Center for Esoteric Testing

Validation Addendum

For

2019-Novel Coronavirus (COVID-19, SARS CoV2, 2019-nCoV) QuantStudio 7

Young Innovations MicroBrush Foam Swabs

Molecular Microbiology

Date: July 15, 2020

Laboratory Corporation of America, 1447 York Court, Burlington, NC
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I. Introduction

The Molecular Research and Development Department of Laboratory Corporation of America in Burlington, NC performed a validation study for the detection of the 2019-Novel Coronavirus (COVID-19). LabCorp received an Emergency Use Authorization to perform this testing on March 16, 2020. To prevent any lapses in the collection swab supply chain, LabCorp has validated the Young Innovations MicroBrush Foam swab as an additional collection device.

This validation summary is intended to provide data to document that the performance characteristics of the qualitative RT-PCR test are reliable and suitable when samples are collected using the Young Innovations Foam Swab.

The sample type validated in this summary is nasopharyngeal or nasal swab collection using the Young Innovations MicroBrush Foam Swab.

Testing of samples proceeded using the FDA Authorized LabCorp COVID-19 RT-PCR Test.

II. Sample Stability Testing

1. Validation Method

20 contrived positives and 20 negative samples were tested for stability at 0hr, after a 50hr temperature excursion (Table 1), after sitting at 20C (room temperature, RT) for an additional 72hrs, and after sitting at 20C (RT) for an additional 24hrs for a total stability study duration of 146hrs. 40 negative saline samples were pulled from the lab and served as the negative sample matrix. 20 positive samples were then contrived by dipping the Young Innovations MicroBrush swab into a positive sample and then placing the swab into the negative sample matrix. Because positive swabs were contrived by dipping, the signal will be reduced approximately 100 fold, or 6-8 Ct, from the original result due to the dilution of the sample (~30uL) within the negative sample matrix (3mL).

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
40°C	1	6	6
22°C	2	16	22
40°C	3	2	24
35°C	4	22	46
40°C	5	4	50

Table 1: Temperature Excursion Conditions

2. Validation Result

20/20 negative swabs resulted negative at 0hr, 19/20 negative swabs resulted negative after the

temperature excursion, 19/20 samples resulted as negative after an additional 72hr at RT, and 20/20 negative samples resulted negative after an additional 24hr at RT (Table 2). The one sample that resulted invalid with an RP Ct >40 after the temperature excursion was recovered at the 72hr and 24hr RT incubations indicating that sample was present but due to sample dilution it was near the limit of detection of the RP assay so detection was variable. The same was also true for the sample that resulted as invalid after the 72hr incubation at RT which was recovered after an additional 24hr incubation at RT. Both samples had original RP Cts of approximately 37.

20/20 positives were positive at all time points. The average Cts for N1, N2 and RP did not deviate substantially throughout the stability experiment (1-2 Ct on average) (Table 2 and Figure 1).

As expected, all samples saw an average loss of no more than 8 Ct for N1 (7), N2 (7.5), and RP (4.7) (Figure 2).

