Field laboratory site visit check list

Name of laboratory: Glasgow mass testing SARS-CoV-2 (COVID-19) laboratory
Date: 7th April 2020
Reviewer(s): NR and Rory Gunson

Evidence required	Requirements	Reviewer comments	Recommendation for development	Implementation timeline
Operational management				
Scope of service	High volume through-put supported by automation.	Initially manual processes but plan to install automated extraction and liquid handlers to remove staff risk.	Validation to be repeated and staff retrained if processes change.	
Capacity	High volume through-put supported by automation/indication of daily testing volume.	Goal to perform 7,000 tests per shift then increase to 3 shifts per 24 hours to deliver 20,000 tests per day.		7,000 per day by Day 30
Quality management	In line with national protocols and ISO 15189.	No plans to seek accreditation. No quality management system in place yet.	Need protocols for audit, competencies, responsibilities etc. Require a policy to deal with incidents and subsequent root cause analysis.	
Operational Lead	Leads with scientific and infectious sciences / virology expertise.	Current posts: NR NR to implement facility	Require operational leads when site is fully running	
Clinical Lead	Lead with infectious sciences / virology expertise.	Virology lead - Prof Rory Gunson, West of Scotland Specialist Virology Centre, Glasgow Royal Infirmary	Ongoing role and workload needs to be clarified.	
Staffing numbers and structure	Experienced staff, including BMS staff, to support 24/7 working and high-volume throughput.	Volunteers selected according to defined criteria but didn't include scientific knowledge. Will review to appoint further staff.	Governance structure to be defined. Require molecular diagnostic expertise during shifts.	
Staff supervision in place	Assessment of staff supervision undertaken.	None appointed and unclear how this will be carried out.	Needs senior staff structure with appropriate experience and competencies. Unclear how this will be decided and who they will report too.	
Working patterns/ staff illness/ social distancing protocols / 24/7 service	Shift work in place, with separate workspaces to mitigate against staff illness.	3 x 8 hour shifts or considering 4 x 6 hour shifts. Focussing on staff well being due to the strain of the manual checking and sample preparation procedures.	Utilise a work pattern to adhere to social distancing in the laboratory	

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		Workflow and staff space clear and well thought out.		
Business Continuity	Business continuity plans reviewed by expert panel.	Unclear at present. Overarching business continuity being organised at higher level. Been reviewed by Scottish lawyers to comply with Scots Law.	Need to address: Will there be back up staff to cover illness? How will the staffing per shift cover the workload? Will it be linked to surge periods? What about other laboratories role in helping with this?	
Liability and indemnity cover for staff	Legal support appointed and policy to be reviewed by expert panel.	Overarching cover being organised at higher level. Been reviewed by Scottish lawyers to comply with Scots Law.	Need clarification	
Policy for testing own staff	Policy to be reviewed by expert panel.	No policy in place. Discussed if required an what would be the outcomes of positive/negative results.	Policy to be agreed by all mass testing laboratories.	
SOPs	SOPs covering the end to end processes in place and reviewed by expert panel e.g. but not limited to - Sample handling - Validation and verification - Reporting - Batch acceptance	No SOPs as yet as waiting for protocols to come from Milton Keynes. Lots of thought re existing procedures. Sample handling procedures were described and had some local solutions. Well thought out flow and inventive approaches such as 3D printing for bespoke tube racks. Verification/validation needs to be organised centrally and to ensure consistency with Milton Keynes and Manchester laboratories. AI software not in place yet. Discussed requirement for batch acceptance criteria and potential parallel testing of clinical samples prior to changing of consumable batches.	Urgently require sight of draft Milton Keynes SOPs so they can be adapted for local use. Need validation plan and access to controls/clinical material. Batch control to be implemented.	
Trouble shooting team	Trouble shooting processes appropriately set out in SOPs with a list of scenarios and appropriate subsequent actions. Appropriate scientific and virology expert leadership in place to support trouble shooting.	Concern around this. How do you build up experience within the teams to troubleshoot assays, interpret curves etc. Who coordinates, documents and decides actions? Competency issues around this also. What happens to the routine service whilst this takes place?	Require appropriately experienced individuals to be present during each shift to enable troubleshooting. Training may be provided onsite in Royal Infirmary laboratory. Competencies will take time to achieve.	

