |                                           |
|                                                          |                                   | HepDelta assay                                           |                                           |
|                                                          |                                   | HIV-1 group M assay 1                                    |                                           |
|                                                          |                                   | HIV-1 group M assay 2                                    |                                           |
|                                                          |                                   | HIV-1 group O1                                           |                                           |
|                                                          |                                   | HIV-1 group O3                                           |                                           |
|                                                          |                                   | HIV-2 Group A                                            |                                           |
|                                                          |                                   | HIV-2 Group B                                            |                                           |
|                                                          |                                   | Urinary Tract Infection Panel                            |                                           |
|                                                          |                                   | <i>Enterococcus faecalis</i>                             |                                           |
|                                                          |                                   | <i>Enterococcus faecium</i>                              |                                           |
|                                                          |                                   | <i>Escherichia coli</i>                                  |                                           |
|                                                          |                                   | <i>Klebsiella pneumoniae</i>                             |                                           |
|                                                          |                                   | KPC resistance gene                                      |                                           |
|                                                          |                                   | <i>Mycoplasma hominis</i>                                |                                           |
|                                                          |                                   | <i>Proteus mirabilis</i>                                 |                                           |
|                                                          |                                   | <i>Proteus penneri</i>                                   |                                           |
|                                                          |                                   | <i>Proteus vulgaris</i>                                  |                                           |
|                                                          |                                   | <i>S. saprophyticus</i>                                  |                                           |
|                                                          |                                   | Spike-in control                                         |                                           |
|                                                          |                                   | <i>Ureaplasma urealyticum</i>                            |                                           |
|                                                          |                                   | vanA resistance gene                                     |                                           |
|                                                          |                                   | vanB resistance gene                                     |                                           |

Fig. 22

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|                 | Organism                     | LOD        |
|-----------------|------------------------------|------------|
| Influenza Panel | Influenza A                  | < 100 c/uL |
|                 | Influenza A H3N2             | < 10 c/uL  |
|                 | Influenza A H5N1             | < 100 c/uL |
|                 | Influenza A H7N9 - HA gene   | < 10 c/uL  |
|                 | Influenza A H7N9 - NA gene   | < 10 c/uL  |
|                 | Influenza B                  | < 10 c/uL  |
|                 | Influenza H1N1 novel (pdm09) | < 10 c/uL  |
|                 | Influenza H1N1 seasonal      | < 10 c/uL  |

