Recommendations from RCPPath and Professional Bodies (IBMS, ACP and ACB)

Prioritisation/deferral of Pathology Laboratory Work (in light of SARS-CoV-2 (COVID19) epidemic)
Version 1.1
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Version Control:
Version 1.0 Published 24/03/2020
Version 1.1 Amended 02/04/2020
1.0 Background

In light of unprecedented stress on laboratory systems from the COVID-19 (SARS-CoV-2) epidemic testing, the recommendations below have been provided by Clinical Experts from the Royal College of Pathologists (RCPath), Institute of Biomedical Science (IBMS), the Association of Clinical Biochemistry and Laboratory Medicine (ACB) and the Association of Clinical Pathologists (ACP), as a guide to prioritisation of resources during this time of unprecedented emergency. The clinical input has been collated and coordinated by Prof JE Martin (MA, PhD, RCPathME, FRCPath), President of the Royal College of Pathologists, Professor of Pathology at Queen Mary University of London and Director of Academic Health Sciences, Bart’s Health NHS Trust, and has been agreed by IBMS, ACB and ACP.

2.0 Aims and Objectives

Pathology services must be in a position to continue to support clinical services over the coming difficult period. Many laboratories have already reviewed their work in order to safeguard core services whilst moving to minimal staffing levels to promote resilience and social distancing. This document outlines a range of measures that laboratories can use to prioritise work, to release staff, facilities, equipment and reagents to cope with the viral outbreak and maximise SARS-CoV-2-19 testing capacity.

1. There is significant unwarranted variation in laboratory testing, identified by the Getting it Right First Time Programme. A reduction in non-essential testing, and unnecessary testing, is a pre-requisite to release staff, and should be implemented without delay.

2. In general, tests which are not essential to managing a patient’s condition safely should be stopped. For example, mild infections can often be treated empirically without the need for confirmatory microbiology. Many other laboratory tests can be deferred. This document provides a guide for local tests that could be high priority for review, and laboratories can use this document to provide the necessary permission to accelerate these decisions.

3. Plans should be made to explore the potential for multi-disciplinary working within pathology and utilising staff from other areas (in a support role) to ensure service continuity.

4. All laboratories should review the measures outlined in this document and undertake a local review of activities. Where appropriate, but within a competency framework, flexibility of staff between the different disciplines should be reviewed locally.
3.0 Scope

The following measures should be considered urgently, by all Pathology Laboratory and Clinical Pathology providers, working with primary care, community and acute care providers, including NHS and Public Health England.

4.0 Overview and Recommendations

The Royal College of Pathologists, working with the IBMS, ACP and ACB recommend the following steps:

**Recommendation 1) Respiratory Virus Testing:**

1) Stop routine testing for influenza viruses and other respiratory viruses. Only consider testing if SARS-CoV-2 negative with ongoing fevers, respiratory symptoms and the patient remains in hospital. Stop ambulatory care testing.

2) Repeat SARS-CoV-2 testing after a negative result in patients with a compatible syndrome should only be carried out if a deep lower respiratory tract sample can be obtained after intubation. A patient with a negative test, an abnormal chest X-ray and requiring oxygen should be managed in a single room or cohort with other similar patients.

3) Private lab SARS-CoV-2 screening should be ceased unless in line with national guidance and clinically indicated, and coordinated with NHS services.

**Recommendation 2) Reduce and refine drug resistant organism testing:**

1) Reduce and refine MRSA screening, especially if multiple body sites are being screened, to save capacity. For instance, it may be appropriate to limit screening to high risk areas (e.g. ICU) using only nasal swabs.

2) Similar opportunities exist for reducing the need for screening of CRE (*Carbapenem-Resistant Enterobacteria*) and VRE (*Vanomycin-Resistant Enterococcus*) in low risk areas.

3) Testing for *Pseudomonas* outside of neonatal units is of low value and could be stopped unless particular local risk
**Recommendation 3) Swab specimens**

Genital and wound swabs should be reconsidered for reduction and refining.

1) Most genital swabs can be rejected as low clinical value, and superficial wound swabs should have minimum processing, or be rejected if no clinical details.