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		Need to think about how to employ appropriate people or how to involve NHS/other staffing to help.		
Training and competencies				
Training	Record of training provided for each staff member. Training manager in place.	Since it is only one testing stream the training aspects are minor. PPE training is essential and has already started.	Needs documented in an SOP and individual training records. Needs senior staff/competencies/quality manual.	
Competencies	Participation in EQA competency tool when available.	Aware that this is required.		
IQC and EQA				
Positive run controls	Policy to be reviewed by expert panel and evidence of controls checked.	?National policy – needs to be decided. Draft plate layout proposed. Internal policy regards troubleshooting when systemic failure occurs.	Urgent agreement on policy and local actions, roles and responsibilities	
IQC	Policy to be reviewed by expert panel and evidence of controls checked.	As above	Urgent agreement on policy and local actions, roles and responsibilities	
Validation	Validation performed in line with national protocols.	Various options. Needs to be linked to Milton Keynes and Manchester laboratories.	Need validation plan and standardisation of approach, controls etc.	
EQA	Policy to be reviewed by expert panel and evidence of registration to be checked.	Various options. Needs to be linked to Milton Keynes and Manchester laboratories.	Register for QCMD and UK NEQAS Covid EQA.	
Pre-analytical				
Sample Transport Arrangements	Process in place to monitor predicted sample delivery and using LIMS and barcoding system to support sample management.	No knowledge of where samples will be received from. No process to monitor expected delivery/surges. Needs to be sorted as it would impact staff planning. Barcoding will be present for booking in of samples	Need confirmation of sample sources and notification processes for delivery. Bar coding need to be progressed. No readers etc in place.	
Processes for arranging and monitoring collection of samples by courier and Royal Mail.	Process in place using LIMS and barcoding system to support sample management.	There is a barcode system and LIMS which needs to be utilised for sample receipt tracking.	Process needs documenting.	

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Packaging guidance for users available and compliance	To be reviewed by expert panel.	?National instruction – needs put in place	Urgently require detail.	
Process for follow up of samples not received	To be reviewed by expert panel.	No knowledge of where samples will be received from. No process to monitor expected delivery/surges.	Need confirmation of sample sources and notification processes for delivery. Process needs documenting and trialled.	
Sample reception				
Processes for receipt of sample and tracking within laboratory process	Process in place using barcoding system and LIMS to support sample management. Samples to be logged prior to unpacking. To be reviewed by expert panel.	Samples arrive with barcodes. Clarity required around barcode on sample and bag and if both need checked/?rejected if non matching.	Require some mechanism to list expected samples.	
Process to take through to containment area for viral inactivation including appropriate PPE	Streamlined process including: - unpacking samples from packaging in the hood - aliquot samples into the pre prepared 96 well plate containing the viral inactivation lysis buffer, preferably in a separate hood - Separate waste bin for tips and for bags and gloves to reduce contamination and infection risk. - Minimal numbers of staff involved at each stage.	Processes in place. ?storage in place for swab samples Local racking solutions in place. PPE present Waste in place. Waste removal in place Thoughts about staff numbers and arrangement in place	Require SOPs in line with Milton Keynes and Manchester but tailored to local practice.	
Time/Date stamp	LIMS registration of specimen.	Barcode in place. Registered in LIMS at five different stages of process for good sample tracking and auditing.		
PPE worn at receipt stage	Laboratory coat, gloves and eye protection (safety goggles) worn. Separate room to get prepared with PPE prior to entry into the sample receipt room.	Clear PPE in place including mask, gloves, gowns etc. Dedicated staff area for PPE preparation, separate form sample areas.		

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Damaged or samples received in non-compliant packaging	Processes in place for recoverable and non-recoverable specimens, including informing and resulting of lost or unrecoverable specimens, timely informing of source and incidence recording. Experienced sample reception lead required to support decision making.	Processes thought about. Samples will be triaged into trays at point of unpacking. Unclear regards mismatch sample barcode and bag barcode. ?who decides what gets tested and what doesn't (need SOP and set person?)	Require SOPs for sample acceptance and subsequent actions for rejected samples. Experienced sample reception lead required to support decision making during each shift.	
Sample traceability and tracking	Vertical audit by expert panel of sample tracking.	No auditing in place. LIMS set up to trace progress of samples through pipeline with time monitoring.	Need SOPs	
Internal tracking of samples received and awaiting testing	To be reviewed by expert panel. Process required particularly as capacity increases.	Barcoding in place. Protocol for tracing samples through the system is unclear. Roles and responsibilities unclear and also frequency of monitoring.	Need SOPs	
Process for sample triage	As capacity increases, triage may be required as outlined in the national reporting document. To be reviewed by expert panel.	High level processes but not yet defined	Need SOPs	
Plating for elution	To be reviewed by expert panel.	Protocol in place with checking processes, and use of multichannel pipettes to increase throughput.	Need SOPs	
Cleaning	Monitoring of laboratory cleaning of bench tops and floor in place. Daily swab of door handle, work surfaces for testing to ensure QA and governance.	Cleaning discussed and regular cleaning in place performed by NHS staff. Hourly collection of clinical/non-clinical waste by NHS.	Needs clarity regards contamination prevention measures/molecular specific cleaning. Is this carried out by own staff?	
Analytical				
RNA extraction and reverse transcription				
Containment level	Use of multichannel pipettes Working environment	Well thought out working environment. Use of multichannel pipettes.	Need SOPs	
Appropriate PPE in place	Laboratory coat, gloves and eye protection (safety goggles) worn.	PPE in place		

