

Claims

1. A method for concentrating and purifying at least one target analyte from a clinical biological sample, comprising the steps of
 - (a) combining the clinical biological sample with a first aqueous two-phase system (ATPS) composition comprising a polymer, a salt component comprising at least one salt, a surfactant, or any combination thereof dissolved in an aqueous solution to form a target-rich phase solution and a target-poor phase solution, such that the target analyte is concentrated in the target-rich phase;
 - (b) collecting the target-rich phase;
 - (c) contacting the target rich phase from step (b) with a solid phase medium configured to selectively bind the target analyte such that the solid phase medium binds to the target analyte; and
 - (d) eluting and collecting the target analyte from the solid phase medium with an eluting solution, resulting in a final solution containing the concentrated and purified target analyte.
2. The method of claim 1, after the step (b), further comprising the step of:
 - (e) adding the target-rich phase to a second ATPS composition comprising a polymer, a salt component comprising at least one salt, a surfactant, or any combination thereof dissolved in an aqueous solution to form a second target-rich phase solution and a second target-poor phase solution, such that the target analyte is concentrated in the second target-rich phase, and collecting the second target-rich phase; andwherein the step (c) further comprising the step of:
 - contacting the target rich phase from the second target-rich phase from step (e) with a solid phase medium configured to selectively bind the target analyte such that the solid phase medium binds to the target analyte.
3. The method of claim 2, further comprising the step of:
 - (f) mixing the target-rich phase from step (b) or the second target-rich phase from step (e) with a binding buffer to form a mixed solution; andwherein the step (c) further comprising the step of:
 - contacting the mixed solution from the step (f) with a solid phase medium configured to selectively bind the target analyte such that the solid phase medium binds to the target analyte.

4. The method of claim 1, further comprising the step of washing the solid phase medium with one or more appropriate solvents to remove impurities after step (c) and before step (d).
5. The method of claim 1, further comprising the step of treating the clinical biological sample with a lysing composition before step (a).
6. The method of claim 1, wherein the binding buffer comprises a chaotropic agent comprising an anion selected from the group consisting of thiocyanate, isothiocyanate, perchlorate, acetate, trichloroacetate, trifluoroacetate, chloride, and iodide.
7. The method of claim 1, wherein the binding buffer comprises a 2M to 7M solution of a chaotropic agent selected from the group consisting of guanidinium hydrochloride (GHCl), guanidinium thiocyanate, guanidinium isothiocyanate (GITC)), sodium thiocyanate, sodium iodide, sodium perchlorate, sodium trichloroacetate, sodium trifluoroacetate, lithium perchlorate, lithium acetate, magnesium chloride, phenol, 2-propanol, thiourea, and urea; wherein the binding buffer further comprises a polymer at a concentration of 5-20% (w/v).
8. The method of claim 1, wherein the clinical biological sample is blood, plasma, or urine.
9. The method of claim 1, wherein the target analyte is a nucleic acid, and the nucleic acid is gDNA, cDNA, plasmid DNA, mitochondrial DNA, cell-free DNA (cfDNA), circulating tumor DNA (ctDNA), circulating fetal DNA, cell-free fetal DNA, cell-free microbial DNA, micro RNA (miRNA), messenger RNA (mRNA), transfer RNA (tRNA), ribosomal RNA (rRNA), circular RNA, long non-coding RNA (lncRNA) or combinations thereof.
10. The method of claim 1, wherein step (c) comprises the following steps:
 - (i) contacting a portion of the mixed solution with the solid phase medium such that the target analyte binds to the solid phase medium to form a solid phase extraction complex;
 - (ii) perturbing the solid phase extraction complex and discarding the flow-through; and
 - (iii) optionally repeating steps (i) and (ii).
11. The method of claim 1, wherein the solid phase medium is a plurality of beads, wherein the beads are selected from the group consisting of magnetic beads, silica-based beads, carboxyl beads, hydroxyl beads, and amine-coated beads; the solid phase extraction complex is a beads-analyte complex; perturbing is spinning; and the flowthrough is the supernatant.

