Guide for use of the simple antigen test kits in schools for foreign students

International Affairs Division, Minister's Secretariat Ministry of Education, Culture, Sports, Science and Technology

Novel Coronavirus Response Headquarters Ministry of Health, Labour and Welfare

In order to guarantee children the right to continuous education amid the impact of COVID-19 at facilities aimed at exclusively educating children of foreign nationals (hereinafter referred to as "schools for foreign students"), the Ministry of Education, Culture, Sports, Science and Technology (MEXT) has repeatedly provided the information necessary to continue operating the schools with reducing the risk of infection and its spread in schools as far as possible.

In terms of the measures against infection, as well as the basic measures against infectious disease, we have been publicizing the specific points to note through such publications as the "COVID-19 Infection Control Manuals and Guidelines for schools" (hereinafter referred to as "Infection Control Manuals") such as avoiding the 3Cs where the risk of infection is high, thorough measures against infectious diseases such as keeping a physical distance, and implementing preventive measures against infectious diseases for each specific setting of activities, but prompt detection and responses are also required in the unlikely event of an infected person being in school.

From this perspective, the government will be <u>distributing simple antigen test kits</u> (hereinafter referred to as the "kits") that will easily and quickly confirm the presence or <u>absence of infection (test result time of about 15 to 20 minutes) free of charge</u> to schools for foreign students that wish to use them, and moreover, have the right conditions in place for use of the kits.

One feature of the <u>antigen tests</u> performed using the kits is that <u>the results can be obtained</u> <u>quickly on the spot, especially when used on a person exhibiting symptoms</u>. For this reason, <u>each school for foreign students</u> that receives the kits is asked to consider how they will be used depending on the characteristics of the kits and the actual situation of the particular schools for foreign students such as <u>keeping the kits at a facility such as a health management center</u>, and testing students, faculty members and office staff (hereinafter referred to as "students, etc.") who complain of feeling ill with initial symptoms of COVID-19 (such as a cough, sore throat or fever) after arriving at the school.

An additional point is that it is also possible to consider using the kits to test, for example, students living in dormitories and students participating in extracurricular activities such as club activities (especially students participating in off-campus tournaments, athletic meets,

presentations, etc.) who exhibit such symptoms as a cough or sore throat. (Even if the test result is negative, this does not mean that you will be able to continue taking part in extracurricular activities, and you will need to undergo a diagnosis by a medical institution or wait at home (described later).)

In addition, the health management of students, etc is also important from the viewpoint of early detection of potential infections at schools. MEXT gives advice in the Infection Control Manuals so that the health condition of the students can be monitored when they arrive at school through use of such guides as the "Health Observation Chart". The government knows that each school is already implementing its own health condition observations, and will introduce an app to centrally monitor and manage the health status of the students in due course, so please consider using it if necessary.

This Guide outlines the procedures and points to note for early detection of students who have COVID using the kits as well as responses and is to be used as reference by the schools for foreign students, etc. Therefore, when using the kit, please use it in an appropriate manner paying close attention to the contents given below. However, the kits distributed this time are one of the products manufactured by three companies, and the specific storage method, usage method, etc. differ depending on the product. Therefore, please be sure to carefully read the instruction manual for each product enclosed in the kit pack.

In addition, this Guide basically envisages a situation in schools for foreign students where doctors, etc. are not stationed full-time, and shows the testing method when a student, etc. is to perform the test on himself or herself under the supervision of a staff member. If it is possible for a doctor or other healthcare professional to perform the test, please have the test carried out by such doctor or healthcare professional in order to ensure greater accuracy in the test.

In addition, as mentioned above, students with symptoms such as a fever should first be asked to rest at home without going to the schools for foreign students. Therefore, please note that the distribution of the kits is not intended to supersede this instruction, and it is assumed that the kits will be used to deal with any changes in the physical health condition of the student, etc. after he or she has come to the school. Please make sure that students with symptoms of a cold such as a fever do not go to the school for the purpose of undergoing a test using the kit.

Furthermore, the use of kits in a school for foreign students is not a substitute for a medical examination. In order not to delay a diagnosis due to the use of the antigen kit, please make sure that, in principle, the student, etc. undergoes a medical examination at times when he or she is not feeling well.

(1) About the kits (product specifications and points to note concerning storage and use)

When managing and using the kits, please pay attention to the following points and use them in the correct way.

Specific product specifications and management methods

- The kits distributed free of charge by the government have been approved by the Minister of Health, Labour and Welfare under the Pharmaceutical Affairs Act, and we plan to send one of the products from the following three companies (please note that you will not be able to select a specific product).