		0 hr - Pre-Excursion			50 hr - Post Excursion			72 hr RT - Post Excursion			96 hr RT - Post Excursion		
	Sample Name	N1	N2	RP	N1	N2	RP	N1	N2	RP	N1	N2	RP
Positive	1900985001P	28.726	27.188	34.570	30.718	28.982	35.592	30.913	29.096	36.476	31.071	29.763	34.984
	1900985002P	33.605	32.229	32.571	35.237	33.361	33.801	36.219	34.176	34.200	35.330	34.034	33.811
	1900985003P	29.775	28.293	31.972	30.562	28.981	32.982	31.532	29.925	33.375	30.532	29.522	32.801
	1900985004P	34.543	33.976	34.627	37.240	36.042	36.380	38.705	36.893	37.804	39.866	38.327	37.366
	1900985005P	26.284	25.003	37.453	27.057	25.711	32.360	27.475	26.201	32.380	27.116	26.482	32.026
	1900985006P	24.339	22.874	33.170	24.545	22.919	34.142	25.027	23.342	33.413	25.457	23.993	33.454
	1900985007P	27.367	25.981	32.072	28.152	26.810	32.218	28.363	26.821	32.638	28.907	27.974	32.410
	1900985008P	28.074	26.358	29.958	29.655	27.721	30.423	29.568	27.686	30.003	29.767	28.049	30.655
	1900985009P	33.618	32.320	35.121	35.325	34.139	36.366	35.849	34.965	36.378	35.905	35.813	35.760
	1900985010P	29.603	28.113	30.822	30.948	28.969	31.621	29.951	28.250	31.956	30.899	29.231	31.767
	1900985011P	28.708	27.154	34.332	30.096	28.691	35.879	30.605	29.281	35.336	30.857	29.387	35.639
	1900985012P	34.039	33.189	32.582	35.280	34.559	33.726	34.466	33.991	33.637	35.517	35.156	33.623
	1900985013P	29.899	29.318	31.876	30.399	29.875	32.481	30.961	30.214	32.587	30.484	29.951	32.433
	1900985014P	34.315	33.440	34.512	36.291	36.488	35.753	36.680	35.830	35.688	38.302	37.281	35.646
	1900985015P	26.042	24.813	35.560	26.907	25.874	33.865	26.845	25.278	33.472	27.235	26.293	32.786
	1900985016P	24.418	22.458	32.665	25.135	23.213	32.865	25.175	23.026	32.382	25.467	23.810	33.205
	1900985017P	27.464	25.586	32.370	28.073	25.975	32.681	28.253	26.324	33.046	28.511	26.805	32.503
	1900985018P	28.175	26.309	29.664	29.530	27.783	30.191	29.562	27.492	30.285	29.812	28.373	30.588
	1900985019P	34.271	33.088	35.368	37.336	35.673	36.945	37.768	36.585	37.021	37.537	38.710	38.320
	1900985020P	30.104	29.227	31.151	31.397	30.429	31.573	31.420	30.105	31.698	31.647	31.020	32.133
Negative	1900985021N	UD	UD	34.595	UD	UD	35.852	UD	UD	35.510	UD	UD	35.398
	1900985022N	UD	UD	34.519	UD	UD	33.455	UD	UD	34.121	UD	UD	35.948
	1900985023N	UD	UD	35.725	UD	UD	35.521	UD	UD	36.113	UD	UD	35.802
	1900985024N	UD	UD	30.368	UD	UD	30.617	UD	UD	30.530	UD	UD	30.875
	1900985025N	UD	UD	34.027	UD	UD	33.791	UD	UD	34.317	UD	UD	34.200
	1900985026N	UD	UD	32.754	UD	UD	33.934	UD	UD	32.673	UD	UD	33.238

	1900985027N	UD	UD	33.471	UD	UD	33.817	UD	UD	34.820	UD	UD	34.333
	1900985028N	UD	UD	36.833	UD	UD	35.387	UD	UD	UD	UD	UD	36.023
	1900985029N	UD	UD	36.275	UD	UD	36.631	UD	UD	35.825	UD	UD	35.984
	1900985030N	UD	UD	34.314	UD	UD	34.654	UD	UD	34.498	UD	UD	36.087
	1900985031N	UD	UD	34.580	UD	UD	35.416	UD	UD	34.368	UD	UD	35.064
	1900985032N	UD	UD	34.077	UD	UD	35.514	UD	UD	35.202	UD	UD	35.965
	1900985033N	UD	UD	36.671	UD	UD	35.993	UD	UD	36.855	UD	UD	35.372
	1900985034N	UD	UD	30.768	UD	UD	30.547	UD	UD	30.758	UD	UD	30.785
	1900985035N	UD	UD	33.844	UD	UD	33.839	UD	UD	32.990	UD	UD	34.207
	1900985036N	UD	UD	32.547	UD	UD	33.226	UD	UD	33.292	UD	UD	32.730
	1900985037N	UD	UD	34.209	UD	UD	34.368	UD	UD	34.638	UD	UD	33.970
	1900985038N	UD	UD	37.141	UD	UD	UD	UD	UD	38.042	UD	UD	37.549
	1900985039N	UD	UD	36.343	UD	UD	36.565	UD	UD	37.304	UD	UD	36.474
	1900985040N	UD	UD	34.837	UD	UD	35.721	UD	UD	34.886	UD	UD	35.749