12. The method of claim 11, wherein
 - the target analyte is a nucleic acid less than a target size;
 - the plurality of beads binds to the target analyte and to other nucleic acids;
 the eluting solution is a fractionation buffer that, when contacted with the beads during the elution step (d), causes the target analyte to be released while not releasing the other nucleic acids, resulting in a final solution containing the concentrated and purified target analyte(s); wherein the fractionation buffer comprises a polymer, a chaotropic agent, or any combination thereof.
13. The method of claim 1, wherein the solid phase medium is an extraction column, wherein the extraction column is a spin column.
14. The method of claim 13, wherein step (c) comprises the following steps:
 - (i) loading a portion of the mixed solution from step (f) onto the extraction column;
 - (ii) centrifuging the extraction column and discarding the flow-through; and
 - (iii) optionally repeating steps (i) and (ii) above one or more times, until all of the mixed solution has been passed through the extraction column.
15. The method of claim 1, wherein the salt comprises a cation selected from the group consisting of sodium, potassium, calcium, ammonium, lithium, magnesium, aluminium, cesium, barium, straight or branched trimethyl ammonium, triethyl ammonium, tripropyl ammonium, tributyl ammonium, tetramethyl ammonium, tetraethyl ammonium, tetrapropyl ammonium and tetrabutyl ammonium; and an anion selected from the group consisting of phosphate, hydrogen phosphate, dihydrogen phosphate, sulfate, sulfide, sulfite, hydrogen sulfate, carbonate, hydrogen carbonate, acetate, nitrate, nitrite, sulfite, chloride, fluoride, chlorate, perchlorate, chlorite, hypochlorite, bromide, bromate, hypobromite, iodide, iodate, cyanate, thiocyanate, isothiocyanate, oxalate, formate, chromate, dichromate, permanganate, polyacrylate, hydroxide, hydride, citrate, borate, and tris.
16. The method of claim 1, wherein the polymer is selected from the group consisting of polyethers, polyimines, polyacrylates, polyalkylene glycol, vinyl polymer, alkoxylated surfactant, polysaccharides, alkoxylated starch, alkoxylated cellulose, alkyl hydroxyalkyl cellulose, polyether-modified silicones, polyacrylamide, polyacrylic acid and one or more copolymers thereof.
17. The method of claim 1, wherein the polymer is selected from the group consisting of

dipropylene glycol, tripropylene glycol, polyethylene glycol, polypropylene glycol, poly(ethylene glycol-propylene glycol), poly(ethylene glycol-ran-propylene glycol), polyvinyl pyrrolidone, polyvinyl alcohol, polyvinyl caprolactam, polyvinyl methylether, dextran, carboxymethyl dextran, dextran sulfate, hydroxypropyl dextran, starch, carboxymethyl cellulose, polyacrylic acid, hydroxypropyl cellulose, methyl cellulose, ethylhydroxyethylcellulose, maltodextrin, polyethyleneimine, poly N-isopropylacrylamide and copolymers thereof.

18. The method of claim 1, wherein

the surfactant is selected from the group consisting of an anionic surfactant, a nonionic surfactant, a cationic surfactant, and an amphoteric surfactant;

wherein

the anionic surfactant is carboxylates, sulphonates, petroleum sulphonates, alkylbenzenesulphonates, naphthalenesulphonates, olefin sulphonates, alkyl sulphates, sulphates, sulphated natural oils, sulphated natural fats, sulphated esters, sulphated alkanolamides, sulphated alkylphenols, ethoxylated alkylphenols, or sodium N-lauroyl sarcosinate (NLS);

the nonionic surfactant is ethoxylated aliphatic alcohol, polyoxyethylene surfactants, carboxylic esters, polyethylene glycol esters, anhydrosorbitol ester, glycol esters of fatty acids, carboxylic amides, monoalkanolamine condensates, or polyoxyethylene fatty acid amides;

the cationic surfactant is quaternary ammonium salts, amines with amide linkages, polyoxyethylene alkyl amines, polyoxyethylene alicyclic amines, n,n,n',n' tetrakis substituted ethylenediamines, or 2- alkyl 1- hydroxethyl 2-imidazolines; and

the amphoteric surfactant is n-coco 3-aminopropionic acid or a sodium salt thereof, n-tallow 3 - iminodipropionate or a disodium salt thereof, n-carboxymethyl n dimethyl n-9 octadecenyl ammonium hydroxide, or n-cocoamidethyl n hydroxyethylglycine or a sodium salt thereof.

