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Preliminary results: Sienna Covid 19 Rapid Test Cassettes

This report summarizes results obtained with our full set of 460 samples, however the final analysis and comparison with other tests is still pending and the results are still preliminary. Fourteen additional samples from suspected COVID-19 patients were tested, but were not confirmed by RT-PCR and were not included in this report. Tests were performed according to the instructions of the manufacturer. Analysis was performed for 292 plasma samples collected in the hospital (WU350, acute Covid-19 cases with positive RT-PCR results; WU353 convalescent samples from proven cases collected at least 2 weeks after resolution of symptoms and now negative by RT-PCR) and 168 archived at Washington University (US pre-COVID-19; African pre-COVID-19). The RT-PCR test for the WU353 convalescent samples was sometimes not performed by Washington University, but by local hospitals and records need to be verified. The Sienna test was performed in parallel with other commercial RTD. The test was easy to perform.

1. Sensitivity

The overall sensitivity (any COVID-19 confirmed sample, IgM or IgG positive) was 75%. The sensitivity was lower in the early acute patients and higher in the convalescent patients. The detailed results are summarized in Table 1. Test results from confirmed COVID-19 samples stratified by day after presentation at the hospital are recorded in Table 2. The highest sensitivity was at day 14 (96.4%) or with samples from convalescent patients (95%). Note we just received the data on the duration of symptoms in acute cases prior to collection of day 0 samples and they will be included in the final analysis.

2. Specificity

The overall specificity (true negative samples, IgM or IgG positive) was 95.8% (Table 1). The IgG test was more specific than IgM (100% vs 95.8%). False positives were detected only among African samples and not among the USA samples.

3. Summary and conclusion

The preliminary analysis of the results from 460 plasma samples indicates that the Sienna Covid 19 Rapid Test Cassettes have an average sensitivity of about 75% in detecting acute and convalescent cases, with lower sensitivity in early cases and higher sensitivities of 95-96% in later or convalescent cases. The test has a high specificity of 96% when tested with pre-COVID-

19 samples from the USA or from sub-saharan Africa. The test appears to be a promising tool for antibody detection against SARS CoV-2.

Table 1 Overview about the Sienna IgM and IgG test results

Sienna Lot: 20051104							
Participant Group	N tested	IgM pos	IgM %	IgG pos	IgG %	% IgM and IgG pos	% IgM or IgG or both pos
WU350 (D0-14)	213	139	65.2%	112	52.6%	51.2%	66.7%
WU353 convalescent	80	71	88.7%	66	82.5%	76.2%	95.0%
Total SARS-CoV-2 RT-PCR pos	292	210	71.9%	178	60.9%	58.3%	74.6%
US pre-COVID-17	80	0	-	0	-	-	0
Uganda 1996	58	6	10.3%	0	-	-	10.3%
Cote d'Ivoire 2016	30	1	3.3%	0	-	-	3.3%

Table 2 Sienna IgM and IgG test results for confirmed COVID-19 cases by day after presentation with clinical symptoms at the hospital

Sienna Lot: 20051104							
Participant Group	N tested	IgM pos	IgM %	IgG pos	IgG %	% IgM and IgG pos	% IgM or IgG or both pos
D0	82	32	39.0%	23	28.0%	26.8%	40.2%
D3	54	38	70.4%	27	50.0%	48.1%	72.2%
D7	49	42	85.7%	36	73.5%	71.4%	87.7%
D14	28	27	96.4%	26	92.8%	92.8%	96.4%
WU353 convalescent	80	71	88.7%	66	82.5%	76.2%	95.0%
Total	292	210	71.9%	178	60.9	58.3%	74.6%