WEEKLY EPIDEMIOLOGICAL REPORT

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Role of antigen testing in the control of COVID 19

In the context of the current pandemic of COVID 19, diagnostic tests are mainly performed to verify disease status in individuals with signs and symptoms suggestive of COVID 19 and in individuals identified through contact tracing regardless of their symptom profile. Nucleic acid amplification tests (NAATs), such as real time reverse transcription polymerase chain reaction (rRT-PCR) assays, and have been widely used in diagnosis with varying accessibility for testing across countries due to the high cost and longer turnaround time.

Antigen tests are immunoassays that directly detect SARSCoV-2 proteins produced by replicating virus, which implies current viral infection. Rapid diagnostic tests (Ag-RDTs) for antigens, appropriate for near-patient use have been developed that are performed on nasopharyngeal or nasal swab specimens of patients. The Ag-RDTs have a rapid turnaround time, are less resource intensive and cheaper compared to NAATs and offer the opportunity to decentralize testing of patients with early symptoms thus decreasing delays in diagnosis. The downside is that the Ag-RDTs are less sensitive than NAATs and their performance depends greatly on the circumstances in which they are used.
Table 1 illustrates the differences and similarities between RT-PCR tests and antigen tests.

Table 1: Comparison of RT-PCR and antigen tests

Source: Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#table1

	RT-PCR tests	Antigen tests
Intended use	Detect current infection	Detect current infection
Analyte detected	Viral RNA	Viral antigens
Specimen type (s)	Nasal swab, sputum, saliva	Nasal swab
Sensitivity	High	Moderate
Specificity	High	High
Test complexity	Varies	Relatively easy to use
Authorized for use at the point-of-care	Most devices are not, some devices are	Yes
Turnaround time	Ranges from 15 minutes to more than 2 days	Approximately 15 minutes
Cost/Test	Moderate	Low

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NAATs remain the "gold standard" for diagnostic detection of SARS-CoV-2. When compared to this gold standard, the sensitivity of Ag-RDTs in samples from upper respiratory tract (nasal or nasopharyngeal swabs) has shown high variability, ranging from 0-94%, whereas specificity has been consistently high (>97%). Available evidence indicates that Ag-RDTs perform well when patients are tested in the early stages of infection when they carry a high viral load (Ct values ≤25 or >106 genomic virus copies/mL). This period usually corresponds to the pre-symptomatic (1-3 days before symptom onset) and early symptomatic phases of the illness (within the first 5-7 days of illness).

When Ag-RDTs are recommended for use it is important to take account of the fact that timing of test is paramount to obtain a reliable result. Performing the test in patients beyond 5-7 days of the onset of symptoms, when the viral load is less, is likely to return a false negative result. Regardless of these limitations, Ag-RDTs have significant value in clinical and public health decision making and in surveillance of COVID 19 if appropriately administered and interpreted. The higher reliability of the test during the early stages of infection offers the opportunity to diagnose patients early and take measures to isolate the most infectious cases and quarantine their close contacts thus enabling interruption of transmission.

The selection of appropriate scenarios for use of Ag-RDTs are guided by the prevalence of infection, the specific test's performance parameters such as the sensitivity and specificity, and the patient's clinical profile, and epidemiological context. The pretest probability of the disease in the patient being tested influence the positive and negative predictive values of all in vitro diagnostic tests. The pretest probability in turn is impacted by the prevalence of the infection in the community at the time of testing and the clinical context of the patient.

WHO recommends that Ag-RDT that conform to minimum performance requirements of ≥80% sensitivity and ≥97% specificity against NAAT reference assay can be used to diagnose SARS-CoV-2 infection in a range of settings with limited access to NAAT and where the longer turnaround times limit its clinical use. The Ag-RDTs should be performed by trained healthcare workers within the first 5-7 days following the onset of symptoms in patients and in strict accordance with manufacturer's instructions for use to ensure the optimal test performance.

The Ag-RDT is recommended for use by WHO in the following contexts:

