



## Quality Assurance for Mass Testing with Lateral Flow Antigen Testing Devices and Serial Contact Testing in Schools

### Accountable person

Cardinal Wiseman is required to put in place a quality management system and designate a member of the team to act as Quality Lead who will have the accountability for quality and risk management of the service within the context of a non-laboratory environment. It is not necessary for this person to have clinical background but they should have appropriate training for the role. In smaller settings, it may be optimal for the site Covid-19 coordinator to take on the role of quality lead.

Schools should have clear escalation and decision mechanisms in place to support the Quality Lead.

The Quality Lead is **Zoe Seth**

The Quality Lead is supported by **Helen Quinn** (to support escalation and decision mechanisms)

### Quality management plan

Each school is responsible for creating a quality management plan prior to the start of the testing, which should include the following:

- 1. Training:**
  - Knowledge assessment at the end of on-line training- this is done as part of online training
  - A dry run as a team during mobilisation or on the first day
- 2. Observing testing process:**
  - Daily/weekly clinical quality audits by site supervisor (a sample quality checklist is enclosed in Appendix A)
  - Staff competence checks. Competency checklists for key roles are provided in Appendix B1, B2 & B3.
- 3. Monitoring**
  - Void rates and invalid test rates by day and by operator
  - Recording errors
  - Serious incident rates and escalation
- 4. Risk assessment**
  - Risk and incident management system setting out the management of safety concerns, safety incidents and risk mitigation. A risk assessment template is provided in Appendix C .



## Records and reporting

A clinical governance record should be used to document that the checks have been undertaken and that if any actions are necessary that they are documented and followed up in a timely manner.

In addition to the internal incident management by the testing sites, all incidents that could potentially impact quality or safety of testing should be reported to DfE who will in turn escalate the issues to DHSC through the clinical governance process for mass testing. Relevant incidents will be reported to the MHRA yellow card scheme in consultation with the DHSC incident response team.



## Appendix A: Quality Checklist

<b>Set-up</b>	<ul style="list-style-type: none"><li>• Supplies appropriate and enough</li><li>• Surface and space requirements are met</li><li>• Air supply- no recirculation, good airflow</li><li>• Temperature : 15-30*C</li></ul>
<b>Registration</b>	<ul style="list-style-type: none"><li>• Face covering/ masks</li><li>• Hand and respiratory hygiene,</li><li>• Social distancing</li></ul>
<b>Consent</b>	<ul style="list-style-type: none"><li>• Barcodes</li><li>• Crowd control</li><li>• Queue Management</li></ul>
<b>Swabbing Key checkpoints:</b>	<ol style="list-style-type: none"><li>1. Appropriate PPE at all times</li><li>2. Explanation of procedure to testing subjects</li><li>3. Swabbing process:<ul style="list-style-type: none"><li>- Buffer drops/tube</li><li>- Tonsil swabs</li><li>- Mid turbinate 1.5- 2.5 cm</li><li>- No touching of swab with mouth etc</li><li>- Handling gags, active tongue, bleeds, coughs &amp; colds</li><li>- Hand-over of swabs to processing operative</li></ul></li><li>4. Appropriate PPE at all time</li><li>5. Explanation of procedure to testing subjects (staff, student and pupils)</li></ol>



<b>Processing</b>  <b>Key checkpoints:</b>	<ol style="list-style-type: none"><li>1. Appropriate PPE at all time</li><li>2. Sample processing - LFD loading<ul style="list-style-type: none"><li>- Air bubbles check</li><li>- Timer setting</li><li>- Reading and marking</li><li>- Voids count/operator</li><li>- Movement of LFD</li><li>- Hand-over to recorder</li></ul></li><li>3. Cleaning</li><li>4. Glove change</li><li>5. Hand and respiratory hygiene, social distancing</li></ol>
<b>Data integrity</b>	<ul style="list-style-type: none"><li>• Barcode journey ( audit ) : correct barcode on LFD and results recorded against correct student</li></ul>
<b>PPE doffing (removing) and donning (putting on)</b>	<ul style="list-style-type: none"><li>• Observations audits</li></ul>
<b>Cleanliness</b>	<ul style="list-style-type: none"><li>• Cleaning frequency</li><li>• Cleaning solutions</li><li>• Spot checks</li></ul>
<b>Hand-overs and flow</b>	<ul style="list-style-type: none"><li>• Overall user , sample and data flow integrity and efficiency</li><li>• Improvement opportunities</li></ul>
<b>Site culture</b>	<ul style="list-style-type: none"><li>• Communication, teamwork and open culture with emphasis on learning from mistakes.</li><li>• Safeguarding approach</li><li>• Respect towards each other, school staff and students</li></ul>
<b>Off-duty</b>	<ul style="list-style-type: none"><li>• Face covering; social distancing ; follow school rules on smoking etc</li><li>• Safeguarding approach</li><li>• Respect towards each other, school staff and students</li></ul>



## Appendix B1: Schools and Colleges Testing Assistant / Swabber Competency Assessment

Name:

Date:

Assessor:

**Pre-requirement:** Testing Operator has read and understood all the relevant documentation and completed relevant online training modules.