19. The method of claim 18, wherein the surfactant is Triton X-100, Triton X-114, Triton X-45, Tween 20, Igepal CA630, Brij 58, Brij O10, Brij L23, Pluronic L-61, Pluronic F-127, sodium dodecyl sulfate, sodium cholate, sodium deoxycholate, sodium N-lauroyl sarcosinate (NLS), Hexadecyltrimethylammonium bromide, or span 80.

20. The method of claim 1, wherein the polymer has an average molecular weight in the range of 200-1,000 Da, 200-35,000 Da, 300-35,000 Da, 400-2,000 Da, 400-35,000 Da, 2,500-2,500,000 Da, 1,250-4,000,000 Da, or 6,000-5,000,000 Da.

21. The method of claim 1, wherein the polymer of the first ATPS composition or the second ATPS

composition is dissolved in an aqueous solution at a concentration of 0.5-80% (w/v);
 the salt component of the first ATPS composition or the second ATPS composition is dissolved in an aqueous solution at a concentration of 0.1% to 80% (w/v); and
 the surfactant of the first ATPS composition or the second ATPS composition is dissolved in an aqueous solution at a concentration of 0.1%-90% (w/v).

22. The method of claim 1, wherein

the first ATPS composition or the second ATPS composition is a polymer-salt system;
 the polymer is dissolved in an aqueous solution at a concentration of 0.5-80% (w/v); and
 the salt component is dissolved in an aqueous solution at a concentration of 0.1%-80% (w/v).

23. The method of claim 22, wherein

the polymer of the first ATPS composition is dissolved in an aqueous solution at a concentration of 5-80% (w/v); and
 the salt component of the first ATPS composition is dissolved in an aqueous solution at a concentration of 0.1%-80% (w/v); and
 the polymer of the second ATPS composition is dissolved in an aqueous solution at a concentration of 0.5-30% (w/v); and
 the salt component of the second ATPS composition is dissolved in an aqueous solution at a concentration of 5%-60% (w/v);
 wherein the first ATPS composition or the second ATPS composition further comprises at least one salt at a concentration of 0.01%-10% (w/v), or at least one surfactant at a concentration of 0.01%-10% (w/v).

24. The method of claim 1, wherein the first ATPS composition or the second ATPS composition is a polymer-polymer system comprising at least two polymers, and each polymer is dissolved in an aqueous solution at a concentration of 0.2-50% (w/v).

25. The method of claim 24, wherein the first ATPS composition or the second ATPS composition further comprises at least one salt at a concentration of 0.01%-10% (w/v), or at least one surfactant at a concentration of 0.01%-10% (w/v);

wherein

the at least one salt comprises a cation selected from the group consisting of sodium, potassium, calcium, ammonium, lithium, magnesium, aluminium, cesium, barium, straight or branched trimethyl ammonium, triethyl ammonium, tripropyl ammonium, tributyl ammonium, tetramethyl ammonium, tetraethyl ammonium, tetrapropyl ammonium and tetrabutyl ammonium; and

the at least one surfactant is selected from the group consisting of an anionic surfactant, a nonionic surfactant, a cationic surfactant, and an amphoteric surfactant;

wherein

the anionic surfactant is carboxylates, sulphonates, petroleum sulphonates, alkylbenzenesulphonates, naphthalenesulphonates, olefin sulphonates, alkyl sulphates, sulphates, sulphated natural oils, sulphated natural fats, sulphated esters, sulphated alkanolamides, sulphated alkylphenols, ethoxylated alkylphenols, or sodium N-lauroyl sarcosinate (NLS);

the nonionic surfactant is ethoxylated aliphatic alcohol, polyoxyethylene surfactants, carboxylic esters, polyethylene glycol esters, anhydrosorbitol ester, glycol esters of fatty acids, carboxylic amides, monoalkanolamine condensates, or polyoxyethylene fatty acid amides;