- When an outbreak of COVID 19 is suspected in a remote setting, institution, or semi-closed community where access to NAAT is not immediately guaranteed. In this scenario, an outbreak is highly likely when multiple positive Ag-RDT results are obtained and would pave the way for early initiation of infection control measures. Confirmatory testing with NAAT should be performed in all or a subset of antigen-positive cases where feasible.
- When an outbreak of COVID 19 in closed or semi-closed environments such as schools, care-homes, cruise ships, prisons, work-places and dormitories is confirmed with NAAT, Ag-RDTs can be employed to screen individuals at risk and isolate positives rapidly and prioritize sample collection from RDT-negative individuals for NAAT.
- To monitor the trends in incidence in situations of widespread community transmission or outbreaks among frontline staff where the positive predictive value and negative predictive value of an Ag-RDT result is sufficient to enable effective infection control.
- For early detection and isolation of positive cases in high-risk congregate settings such as healthcare institutions, elderly homes, prisons, schools and among frontline staff when there is widespread community transmission. The interpretation of a negative RDT result will depend on the performance of the RDT test and the community prevalence of COVID-19. In such instances, a repeat RDT or preferably a confirmatory NAAT should be performed as a negative Ag-RDT result cannot completely exclude an active COVID-19 infection, particularly in symptomatic patients. Ideally, confirmatory NAAT should be performed within two days of the initial antigen testing.
- Since it has been shown that asymptomatic cases of COVID 19 have viral loads similar to symptomatic cases, asymptomatic contacts of cases may be tested with Ag-RDT. It should be noted that Ag-RDTs are not specifically authorized for this use and data to guide the use of Ag-RDT as screening tests on asymptomatic individuals is limited. Further, a negative Ag-RDT should not preclude a contact from being quarantined.

Ag-RDTs is not recommended for use in settings or populations with low expected prevalence of disease (e.g. screening at points of entry, blood donation, elective surgery), especially where confirmatory testing by NAAT is not readily available or to determine whether a previously confirmed case is still infectious.

References

World Health Organization. (2020). Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays: Interim guidance. *WHO Publications, September*, *11*, 2.

Centers for Disease Control and Prevention. (2020). Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. Retrieved 15/11/2020, from https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Compiled by Dr Nimali Widanapathirana, Senior Registrar, Epidemiology Unit

Table 1: Selected notifiable diseases reported by Medical Officers of Health 26th– 02nd Oct 2020 (40th Week)

RDHS Division	Dengue Fever		Dysentery		Encephalitis		Enteric Fever		Food Poisoning		Leptospirosis		Typhus Fever		Viral Hepatitis		Human Rabies		Chickenpox		Meningitis		Leishmaniasis		WRCD	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	T*	C**
Colombo	34	3989	1	31	0	9	0	7	2	18	20	356	0	3	0	3	0	0	4	209	3	45	0	2	**56**	**100**
Gampaha	14	2489	0	12	0	8	0	7	0	19	8	279	0	8	1	7	1	2	5	256	0	33	0	60	**43**	**96**
Kalutara	10	1687	0	16	0	6	0	6	0	6	15	786	1	15	0	6	0	2	10	289	0	38	0	0	**53**	**86**
Kandy	51	3120	0	25	0	1	0	9	0	15	11	216	1	107	3	10	0	0	3	156	0	28	3	66	**63**	**100**
Matale	3	560	0	9	0	4	1	6	0	6	1	96	0	8	1	11	0	1	0	60	0	5	5	284	**63**	**100**
NuwaraEliya	0	166	0	35	0	1	0	6	0	9	5	118	3	91	0	4	0	0	1	78	0	15	0	0	**22**	**100**
Galle	11	1614	1	39	0	18	0	4	0	48	50	755	3	59	2	8	2	2	1	300	2	63	0	5	**33**	**99**
Hambantota	2	345	0	12	0	4	0	2	0	48	2	210	0	60	0	4	0	1	5	178	1	48	12	590	**70**	**100**
Matara	4	497	0	25	0	17	0	1	0	4	2	476	0	15	1	15	0	0	0	126	0	22	7	330	**21**	**100**
Jaffna	12	2057	4	94	0	0	1	21	3	75	1	26	12	552	0	1	0	2	0	102	0	12	0	2	**26**	**93**
Kilinochchi	1	127	0	40	0	2	0	11	2	23	0	20	1	39	0	1	0	0	0	16	0	11	0	13	**64**	**100**
Mannar	0	134	0	0	0	0	0	1	0	2	1	7	0	2	0	0	0	1	0	2	0	9	0	0	**40**	**100**
Vavuniya	0	249	0	13	0	0	0	6	0	3	0	43	0	3	0	0	0	0	1	33	0	4	0	1	**64**	**100**
Mullaitivu	0	85	0	14	0	0	0	6	0	5	0	26	0	15	0	3	0	2	0	12	0	7	0	7	**39**	**99**
Batticaloa	16	2381	2	89	0	7	0	1	0	49	1	33	0	0	1	6	0	1	2	93	0	32	0	1	**48**	**100**
Ampara	0	310	0	21	0	4	0	0	0	0	0	88	0	0	0	4	0	0	0	116	0	15	0	5	**69**	**100**
Trincomalee	1	2279	2	17	0	0	0	0	0	2	0	31	0	9	0	8	0	0	0	100	0	9	0	1	**43**	**98**
Kurunegala	3	894	0	23	0	12	0	4	0	36	4	228	0	30	1	8	0	3	4	308	1	41	11	418	**49**	**99**
Puttalam	3	465	0	10	1	5	0	3	0	1	0	60	0	17	0	2	0	1	0	77	3	54	0	10	**56**	**100**
Anuradhapur	3	408	0	19	0	3	0	4	0	30	5	253	1	26	2	15	0	2	3	180	1	61	9	233	**40**	**98**
Polonnaruwa	1	230	0	7	0	0	0	0	3	8	3	129	0	1	3	24	0	1	4	136	2	18	5	246	**56**	**91**
Badulla	2	444	1	23	0	5	0	3	0	4	4	332	0	93	0	13	0	0	8	141	1	34	0	19	**55**	**91**
Monaragala	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Ratnapura	10	1893	2	88	0	29	0	6	0	37	17	1383	1	53	1	17	0	1	3	175	0	98	0	117	**51**	**100**
Kegalle	8	775	0	18	0	10	0	4	0	18	20	488	1	42	0	20	0	0	2	170	2	61	4	42	**55**	**100**
Kalmune	5	934	0	54	0	3	0	1	0	6	0	22	0	2	0	3	0	0	0	274	1	42	0	0	**60**	**100**
SRILANKA	**194**	**28132**	**13**	**734**	**1**	**148**	**2**	**119**	**10**	**472**	**17**	**6461**	**24**	**1250**	**16**	**193**	**3**	**22**	**56**	**3587**	**17**	**805**	**56**	**2452**	**49**	**95**