Fig. 23A

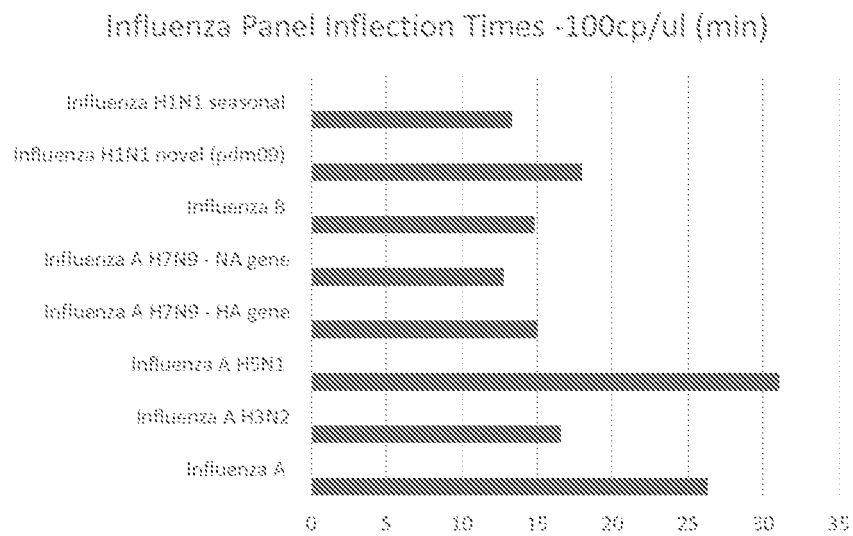


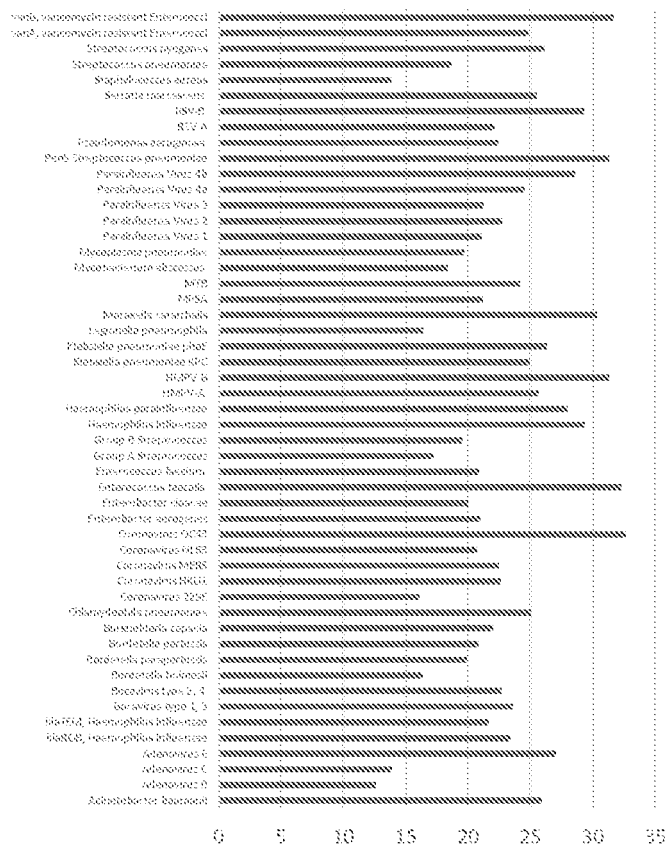
Fig. 23B

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|                   | Organism                                      | LOD        |
|-------------------|-----------------------------------------------|------------|
| Respiratory Panel | <i>Acinetobacter baumannii</i>                | < 10 c/uL  |
|                   | Adenovirus B                                  | < 10 c/uL  |
|                   | Adenovirus C                                  | < 10 c/uL  |
|                   | Adenovirus E                                  | < 10 c/uL  |
|                   | blaRQR, <i>Haemophilus influenzae</i>         | < 10 c/uL  |
|                   | blaTEM, <i>Haemophilus influenzae</i>         | < 10 c/uL  |
|                   | Bocavirus type 1, 3                           | < 100 c/uL |
|                   | Bocavirus type 2, 4                           | < 10 c/uL  |
|                   | <i>Bordetella holmesii</i>                    | < 10 c/uL  |
|                   | <i>Bordetella parapertussis</i>               | < 10 c/uL  |
|                   | <i>Bordetella pertussis</i>                   | < 4 c/uL   |
|                   | <i>Burkholderia cepacia</i>                   | < 10 c/uL  |
|                   | <i>Chlamydia pneumoniae</i>                   | < 10 c/uL  |
|                   | Coronavirus 229E                              | < 10 c/uL  |
|                   | Coronavirus HKU1                              | < 100 c/uL |
|                   | Coronavirus MERS                              | < 100 c/uL |
|                   | Coronavirus NL63                              | < 10 c/uL  |
|                   | Coronavirus OC43                              | < 100 c/uL |
|                   | <i>Enterobacter aerogenes</i>                 | < 10 c/uL  |
|                   | <i>Enterobacter cloacae</i>                   | < 10 c/uL  |
|                   | <i>Enterococcus faecalis</i>                  | < 10 c/uL  |
|                   | <i>Enterococcus faecium</i>                   | < 10 c/uL  |
|                   | Group A <i>Streptococcus</i>                  | < 10 c/uL  |
|                   | Group B <i>Streptococcus</i>                  | < 10 c/uL  |
|                   | <i>Haemophilus influenzae</i>                 | < 10 c/uL  |
|                   | <i>Haemophilus parainfluenzae</i>             | < 10 c/uL  |
|                   | HMPV-A                                        | < 100 c/uL |
|                   | HMPV-B                                        | < 100 c/uL |
|                   | <i>Klebsiella pneumoniae</i> KPC              | < 10 c/uL  |
|                   | <i>Klebsiella pneumoniae</i> <i>phoE</i>      | < 10 c/uL  |
|                   | <i>Legionella pneumophila</i>                 | < 10 c/uL  |
|                   | <i>Moraxella catarrhalis</i>                  | < 10 c/uL  |
|                   | MRSA                                          | < 10 c/uL  |
|                   | MTB                                           | < 10 c/uL  |
|                   | <i>Mycobacterium abscessus</i>                | < 10 c/uL  |
|                   | <i>Mycoplasma pneumoniae</i>                  | < 10 c/uL  |
|                   | Parainfluenza Virus 1                         | < 100 c/uL |
|                   | Parainfluenza Virus 2                         | < 100 c/uL |
|                   | Parainfluenza Virus 3                         | < 100 c/uL |
|                   | Parainfluenza Virus 4a                        | < 100 c/uL |
|                   | Parainfluenza Virus 4b                        | < 10 c/uL  |
|                   | PanS <i>Streptococcus pneumoniae</i>          | < 10 c/uL  |
|                   | <i>Pseudomonas aeruginosa</i>                 | < 10 c/uL  |
|                   | RSV-A                                         | < 100 c/uL |
|                   | RSV-B                                         | < 100 c/uL |
|                   | <i>Serratia marcescens</i>                    | < 10 c/uL  |
|                   | <i>Staphylococcus aureus</i>                  | < 10 c/uL  |
|                   | <i>Streptococcus pneumoniae</i>               | < 10 c/uL  |
|                   | <i>Streptococcus pyogenes</i>                 | < 10 c/uL  |
|                   | vanA, vancomycin resistant <i>Enterococci</i> | < 10 c/uL  |
|                   | vanB, vancomycin resistant <i>Enterococci</i> | < 10 c/uL  |

