

Inspection Report for 2019-nCoV Diagnostic Kits

543516-02 V00

Inspection Report No: B-7-2019-nCoV - 1-2020115

Product Name	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Packing volume	48 tests/kit
Quantity of each batch	14947 kits	Lot Number	2020115
Inspection Request Sheet No	99wb120200827-01	Expiry Date	08/25/2021 (month/date/year)
Sampling Date	08/27/2020 (month/date/year)	Report Date	08/27/2020 (month/date/year)
Inspection standard	313061 Quality Standard for 2019-nCoV Diagnostic Kit		
Inspection Items	Quality Standard	Test Results	
Visual inspection	Outer packaging box should be intact with clear labels for product name, batch number and shelf life. Tubes inside the box should be intact with clear labels. Product manual inside the box should be clear and complete. When reagents are fully thawed, all solutions should be limpid with no precipitate or suspension.	☒ Qualified ☐ Unqualified	
Quality control test	1. positive control should be tested positive.FAM/ROX/CY5 channel with a Ct value ≤ 35 . 2. Negative control should be tested repeatedly 8 times.The Ct values for 8 times negative control of FAM/ROX/CY5 should not be displayed, or Ct >40.	☒ Qualified ☐ Unqualified	
Consistency rate of positive results	Positive references should be tested positive with a consistency rate of 100% (10/10).	☒ Qualified ☐ Unqualified	
Consistency rate of negative results	Negative references should be tested negative with a consistency rate of 100% (15/15).	☒ Qualified ☐ Unqualified	
Precision	Precision references R1 and R2 should be tested repeatedly 10 times, the CV of Ct should be <5%.	☒ Qualified ☐ Unqualified	
Sensitivity	Sensitivity references S should be tested repeatedly 10 times,which are $\geq 2.0E+02$ copies/mL should be tested positive.	☒ Qualified ☐ Unqualified	
Conclusion:	☒ Qualified ☐ Unqualified		
Inspector: Shany Wang	Reviewer: Xinyan Tang		
Person in charge of inspection: Zihao He	08/27/2020 (month/day/year)		
Remarks:			

This report is made in duplicate. One copy is distributed to inspection request dept. and the other one is kept by quality management dept.