the cationic surfactant is quaternary ammonium salts, amines with amide linkages, polyoxyethylene alkyl amines, polyoxyethylene alicyclic amines, n,n,n',n' tetrakis substituted ethylenediamines, or 2- alkyl 1- hydroxethyl 2-imidazolines; and

the amphoteric surfactant is n-coco 3-aminopropionic acid or a sodium salt thereof, n-tallow 3 -iminodipropionate or a disodium salt thereof, n-carboxymethyl n dimethyl n-9 octadecenyl ammonium hydroxide, or n-cocoamidethyl n hydroxyethylglycine or a sodium salt thereof.

26. The method of claim 1, wherein the first ATPS composition or the second ATPS composition is a micellar system comprising at least two surfactants, and each surfactant is dissolved in an aqueous solution at a concentration of 0.1%-90% (w/v).

27. The method of claim 26, wherein the first ATPS composition or the second ATPS composition further comprises at least one salt at a concentration of 0.01%-30% (w/v); wherein the at least one salt comprises a cation selected from the group consisting of sodium, potassium, calcium, ammonium, lithium, magnesium, aluminium, cesium, barium, straight or branched trimethyl ammonium, triethyl ammonium, tripropyl ammonium, tributyl ammonium, tetramethyl ammonium, tetraethyl ammonium, tetrapropyl ammonium and tetrabutyl ammonium.

28. The method of claim 1, wherein the first ATPS composition and/or the second ATPS composition are selected from 3-18% PEG 6000, 1-6% dextran 450-650 kDa, and 5-50mM $\text{Na}_2\text{HPO}_4/\text{NaH}_2\text{PO}_4$; 1-9% PEG 6000 and 17-25% dextran 2,200,000 Da; 9-18% PEG 6000 and 9-17% dextran 2,200,000 Da; 18-25% PEG 6000 and 0.5-9% dextran 2,200,000 Da; 1-9% PEG

