

CLAIMS

What is claimed is:

1. An isolated antibody that specifically binds to tenofovir, wherein the antibody comprises:
 - (1) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 17, 25, and 33, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 18, 26, and 34, respectively;
 - (2) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 19, 27, and 35, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 20, 28, 36, respectively;
 - (3) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 21, 29, and 37, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 22, 30, 38, respectively; or
 - (4) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 23, 31, and 39, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 24, 32, and 40, respectively.
2. The isolated antibody of claim 1, wherein the antibody comprises an immunoglobulin variable light chain region comprising an amino acid sequence of SEQ ID NO: 41 and an immunoglobulin variable heavy chain region comprising an amino acid sequence of SEQ ID NO: 42.
3. An isolated nucleic acid molecule encoding the antibody of claim 1, wherein the isolated nucleic acid is selected from the group consisting of a cloning vector, an expression vector, a heterologous recombination vector and a viral integration vector.
4. A cell transformed with the isolated nucleic acid of claim 3, wherein the cell is selected from the group consisting of rabbit, hamster, mouse, rat, chicken, goat, monkey, sheep, pig, horse, cow, and human.
5. A method of detecting tenofovir in a biological fluid sample of a subject, comprising contacting the antibody of claim 1 with a biological fluid sample from the subject.

6. A method for performing a lateral flow assay to detect tenofovir in a fluid sample, the method comprising the steps of:
- (a) applying the fluid sample to a sample pad;
 - (b) allowing the sample to flow laterally along the sample pad to a conjugated label pad that is in fluid communication with the sample pad and comprises a labeled first reagent specific for tenofovir, wherein a portion of the conjugated label pad and a portion of the sample pad forms a first interface;
 - (c) allowing the labeled first reagent to bind tenofovir, if present in the fluid sample, to form a labeled first reagent-tenofovir complex;
 - (d) allowing the sample to flow laterally along the conjugated label pad to a membrane that is in fluid communication with the conjugated label pad, wherein a portion of the conjugated label pad and a portion of the membrane forms a second interface, wherein the membrane comprises a second reagent bound to the membrane to form a test line, and wherein the second reagent can bind the labeled first reagent;
 - (e) allowing the labeled first reagent to bind to the second reagent to form a labeled first reagent-second reagent complex at the test line; and
 - (f) detecting the label at the test line,
- wherein the first reagent is an antibody comprising:
- (1) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 17, 25, and 33, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 18, 26, and 34, respectively;
 - (2) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 19, 27, and 35, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 20, 28, 36, respectively;
 - (3) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 21, 29, and 37, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 22, 30, 38, respectively; or
 - (4) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 23, 31, and 39, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 24, 32, and 40, respectively.

7. The method of claim 6, wherein the membrane is nitrocellulose.
8. The method of claim 6, wherein the membrane further comprises a third reagent bound to the membrane downstream or upstream of the test line to form a control line.
9. The method of claim 8, wherein the third reagent binds to the labeled first reagent to cause the label to form a detectable signal at the control line, wherein the presence of the detectable signal at the control line indicates proper performance of the lateral-flow assay.
10. The method of claim 6, comprising the steps of:
 - (a) applying the fluid sample to a sample pad;
 - (b) allowing the sample to flow laterally along the sample pad to a conjugated label pad that is in fluid communication with the sample pad and comprises a labeled first reagent specific for tenofovir, wherein a portion of the conjugated label pad and a portion of the sample pad forms a first interface;
 - (c) allowing the labeled first reagent to bind tenofovir, if present in the fluid sample, to form a labeled first reagent-tenofovir complex;
 - (d) allowing the sample to flow laterally along the conjugated label pad to a membrane that is in fluid communication with the conjugated label pad, wherein a portion of the conjugated label pad and a portion of the membrane forms a second interface, wherein the membrane comprises a second reagent bound to the membrane to form a test line, and wherein the second reagent is can bind the labeled first reagent when the labeled first reagent is not bound to tenofovir in the fluid sample; and
 - (e) if tenofovir is absent in the fluid sample, allowing the labeled first reagent to bind to the second reagent to form a labeled first reagent-second reagent complex at the test line, or if tenofovir is present in the fluid sample, allowing the labeled first reagent-tenofovir complex to flow past the test line without binding the second reagent; and
 - (f) detecting the labeled first reagent-second reagent at the test line, wherein detecting the detectable signal indicates the absence of tenofovir in the fluid sample.

11. The method of claim 6, wherein the fluid sample is a urine sample from a patient, wherein the patient is prescribed or administered tenofovir or a prodrug thereof.
12. The method of claim 6, wherein the antibody comprises immunoglobulin variable light chain CDRs according to SEQ ID NOs: 23, 31, 39, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 24, 32, 40, respectively.
13. The method of claim 12, wherein the antibody comprises an immunoglobulin variable light chain region according to SEQ ID NO: 41 and an immunoglobulin variable heavy chain region according to SEQ ID NO: 42.
14. A device for performing a lateral flow assay to detect tenofovir in a fluid sample, the device comprising:
- (a) a sample pad for receiving the fluid sample;
 - (b) a conjugated label pad located downstream of the sample pad comprising a labeled first reagent specific for tenofovir, wherein a portion of the conjugated label pad and a portion of the sample pad form a first interface;
 - (c) a membrane located downstream of the conjugated label pad, wherein a portion of the membrane and a portion of the conjugated label pad form a second interface; and
 - (d) a second reagent bound to the membrane to form a test line, wherein the second reagent is capable of binding the labeled first reagent,
- wherein the first interface allows the fluid sample to flow from the sample pad to the conjugated label pad and contact the labeled first reagent, and the second interface allows the fluid sample to flow from the conjugated label pad to the membrane and to contact the second reagent to form a labeled first reagent-second reagent complex and cause the label to form a detectable signal at the test line,
- wherein the first reagent is an antibody comprising:
- (1) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 17, 25, and 33, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 18, 26, and 34, respectively;

(2) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 19, 27, and 35, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 20, 28, 36, respectively;

(3) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 21, 29, and 37, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 22, 30, 38, respectively; or

(4) immunoglobulin variable light chain CDRs according to SEQ ID NOs: 23, 31, and 39, respectively, and immunoglobulin variable heavy chain CDRs according to SEQ ID NOs: 24, 32, and 40, respectively.

15. The device of claim 14, wherein the membrane is nitrocellulose.

16. The device of claim 14, wherein the membrane further comprises a third reagent bound to the membrane downstream or upstream of the test line to form a control line.

17. The device of claim 16, wherein the third reagent binds to the labeled first reagent to cause a detectable signal at the control line, wherein the presence of the detectable signal at the control line indicates proper performance of the lateral-flow assay.

18. A kit, comprising:

- (a) a sample collection receptacle for receiving a biological sample; and
- (b) the device of claim 14 for assaying the biological sample.