

## 2019-nCoV Ag Rapid Test Kit (Immunochromatography)

Catalog Number:  
0685C2X001 (1 Test/Kit) 0685C2X005 (5 Tests/Kit) 0685C2X025 (25 Tests/Kit)

### INTENDED USE

This kit is used for the in vitro qualitative detection of 2019-nCoV antigen. It is an immunochromatography sandwich assay, and intended to detect 2019-nCoV N-protein antigen in human nasal (NS) swab specimens. This kit can be used for individuals with or without symptoms or other epidemiological exposures to suspect COVID-19 infection.

A positive result indicates the presence of the target antigen and contact a doctor. A PCR confirmation test is necessary.

A negative result should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Confirm with a PCR test, if

In vitro use only. Suitable for self-testing use.

### SUMMARY AND EXPLANATION

The novel coronavirus belongs to the β genus, COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source.

Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. Common symptoms include fever, dry cough, Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

### PRINCIPLE OF THE TEST

This kit uses double antibody sandwich to rapidly detect the antigen of novel coronavirus (2019-nCoV). The sample is collected from the nasal cavity, and the anti-nCoV monoclonal antibody in the labeling pad binds to the 2019-nCoV antigen in the sample to form a complex. This complex reacts with the anti-nCoV monoclonal antibody labeled under the action of chromatography. It is captured by the anti-nCoV monoclonal antibody pre-coated in the Test area (T) on the Nitrocellulose membrane. Finally a red color reaction line is formed in the Test area (T). Regardless of whether the sample to be tested contains 2019-nCoV antigen, a red reaction line will always form in the quality control area (C), if the test has been performed properly.

### MATERIALS AND COMPONENTS

Materials provided with the test kits

REF	0685C2X001	0685C2X005	0685C2X025
Pouch/test cassette and desiccant	1	5	25
Swab	1	5	25

1  
2  
3  
4  
5  
6  
7  
8  
9

Tube with buffer	1	5	25
Instructions for use	1	1	1
Quick reference instructions	NA	1	1
Workstation	NA	NA	1

### Sample processing:

- Open the cap of the tube.
- Immmerge the swab tip with the sample into the buffer tube and rotate the swab tip at least 10 times in the buffer liquid while applying pressure with your fingers.
- Remove the swab tip and use the sides of the tube to extract the liquid with the sample from the swab.
- Break off the tip of the cap, the sample solution in the tube is ready for test.

5.

6.

7.

8.

9.

10.

11.

12.

13.

14.

15.

16.

17.

18.

19.

20.

21.

22.

23.

24.

25.

26.

27.

28.

29.

30.

31.

32.

33.

34.

35.

36.

37.

38.

39.

40.

41.

42.

43.

44.

45.

46.

47.

48.

49.

50.

51.

52.

53.

54.

55.

56.

57.

58.

59.

60.

61.

62.

63.

64.

65.

66.

67.

68.

69.

70.

71.

72.

73.

74.

75.

76.

77.

78.

79.

80.

81.

82.

83.

84.

85.

86.

87.

88.

89.

90.

91.

92.

93.

94.

95.

96.

97.

98.

99.

100.

101.

102.

103.

104.

105.

106.

107.

108.

109.

110.

111.

112.

113.

114.

115.

116.

117.

118.

119.

120.

121.

122.

123.

124.

125.

126.

127.

128.

129.

130.

131.

132.

133.

134.

135.

136.

137.

138.

139.

140.

141.

142.

143.

144.

145.

146.

147.

148.

149.

150.

151.

152.

153.

154.

155.

156.

157.