6000 and 20-30% dextran 460,000 Da; 9-18% PEG 6000 and 9-20% dextran 460,000 Da; 18-25% PEG 6000 and 0.5-9% dextran 460,000 Da; 1-9% PEG 6000 and 17-25% dextran 179,000 Da; 9-18% PEG 6000 and 9-17% dextran 179,000 Da; 18-25% PEG 6000 and 0.5-9% dextran 179,000 Da; 1-9% PEG 8000 and 17-25% dextran 70,000 Da; 9-18% PEG 8000 and 9-17% dextran 70,000 Da; 18-25% PEG 8000 and 0.5-9% dextran 70,000 Da; 1-16% PEG 6000 and 33-50% dextran 3,400 Da; 16-33% PEG 6000 and 16-33% dextran 3,400 Da; 33-50% PEG 6000 and 1-16% dextran 3,400 Da; 1-16% PEG 4000 and 33-50% dextran 3,400 Da; 16-33% PEG 4000 and 16-33% dextran 3,400 Da; 33-50% PEG 4000 and 1-16% dextran 3,400 Da; 1-5% PEG 20000 and 20-30% dextran 500,000 Da; 6-11% PEG 20000 and 9-20% dextran 500,000 Da; 11-15% PEG 20000 and 0.5-9% dextran 500,000 Da; 1-7% PEG 8000 and 20-30% dextran 500,000 Da; 7-14% PEG 8000 and 9-20% dextran 500,000 Da; 14-20% PEG 8000 and 0.5-9% dextran 500,000 Da; 2-16% PEG 3400 and 20-30% dextran 500,000 Da; 16-33% PEG 3400 and 9-20% dextran 500,000 Da; 33-50% PEG 3400 and 0.5-9% dextran 500,000 Da; 0.1-7% methylcellulose and 14-20% dextran 2,200,000 Da; 7-14% methylcellulose and 7-14% dextran 2,200,000 Da; 14-20% methylcellulose and 0.1-7% dextran 2,200,000 Da; 0.5-16% PolyViol 28/20 and 33-50% dextran 2,200,000 Da; 16-33% PolyViol 28/20 and 16-33% dextran 2,200,000 Da; 33-50% PolyViol 28/20 and 0.5-16% dextran 2,200,000 Da; 4-21% PEG 600 and 58-70% PPG 400; 21-42% PEG 600 and 36-58% PPG 400; 42-60% PEG 600 and 4-36% PPG 400; 0.5-7% hydroxypropyl dextran 70 and 14-20% dextran 2,200,000 Da; 7-14% hydroxypropyl dextran 70 and 7-14% dextran 2,200,000 Da; 14-20% hydroxypropyl dextran 70 and 0.5-7% dextran 2,200,000 Da; 0.5-7% PEG 8000 and 20-30% hydroxypropyl starch 60-70 kDa; 7-14% PEG 8000 and 10-20% hydroxypropyl starch 60-70 kDa; 14-20% PEG 8000 and 1-10% hydroxypropyl starch 60-70 kDa; 10-20% Triton X-100; 20-30% Triton X-100; 30-40% Triton X-100; 5-18% Triton X-114; 18-29% Triton X-114; 29-40% Triton X-114; 60-90% Triton X-114 and 5-17% Triton X-45; 3-19% C10E4 (decyl tetraethylene glycol ether); 19-34% C10E4 (decyl tetraethylene glycol ether); 34-50% C10E4 (decyl tetraethylene glycol ether); 1-10% Pluronic F68 and 14-20% potassium phosphate; 10-20% Pluronic F68 and 7-14% potassium phosphate; 20-30% Pluronic F68 and 1-7% potassium phosphate; 5-21% Pluronic 17R4 and 7-10% potassium phosphate; 21-42% Pluronic 17R4 and 3-7% potassium phosphate; 42-60% Pluronic 17R4 and 1-3% potassium phosphate; 2-21% Pluronic L-35 and 14-20% sodium sulfate; 21-42% Pluronic L-35 and 7-14% sodium sulfate; 42-60% Pluronic L-35 and 1-7% sodium sulfate; 8-18% PEG 600, 7-20% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 8-30% PEG 600, 1-6% K_2HPO_4 , and 12-20% KH_2PO_4 ; 8-25% PEG 200, 40-50% K_2HPO_4 , and 4-16% KH_2PO_4 ; 8-18% PEG 600, 7-20% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 6-18% PEG 600, 2-12% K_2HPO_4 , 0.1-5% KH_2PO_4 , and 0.01-10% (v/v) Triton X-114; 6-18% PEG 600, 2-12% K_2HPO_4 , and 0.1-5%

