Table 1. NeuMoDx SARS-CoV-2 Assay Results Interpretation

OVERALL RESULT	TARGET 1 (Nsp2-gene) FAM	TARGET 2 (N-gene) HEX	PROCESS CONTROL (SPC2) Q-705	Interpretation
POSITIVE	**AMPLIFIED** [4 ≤ Ct < 12 AND EPR ≥ 1.2 AND EP ≥ 700] OR (12≤ Ct ≤40 AND EP ≥700)	N/A	N/A	SARS-CoV-2 RNA detected**
	N/A	**AMPLIFIED** (4 ≤ Ct < 12 AND EPR ≥1.5) AND EP ≥ 1000) OR (12 ≤ Ct ≤ 40 AND EP >1000)		
NEGATIVE	**NOT AMPLIFIED** N/A **OR** (4 < Ct < 12 AND EPR <1.2) **OR** (12 ≤ Ct ≤ 40 AND EP <700) **OR** (Ct > 40)	**NOT AMPLIFIED** N/A **OR** (4 < Ct < 12 AND EPR <1.5) **OR** (12 ≤ Ct ≤ 40 AND EP <1000) **OR** (Ct > 40)	**AMPLIFIED** (24≤ Ct ≤33 AND EP ≥1000)	SARS-CoV-2 RNA not detected
IND*	**NOT AMPLIFIED/System Errors Noted**			All target results were invalid; retest sample
UNR*	**NOT AMPLIFIED/No System Errors Noted**			All target results were invalid; retest sample

*The System is equipped with automatic Rerun/Repeat capability that the end user can choose to use to ensure that an IND/UNR result is automatically reprocessed to minimize delays in result reporting.

**A re-test may be performed if desired in the event of only one of the two SARS-CoV-2 targets being amplified.

A positive result may be reported for samples yielding a differential amplification status, such that only one of the targets—Target 1 (Nsp2 gene) or Target 2 (N gene)—amplifies. This may occur due to 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in one of the target regions, or 3) other factors. In the case of a positive test where only one of the targets amplifies, repeat testing may be considered if the SPC2 control is negative. If the repeat result remains the same, additional confirmation testing should be conducted if clinically indicated.

Invalid Results

If a NeuMoDx SARS-CoV-2 Assay performed on the NeuMoDx System fails to produce a valid result, it will be reported as either Indeterminate or Unresolved based on the type of error that occurred, and the test should be repeated to obtain a valid result.

An Indeterminate result will be reported if a NeuMoDx System error is detected during sample processing. In the event of an Indeterminate result, a retest is recommended.

An Unresolved result will be reported if no target is detected and there is no amplification of the Sample Process Control, which indicates possible reagent failure or the presence of inhibitors. In the event of an Unresolved result, a retest is recommended as a first step. If the retest fails, a diluted specimen may be used to mitigate the effect of possible inhibition.