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- Department of Health & Social Care (<https://www.gov.uk/government/organisations/department-of-health-and-social-care>)

Guidance

First wave of lateral flow test and non-machine based LFT assessment

Updated 23 December 2020

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Test 1: SD Biosensor Lateral Flow Test

Date of phase 2 test: 18 August 2020

Product overview

Manufacturer: SD Biosensor

Product: SD Biosensor Lateral Flow Test

Type: Saliva

Phase 2

- sample panel size = 131
- Porton Down negatives (x71) and spiked positives (x60)

Overall: Pass

Kit failure: Pass

Specificity: Pass

Sensitivity: Pass

Phase 2A (3 seasonal strains)

Cross-reactivity: Pass

Phase 3

- sample panel size = 1,200
- Oxford fresh negatives (x1,000) and banked positives from 03/2020 (x200)

Kit failure: Pass

Specificity: Pass

Sensitivity: Pass

Test 2: Innova SARS-Cov-2 Antigen test

Date of phase 2 test: 31 August 2020

Product overview

Manufacturer: Innova Tried & Tested

Product: Innova SARS-Cov-2 Antigen test

Type: Swab

Phase 2

- sample panel size = 131
- Porton Down negatives (x71) and spiked positives (x60)

Overall: Pass

Kit failure: Pass

Specificity: Pass

Sensitivity: Pass

Phase 2A (3 seasonal strains)

Cross-reactivity: Pass

Phase 3

- sample panel size = 1,200
- Oxford fresh negatives (x1,000) and banked positives from 03/2020 (x200)

Kit failure: Pass

Specificity: Pass

Sensitivity: Pass

Test 3: Coronavirus Antigen Rapid Test

Date of phase 2 test: 7 and 8 September 2020

Product overview

Manufacturer: Healgen

Product: Coronavirus Antigen Rapid Test

Type: Swab

Phase 2

- sample panel size = 131
- Porton Down negatives (x71) and spiked positives (x60)

Overall: Pass

Kit failure: Pass

Specificity: Pass

Sensitivity: Pass

Phase 2A (3 seasonal strains)

Cross-reactivity: Pass

Phase 3

- sample panel size = 1,200
- Oxford fresh negatives (x1,000) and banked positives from 03/2020 (x200)

Kit failure: week commencing 28 September 2020

Specificity: week commencing 28 September 2020

Sensitivity: week commencing 28 September 2020

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