

Coronavirus (COVID-19) (/coronavirus)

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1. [Home \(https://www.gov.uk/\)](https://www.gov.uk/)
 2. [Coronavirus \(COVID-19\) \(https://www.gov.uk/coronavirus-taxon\)](https://www.gov.uk/coronavirus-taxon)
 3. [Testing for coronavirus \(COVID-19\) \(https://www.gov.uk/coronavirus-taxon/testing\)](https://www.gov.uk/coronavirus-taxon/testing)
 4. [Assessment and procurement of coronavirus \(COVID-19\) tests \(https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests\)](https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests)
- [UK Health Security Agency \(https://www.gov.uk/government/organisations/uk-health-security-agency\)](https://www.gov.uk/government/organisations/uk-health-security-agency)

Guidance

Products in the pipeline (TVG): validation concluded or paused

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The Technical Validation Group (TVG) have concluded or paused the validation of the following products.

TVG reference	Primary use location	Product type	High-level justification
4	Near patient test	Bespoke	Multiplex assay and validation sits outside of DHSC (to be performed locally)
5	Point of care test	PCR	Rejected for commercial reasons following the commencement of validation activities
7	Near patient test	LAMP	Supplier non-engagement, difficulty in obtaining technical data
9	Near patient test or point of care test	PCR	Product withdrawn from validation by the supplier
10	Near patient test or point of care test	PCR	Product withdrawn from validation by the supplier
11	Laboratory	PCR	Product currently research only, with significant transportation constraints
18	Point of care test	Direct LAMP	Assay does not meet TPP standards for sensitivity. Biosafety concerns also noted
20	Near patient test	Direct LAMP	Scalability, manufacturing and biosafety concerns
21	Near patient test	RNA and direct LAMP	Product not market ready – reliability issues and does not meet TPP standards
22	Near patient test	Direct LAMP	Protocol being updated by the company to improve clinical performance
23	Point of care test	Antigen	Assay does not provide additional capacity to meet DHSC 's current needs
24	Point of care test	PCR	Processing through alternative route
25	Laboratory	PCR	Product withdrawn from validation by the supplier
27	Point of care test	Lateral flow	Product already being supplied by another distributor
28	Laboratory	RNA and direct LAMP	Resilience and scalability concerns

TVG reference	Primary use location	Product type	High-level justification
29	Point of care test	Microelectronics and microfluidics	Product is not ready for market – very early stages of development
30	Point of care test	LAMP	Supplier non-engagement, difficulty in obtaining technical data
31	Laboratory	RNA LAMP	Product is not ready for market – very early stages of development
33	Laboratory	PCR	Processing through alternative route
34	Point of care test	Lateral flow	Supplier non-engagement, difficulty in obtaining technical data
35	Laboratory	LAMP	Rejected due to little differentiation between negative reaction and presumes positive result, and low throughput
36	Laboratory; near patient test	Other	Supplier non-engagement, difficulty in obtaining technical data
37	Point of care test	PCR	Processing through alternative route
38	Laboratory	PCR	Supplier non-engagement, difficulty in obtaining technical data
42	Point of care test	Lateral flow	Supplier non-engagement, difficulty in obtaining technical data
43	Laboratory	Mass spectrometry	Validated as a part of a broader pilot (different validation route)
44	Point of care test	POCT	Assay does not provide additional capacity to meet DHSC's current needs
45	Point of care test	Lateral flow	Processing through alternative routes
46	Point of care test	Direct LAMP	Supplier non-engagement, difficulty in obtaining technical data
47	Point of care test	PCR	Supplier non-engagement, difficulty in obtaining technical data

