1. Can the test be performed by the patient themselves?
No, the test is to be performed and results interpreted by healthcare professionals only.

Blood sampling

2. How can I optimize capillary blood flow?
Pinch fingertip and/or put it into warm water for a few minutes before blood sampling. Press the lancet firmly at one side of the fingertip. Make sure the hand is below the heart level during blood flow. If possible, the blood donor may drink an adequate volume of water several hours prior the blood draw.

3. How can I optimize blood uptake with the blood-sampling capillary?
Place the blood-sampling capillary in a horizontal position to the bottom of the drops of blood to avoid uptake of air bubbles into the capillary. Do not press the capillary against the skin. Make sure the tip of the capillary is just touching the top of the blood bubble. Do not press the plunger or shut the airhole at the end of the capillary.

4. The blood flow from the fingertip stopped too early. What can I do?
Massage the finger, squeeze the finger tip for a moment and let the blood flow. You may use any other lancet available, use venous blood or order a new lancet.

5. The lancet is already unlocked. Can I still use it?
No, don't use an unlocked lancet because the sterility of the lancet cannot be guaranteed anymore.

6. I removed the protective cap of the lancet without unlocking it first by twisting. Can I still use it?
No, don't use a lancet without properly twisting the protective cap. The lancet will be damaged irreparably. Please dispose off the damaged lancet in a secure way.

7. Can I reuse the lancet?
No, the lancets are for single use only. Once triggered, the lancet cannot be triggered twice.

8. The tip of the blood-sampling capillary is agglutinated with blood, preventing further blood uptake using this capillary. What do I have to do?
You may use another method to add 50 µl of blood to the test (e.g. a lab pipette) or order a new capillary.

9. The blood-sampling capillary is not filled until the white marker in the capillary. Is the blood volume still adequate for performing the NutriSMART test?
No, you need a blood volume of 50 µl to perform the test.

10. Can I use a blood volume of more than 50 µl for the test?
No, you need a blood volume of exactly 50 µl to perform the test. The blood sampling capillary can collect exactly the necessary amount of blood.

11. Can I use a plasma or serum volume of more or less than 20 µl for the test?
No, you need a plasma or serum volume of exactly 20 µl to perform the test. Measuring should be performed with a lab pipette.
An increased plasma or serum volume (i.e. 100 µl or 200 µl) will increase the sensitivity of the test but also decrease the specificity of the test.

12. Can I keep the blood within the capillary for long-term storage?
No, we recommend storing the blood mixed with the DILUT (sample dilutor) at 2-8 °C for up to 72 hours. If untreated blood is used (i.e. without adding whole blood to DILUT) then the tests results will not be valid.

13. Can I reuse the blood-sampling capillary?
No, the blood-sampling capillaries are for single use only.

14. The blood has coagulated. Can I still use the blood?
No, coagulated blood may block and/or precipitate inside the NutriSMART assay device.

Test procedure

15. The test kit was frozen upon arrival because the temperature during the transport was below 0 °C. Do I have to pay attention to anything?
Yes, please wait 4 days prior to perform the first test and store the test kit at 2-8 °C in the meanwhile.

16. Can I store the test kit below 0 °C?
No, storage temperature is 2-8 °C.

17. Is it important to carry out the test at room temperature?
We suggest all test components to be adjusted to room temperature prior to use the test, i.e. at least 18 °C. However, valid test results are also obtained when the test is performed immediately after taking the test kit out of the fridge.

18. The test can be performed with 50 µl blood or 20 µl plasma/serum. Do I have to remove 30 µl DILUT (dilute solution) when I am working with blood?
No, for both (blood as well as plasma/serum) you need to use the entire volume of the DILUT.

19. Do I have to use the entire volume of reagent that is inside the reagent vials?
Yes, you have to use the entire volume of each vial in the corresponding step of the test assay.