Criteria	Method O/D*	Assessor Comments	Next Review Date
<p><b>Self swabbing:</b></p> <ul style="list-style-type: none"> <li>• Wears full correct PPE</li> <li>• Dons PPE correctly</li> <li>• Gives clear and concise directions to subjects</li> <li>• Informs about gag reflex and use of emesis bowls</li> <li>• Maintains polite and courteous manners whilst interacting with the subject</li> <li>• Dismisses pupil in reassuring manner</li> <li>• Manages issues/incidents such inability to swab, bleeding nose etc adequately</li> <li>• Demonstrates understanding of escalation protocol to report incidents and seeks advice quality lead</li> </ul>	<p>O</p> <p>O</p> <p>O</p> <p>O</p> <p>O</p> <p>O</p> <p>O/D</p> <p>O/D</p>		



<p><b>Administered Swabbing (in addition to above)</b></p> <ul style="list-style-type: none"> <li>• Prepares test-tube with extraction fluid</li> <li>• Explains procedure in calm and reassuring tone</li> <li>• Asks for permission to swab</li> <li>• Performs swab to correct position, depth and time</li> <li>• Dismisses subject in reassuring manner</li> </ul>	<p>O/D</p> <p>O/D</p> <p>O/D</p> <p>O/D</p> <p>O/D</p>		
<p><b>End of Shift</b></p> <ul style="list-style-type: none"> <li>• Understands protocol for breaks and PPE change between breaks</li> <li>• Disinfects all contact surfaces and work area before hand-over</li> <li>• Removes PPE appropriately</li> </ul>	<p>O</p> <p>O</p> <p>O</p>		
<p><b>Comments / Remedial Actions (if required)</b></p>			
<p><b>Operator Sign &amp; Date:</b></p>			
<p><b>Assessor Sign &amp; Date:</b></p>			

\* O/D: Observation/ Demonstration



## Appendix B2: Schools and Colleges Processing Operative Competency Assessment

Name:

Date:

Assessor:

**Pre-requirement:** Processing Operative has read and understood all the relevant documentation and completed relevant online training modules.

Criteria	Method O/D*	Assessor Comments	Next Review Date
<b>General Duties</b> <ul style="list-style-type: none"> <li>Wears correct PPE throughout the testing procedure</li> </ul>	O		
<b>Mixing</b> <ul style="list-style-type: none"> <li>Mixes swab with extraction fluid with squeezing action</li> <li>Operates with due care and attention as to not lose sample on mixing</li> <li>Checks for bubbles when loading device</li> </ul>	O  O  O/D		
<b>Sampling</b> <ul style="list-style-type: none"> <li>Asks for barcode and applies barcode to LFD</li> <li>Adds two drops of sample to device without air-bubble</li> <li>Records 'read-time' on device</li> <li>Removes gloves and sanitizes hands, dons on new gloves</li> <li>Sanitises test area with disinfectant wipe</li> <li>Discards sanitising wipe and gloves in correct waste bin</li> </ul>	O/D  O/D  O/D  O/D  O/D		





<ul style="list-style-type: none"> <li>• Sanitises hands and dons on new gloves</li> </ul>	O/D		
<ul style="list-style-type: none"> <li>• Reads device at correct time</li> </ul>	O/D		
<ul style="list-style-type: none"> <li>• Records results clearly or hands device correctly to the recorder</li> </ul>	O/D		
<ul style="list-style-type: none"> <li>• Confidently manages issues such as; air bubbles instead of fluid, void results, weak positive readings</li> </ul>	O/D		
<ul style="list-style-type: none"> <li>• Demonstrates understanding of escalation protocol to report incidents and seeks advice quality lead</li> </ul>	D		
<p><b>End of Shift</b></p> <ul style="list-style-type: none"> <li>• Understands protocol for breaks and PPE change between breaks</li> </ul>	O		
<ul style="list-style-type: none"> <li>• Hands over still incubating devices to experienced operator holding device horizontally</li> </ul>	O/D		
<ul style="list-style-type: none"> <li>• Disinfects all contact surfaces and work area before hand-over</li> </ul>	O		
<ul style="list-style-type: none"> <li>• Removes PPE appropriately</li> </ul>	O		
<b>Comments / Remedial Actions (if required)</b>			
<b>Operator Sign &amp; Date:</b>			
<b>Assessor Sign &amp; Date:</b>			

\* O/D: Observation/ Demonstration





## Appendix B3: Schools and Colleges Results Recorder Competency Assessment

Name:

Date:

Assessor:

**Pre-requirement:** Results Recorder has read and understood all the relevant documentation and completed relevant online training modules.

Criteria	Method O/D*	Assessor Comments	Next Review Date
<b>General Duties</b> <ul style="list-style-type: none"> <li>Has appropriate device for scanning and recording results</li> <li>Wears correct PPE in test area</li> </ul>	O/D  O/D		
<b>Recording Duties</b> <ul style="list-style-type: none"> <li>Collects completed test units in timely manner</li> <li>Scans barcode and confirms results correctly</li> <li>Disinfects collection tray (if used) correctly</li> <li>Keeps manual tally of positive and void results</li> <li>Escalates issues with designated supervisor for follow-up e.g. void test kits</li> <li>Wipes keyboard thoroughly on regular intervals</li> </ul>	O/D  O/D  O/D  O/D  O/D		
<b>End of Shift</b> <ul style="list-style-type: none"> <li>Ends shifts on portable device</li> <li>Sanitises device</li> </ul>	O/D  O/D		



**Comments / Remedial Actions (if required)**

**Operator Sign & Date:**

**Assessor Sign & Date:**

\* O/D: Observation/ Demonstration