KH_2PO_4 ; 5-20% PEG 600, 0.1-6% K_2HPO_4 , and 6-18% KH_2PO_4 ; 5-20% PEG 600, 2-12% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 5-17% PEG 200, 3-12% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 5-17% PEG 200, 0.1-4% K_2HPO_4 , and 5-16% KH_2PO_4 ; 5-15% PEG 200, 3-13% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 5-15% PEG 200, 0.1-4% K_2HPO_4 , and 6-20% KH_2PO_4 ; 36-60% PPG 425, 0.1-5% K_2HPO_4 , and 0.1-3% KH_2PO_4 ; 40-60% PPG 425, 0.1-4% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 40-50% PPG 425, 0.1-4% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 36-60% PPG 425, 0.1-3% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 3-20% PEG 200, 10-30% K_2HPO_4 , and 1-9% KH_2PO_4 ; 3-13% PEG 200, 3-12% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 3-13% PEG 200, 1-4% K_2HPO_4 , and 5-20% KH_2PO_4 ; 3-13% PEG 200, 13-20% K_2HPO_4 , and 1-7% KH_2PO_4 ; 3-13% PEG 200, 0.1-12% K_2HPO_4 , and 16-36% KH_2PO_4 ; 3-12% PEG 200, 2-8% K_2HPO_4 , and 20-40% KH_2PO_4 ; 3-12% PEG 200, 10-30% K_2HPO_4 , and 1-7% KH_2PO_4 ; 30-50% PEG-ran-PPG, 0.1-5% K_2HPO_4 , and 0.1-3% KH_2PO_4 ; 2-9% PEG 200, 8-20% K_2HPO_4 , and 1-7% KH_2PO_4 ; 2-9% PEG 200, 5-20% K_2HPO_4 , and 0.1-4% KH_2PO_4 ; 2-9% PEG 200, 2-8% K_2HPO_4 , and 20-40% KH_2PO_4 ; 2-9% PEG 200, 2-8% K_2HPO_4 , and 16-36% KH_2PO_4 ; 2-9% PEG 200, 1-8% K_2HPO_4 , and 20-40% KH_2PO_4 ; 2-9% PEG 200, 1-7% K_2HPO_4 , and 8-32% KH_2PO_4 ; 2-9% PEG 200, 10-30% K_2HPO_4 , and 1-7% KH_2PO_4 ; 2-8% PEG 200, 4-13% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 2-8% PEG 200, 1-5% K_2HPO_4 , and 6-20% KH_2PO_4 ; 2-12% PEG 200, 5-20% Na_2SO_4 , 0.01-0.1M Na_2HPO_4 , and 0.01-0.1M NaH_2PO_4 ; 20-40% PEG 600, 2-12% K_2HPO_4 , and 0.1-5% KH_2PO_4 ; 20-40% PEG 600, 0.1-4% K_2HPO_4 , and 2-9% KH_2PO_4 ; 20-40% PEG 1000, 1-12% K_2HPO_4 , and 0.1-3% KH_2PO_4 ; 20-40% PEG 1000, 0.1-4% K_2HPO_4 , and 3-12% KH_2PO_4 ; 20-40% PEG 1000, 0.1-4% K_2HPO_4 , and 2-9% KH_2PO_4 ; 16-36% PEG 600, 2-12% Na_2SO_4 , 0.01-0.1M Na_2HPO_4 , and 0.01-0.1M NaH_2PO_4 ; 1-6% PEG 200, 3-12% K_2HPO_4 , and 25-50% KH_2PO_4 ; 1-6% PEG 200, 0.1-5% K_2HPO_4 , and 6-36% KH_2PO_4 ; 1-6% PEG 200, 0.1-5% K_2HPO_4 , and 5-20% KH_2PO_4 ; 11-33% PEG 3000, 0.1-6% K_2HPO_4 , and 0.1-3% KH_2PO_4 ; 11-33% PEG 3000, 0.1-4% K_2HPO_4 , and 1-8% KH_2PO_4 ; 10-32% PEG-ran-PPG, 0.1-4% citric acid, and 3-12% sodium citrate; 10-32% PEG-ran-PPG, 0.1-4% citric acid, and 2-9% sodium citrate; 10-32% PEG-ran-PPG, 0.1-3% citric acid, and 1-6% sodium citrate; 10-32% PEG-ran-PPG, 0.1-3% citric acid, and 0.1-4% sodium citrate; 10-32% PEG 8000, 0.1-6% K_2HPO_4 , and 0.1-3% KH_2PO_4 ; 10-32% PEG 8000, 0.1-4% K_2HPO_4 , and 2-8% KH_2PO_4 ; 10-32% PEG 8000, 0.1-4% K_2HPO_4 , and 0.1-9% KH_2PO_4 ; 10-30% PEG-ran-PPG, 0.1-4% K_2HPO_4 , and 0.1-6% KH_2PO_4 ; 10-30% PEG-ran-PPG, 0.1-3% K_2HPO_4 , and 2-8% KH_2PO_4 ; 10-25% polyvinyl pyrrolidone 3,500 Da and 15-20% potassium phosphate; 25-35% polyvinyl pyrrolidone 3,500 Da and 10-15% potassium phosphate; 35-50% polyvinyl pyrrolidone 3,500 Da and 5-10% potassium phosphate; 2-12% PEG 600, 35-50% sodium phosphate; 12-18% PEG 600, 20-35% sodium phosphate; 18-25% PEG 600, 10-20% sodium phosphate; 5-20% polyvinyl pyrrolidone 10,000 Da and 30-40%