20. I have large air bubbles inside the syringe. How can I remove them?
Hold the syringe with the inlet upwards. Then, move the stamp of the syringe downwards and repeatedly move the stamp up and down carefully. Minor air bubbles have no negative effects on the test results.

21. How fast do I have to press down the stamp of the syringe during injection of the test solutions?
Average time is about one to two seconds but you may also press down the stamp faster or slower. It is advisable to press down the stamp in one fluid motion.

22. None of the reagents can be filled into the device properly because of back pressure. What can I do?
Make sure that the four very little ventilation holes at the top of the backside of the device are free. Make sure to place the device on a hard surface.

23. Do I have to remove the syringe out of the fluid port (inlet) during the incubation steps?
It does not matter whether you leave the syringe in the fluid port (inlet) or remove it during the incubation steps. Also, you may fill the syringe with the next solution and insert it in the fluid port (without injection of the solution until the end of the incubation step).

24. The injected solution soaks a little out of the fluid port (inlet). Does this influence the test results?
No, little soaking of the fluid port does not influence the test results. Take care to firmly insert the syringe into the fluid port (inlet).

25. The blood sample mix does not cover the whole area of the membrane inside the assay device. Can I correct this?
No, do not try to manipulate the test procedure and continue to perform the test as described. If the test membrane is soaked with the blood sample mix, the test results will be valid. As this is a microfluidics based device, at times although one does not see the blood sample on the top of the window, the membrane could come in contact with the sample from the bottom. Hence, just continue to follow the steps, do not try to manipulate.

26. There are air bubbles inside the assay device. Can I correct this?
No, do not try to manipulate the test procedure and continue to perform the test as described.

27. Some small air bubbles are within the assay device, can I still read out the test?
Small air bubbles don't have a negative effect on the performance of the test. However, this should be avoided by making sure, that no air is trapped in the syringe when injecting the different liquids.

28. Do large air bubbles within the assay device influence the test results?
After performing the test, the control band in each test field enable the user to decide the impact of the air bubbles on each test result. If the control band in a test field is acceptable for proper test reading, the test result of the appropriate food will be valid. Failing this, the appropriate test result may not be valid.

29. The color from the first WASH (washing solution) becomes red in the syringe caused by the remaining blood of the first injection step. Does this influence the test results and should I use a new syringe?
No, this is a general phenomenon of the test procedure and does not influence the test. Use one syringe for all reagents that need to be inserted into the test.

30. Does the WASH need an incubation time?
No, an incubation time for the WASH is not needed but also has no negative effect.

31. Is there any difference between the three WASH vials?
No, the three WASH vials have the same content.

32. Is there any difference between the two COLR (color reagent) vials?
No, the two COLR vials have the same content.

33. Do I have to protect the COLR from light?
Yes, do not remove the COLR out of the brown vials until the end of the last WASH step. There is no need for light protection during the COLR incubation step and during the read out of the test.

34. I injected the COLR from the second vial after more than 30 sec after the COLR from the first vial. Does this influence the test results?
After performing the test, the control band in each test field allows to decide the impact of this delayed injection on each test result. If the control band in a test field is acceptable for proper test reading, the test result of the appropriate food will be valid. Failing this, the appropriate test result may not be valid.

35. Can I reuse the syringe after performing the test? It looks quite clean.
No, do not reuse the syringe for another test.

36. I feel there is not enough liquid in the DILUT for diluting the blood sample and/or to fill all windows in the device?
The amount of liquid in the DILUT has been optimized for the test and has enough volume, when mixed with blood or serum/plasma, for test peformance. The volume of the diluted sample is sufficient to cover all the windows. Make sure there are no air bubbles while injecting the sample.

37. Can I leave the COLR incubation step longer to get better colour bands?.
Yes, extending the COLR incubation for two or three more minutes than the suggested 5 minutes usually does not affect the test results. But, this sometimes may result in darker background colour on the membrane. It is left to the discretion of the user to decide if he/she wants to leave the COLR reagent incubation a bit longer before injecting the STOP. We do not prefer the user to deviate from the suggested incubation times.