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Vertical audit of sample handling at this stage	Vertical audit of sample handling required.	No auditing in place. LIMS set up to trace progress of samples through pipeline with time monitoring.	Need SOPs	
Protocols	The lab assay protocols to be reviewed by expert panel.	No protocols in place.	Require SOPs in line with Milton Keynes and Manchester but tailored to local practice.	
Sample inactivation process	To be reviewed by expert panel.	Issues around access to lysis buffer.	Require SOPs in line with Milton Keynes and Manchester.	
Checking processes in place	To be reviewed by expert panel.	Double checks in place for all manual steps. Visual checking also in place using light source.	Need to be included in appropriate SOPs.	
Methods for RNA extraction, platform, numbers per run, capacity per day/cooling after elution	To be reviewed by expert panel.	6 Kingfishers in place. Throughput determined. No organisation regards machine use but probably unnecessary to organise more specifically	Machine use may need managed when testing numbers increase.	
Sample Storage if required/where/ temperature -20 or -80	Use of cooled racks (e.g. metal or plastic) to keep RNA cool. To be reviewed by expert panel.	Not discussed.	Need documented process.	
Vertical audit for this stage	Vertical audit to be performed by expert panel.	No auditing in place.		
Tracking during the RNA extraction process	To be reviewed by expert panel.	Not specifically discussed but LIMS tracking in place end to end.		
Processes to determine RNA quantity and A260:280	To be reviewed by expert panel. Internal extraction control process to be in place.	Not discussed.	Require SOPs in line with Milton Keynes and Manchester but tailored to local practice.	
RNA quality control				
Processes for RT if not integral to methodology for RT-PCR	To be reviewed by expert panel.	Awaiting guidance.	Require SOPs in line with Milton Keynes and Manchester.	

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Reverse transcription and QC/ RNA integrity if done separately	To be reviewed by expert panel.	Awaiting guidance.	Require SOPs in line with Milton Keynes and Manchester.	
Testing Platforms and Methodologies				
Numbers per run/ sample handling at this stage/ checking procedure/ how automated	To be reviewed by expert panel.	No checking procedure discussed at PCR set up. Perhaps clarity on the order of control set up to ensure controls are added at the appropriate time.	Require SOPs	
Vertical audit for this stage	Vertical audit to be performed by expert panel.	No auditing in place.		
Testing Protocols	Lab protocols to be reviewed by expert panel.	Awaiting guidance.	Require SOPs in line with Milton Keynes and Manchester.	
Sample Tracking	To be reviewed by expert panel.	Not specifically discussed but LIMS tracking in place end to end.		
Post Analytical				
Analysis and reporting				
Process for generation of data and automation/checking positive, negative and internal controls	Number of NTC and NEC should be reflective of specimens processed, ideally at regular intervals. Format could be PC, NTC, NTC, NEC Samples up to 44, NEC, NTC, samples up to 44, NEC, NTC in a 96 well plate. Positive and negative control monitoring-use of levy Jennings plots.	Awaiting guidance.	Require SOPs in line with Milton Keynes and Manchester.	
Interpretation criteria	Validation of interpretation software required. Results to be reported as either 1. Positive 2. Negative or 3. Retest.	Awaiting guidance but plans to use AI.	Require SOPs in line with Milton Keynes and Manchester.	
Repeat testing criteria	Criteria to be reviewed by expert panel.	Awaiting guidance.	Require SOPs in line with Milton Keynes and Manchester.	

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Primary reporting	QC to be verified as per westgard rules.	Awaiting guidance.	Require SOPs in line with Milton Keynes and Manchester.	
RCPath Decision Tree for Reporting	To be reviewed by expert panel.	Awaiting guidance.	Require SOPs in line with Milton Keynes and Manchester.	
Final report sign out				
Registered Professional	To be reviewed by expert panel.	Awaiting guidance.	Require SOPs in line with Milton Keynes and Manchester.	
LIMS in use	Processes to be reviewed by expert panel.	Implemented end to end.		
Report sent/receipted to subject	Processes to be reviewed by expert panel.	Awaiting guidance.	Require SOPs in line with Milton Keynes and Manchester.	
Turnaround time	Expected and implementation plan to be reviewed by expert panel.	Awaiting guidance.	Require SOPs in line with Milton Keynes and Manchester.	