Table 2: Stability Study Results. UD-Undetermined

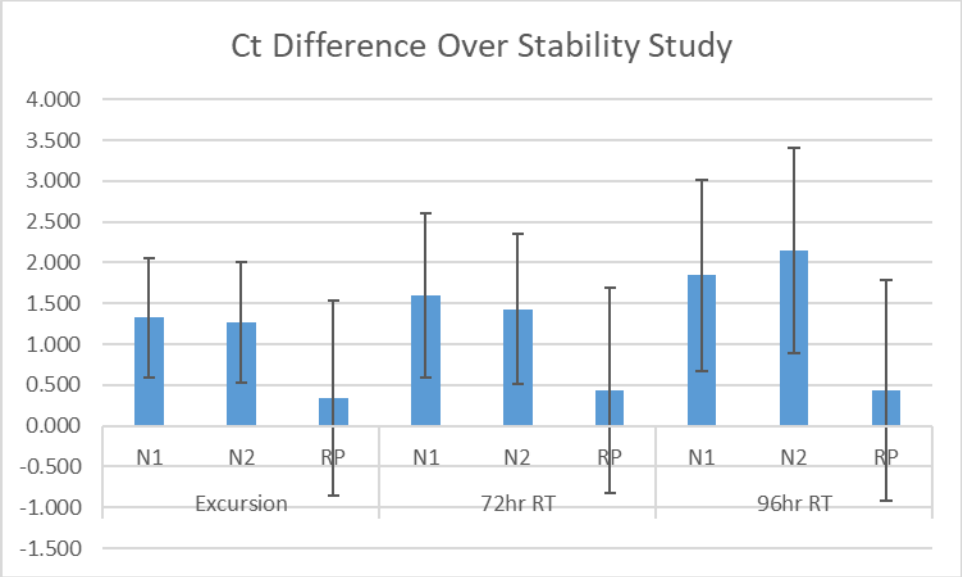

Figure 1: Comparison of Ct Differences Over the Duration of the Stability Study. Error bars are standard deviation.

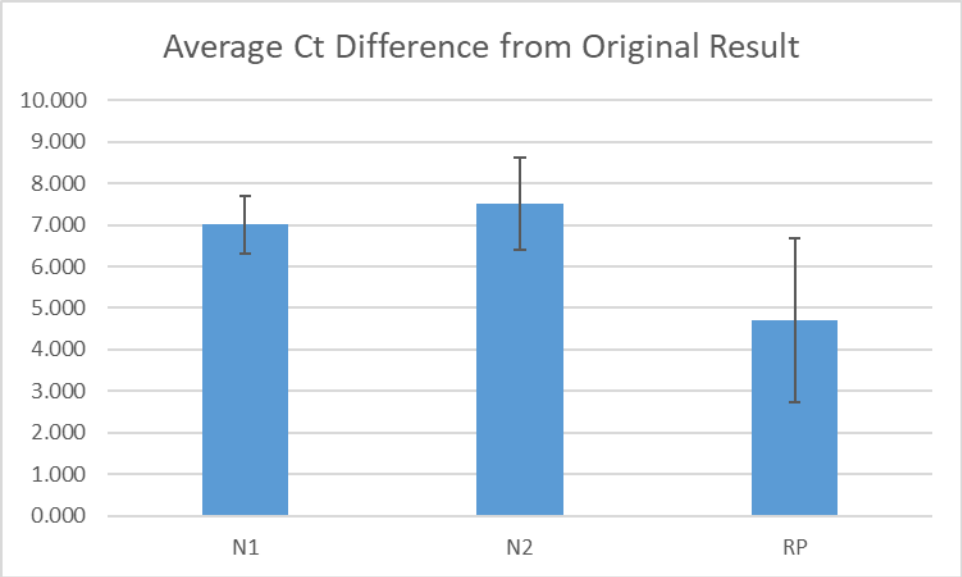

Figure 2: Comparison of Ct Loss Due to Sample Dilution. Error bars are standard deviation.