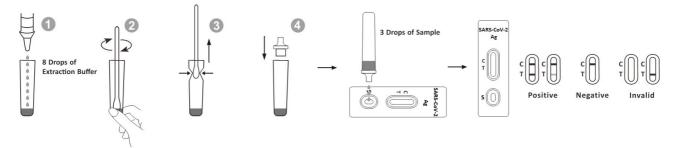


## **CATALOG**

Product Name	Specimen	Catalog No.	Quantity per pack	Certificate
SARS-CoV-2 Ag Cassette	Nasopharyngeal Swab	ABT-IDT-B367	20 tests	CE

### **TEST PROCEDURE**



# PERFORMANCE CHARACTERISTICS

### Sensitivity, Specificity and Accuracy

ACCU-TELL® SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for ACCU-TELL® SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab). Specimens were considered positive if PCR indicated a positive result.

Method		RT-PCR		Total
ACCU-TELL® SARS-	Results	Positive	Negative	Results
CoV-2 Ag Cassette	Positive	38	3	41
(Nasopharyngeal Swab)	Negative	2	360	362
Total Results		40	363	403

Relative Sensitivity: 95.0% (95%CI\*:83.1%-99.4%)\* Relative Specificity: 99.2% (95%CI\*:97.6%-99.8%)\* Relative accuracy: 98.8% (95%CI\*:97.1%-99.6%)\*

#### \* Confidence Intervals

#### **Detection Limit**

The LOD for ACCU-TELL® SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) was established using limiting dilutions of a viral sample inactivated. The material (ZeptoMetrix, 0810587CFHI) was supplied at a concentration of **1.15x10**<sup>7</sup> **TCID**<sub>50</sub>/**mL**. The Estimated LOD is **1000 TCID**<sub>50</sub>/**mL**.

### **MATERIALS PROVIDED**

- ✓ Test cassettes
- Extraction Reagent
- ✓ Extraction Tubes
- Dropper tips

- ✓ Sterile Swabs
- ✓ Package Insert
- ✓ Workstation