**Recommendation 4) Faecal specimens**

1) *C difficile* testing should continue.

2) Routine culture of non-bloody faecal samples from primary care can stop.

3) Enrichment culture for *Salmonella* can stop.

4) There may be scope to reduce faecal microscopy, for instance to patients with a clear travel history, or requested by a consultant gastroenterologist.

**Recommendation 5) Urine specimens**

1) Clear urine samples should not undergo laboratory testing. A suggested comment is “Urine clear. Infection unlikely. Consider repeat or empirical treatment if symptoms change.” In pre-operative urology patients, all specimens before renal stone procedures should be processed as normal. All other pre-operative specimens that are clear can be released with a comment “Urine clear. Use standard prophylaxis”. Most other pre-operative urine screens should stop.

2) Laboratories may wish to promote PHE guidance to users about empirical treatment of urinary tract infection, and the value of catheter specimens. There may be opportunity to reject any specimen which only has dipstick information in the clinical details, but this may create more work, and should be assessed on a local basis.

**Recommendation 8) Sputum specimens**

1) Sputum samples that are non-purulent should not undergo routine culture (but may still be processed for e.g. SARS-CoV-2 rtPCR).

**Recommendation 9) Routine mycology testing**

1) In most cases, this can be stopped.
Recommendation 10) Environmental microbiology

1) If engineering control deemed satisfactory, temporary cessation of microbiological assessment may be considered.

Recommendation 11) *H pylori* antigen and antibody testing

1) In most cases, this can be stopped.

Recommendation 12) Reducing blood science testing

1) There is currently a reduced GP and outpatient testing volume, as reduced face to face visits are taking place.

2) There may be scope to remind users about the potential to reduce non-urgent testing as this will necessitate unnecessary patient contact with health care.

3) There may be scope for individual laboratories to remove some analytes of low value, particularly if not automated. An example would be vitamin D, particularly if performed by tandem mass spectroscopy.

4) There is considerable variation across the country in the guidelines for review of blood films. These are labour intensive, and laboratories with a high rate of film reviews should consider implementing more stringent protocols.

5) Serum electrophoresis may be labour intensive. There is scope to reduce and refine this, for example not doing electrophoresis on all immunoglobulin requests.

6) In the acute setting, tests not necessary for the treatment of the patient are not a priority; for example screening for pre-diabetes, dyslipidaemia, etc especially if patients are in the acute phase of illness.

7) Faecal Calprotectin and FIT test for faecal occult blood. Undertake a risk assessment for health and safety for calprotectin measurement and review batch size. FIT testing for occult blood as part of the investigation of colorectal cancer in symptomatic and screening patients should continue.

Recommendation 13) Allergy testing

1) Allergy testing is not a priority at this time unless there are overriding clinical indications.
Recommendation 14) Newborn and Antenatal Screening Programmes Unchanged:

Action:
1) Newborn and antenatal Screening Programmes must continue

Recommendation 15) Cancer and Cancer Screening Programmes:
Central guidance from NHSE and NHSI for delivery of NHS Cancer screening programmes for breast, bowel cancer and cervical screening is currently under review.

1) Symptomatic cases to be prioritised as usual.

Recommendation 16) Genomics testing

1) The genomics implementation unit has issued guidance for the prioritisation of testing this is included at Appendix 1.

Recommendation 17) Routine andrology testing

1) Routine infertility testing of semen should be deferred for 3-6 months in the first instance.

2) Post vasectomy testing of semen should be continued, although demand for this service is likely to be low

Recommendation 18) Turnaround times for batch testing

1) There are certain specialist tests and batch tests which could, with minimal risk, move to less frequent testing, e.g. testing for thrombophilic disorders. Laboratories should review their repertoire for chlamydia and antenatal serology and modify where appropriate after discussions with clinical users.

2) Laboratories should review the possibility of consolidating more complex tests on fewer sites.
Recommendation 19) Lab to Lab electronic connectivity

1) Connecting labs to avoid repeated data entry and data transcription and allowing end to end transmission of results to patient records is a priority. Significant progress has been made and it is recommended that this is accelerated.