Test result reading

38. What do you mean by "proper light conditions"?
For proper reading of the test results we recommend at least typical office lighting, i.e. about 500 lux. Better light conditions will improve your ability to properly read the test.

39. The backgrounds of the 20 test fields have different absolute intensities. Does this influence the test results?
No, local effects may influence the local background of the test fields. This is why each food band has to be compared only with the standard band in that particular window.

40. The standard band of the 20 test fields has different absolute intensities. Does this influence the test results?
No, local effects may influence the absolute intensities of the bands. This is why each food band has to be compared only with the standard band in that particular window

41. Some band signals are interrupted. Why did that happen?
Interrupted band signals are most probably caused by insertion of large air bubbles during the incubation steps of one of reagents. If the control band in a test field is acceptable for proper test reading, the test result of the appropriate food will be valid. Failing this, the appropriate test result may not be valid.

42. Some food bands are blurred. Are these real signals?
Yes, foods may have different textures that may result in different appearances of the colour bands. The test results are still valid.

43. Some food bands are wider than others. Is this a normal phenomenon?
Yes, food may have different characteristics that may result in different appearances of the bands. The test results are still valid.

44. How do I distinguish between the NutriSMART levels?
Please look at the instruction for use for distinguishing the NutriSMART levels. Note: Do not pay attention to the absolute intensity of the food bands, but on the relative intensity, i.e. compare the intensity of the food band with the intensity of the control band in each test field.

45. The background of the test fields and the absolute intensities of the bands differ according to the sample that was used. Does this influence the test results?
No, different samples have different effects on background and absolute intensities of band signals. This is a frequently observed phenomenon.

46. Some hours after performing the test, little air bubbles emerge inside the test device. How can I still read out the test?
We suggest that all tests should be read immediately after the test performance. However, if little air bubbles inside the test device prevent proper reading of the test, you may inject air inside the assay device using the syringe. Do not inject air prior to the formation of air bubbles to prevent test solution leakage from the test cassette. Please take care to use gloves while injection of air since test solution leakage may occur from the four ventilation holes at the top of the backside of the device. Injection of air does not influence the correct interpretation of the test results.

47. Why do I have to store the assay device in the dark after performing the test?
In case you want to read the test results at a later time after test performance, you need to store the assay device in the dark because the COLR has to be protected from light. Storage in the light decreases the signal intensities. Test results can usually be read upto 12 hours if the device is stored in dark. However, we suggest all tests to be read immediately after the test performance.

48. I don't see any standard bands, what does that mean?
Make sure that you have identified the standard band in each test field. When the fluid port is located to the left, the standard bands are the utmost left bands in each test field. If you still don't see bands, the test has not worked, the likely cause is that either no blood was injected or one of the following steps was not performed: injecting Ab1G4 (the first antibody), injecting Ab2 (the second antibody), injecting COLR.

49. What do I do if I have a high reactivity against some of the foods?
It is important for those affected to know quickly what triggers their symptoms and begin the treatment immediately. Different strategies can be used. To do this, consult your physician.

50. Would the test results be different if read by different users?
Usually, there is not much difference in the test results when read by different users as the colour of the food bands is always compared to the colour of the standard band in that particular window.

51. The colour of the bands from one patient to another is different, is this common (e.g darker bands or weaker bands)?
The test results are always obtained by comparing the colour of the food band with the standard band in that particular window. Hence, the difference in the colour of the bands from one test to another does not influence the test results nor does it indicate any problems with regard to the performance of the test.

52. Is it possible to take a photo of the test results after test performance for reading the results later?
Yes, this is possible if the photo is taken in proper light conditions and the device and the test has been labelled properly to identify the patient. Make sure there are no shadows in the photo or on the device. We prefer test results to be interpreted immediately after the test performance.