	Name of company	Product name	Size / weight
1	Fujirebio Inc.	Espline SARS-CoV-2	Length 75 x Width 210 x Depth 160 mm 240g, 10 tests
2	Denka Company Limited	Quick Navi-COVID19 Ag	Length 80 x Width 197 x Depth 97 mm 250g, 10 tests
3	TAUNS Laboratories, INC.	Imunoace SARS-CoV-2	Length 69 x Width 242 x Depth 88 mm 202g, 10 tests
		Capilia SARS-CoV-2	Length 110 x Width 256 x Depth 255 mm 1,057g, 60 tests

- One pack contains either 10 tests or 60 tests. The kits can be stored at room temperature (between 2 and 30 $^{\circ}$ C), but please handle them properly by storing them in a cool and dark place, bearing in mind hot summer temperatures. If it has been kept in a refrigerator, it is necessary to return it to room temperature before use.
- -The expiration date is about 12 months although this depends on the type of product. Please check the date on the outer box of each product for the actual expiration date of the kits distributed this time round.
- -In addition to the instruction manual for each product, please familiarize yourself with the contents of the educational materials (details will be announced later) that are scheduled to be posted on the website of the Ministry of Health, Labour and Welfare (MHLW) by studying them in advance.
- If there are any unused kits left over (particularly if the kits have reached their expiration date), they can basically be disposed of as general waste.
- For specific disposal procedures of the kits used for the test, please refer to the section on

disposal precautions in the instruction manual of each product and, if necessary, check with the waste collection company.

Notes on use

- The kits are to be used to perform antigen tests, and when it is used on persons who are asymptomatic, it may be less sensitive than the nucleic acid detection test (PCR test). Therefore, it is not recommended to use the kits as a definitive diagnosis for a person who is asymptomatic or for testing a person who has been deemed a close contact.
- Situations where the kits can be used effectively at schools for foreign students. are, for example, envisaged to be when it is discovered that a student, etc. started to exhibit symptoms seen as the initial symptoms of COVID-19 (cough, sore throat, fever or other symptoms*) after he or she arrived at the schools and it is necessary to promptly confirm the presence or absence of infection in such a symptomatic person on schools. Each school for foreign students is asked to make effective use of the kits, bearing the above in mind and consulting with the school doctor or an affiliated medical institution.
- * In addition, symptom such as headache, arthralgia and diarrhea, and the cases where there is only one of those symptoms (cases where there are no multiple symptoms), are also considered to be applicable symptoms.

(2) Implementing the tests

When conducting a test using the kit, it is necessary to pay attention to proper handling, to prepare the environment necessary for appropriate testing, including cooperation with related parties inside and outside the school, and to give a careful explanation to the students and their parents or guardians about the nature of the test and the responses based on the results in order to gain their understanding.

The specific test implementation methods, etc. have been organized as follows, and we ask for the understanding and support of those who will be involved in the testing.

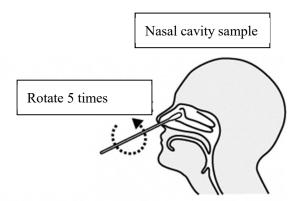
<Development of the test implementation structure>

- It is necessary to collaborate with the school doctor or a local medical institution in case that there is no school doctor in the schools for foreign students to decide in advance the procedures before and after the test. At that time, please make arrangements for the method of contacting the person who was tested after the test and the flow of a medical examination and medical treatment after that.
- When performing the test, it is necessary to have a teacher or office staff member such as a nursing teacher or a school nurse present at the test and for subsequent responses. It is important to divide the roles in advance so that one specific teacher or office staff member is not overburdened.

- It is necessary to fully explain the purpose, nature, method, etc. of the test to the students and parents or guardians in advance and obtain the consent of the parents or guardians. Please refer to Supplementary Materials 2 for an image of the explanatory material for parents and guardians. In addition, the test should be carried out at the request of the student or their parents or guardians, so please be careful not to force the taking of the test.
- Please decide in advance where the test will be performed, taking into consideration the prevention of infection to other students and the privacy of students who complain that they are feeling ill.

<Sample collection method>

- If there is a student, etc. who complains of feeling ill after arriving at school, please confirm whether or not the person wishes to undergo a test and then perform the test at the discretion of the school principal.
- There are two methods when testing with the kit. One is to collect a nasal cavity sample and the other is to collect a nasopharyngeal sample. Since the nasopharyngeal sample needs to be collected by a doctor, or a nurse or clinical laboratory engineer under the instructions of a doctor, the test at the school for foreign students should use the nasal cavity sample collected by the student himself / herself.
- * There are two methods described in the instruction manual for each product, but **be sure to** check the method for collecting the nasal cavity sample.
- In the case of a nasal cavity sample, the student, etc. can collect the sample himself or herself in the presence of a person other than the student, etc. being tested. It is preferable that the person who is present is a healthcare professional such as a doctor or nurse, but if it is difficult for a healthcare professional to be present, the test can be conducted in the presence of a teacher or office staff member of the schools for foreign students. The person who is present is requested to check the contents of this Guide, the educational materials (details will be announced later) and the instruction manual for each product regarding the testing method using the kit.
- The person who is present for the self-collection of the nasal cavity sample is requested to take such protective measures as being separated from the student, etc. being tested by such means as a glass barrier or acrylic plate, or to maintain a sufficient distance, and to wear a non-woven mask or surgical mask and gloves.