Recommendation 20) Minimum retest intervals

1) All organisations should follow the guidelines related to RCPath minimum retest intervals to avoid over testing.
## 5.0 Impact Assessment:

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Action</th>
<th>Impact on Workforce</th>
<th>Impact on Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1) Respiratory Virus Testing</strong></td>
<td>1. Stop routine testing for influenza viruses as most patients with respiratory symptoms will be managed using universal respiratory precautions. This may be reviewed locally if there is a risk of flu outbreaks in Nursing homes etc.</td>
<td>Reduce pressure on workforce</td>
<td>Patients that are symptomatic and require treatment to be treated as appropriate</td>
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<tr>
<td></td>
<td>2. Repeat SARS-CoV-2 testing after negative result in patients with compatible syndrome should only be carried out if a deep lower respiratory tract sample can be obtained after intubation. If a negative test and an abnormal chest X-ray and requiring oxygen keep in single room/cohort with other similar patients.</td>
<td>Reduce pressure on workforce</td>
<td>May release testing capacity for key affected staff</td>
</tr>
<tr>
<td></td>
<td>3. Private lab SARS-CoV-2 screening should be ceased unless in line with national guidance and clinically indicated, and coordinated with NHS services</td>
<td>Optimisation of workforce and testing</td>
<td>Co-ordinated care for patients. Improved patient care by increasing capacity for testing new patients, and reducing risk of reagent shortage</td>
</tr>
<tr>
<td><strong>2) Reduce and refine drug resistant organism testing</strong></td>
<td>1. Reduce and refine MRSA testing, especially if multiple body sites are being screened, to save capacity. For instance, it may be appropriate to limit test to high risk areas (e.g. ICU) using only nasal swabs.</td>
<td>Reduce pressure on workforce allowing for re-deployment on SARS-CoV-2 testing</td>
<td>SARS-CoV-2 infections currently greater danger to patients than MRSA. Maintain screening in high risk areas</td>
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<td>2. Similar opportunities exist for reducing the need for testing of CRE and VRE in low risk areas</td>
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<td>3. Testing for Pseudomonas outside of neonatal units is of low value and could be stopped unless particular local risk</td>
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<td>Minimal impact</td>
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<td><strong>3) Swab specimens</strong></td>
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</tr>
<tr>
<td><strong>4) Faecal specimens</strong></td>
<td><strong>5) Urine specimens</strong></td>
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<td>Reduce pressure on workforce allowing for re-deployment on SARS-CoV-2 testing</td>
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<tr>
<td>This will not impact on C difficile.</td>
<td>Minimal impact</td>
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<td>2. Routine culture of non-bloody faecal samples from primary care can stop.</td>
<td>2. Laboratories may wish to promote PHE guidance to users about empirical treatment of urinary tract infection, and the value of catheter specimens. There may be opportunity to reject any specimen which only has dipstick information in the clinical details, but this may create more work, and should be assessed on a local basis.</td>
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<td>Reduce pressure on workforce allowing for re-deployment on SARS-CoV-2 testing</td>
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<tr>
<td>Minimal impact</td>
<td>Improved patient care by promoting evidence based guidance.</td>
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<td>1. In most cases, this can be stopped</td>
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<td>Minimal impact</td>
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<td>10) Environmental microbiology</td>
<td>1. If engineering control deemed satisfactory, temporary cessation of microbiological assessment may be considered.</td>
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<td>Minimal impact</td>
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<td>11) H pylori antigen and antibody testing</td>
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<td>12) Reducing blood science testing</td>
<td>1. There is currently a reduced GP and outpatient testing volume, as reduced face to face visits are taking place</td>
<td>Reduce pressure on workforce allowing for re-deployment where appropriate and to mitigate any reduction in staff due to illness during this period</td>
<td>Continuing necessary testing is appropriate. Cessation of unnecessary testing will have minimal impact on the patient</td>
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<td>2. There may be scope to remind users about the potential to reduce non-urgent testing as this will necessitate unnecessary patient contact with health care</td>
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<td>Reduce pressure on workforce allowing for re-deployment where appropriate and to mitigate any reduction in staff due to illness during this period</td>
<td>Demand optimisation of blood tests will reduce unwarranted variation, with minimal impact on the patient</td>
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<td>4. There is considerable variation in the use of blood films across the country These are labour intensive,</td>
<td>Optimising blood film production and subsequent</td>
<td>Demand optimisation of blood film production and examination will reduce unwarranted</td>
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and laboratories with a high rate of films should consider implementing more stringent protocols. Examination will reduce staff time variation, with minimal impact on the patient.

