Report Clinical Performance
January 16th, 2022

AS-15 SARS-CoV-2 Antigen Test

For Emergency Use Authorization (EUA)
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CLINICAL PERFORMANCE

The clinical study performed to evaluate the usability of the AS-15 for home users and the accuracy of the test itself is described in detail in the attached protocol.

Data for this submission is from Cohort 1 of the study and included both symptomatic and asymptomatic participants who were presenting for a covid test. A comparator nasopharengeal (NP) swab was first collected by a healthcare worker for a PCR test.
All comparator tests were performed at one central lab (Atlantic Diagnostic Laboratories, Bensalem, PA) using the Roche cobas 6800 SARS-CoV-2 test.

Participants had the comparator NP swab collected by a trained healthcare provider first. Participants were then provided with written instructions for collecting, processing, and reading their own AS-15 test. The healthcare provider observed the AS-15 testing process, but study staff were instructed not to interfere with the testing process except to preempt a perceived safety risk. No such risks were identified.

25 Patients were enrolled at Crystal Run Middletown, NY

The eligibility criteria were as follows for Cohort 1 was as follows:
Inclusion Criteria

- Presenting to be tested for SARS-CoV-2 by PCR/nasopharyngeal swab.
- Participants 2 or more years old.
- Participant or caretaker physically able to self-collect mid-turbinate or lower nares swab and utilize AS-15 test.

- Participant or LAR willing and able to provide informed consent or assent as required by local regulations.
- Willing to allow access to PCR testing results.

Exclusion Criteria

- Participant or sample collecting caregiver is a trained healthcare professional.
- Regular use of at home diagnostic device such as glucometer.
- Confirmed diagnosis of COVID-19 from sample collected >48 hours prior to Screening/Study Entry visit.
- Currently enrolled in another clinical trial that provides an investigational device or drug.

Clinical data

Table 1. Agreement matrix describing the results of AS-15

Method	**RT-PCR positive COVID-19 patients**			**Total**
	Result	**Positive**	**Negative**	
AS-15 Antigen Test	**Positive**	**17**	**30**	**47**
	Negative	**2**	**30**	**32**
Total patients		**19**	**30**	**49**

Table 2. Performance statistics of AS-15 with 95% confidence limits (Pearson-Koppler method)

Statistics	Result cases	Base cases	Value	Lower limit	Upper limit
Percent Positive Agreement (PPA)	17	19	0.90	0.87	0.99
Negative Percent Agreement (NPA)	30	30	1.00	0.88	1.00
Positive Predictive Value (PPV)	17	17	1.00	0.80	1.00

Negative Predictive Value (NPV)	30	32	0.94	0.79	1.00
Overall Percent Agreement	47	49	0.96	0.86	1.00
Prevalence	19	49	0.39	0.25	0.54

The data provided in Tables 1 and 2 had a distribution of Ct values indicated in **Figure 1.**

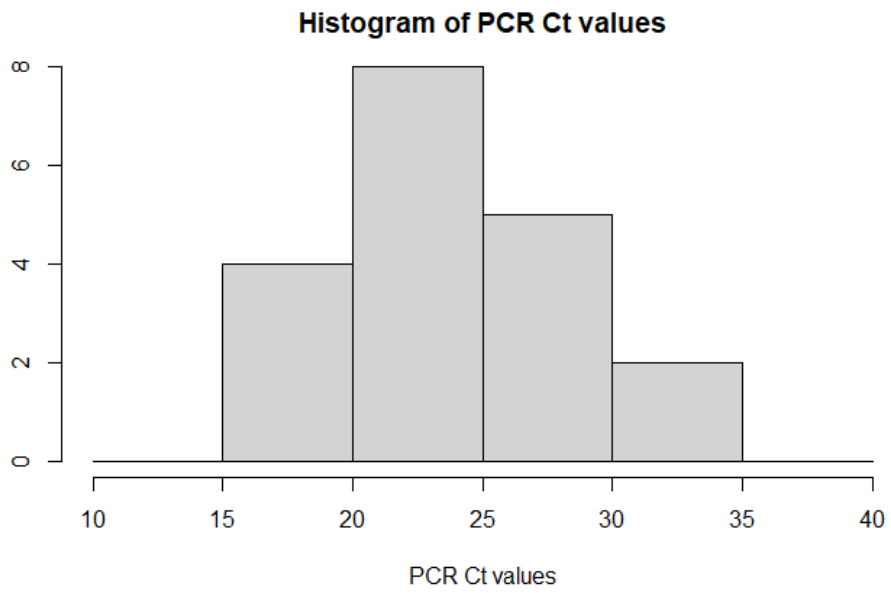

Figure 1. Distribution of the Ct values

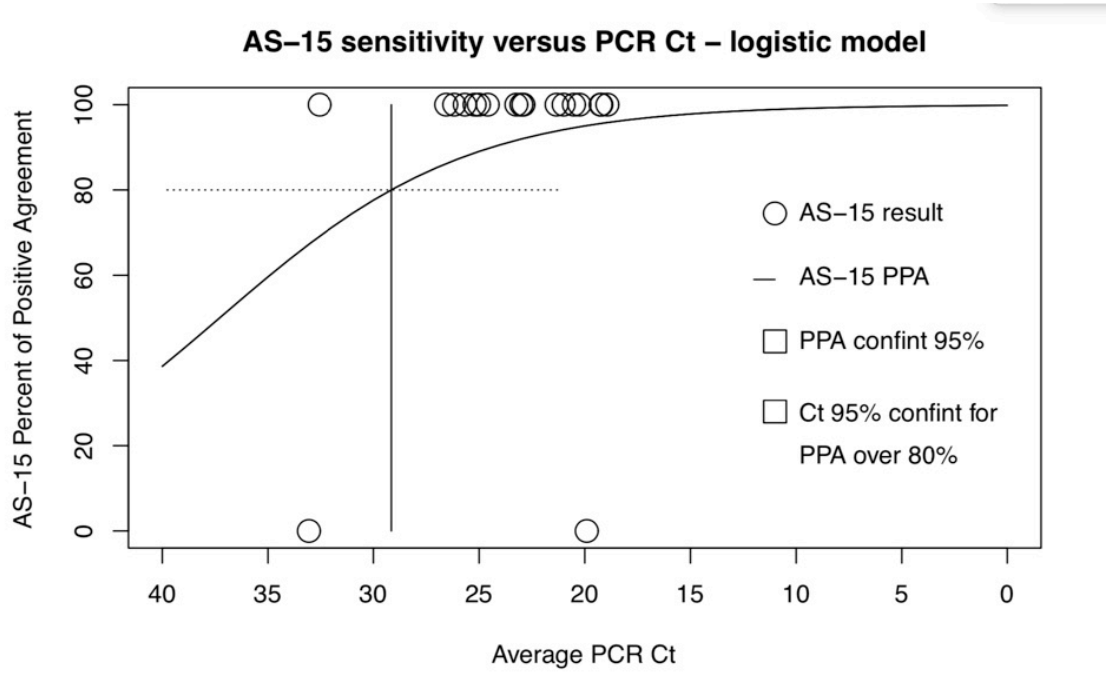

Figure 2. Logistic Regression Model. The figure represents the sensitivity (PPA) using AS-15 with respect to Ct values of the clinical samples for total of 49 patients. The PPA performance at 80% matched a PCR Ct of 29.5 cycles. The model corresponds to data shown in Table 1 and 2.

Conclusions:

AS-15 performance for detection of Omicron SARS-CoV-2 had a PPA=90% and NPA= 100%.
The test is accurately detecting the current strain of SARS-CoV-2 circulating by January 2022 in USA.