Nasal cavity

Insert the cotton swab about 2 cm into the nose, rotate it 5 times, and keep it in the nasal cavity for about 5 seconds (self-collection is possible).

<Steps after collecting the sample>

- After collecting the sample, immerse the cotton swab in the liquid contained in the provided container, pinch the cotton ball part from the outside of the container, and rotate it several times to extract the collected sample from the cotton ball part. After extracting it, pinch the cotton ball part from the top of the container and pull out the cotton swab so as to squeeze the liquid from the cotton ball to use as a sample. After that, attach the provided filter to the container containing the sample, drop the sample on the part where the liquid is to be dropped of the provided device, and let it stand for a set period of time (15 to 30 minutes depending on the product).
- Details vary depending on the product, so be sure to check the instruction manual for the product before use.
- As a general rule, the above steps should be performed by the student himself or herself under the guidance of a teacher or office staff member who understands this Guide and the instruction manual for the product.

(3) About the test results (judging the results and subsequent responses)

- With regard to judging the test results and subsequent responses based on the results, please pay attention to the following items and try to prevent the spread of infection. In addition, please <u>explain to the student</u>, etc. being tested in advance the following measures to be taken based on the test results.

Reading the test results

- The result of the test using the kit is displayed through the presence or absence of a vertical line on the outer surface of the kit. For further details, please check the instruction manual of each product before use.
- Please be sure to check the result of the test using the kit by the teacher or office staff member understanding this Guide and the instruction manual of the product beforehand, not by the students themselves.
- * A doctor's judgment is required to make a definitive diagnosis of whether the student, etc. has COVID-19 based on the kit's test result. Please contact the school doctor or a doctor at an affiliated medical institution about the kit's test result and ask for cooperation in advance so that the doctor is able to make the diagnosis.

If the test result is positive

- If the test result is positive, please be sure to encourage the student, etc. to undergo a medical examination at a medical institution. If the doctor at a medical institution performs a medical examination and diagnoses the student, etc. with COVID-19, the medical institution will notify the Public Health Center.
- Students who have been diagnosed with COVID-19 should follow the instructions from the Public Health Center for medical treatment and hospitalization.
- A student who is found to be positive should return home to convalesce until diagnosed as non-infectious by a doctor and the symptoms have dissipated.
- The Public Health Center that receives the notification from the doctor will take necessary measures such as responding to the student, etc. and identifying close contacts. <u>If the Public Health Center requests cooperation from the schools for foreign students, please respond according to the contents of their request.</u>

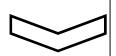
If the test result is negative

- Even if the test using the kit gives a negative result, the result may be a false negative and the student may have COVID-19, especially when the amount of virus in the sample is small, so it is necessary to continue taking infection prevention measures.
- The student, etc. who was tested should promptly return home and receive medical treatment, and take measures to prevent the spread of infection such as waiting at home until seeing a doctor at a medical institution or until the symptoms have dissipated, considering the cases that the result of the test may be a false negative.

■ Flow chart of kit use by schools for foreign students

(1) Receipt of the Guide and confirmation of requests

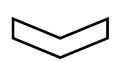
- You will receive the Guide prepared by MHLW and MEXT. At that time, we will confirm whether you wish to use the kits and whether there is a structure in place enabling implementation of the tests, and you will be asked to respond to the enclosed questionnaire.



- There is a structure in place for performing the tests (school doctor, or in the absence of a school doctor, a system has been established in which teachers and other staff attend the examination in collaboration with local medical institutions).

(2) Preparations for receipt, storage and use of the kits

- Each school should establish a structure and environment to enable the tests to be performed in collaboration with the school doctor and, if there is no school doctor, a local medical institution.
- When keeping the kits in the nurse's office or school infirmary, they should be stored and managed appropriately, and the flow of responses with the school, medical institution, and the Public Health Center with jurisdiction should be organized so that the school will be able to respond promptly should the need arises.
- The school should explain the purpose and method of the test kits to the students and their parents or guardians, and obtain the consent of the parents or guardians in advance of any student who wishes to be tested should the need arise.

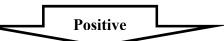


- There is a structure in place for performing the tests (The presence of a healthcare professional is recommended for the test, but a structure has been established where the test may be carried out in the presence of a teacher or office staff member in collaboration with the school doctor or a local medical institution if there is no school doctor.).
- A response flow inside and outside the schools for foreign students have been organized.