Fig. 24A

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Respiratory Panel Infection Times -  
100 cp/ul (min)

### Upper and Lower Respiratory Panel

Fig. 24B

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| HAI | Organism                                      | LOD       |
|-----|-----------------------------------------------|-----------|
|     | <i>Streptococcus pyogenes</i>                 | < 10 c/uL |
|     | <i>Acinetobacter baumannii</i>                | < 10 c/uL |
|     | blaROB, <i>Haemophilus influenzae</i>         | < 10 c/uL |
|     | blaTEM, <i>Haemophilus influenzae</i>         | < 10 c/uL |
|     | <i>Burkholderia cepacia</i>                   | < 10 c/uL |
|     | <i>Chlamydia pneumoniae</i>                   | < 10 c/uL |
|     | <i>Enterobacter aerogenes</i>                 | < 10 c/uL |
|     | <i>Enterobacter cloacae</i>                   | < 10 c/uL |
|     | <i>Enterococcus faecalis</i>                  | < 10 c/uL |
|     | <i>Enterococcus faecium</i>                   | < 10 c/uL |
|     | Group A <i>Streptococcus</i>                  | < 10 c/uL |
|     | Group B <i>Streptococcus</i>                  | < 10 c/uL |
|     | <i>Klebsiella pneumoniae</i> KPC              | < 10 c/uL |
|     | <i>Klebsiella pneumoniae</i> phoE             | < 10 c/uL |
|     | <i>Legionella pneumophila</i>                 | < 10 c/uL |
|     | <i>Moraxella catarrhalis</i>                  | < 10 c/uL |
|     | MRSA                                          | < 10 c/uL |
|     | <i>Mycobacterium abscessus</i>                | < 10 c/uL |
|     | <i>Mycoplasma pneumoniae</i>                  | < 10 c/uL |
|     | PenS <i>Streptococcus pneumoniae</i>          | < 10 c/uL |
|     | <i>Pseudomonas aeruginosa</i>                 | < 10 c/uL |
|     | <i>Serratia marcescens</i>                    | < 10 c/uL |
|     | <i>Staphylococcus aureus</i>                  | < 10 c/uL |
|     | vanA, vancomycin resistant <i>Enterococci</i> | < 10 c/uL |
|     | vanB, vancomycin resistant <i>Enterococci</i> | < 10 c/uL |

Fig. 25A

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Hospital Acquired Infections Panel Inflection Times  
100cp/ul (min)