sodium citrate; 20-35% polyvinyl pyrrolidone 10,000 Da and 20-30% sodium citrate; 35-50% polyvinyl pyrrolidone 10,000 Da and 10-20% sodium citrate; 2-10% PEG 300 and 49-60% sodium citrate; 10-18% PEG 300 and 37-49% sodium citrate; 18-25% PEG 300 and 20-37% sodium citrate; 10-35% PPG 425 and 14-20% sodium sulfate; 35-50% PPG 425 and 8-14% sodium sulfate; 55-70% PPG 425 and 3-8% sodium sulfate; 5-16% PPG 425 and 11-15% sodium polyacrylate 240,000; 16-24% PPG 425 and 5-11% sodium polyacrylate 240,000; 24-40% PPG 425 and 0.5-5% sodium polyacrylate 240,000; 4-12% PEG 8000 and 21-30% sodium carbonate; 12-21% PEG 8000 and 11-21% sodium carbonate; 21-30% PEG 8000 and 3-11% sodium carbonate; 1-5% PEG 8000 and 14-20% sodium polyacrylate 16,000; 6-11% PEG 8000 and 7-14% sodium polyacrylate 16,000; 11-15% PEG 8000 and 2-7% sodium polyacrylate 16,000; 10-25% polyvinyl alcohol 3,500 Da and 7-10% potassium phosphate; 25-35% polyvinyl alcohol 3,500 Da and 4-7% potassium phosphate; 35-50% polyvinyl alcohol 3,500 Da and 2-4% potassium phosphate; 2-5% PEG 400 and 34-50% potassium phosphate; 6-11% PEG 400 and 22-34% potassium phosphate; 11-15% PEG 400 and 10-22% potassium phosphate; 4-12% polyvinyl alcohol 8,000 Da and 21-30% sodium citrate; 12-21% polyvinyl alcohol 8,000 Da and 11-21% sodium citrate; 21-30% polyvinyl alcohol 8,000 Da and 3-11% sodium citrate; 1-5% PPG 425 and 20-30% sodium citrate; 6-11% PPG 425 and 9-20% sodium citrate; 11-15% PPG 425 and 0.5-9% sodium citrate; 2-12% polyvinyl alcohol 20,000 Da and 21-30% sodium sulfate; 12-21% polyvinyl alcohol 20,000 Da and 11-21% sodium sulfate; 21-30% polyvinyl alcohol 20,000 Da and 3-11% sodium sulfate; 0.5-18% PEG-ran-PPG 12,000 Da and 14-20% sodium sulfate; 18-35% PEG-ran-PPG 12,000 Da and 7-14% sodium sulfate; and 35-50% PEG-ran-PPG 12,000 Da and 2-7% sodium sulfate.

29. A kit comprising

a first ATPS composition;

a second ATPS composition;

a binding buffer; and

a solid phase medium; wherein

the first ATPS composition comprises a polymer, a salt component comprising at least one salt, a surfactant, or any combination thereof;

the second ATPS composition comprises a polymer, a salt component comprising at least one salt, a surfactant, or any combination thereof;

the binding buffer comprises a chaotropic agent; and

the solid phase medium is a plurality of beads or an extraction column.

30. Use of the kit of claim 29 in the manufacture of a diagnostic kit for the diagnosis of cancer or infectious disease in a patient in need thereof.

31. The use of claim 30, wherein the cancer is CNS cancer, breast cancer, bladder cancer, pancreatic cancer, lung cancer, melanomas, colon cancer, hematopoietic cancer or ovarian cancer and wherein the infectious disease is HPV.

32. The use of claim 30, wherein

the target analyte for the diagnosis of cancer is transrenal cfDNA or ctDNA, and the cancer is systemic cancer;

the target analyte for the diagnosis of cancer is urogenital cfDNA or ctDNA, and the cancer is urogenital cancer;

the target analyte for the diagnosis of cancer is bladder cancer DNA and the cancer is bladder cancer; or

the target analyte for the diagnosis of infectious disease is HPV viral RNA or HPV viral DNA, and the infectious disease is HPV.