Source: Weekly Returns of Communicable Diseases (WRCD).

*T=Timeliness refers to returns received on or before 02nd Oct, 2020 Total number of reporting units 356 Number of reporting units data provided for the current week: 314 C**-Completeness

Table 2: Vaccine-Preventable Diseases & AFP

26th– 02nd Oct 2020 (40th Week)

Disease	No. of Cases by Province									Number of cases during current week in 2020	Number of cases during same week in 2019	Total number of cases to date in 2020	Total number of cases to date in 2019	Difference between the number of cases to date in 2020 & 2019
	W	C	S	N	E	NW	NC	U	Sab					
AFP*	00	00	00	00	00	00	00	00	00	00	00	35	62	- 43.5 %
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Mumps	00	00	00	00	00	00	00	00	00	00	02	145	263	- 44.2 %
Measles	01	00	00	00	00	00	00	00	00	01	02	46	250	- 81.6 %
Rubella	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
CRS**	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Tetanus	00	00	00	00	00	00	00	00	00	00	00	03	17	- 82.3 %
Neonatal Tetanus	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Japanese Encephalitis	00	00	00	00	00	00	00	00	00	00	00	31	11	181.8 %
Whooping Cough	00	01	00	00	00	00	00	00	00	01	00	08	36	- 77.7 %
Tuberculosis	37	13	10	04	12	08	06	12	00	102	128	4969	6517	- 23.7 %

Key to Table 1 & 2

Provinces: **W**: Western, **C**: Central, **S**: Southern, **N**: North, **E**: East, **NC**: North Central, **NW**: North Western, **U**: Uva, **Sab**: Sabaragamuwa.

RDHS Divisions: **CB**: Colombo, **GM**: Gampaha, **KL**: Kalutara, **KD**: Kandy, **ML**: Matale, **NE**: Nuwara Eliya, **GL**: Galle, **HB**: Hambantota, **MT**: Matara, **JF**: Jaffna, **KN**: Killinochchi, **MN**: Mannar, **VA**: Vavuniya, **MU**: Mullaitivu, **BT**: Batticaloa, **AM**: Ampara, **TR**: Trincomalee, **KM**: Kalmunai, **KR**: Kurunegala, **PU**: Puttalam, **AP**: Anuradhapura, **PO**: Polonnaruwa, **BD**: Badulla, **MO**: Moneragala, **RP**: Ratnapura, **KG**: Kegalle.

Data Sources:

Weekly Return of Communicable Diseases: Diphtheria, Measles, Tetanus, Neonatal Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps., Rubella, CRS,

Special Surveillance: AFP* (Acute Flaccid Paralysis), Japanese Encephalitis

CRS =**Congenital Rubella Syndrome

NA = Not Available

Dengue Prevention and Control Health Messages

Look for plants such as bamboo, bohemia, rampe and banana in your surroundings and maintain them free of water collection.

Comments and contributions for publication in the WER Sri Lanka are welcome. However, the editor reserves the right to accept or reject items for publication. All correspondence should be mailed to The Editor, WER Sri Lanka, Epidemiological Unit, P.O. Box 1567, Colombo or sent by E-mail to **chepid@sltnet.lk. Prior approval should be obtained from the Epidemiology Unit before publishing data in this publication**

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