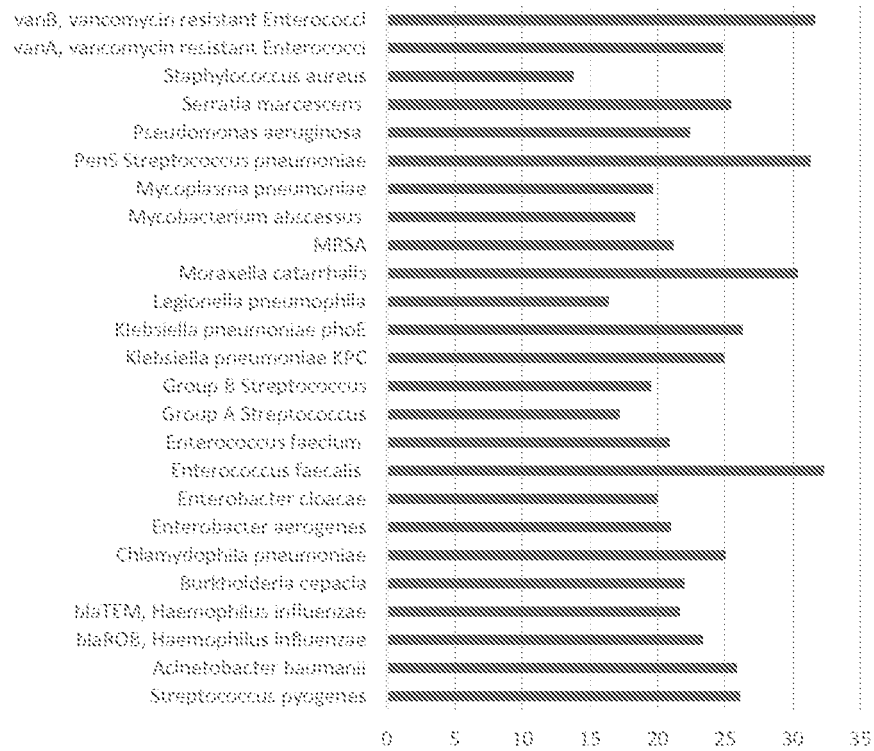
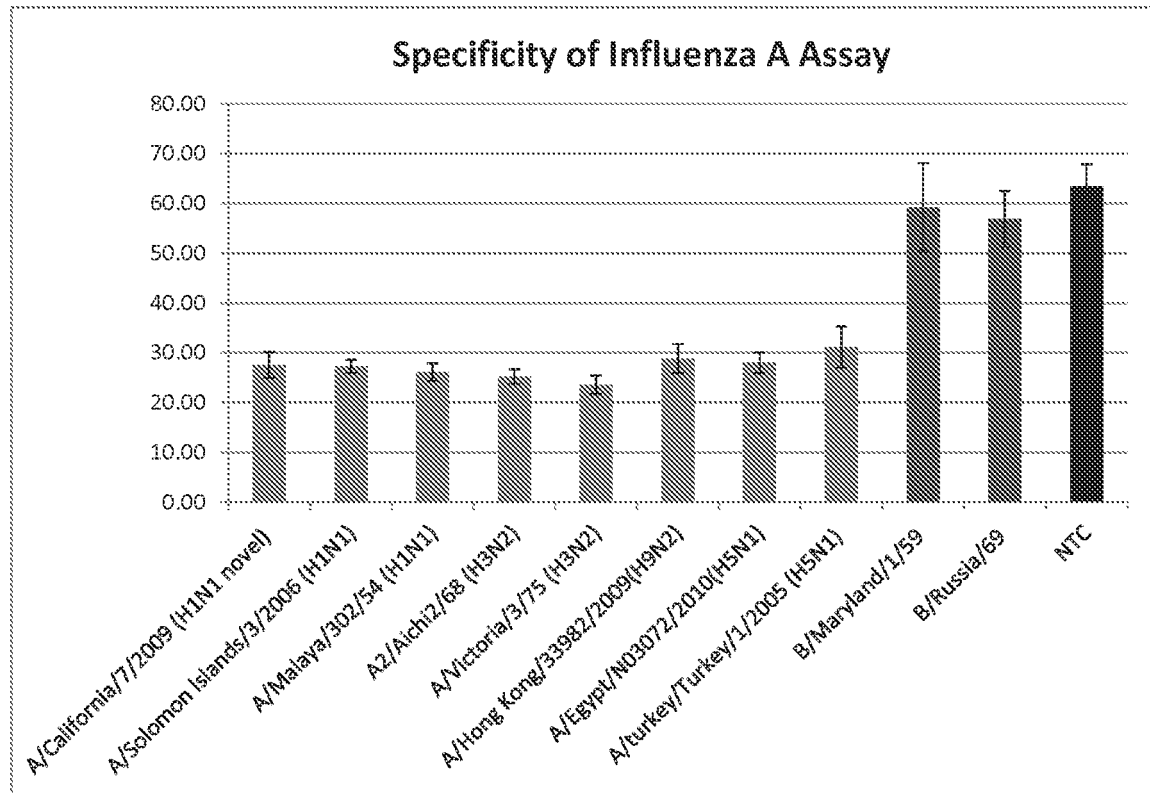


