

Supplemental Information for:

Laboratory Evaluation Links Some False-positive COVID-19 Antigen Test Results Observed in a Field Study to a Specific Lot of Test Strips

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Supplementary Table 1. Complete laboratory evaluation of Ag-RDT test strips. Each trial of the laboratory evaluation assesses one Ag-RDT strip, listed with the corresponding lot number. SARS-CoV-2 concentration is the number of SARS-CoV-2 copies/mL of the test buffer when contrived specimens are applied (see methods). The incubation time is defined as the difference between the time at which the strip was taken out of the test buffer and the time at which the strip was placed in the buffer. The read window is defined as the difference between the time at which the last reader interpreted the results of the test and the time at which the strip was taken out of the buffer. The anticipated result for each trial is based off the concentration of particles applied to each strip. The three reads for each trial are listed and positive results are highlighted in red. The proportion of reads called positive is also listed, and any percentage above 0% when the anticipated result was negative is also highlighted in red.

Trial	Antigen Test Lot Number	SARS-CoV-2 Concentration Spike-in (copies/mL)	Incubation Time	Read Window	Anticipated Result	Reader 1	Reader 2	Reader 3	% Called Positive
1	152194	Quidel Positive Control Swab	11 min	2 min	Positive	Positive	Positive	Positive	100
2	152194	2.0x10 ⁶ copies/mL	10 min	3 min	Negative	Negative	Negative	Negative	0
3	152194	4.0x10 ⁶ copies/mL	10 min	3 min	Negative	Negative	Negative	Negative	0
4	152532	1.0x10 ⁷ copies/mL	10 min	3 min	Positive	Positive	Positive	Positive	100
5	152532	1.3x10 ⁷ copies/mL	10 min	3 min	Positive	Positive	Positive	Positive	100
6	152194	1.5x10 ⁷ copies/mL	10 min	3 min	Positive	Negative	Positive	Positive	66.7
7	152194	0 copies/mL	11 min	2 min	Negative	Negative	Negative	Negative	0
8	152194	0 copies/mL	10 min	2 min	Negative	Negative	Negative	Negative	0
9	152194	0 copies/mL	10 min	4 min	Negative	Negative	Negative	Negative	0
10	152194	0 copies/mL	11 min	3 min	Negative	Negative	Negative	Negative	0
11	000202	0 copies/mL	10 min	2 min	Negative	Negative	Negative	Negative	0
12	000202	0 copies/mL	10 min	2 min	Negative	Negative	Negative	Negative	0
13	000202	0 copies/mL	11 min	2 min	Negative	Negative	Negative	Negative	0
14	000202	0 copies/mL	10 min	2 min	Negative	Negative	Negative	Negative	0
15	000202	0 copies/mL	11 min	3 min	Negative	Negative	Negative	Negative	0
16	152000	0 copies/mL	10 min	3 min	Negative	Positive	Positive	Negative	66.7
17	152000	0 copies/mL	10 min	3 min	Negative	Positive	Positive	Negative	66.7
18	152000	0 copies/mL	10 min	4 min	Negative	Positive	Positive	Negative	66.7
19	152000	0 copies/mL	10 min	3 min	Negative	Positive	Positive	Positive	100
20	152000	0 copies/mL	10 min	4 min	Negative	Positive	Positive	Positive	100
21	152000	0 copies/mL	10 min	4 min	Negative	Positive	Positive	Invalid	66.7
22	152532	0 copies/mL	10 min	4 min	Negative	Negative	Negative	Negative	0
23	152532	0 copies/mL	10 min	2 min	Negative	Negative	Negative	Negative	0
24	152532	0 copies/mL	10 min	3 min	Negative	Negative	Negative	Negative	0

Contribution Statements for Non-Corresponding Authors:

Reid Akana (RA) - Reader for laboratory evaluation blinded to experimental conditions. Wrote Python function to perform statistical testing. Reviewed manuscript draft.

Alyssa M. Carter (AMC) - Designed laboratory evaluation. Operator for laboratory evaluation. Reported issue with lot 152000 to Quidel and interacted with Quidel representatives. Outlined and co-wrote manuscript with AVW. Analyzed field study and laboratory evaluation data with AVW. Drafted Figure 1 with AVW. Prepared Supplementary Table 1. Major contributor to selection of references for manuscript with AVW

Anna E. Romano (AER) – Reviewed participant Ag-RDT photos from field evaluation to extract strip lot information. Performed interim analysis of Ag-RDT results by strip lot. Provided feedback on design of laboratory evaluation. Reader for laboratory evaluation blinded to experimental conditions. Reviewed manuscript draft.

Natasha Shelby (NS) - Study administrator. Interviewed all participants who received false-positive antigen results. Amended IRB protocol to add acquisition of antigen lot numbers. Filed Medline FDA report about lot #152000 and interacted with Quidel representatives. QC of data. Reader for laboratory evaluation blinded to experimental conditions. Reviewed and edited manuscript draft.

Alexander Vilorio Winnett (AVW) – Provided feedback on design of laboratory evaluation. Reader for laboratory evaluation blinded to experimental conditions. Reported issue with lot 152000 to Quidel and interacted with Quidel representatives. Major contributor to selection of references for manuscript with AMC. Managed reference library. Outlined and co-wrote manuscript with AMC. Analyzed field study and laboratory evaluation data with AMC. Drafted Figure 1 with AMC.