## COVID-19 Rapid Test (Abbott ID NOW) Fact Sheet

Abbott ID NOW rapid molecular test for COVID-19 utilizes isothermal amplification of nucleic acid to detect SARS-CoV-2 from nasal swabs, and is one of the five platforms BayCare currently uses for COVID-19 testing (in addition to Roche, DiaSorin, BD Max and Cepheid, which are all RT-PCR assays performed on nasopharyngeal swabs or other specimen types).

Abbott ID NOW performs best in patients tested early during the course of the disease when the viral load and viral shedding are high (within 1st week of symptom onset), while the test's sensitivity decreases during the latter part of the disease (such as in medium to long-term hospitalized patients and patients presenting late in the course of the disease).

At BayCare, the COVID-19 ID NOW Rapid test is used to test three patient populations:

- Emergency Department visits (High pre-test probability)
- Labor and Delivery (Low pre-test probability)
- Pediatric pre-operative (Low pre-test probability)

Several measures exist to assess the value of a diagnostic test, including clinical sensitivity (ability to detect true positive) and clinical specificity (ability to detect true negative). In addition to sensitivity and specificity, prevalence of the disease and degree of clinical suspicion (pre-test probability) are also significant determining factors in usefulness of a test. For example, when the prevalence of the disease in a tested population is low (asymptomatic patients), the Negative Predictive Value (NPV: likelihood of negative results being truly negative) is high, and the chance of having a false negative result is very low (Table 1). This means that following up a negative Abbott COVID-19 results with another test is only clinically valid if there is a very high level of clinical suspicion (high pre-test probability) of COVID-19 disease (Table 2).

Table 1				
Asympt	omatic group, low	Prevalence= 2%		
	COVID + (n=4)	COVID - (n=196)		
Test +	True Pos=3	False Pos=2	PPV= 63%	
Test -	False Neg=1	True Neg=194	NPV= 99.7%	
	Sensitivity 85%	Specificity 99%		

Table 2 Symptomatic group, high prevalence (n=200) Prevalence= 10%				
	COVID + (n=20)	COVID - (n=180)		
Test +	True Pos=17	False Pos=2	PPV= 89%	
Test –	False Neg=3	True Neg=178	NPV= 98.3%	
	Sensitivity 85%	Specificity 99%		

Based on collective literature available to date, the clinical sensitivity and specificity of the Abbott test are estimated at 85% and 99% respectively. That means for patients coming to BayCare for pre-operative screening or Labor and Delivery, the probability of a negative Abbott test being truly negative (NPV) is 99.7%. In cases where there is a concern with the Abbott negative test results when COVID-19 is highly suspected, the test can be repeated using another platform.

From BayCare's internal data, repeat testing conducted upon physicians' requests between May 1<sup>st</sup> and May 25<sup>th</sup> shows that of 1,015 patients initially tested negative with the Abbott test in the Emergency department only 25 (<2.5%) were positive with a follow-up RT-PCR test.

It is also very important to note that virus level changes during the course of the disease; therefore any test could yield a "false negative result" if viral shedding is low and/or sample collection is suboptimal.

**Note:** this fact sheet does not apply to Abbott serology (antibody) test.



1 of 1 Revised 05/28/2020 Internal Distribution Only