TVG reference	Primary use location	Product type	High-level justification
49	Point of care test; near patient test	PCR	Multiplex assay and validation sits outside of DHSC (to be performed locally)
50	Laboratory	PCR	Supplier non-engagement, difficulty in obtaining technical data
51	Laboratory	Digital sequencing test	Product not market ready – does not meet TPP standards and has reliability issues
53	Laboratory	PCR	Processing through alternative routes
54	Laboratory	PCR	Processing through alternative routes
55	Point of care test	PCR	Supplier withdrew product
56	Laboratory	PCR	Supplier non-engagement, difficulty in obtaining technical data
58	Point of care test	PCR	Supplier non-engagement, difficulty in obtaining technical data
60	Near patient test or point of care test	PCR	Supplier non-engagement, difficulty in obtaining technical data
62	Laboratory	PCR	Assay does not provide additional capacity to meet DHSC's current needs
63	POCT		Supplier non-engagement, difficulty in obtaining technical data
64	Point of care test	PCR	Processing through alternative routes
65	Laboratory	PCR	Solution not viable within the timelines required to support with DHSC surge capacity
66	Laboratory	PCR	Processing through alternative routes
67	Laboratory	PCR	Assay does not provide additional capacity to meet DHSC's current needs
68	Point of care test	PCR	Assay does not provide additional capacity to meet DHSC's current needs
70	Point of care test	Direct LAMP	Product is not ready for market – very early stages of development

TVG reference	Primary use location	Product type	High-level justification
72	Point of care test	RNA LAMP	Did not meet TPP Standards on sensitivity, concerns of throughput
73	Laboratory	LAMP	Supplier non-engagement, difficulty in obtaining technical data
74	Near patient test	Antibody	Assay does not provide additional capacity to meet DHSC's current needs
75	Laboratory	PCR	Assay does not provide additional capacity to meet DHSC's current needs
76	Laboratory	PCR	Supplier withdrew product
78	Laboratory	PCR	Processing through alternative routes
80	Point of care test	Lateral flow	Supplier non-engagement, difficulty in obtaining technical data
82	Laboratory	RNA LAMP	Use cases restricted and not adding any additional testing capacity
85	Laboratory	LAMP	Limited use case due to clinical performance and assay being laboratory
86	Laboratory	RT PCR	End-to-end solution and validation routed to an alternative team
87	Laboratory	PCR	Processing through alternative routes
89	Laboratory	PCR	Assay does not provide additional capacity to meet DHSC's current needs
92	Laboratory	PCR	Assay does not provide additional capacity to meet DHSC's current needs
93	Laboratory	PCR	Assay does not provide additional capacity to meet DHSC's current needs
95	Point of care test	Antigen	Validation paused to clarify assay performance. In addition, contradictory statements in the JFU on the assay
96	Point of care test	PCR	Processing through alternative routes
97	Laboratory	Lateral flow	Supplier non-engagement, difficulty in obtaining technical data

TVG reference	Primary use location	Product type	High-level justification
98	Laboratory	PCR	Multiplex assay and validation sits outside of DHSC (to be performed locally)
99	Laboratory	PCR	Processing through alternative routes
100	Laboratory	PCR	Product is very early stage and concerns over the amount of equipment required
101	Point of care test	PCR	Assay does not provide additional capacity to meet DHSC's current needs
103	Laboratory	PCR	Supplier non-engagement, difficulty in obtaining technical data
105	Laboratory	PCR	Assay does not provide additional capacity to meet DHSC's current needs
106	Point of care test	Lateral flow	Supplier non-engagement, difficulty in obtaining technical data
108	Laboratory	PCR	Product is at very early stage and requires CE mark
112	Laboratory	LAMP	Concerns over extensive manual pipetting requirement being prone to error and inconsistencies between sensitivity and specificity
114	Laboratory	LAMP	Assay does not meet TPP standards for performance. Biosafety concerns also noted
121	Laboratory	Mass spectrometry	No-go because of product irregularities (turnaround time, too complex, high error probability and associated costs)
123	Laboratory	Mass spectrometry	Assay does not meet TPP standards for performance
125	Laboratory	PCR	Assay does not meet TPP standards for performance



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