VALIDATION

Tester Equipment Ustar Nucleic acid Amplification analyzer
Test Kit Easy NAT Novel-Coronavirus (2019-nCoV) RNA

COVID-19 Lot No.	20200421
Expiration Date	10/20/2020
TEST	COVid-19

Transport Medium
VTM

210218070003A	
COVID-19 Lot No.	
Expiration Date	
TEST	SARS-CoV-2 1.1.6.1

COMPARATOR POSITIVE
Test Platform ABI 7500 Fast DX
Protocol CDC 2019-Novel Coronavirus (2019-nCoV)
Real-Time RT-PCR Diagnostic Panel Emergency Use Au[redacted]
State Public Health Lab for the state of West Virginia (WV DHHR)

COMPARATOR POSITIVE
GenMarkDx instrument number **1903100395**
Software Version : **2.5.2.0**

UC0102 SN			Patient		ID					Test Results									Re-test										
										ORF1ab_Ct	N_CT			Ustar	CONTROL								ORF1ab_Ct	N_CT			CONTROL		
	Date	Age	Sex	Test Source	Sample		Cartridge	Expiration of Cart	Clinical Symptoms	left leg Tt value	Right leg Tt value	ICL	ICR	Result	W.V. Lab	Comments	Technician	Test Description	Date			ICL	ICR	ROX	Result	W.V. Lab	Comments	Technician
210218070003A	6/3/2020	0	MALE	COVID-19	E20MO13953		CoV102004210614380	10/20/2020	West Virgina State Lab Positive for COVID-19	15.66	N/A	10000	10000	Positive	Positive		TMS												
210218070003A	6/3/2020	0	MALE	COVID-19	E20MO11743		CoV102004210614375	10/20/2020	West Virgina State Lab Positive for COVID-19	7.5	N/A	10000	10000	Positive	Positive		TMS												
210218070003A	6/4/2020	0	MALE	COVID-19	E20MO11748		CoV102004210614385	10/20/2020	West Virgina State Lab Positive for COVID-19	10.5	8.33	10000	10000	Positive	Positive		TMS												
210218070003A	6/4/2020	0	MALE	COVID-19	E20MO14097		CoV102004210610186	10/20/2020	West Virgina State Lab Positive for COVID-19	6.5	N/A	10000	10000	Positive	Positive		TMS												
210218070003A	6/4/2020	0	MALE	COVID-19	E20MO11727		CoV102004210614368	10/20/2020	West Virgina State Lab Positive for COVID-19	15.33	3.83	10000	10000	Positive	Positive		TMS												
210218070003A	6/4/2020	0	MALE	COVID-19	E20MO11733		CoV102004210614365	10/20/2020	West Virgina State Lab Positive for COVID-19	8.83	N/A	10000	10000	Positive	Positive		TMS												
210218070003A	6/4/2020	0	MALE	COVID-19	E20MO11728		CoV102004210613052	10/20/2020	West Virgina State Lab Positive for COVID-19	15.33	23.33	10000	10000	Positive	Positive		TMS												
210218070003A	6/4/2020	0	MALE	COVID-19	E20MO13950		CoV102004210614367	10/20/2020	West Virgina State Lab Positive for COVID-19	8.66	7.5	10000	10000	Negative	Positive	Re-test (2)	TMS	Ustar	6/4/2020						Positive			TMS
210218070003A	6/5/2020	0	MALE	COVID-19	E20MO12362		CoV102004210610817	10/20/2020	West Virgina State Lab Positive for COVID-19	N/A	10.83	10000	10000	Negative	Positive	Re-test (2)	TMS	Ustar	6/5/2020						Positive			TMS
210218070003A	6/5/2020	0	MALE	COVID-19	E20MO12187		CoV102004210611851	10/20/2020	West Virgina State Lab Positive for COVID-19	15.16	12.5	10000	10000	Positive	Positive		TMS												
210218070003A	6/8/2020	0	MALE	COVID-19	E20MO13117		CoV102004210611833	10/20/2020	West Virgina State Lab Positive for COVID-19	12.83	11	10000	10000	Positive	Positive		TMS												
210218070003A	6/8/2020	0	MALE	COVID-19	E20MO13118		CoV102004210610996	10/20/2020	West Virgina State Lab Positive for COVID-19	N/A	12.5	10000	10000	Positive	Positive		TMS												
210218070003A	6/8/2020	0	MALE	COVID-19	E20MO13035		CoV102004210610969	10/20/2020	West Virgina State Lab Positive for COVID-19	N/A	14	10000	10000	Positive	Positive		TMS												