Fig. 25B

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Influenza A – Matrix Protein assay: designed to be inclusive for all Influenza A subtypes.

Fig. 26

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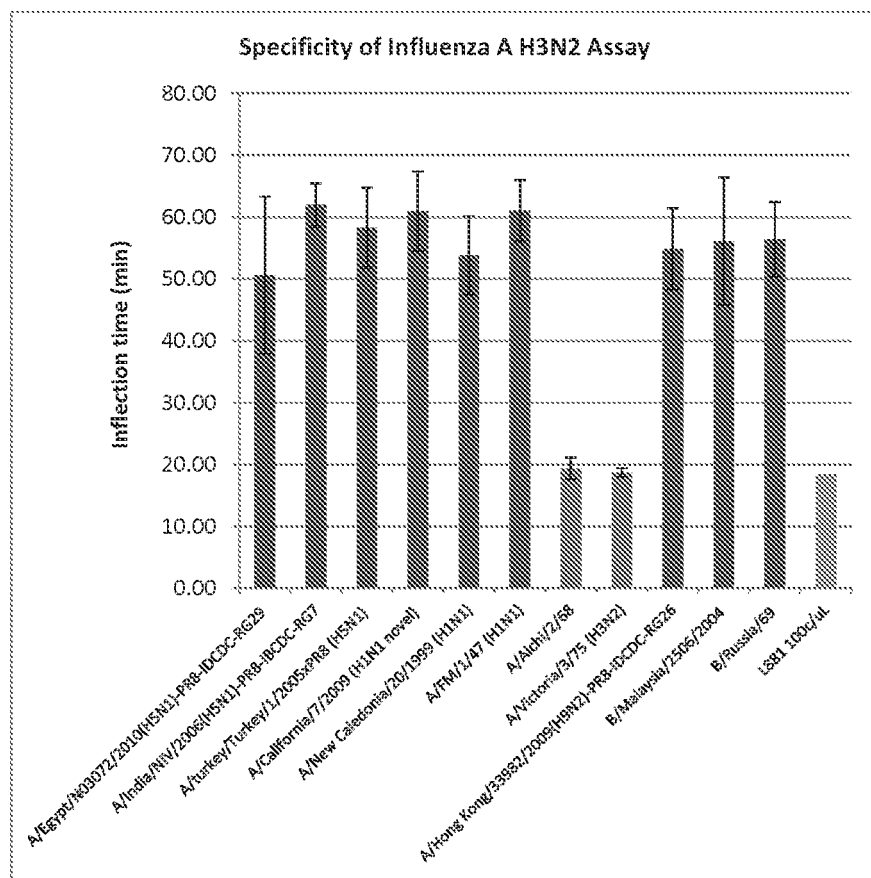


