

## Greater Manchester Mass Testing Expert Group: Rapid Antigen Testing Principles

27th November 2020

### Introduction

MTEG welcomes the recent rapid expansion in testing capacity, particularly the increase in RT-PCR capacity in Pillars 1 & 2 and the access to large quantities of Rapid Antigen Testing (RAgT) devices. This additional resource will permit the routine testing of asymptomatic NHS staff in hospitals and primary care facilities, and other high-risk environments.

The rapid turn-around time of RAgT should also help to improve decision making in acutely unwell patients, particularly in ensuring infectious patients are not admitted, while awaiting the results of PCR, into wards with uninfected patients (Amber Zones). The combination of asymptomatic staff screening and improved admission pathways should significantly reduce nosocomial infection rates and staff absence.

As requested by the GM System, MTEG has endeavoured to provide guidance on the optimal utilisation of the expansion in PCR capacity and availability of RAgT.

### GM Mass Testing Expert Group: Overarching principles for RAgT

Rapid antigen testing (RAgT) aims to identify patients with COVID-19 at the point where they are in the infectious stage of the condition. A number of RAgT technologies are available (lateral flow devices) and these are being urgently rolled out across a number of health and care settings.

The primary basis on which these tests were initially approved was for rapid diagnosis of *symptomatic* cases. The key advantages are the rapid turn-around (approx 30 minutes), Point-of-Care convenience and simplicity of the performing the test ('pregnancy' test technology).

More recently the use of these tests for asymptomatic detection of COVID-19 infection in populations has been evaluated and strongly recommended for a wide number of clinical and community purposes.

In order to provide some consistency in the approach to using RAgT, MTEG have developed a number of key principles that can be applied to any of setting in which these tests may be deployed.

- RAgT have a reported sensitivity (*when used by trained staff*) of approximately 80%.
- The specificity is quoted to be approx. 99.6%; resulting in 0.4% false positives.

It is important to bear these figures in mind when considering use of these tests in any setting so that any potential risks/harms associated with false negatives or false positives are fully appreciated, and noted both by the organisation administering the testing and subjects being tested. For example, in settings of low infection rates, false positives will be greater than true positives; also subjects need to understand that a single negative test *is not unequivocal evidence* of the absence of infection.

### **Clinical and Community Contexts:**

- 1: In clinical contexts with very high risk and/or very high consequences in which an established RT-PCR-based testing programme is already in place, we do not recommend that RAgT replaces such a staff-testing programme. This includes programmes in areas such as haematology, oncology, surgical or systemic immunotherapy settings.
- 2: Outside of these areas, RAgT is likely to have a wide role in rapid identification of infectious cases and of potential/actual outbreaks in a range of clinical and care settings within hospitals (patient-facing and support staff areas), mental health and community-based health and care settings including primary care, community services, care homes and staff providing care in patient homes etc. It may also form an important pillar of any programme to enable visitors in to care homes. In each settings, local and regional public health teams would work together with the relevant delivery cells to organise and implement the programme according to these recommendations.
- 3: Communities: RAgT can also be used to identify outbreaks in higher risk or higher consequence community settings. This would include higher risk workplaces e.g. food processing plants, as well as public-facing occupations such as bus and taxi drivers, police and fire services, school teachers etc.
- 4: A more systematic general population screening programme is not recommended. Such an approach will identify a large number of false positives and will have significant consequences at a population level. MTEG recommends that RAgT could be rapidly deployed in geographical areas where spikes of outbreaks are occurring as part of an overall outbreak management plan. This overall strategy is likely to be more cost-effective and better able to coordinate with local contact tracing agencies.

### **RAgT use within Testing programmes:**

- 1: Given the reported sensitivity (approx 80%), a single negative test cannot be relied on to confidently exclude infection and therefore RAgT should be used in contexts where repeat testing can be organised at a suitable (3-5 days) interval (e.g. in a staff testing programme) and/or in a context where a confirmatory RT-PCR test has been taken in parallel and the RAgT is being used for a quicker decision-making, rather than as the sole diagnostic test (e.g. in acute admission settings).

We do not recommend the use of single, one-off RAgT for clinical decision making.

- 2: The specificity (99.6%) means that in any large population, the number of patients with a false positive test (0.4%) is appreciable and in lower prevalence settings the false positive rate may approximate to, or exceed, the true positive rate. Relying solely on RAgT will mean significant numbers (index case and contacts) self-isolating unnecessarily.

We recommend that a positive RAgT should be confirmed with a RT-PCR test performed through the usual Pillar 1/ Pillar 2 routes.

- 3: Self-testing and self-reading of RAgT is the principle on which a number of RAgT are developed. There is however a level of training required for individuals to self-swab and also to interpret the test result. An organised system of *ongoing support* during testing programmes is needed to be promoted and provided by the relevant organisation. This will help maintain high levels of adherence to testing and support test interpretation by individuals.