210218070003A	6/8/2020	0	MALE	COVID-19	E20MO12374		CoV102004210611622	10/20/2020	West Virgina State Lab Positive for COVID-19	N/A	35.16	10000	10000	Positive	Positive		TMS												
210218070003A	6/9/2020	0	MALE	COVID-19	E20MO13202		CoV102004210613676	10/20/2020	West Virgina State Lab Positive for COVID-19	1300	N/A	10000	10000	Positive	Positive		TMS												
210218070003A	6/9/2020	0	MALE	COVID-19	E20MO13195		CoV102004210612158	10/20/2020	West Virgina State Lab Positive for COVID-19	8.5	14.5	10000	10000	Positive	Positive		TMS												
210218070003A	6/9/2020	0	MALE	COVID-19	E20MO13196		CoV102004210611926	10/20/2020	West Virgina State Lab Positive for COVID-19	21.66	N/A	10000	10000	Positive	Positive		TMS												
210218070003A	6/11/2020	0	MALE	COVID-19	E20MO13119		CoV102004210610140	10/20/2020	West Virgina State Lab Positive for COVID-19	6.83	N/A	10000	10000	Positive	Positive		TMS												
210218070003A	6/11/2020	0	MALE	COVID-19	E20MO13192		CoV102004210610097	10/20/2020	West Virgina State Lab Positive for COVID-19	N/A	5.83	10000	10000	Positive	Positive		TMS												
210218070003A	6/15/2020	0	MALE	COVID-19	E20MO13412		CoV102004210610246	10/20/2020	West Virgina State Lab Positive for COVID-19	13.33	N/A	10000	10000	Positive	Positive		TMS		Cartridge	lot no.	date								
210218070003A	6/15/2020	0	MALE	COVID-20	RO150711		CoV102004210610871	10/20/2020	GenMarkDx	10.33	N/A	10000	10000	Positive	Positive	GHHH (1)	TMS	Genmark eplex	ZZ000713973	53541574	5/29/2020				Positive		Correlation	TMS
210218070003A	6/15/2020	0	MALE	COVID-19	R0150716		CoV102004210613683	10/20/2020	GenMarkDx	N/A	10	10000	10000	Positive	Positive	GHHH (1)	TMS	Genmark eplex	ZZ000713474	53541574	5/29/2020				Positive		Correlation	TMS
210218070003A	6/16/2020	0	MALE	COVID-19	E20MO13208		CoV102004210612312	10/20/2020	West Virgina State Lab Positive for COVID-19	11.16	N/A	10000	10000	Positive	Positive		TMS												
210218070003A	6/16/2020	0	MALE	COVID-19	E20MO13211		CoV102004210610955	10/20/2020	West Virgina State Lab Positive for COVID-19	9.33	N/A	10000	10000	Positive	Positive		TMS												
210218070003A	6/16/2020	0	MALE	COVID-19	E20MO13215		CoV102004210612369	10/20/2020	West Virgina State Lab Positive for COVID-19	20.5	39.16	10000	10000	Positive	Positive		TMS												
210218070003A	6/17/2020	0	MALE	COVID-19	E20MO13694		CoV102004210612336	10/20/2020	West Virgina State Lab Positive for COVID-19	8.66	13.16	10000	10000	Positive	Positive		TMS												
210218070003A	6/17/2020	0	MALE	COVID-19	E20MO13114		CoV102004210612363	10/20/2020	West Virgina State Lab Positive for COVID-19	N/A	11	10000	10000	Positive	Positive		TMS												
210218070003A	6/18/2020	0	MALE	COVID-19	E20MO13568		CoV102004210611384	10/20/2020	West Virgina State Lab Positive for COVID-19	15.66	21	10000	10000	Positive	Positive		TMS												
210218070003A	6/18/2020	0	MALE	COVID-19	E20MO13814		CoV102004210612363	10/20/2020	West Virgina State Lab Positive for COVID-19	N/A	11	10000	10000	Positive	Positive		TMS												
210218070003A	6/22/2020	0	MALE	COVID-19	R0211050		CoV102004210610992	10/20/2020	GenMarkDx	28.33	4.33	10000	10000	Positive	Positive	GHHH (1)	TMS	Genmark eplex	ZZ000736433	535388858	5/27/2020				Positive		Correlation	TMS

(1) Genmark Eplex has EUA FDA authorization
a. Previously collected.
(2) New Cartridge prepared using the Initial test sample.