Fig. 27

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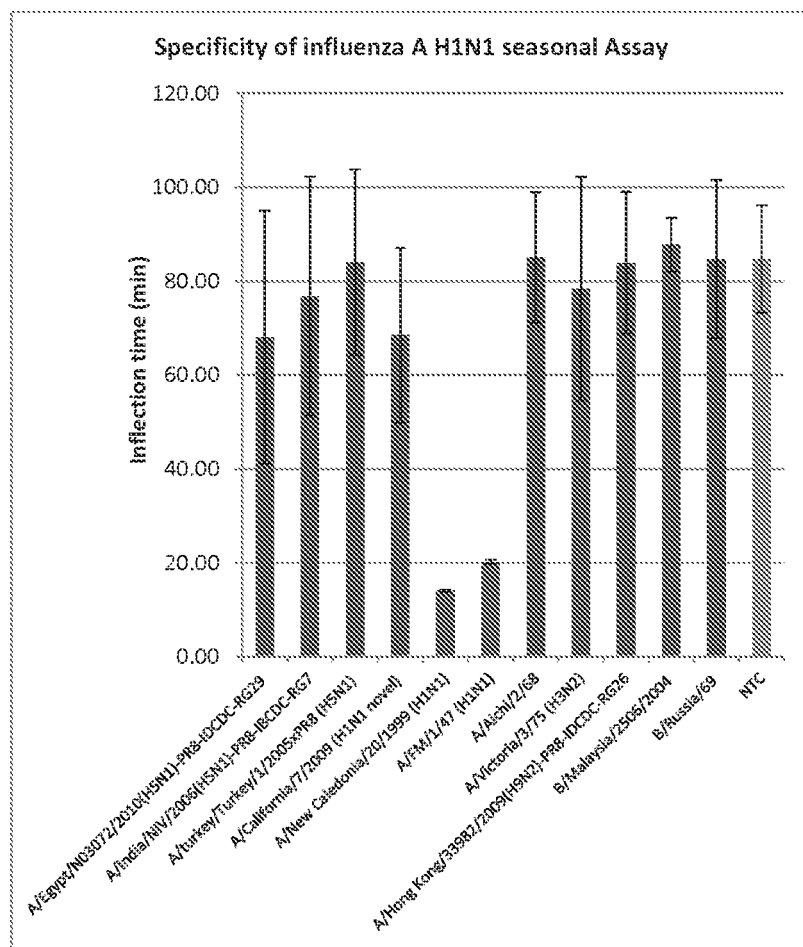


Fig. 28

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| STD Swab Interfering Substance Panel                |                  |                    |  |
|-----------------------------------------------------|------------------|--------------------|--|
| Substance                                           | 1x Concentration | 0.1x Concentration |  |
| 1 KY lubricant                                      | 2.5% w/v         | 0.25% w/v          |  |
| 2 Options Gynol II Contraceptive Jelly (spermicide) | 2.5% w/v         | 0.25% w/v          |  |
| 3 Vagisil feminine powder                           | 2.5% w/v         | 0.25% w/v          |  |
| 4 Preparation H hemorrhoid cream                    | 2.5% w/v         | 0.25% w/v          |  |
| 5 Monistat 3 (miconazole)                           | 2.5% w/v         | 0.25% w/v          |  |
| 6 hgDNA                                             | 200 ng/mL        | 20 ng/mL           |  |
| 7 Vagisil anti-itch cream                           | 2.5% w/v         | 0.25% w/v          |  |
| 8 Clotrimazole vaginal cream                        | 2.5% w/v         | 0.25% w/v          |  |
| 9 Universal transport media (viral)                 | 50% v/v          | 5% v/v             |  |
| 10 Amies transport media (bacteria)                 | 50% v/v          | 5% v/v             |  |
| 11 DNA/RNA Shield                                   | 50% v/v          | 5% v/v             |  |
| 12 blood                                            | 10% v/v          | 1% v/v             |  |
| 13 mucin                                            | 2.5% w/v         | 0.25% w/v          |  |
| 14 acyclovir                                        | 0.125% w/v       | 0.013% w/v         |  |
| 15 Abreva cold sore treatment                       | 2.5% w/v         | 0.025% w/v         |  |
| 16 urine                                            | 50% v/v          | 5% v/v             |  |
| 17 feces (1 swab diluted in 1.2 mL)                 | 50% v/v          | 5% v/v             |  |