(3) Tests using the kits

- If a person who feels ill requests to be tested, the school principal decides whether or not the test should be carried out and the test should be carried out in accordance with the Guide.
- (* The presence of a healthcare professional is recommended for the test, but the test may still be carried out as long as a structure has been established where the test may be carried out in the presence of a teacher or office staff member in collaboration with the school doctor or a local medical institution if there is no school doctor.)

(4) Response for a positive result



(4a) Response for a positive result

- Promptly contact school doctors, medical institutions, etc., and introduce a medical institution that is able to make a definitive diagnosis.
- If the student, etc. is diagnosed to have COVID as a result of a definitive diagnosis, the medical institution will notify the Public Health Center.
- -The school informs the results to their parents or guardians.

Negative

(4b) Response for a negative result

- -Since there is the possibility of a false negative, encourage the student, etc. to go home and seek medical treatment.
- -Take measures to prevent the spread of infection on account of the possibility of a false negative, such as having the student, etc. wait at home until receipt of a diagnosis from a medical institution or until the symptoms have dissipated.
- -The school informs the results to their parents or guardians.

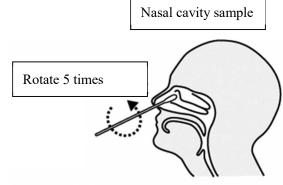
Example (image) of dissemination and publicizing to their parents or guardians of information about tests using the kits

Implementation of tests using the simple antigen test kits

In order to ensure the safety of students, teachers and office staff and to prevent the spread of COVID-19, a decision has been made by the school to carry out tests using the antigen test kits.

This test allows the presence or absence of infection to be quickly confirmed with a simple test if you start to feel ill while at schools.

* Tests are only envisaged for cases where the student starts to feel ill after arriving at school. If the student has symptoms of a cold such as a fever, please ensure that the student rests at home without coming to school.



Please read this and discuss it with your child before submitting a consent form if you wish your child to be tested should the need arises.

Details

Persons eligible to take the test

Students, teachers and office staff of the schools for foreign students who start to feel ill (cough, sore throat, fever, etc.*) with what may be the initial symptoms of COVID-19 after arriving at the school.

* In addition, symptom such as headache, arthralgia and diarrhea, and the case where there is only one of those symptoms (cases where there are no multiple symptoms), are also considered. However, testing using the kits is not suitable if you are asymptomatic.

Test location

- The test uses a nasal cavity sample.
- The nasal cavity sample is taken by inserting a cotton swab about 2 cm into the nose, rotating it 5 times, and keeping it in the nasal cavity for about 5 seconds, and is performed by the student himself or herself.

Consent form

I have confirmed the purpose, testing method, points to note, etc. of the simple antigen test kit.

I agree that my child may be tested if feeling ill.

Month Day, 2021

Name of student:

Name of parent/guardian:

(Image of the test)

- 1) The school checks the consent form to confirm that the parent or guardian has given consent for the test.
- * If consent has not been given by the parent or guardian, the test cannot be carried out even if the student himself/herself requests for it to be carried out. If the student wishes to have a test when feeling ill, ensure that the consent form has been submitted in advance.
- 2) Upon the request of students who feel ill, the school conduct the test for them.
- 3)-1 If the test result is positive
- If a doctor at a medical institution performs a medical examination and the student is diagnosed with COVID-19, the medical institution will notify the Public Health Center.
- Students who have been diagnosed with COVID-19 should follow the instructions from the Public Health Center for medical treatment and hospitalization. A student who is found to be positive should return home to convalesce until diagnosed as non-infectious by a doctor and the symptoms have dissipated.

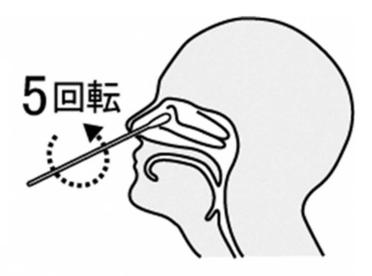
3)-2 If the test result is negative

- Since there is the possibility of a false negative, the student should return home and undergo a medical examination by a medical institution where possible, and wait at home until the symptoms have dissipated.

(Points to remember, etc.)

- * Please note that parents or guardians may be asked to come and pick up their child depending on the child's physical condition and situation
- *There is no charge for the test.

■ Image of the explanation to students on how to collect samples when using the kits



- (1) Insert the cotton swab included in the kit slowly about 2 cm from the entrance of the nasal cavity, rubbing the mucous membrane.
- (2) After inserting the cotton swab, rotate it slowly about 5 times.
- (3) Leave the cotton swab in the nose for about 5 seconds, ensure that the cotton ball is moistened sufficiently, and then gently pull it out so that the tip does not touch other parts.
- (4) Put the cotton swab sample in the designated container.