Technical Brief - February 2021

BinaxNOW™ COVID-19 Ag Card
Extraction Reagent

The volume of extraction reagent contained within the bottle is 7.5mL. There is sufficient volume provided for the 40 tests and the drop size was determined to be 20-32µL (average 27µL).

Bottle Fill Volume		7.5mL
Average Drop Volume		27µL
Patient Tests	**Drops**	6 drops
	Volume per test	6 drops x 27µL = 162µL
External Control Tests	**Drops**	8 drops
	Volume per test	8 drops x 27µL = 216µL

Standard Use Scenario:

Assuming that for each kit (40 tests) opened quality control testing is performed, a user would run one (1) positive control swab, one (1) blank patient swab, and thirty-eight (38) patient tests. In this scenario the volume of reagent consumed equals 6.59mL.

- 38 patient tests x 162µL = 6.16 mL
- 2 external control tests x 216µL = 0.43mL
- Volume Consumed: 6.16mL + 0.43mL = 6.59mL
- Remaining Volume: 0.91mL, or approx. enough reagent for another five (5) tests

Multiple User Training Scenarios

For multiple user training scenarios where the customer has purchased a positive control swab accessory kit (195-080; containing 10 positive swabs):

Scenario #1

The customer runs five (5) positive control swabs and five (5) blank patient swabs to train multiple users on how to properly run and interpret the test for a total of ten (10) control tests and thirty (30) patient tests. In this scenario the volume of reagent consumed equals 7.02mL.

- 30 patient tests x 162µL = 4.86mL
- 10 control tests x 216µL = 2.16mL
- Volume Consumed: 4.86mL + 2.16mL = 7.02mL
- Remaining Volume: 0.48mL, or approx. enough reagent for another two (2) tests

Scenario #2

In this scenario the customer runs twenty (20) control tests and (20) patient tests. The volume of reagent required, 7.56mL, exceeds the volume provided in the bottle.

- 20 patient tests x 162µL = 3.24mL
- 20 control tests x 216µL = 4.32mL
- Volume Consumed: 3.24mL + 4.32mL = 7.56mL
- Volume consumed exceeds capacity

Technical Services should be contacted for an additional bottle of reagent to support expanded external control testing.

- Phone: 1 800 257 9525
- Email: ts.scr@abbott.com

The BinaxNOW™ COVID-19 Ag Test Card has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization for use by authorized laboratories. The test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.