### Potential Interfering Substances – STD Swab Panel

Fig. 29

| STD Urine Interfering Substance Panel                   |                      |                         |  |
|---------------------------------------------------------|----------------------|-------------------------|--|
| Substance                                               | 1x Concentration     | 0.1x Concentration      |  |
| 1 BSA                                                   | 120 g/L              | 12 g/L                  |  |
| 2 glucose                                               | 10 mg/mL             | 1 mg/mL                 |  |
| 3 bilirubin                                             | 40 mg/dL             | 4 mg/dL                 |  |
| 4 nitrites                                              | 1354 µmol/L          | 135.4 µmol/L            |  |
| 5 beta-hCG                                              | 300,000 mIU/mL       | 30,000 mIU/mL           |  |
| 6 acetone                                               | 12 mmol/L            | 1.2 mmol/L              |  |
| 7 low pH urine (pH 4.0)                                 | 50% v/v              | 5% v/v                  |  |
| 8 high pH urine (pH 9.0)                                | 50% v/v              | 5% v/v                  |  |
| 9 acetaminophen                                         | 1.95 mg/mL           | 0.195 mg/mL             |  |
| 10 aspirin                                              | 0.652 mg/mL          | 0.065 mg/mL             |  |
| 11 Bactrim                                              | 308 µM               | 30.8 µM                 |  |
| 12 progestin + ethinyl estradiol                        | 7 mg/mL + 0.07 mg/mL | 0.7 mg/mL + 0.007 mg/mL |  |
| 13 Abbott Multi-collect urine specimen transport buffer | 50%                  | 5%                      |  |
| 14 Gen-Probe Aptima urine specimen transport media      | 50%                  | 5%                      |  |
| 15 Norgen Biotek urine preservative                     | 15%                  | 1.5%                    |  |
| 16 seminal fluid                                        | 5% v/v               | 0.5% v/v                |  |

### Potential Interfering Substances – STD Urine Panel

Fig. 30

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| Blood Interfering Substance Panel |                                             |                                   |                                    |
|-----------------------------------|---------------------------------------------|-----------------------------------|------------------------------------|
|                                   | Substance                                   | 1x Concentration                  | 0.1x Concentration                 |
| 1                                 | hemoglobin                                  | 5 g/L                             | 0.5 g/L                            |
| 2                                 | triglycerides                               | 1430 mg/dL                        | 143 mg/dL                          |
| 3                                 | BSA                                         | 120 g/L                           | 12 g/L                             |
| 4                                 | EDTA, pH 8.0 (anticoagulant)                | 10 mg/mL                          | 1 mg/mL                            |
| 5                                 | heparin sodium salt (anticoagulant)         | 106 U/mL                          | 10.6 U/mL                          |
| 6                                 | cholesterol                                 | 13 mmol/L                         | 1.3 mmol/L                         |
| 7                                 | $\gamma$ -globulin                          | 60 g/L                            | 6 g/L                              |
| 8                                 | universal transfer media (viral)            | 50% v/v                           | 5% v/v                             |
| 9                                 | Amies transfer media (bacteria)             | 50% v/v                           | 5% v/v                             |
| 10                                | BACTEC™ Plus Anaerobic/F Medium             | 50% v/v                           | 5% v/v                             |
| 11                                | BACTEC™ Standard/10 Aerobic/F Medium        | 50% v/v                           | 5% v/v                             |
| 12                                | bilirubin                                   | 684 $\mu$ mol/L                   | 68.4 $\mu$ mol/L                   |
| 13                                | hgDNA                                       | 200 ng/mL                         | 20 ng/mL                           |
| 14                                | ampicillin sodium salt                      | 152 $\mu$ mol/L                   | 15.2 $\mu$ mol/L                   |
| 15                                | Bactrim (1:5 trimethoprim:sulfamethoxazole) | 308 $\mu$ mol/L                   | 30.8 $\mu$ mol/L                   |
| 16                                | azithromycin                                | 1.38 mg/mL                        | 0.138 mg/mL                        |
| 17                                | nicotine/cotinine                           | 6.2 $\mu$ mol/L; 10.8 $\mu$ mol/L | 0.62 $\mu$ mol/L; 1.08 $\mu$ mol/L |
| 18                                | DNA/RNA shield                              | 50% v/v                           | 5% v/v                             |

Potential Interfering Substances - Blood Panel

Fig. 31