5. Serum electrophoresis may be labour intensive. There is scope to reduce and refine this, for example not doing electrophoresis on all immunoglobulin requests. Optimising the cascade testing of serum electrophoresis will release staff. This will have minimal impact on the patient.

6. In the acute setting, tests not necessary for the treatment of the patient are not a priority, for example screening for pre-diabetes, dyslipidaemia, and so forth especially if patients are in the acute phase of illness. Reduce pressure on workforce allowing for re-deployment where appropriate and to mitigate any reduction in staff due to illness during this period. Wellness screening in patients with acute illness is not recommended. However certain acute tests should be measured as appropriate. Patient should be assessed appropriately when recovered.

7. Faecal Calprotectin and FIT test for faecal occult blood. Undertake a risk assessment for health and safety for calprotectin measurement and review batch size. FIT testing for occult blood as part of the investigation of colorectal cancer in symptomatic patients should continue. Minimal impact Minimal impact

13) Allergy testing

| 1. Allergy testing is not a priority at this time unless there are overriding clinical indications. | No Impact | No Impact |

14) Newborn and Antenatal Screening Programmes

| 1. Newborn and antenatal Screening Programmes must continue | No change | No Impact |

15) Cancer and Cancer Screening Programmes

| 1. Symptomatic cases to be prioritised as usual | No change | No impact |

| 2. All Cancer screening programmes for breast, bowel and cervical cancer to continue until further guidance | No change | No impact |

| 3. HPV screening to continue | No change | No impact |

16) Genomics testing

| 1. Urgent work to continue will be reviewed in 3 to 6 months. See Appendix 1 | Reduce pressure on workforce allowing for re-deployment where appropriate and to mitigate any reduction in staff due to illness during this period. See appendix 1. | For the 3-6 months period, for some, the impact will be no change, for others i.e. RD, this will have minimal impact on the patient. The recommendation should be reviewed in 6 |

| NHS England and NHS Improvement | 12 |
### 17) Routine andrology testing

1. Routine infertility testing of semen should be deferred for 3-6 months in the first instance.

2. Post vasectomy testing of semen should be continued, although demand for this service is likely to be low.

### 18) Turnaround times for batch testing

1. There are certain specialist tests and batch tests which could, with minimal risk, move to less frequent testing, e.g. thrombophilia and lupus in Coagulation; Chlamydia testing; antenatal serology. Laboratories should review their repertoire and modify where appropriate after discussions with clinical users.

2. Laboratories should review the possibility of consolidating more complex tests on fewer sites.

### 19) Lab to Lab electronic connectivity

1. Connecting labs to avoid repeated data entry and data transcription and allowing end to end transmission of results to patient records is a priority. Significant progress has been made and it is recommended that this is accelerated.

### 20) Minimum retest intervals

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<td>1.</td>
<td>All organisations should follow the guidelines related to RCPath minimum retest intervals to avoid over testing.</td>
<td>Reduce pressure on workforce allowing for re-deployment where appropriate and to mitigate any reduction in staff due to illness during this period</td>
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</tbody>
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**NHS England and NHS Improvement**

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From current data women are already much less likely to attend cervical screening at this time and so formal deferral would allow better planning in the future (3-6 months’ time).
6.0 Conclusion

These recommendations have been agreed by the Pathology and Laboratory Medicine professional bodies. Local Pathology Laboratories should review their current local practices and if other local services can be reduced and refined then a local assessment should take place.

7.0 Further Information

Further information can be found below:

1) National minimum retesting intervals in pathology

https://www.rcpath.org/uploads/assets/253e8950-3721-4aa2-8ddd4bd94f73040e/q147_minretestingintervalsinpathology_dec15.pdf
Dear Colleague

Re: Guidance to the NHS Genomic Medicine Service in response to COVID-19

We are writing to provide additional advice for the NHS Genomic Medicine Service to assist with the prioritisation of work.

During this period our priority is to ensure the continued delivery of urgent and essential genomic testing and to enable the release of genomic laboratory capacity to support SARS-CoV-2 testing where needed. In recognition of these pressures, we have worked with laboratory teams to develop a prioritisation for genomic testing services as per the table in Appendix 1.

Services should be directed to those groups of patients with urgent needs. This will include:

- pregnant women undergoing prenatal diagnosis;
- patients needing urgent advice on carrier testing relating to pregnancy examples include cystic fibrosis, thalassaemia;
- those faced with abnormal fetal scans; critically ill neonates and children requiring assessment and those for whom the rapid PICU/NICU WES is appropriate;
- conditions where rapid genetic testing may alter clinical treatment or decision making; and
- patients requiring urgent testing, for example BRCA testing, to inform chemotherapy options.
Medical, genetic counsellor, laboratory and nursing staff in genomic medicine have significant transferable skills and may be required to be redeployed to support or provide other clinical services.

For the period 1 April to 31 July, funding for genomic services will be managed in line with all other NHS services. During this period, NHS Trusts will be funded a block amount to cover all NHS services, this block includes genomic services. The block figures will be based on the average monthly expenditure implied by the provider figures in the M9 Agreement of Balances return plus an uplift to recognise the impact of pay uplifts and other cost increases.

Arrangements for pass through drugs and devices costs (this includes 6+1 molecular diagnostics) will continue to operate as currently on a cost and volume basis.

A retrospective top-up will be provided to providers to reflect the difference between actual costs and the block funding.

For the Genomic Laboratory Hubs (GLH) and NHS Genomic Medicine Centres (NHS GMCs), this means that:

- There will be no separate arrangement for funding or contracting for services. All funding will be issued and managed through the national process; and
- Funding will flow directly to the provider delivering the service – i.e. Lead Contractors and Local Genomic Laboratories should record expenditure relating to the provision of their services only in their expenditure submissions to NHS England and NHS Improvement. All organisations will therefore be funded directly by NHS England and NHS Improvement through the block funding and top-up process.

Where services have changed since 2019/20 and changes in cost base are not included in the M9 Agreement of Balances submission, the top-up reconciliation process will address changes in cost, e.g. transfers of activity between laboratories and any other changes in a Trust’s cost base as a consequence of changes in service provision.

For the process to operate fairly for all Trusts and ensure that Trusts are reimbursed for appropriate spend only, all GLH and NHS GMCs will require formal approval from NHS England and NHS Improvement for all service changes from 1 April 2020, including investment in GLH infrastructure.

We are continuing to work with colleagues to confirm the position regarding provider-to-provider billing for this period and we will provide an update once this has been confirmed.

We were scheduled to hold the Q4 GLH assurance meetings over the coming weeks. The Q4 assurance meetings will not take place as currently planned, and GLHs will not be required to complete any materials or updates at this time. GLHs can still request 30 minutes to 1 hour of the currently allocated slot to talk to us about your service or to ask any questions.

NHS England and NHS Improvement
In areas where GLHs are in a position to continue with planned service changes (i.e. mobilisation of geographical boundaries/specialist testing/investment in laboratory infrastructure related to mobilisation of the NHS GMS) we will support you to do this but formal approval from NHS England and NHS Improvement will be required to ensure that resources are being managed appropriately during this period and that we can support the changes on a recurrent basis once the financial regime measures end.

Where GLHs have identified there is available capacity, testing of the informatics platform to support the ordering of whole genome sequencing will continue on a best endeavours basis. This position will be reviewed on an ongoing basis. We will work with Genomics England to make the testing process more accessible for remote working. At this stage, plans to begin User Acceptance Testing and enter phased clinical implementation have been paused.

The return of primary findings from the 100,000 Genomics Project should continue if there is capacity in the system to do so.

In recognition of the pressures on the service, the return of additional findings will not begin as planned from May 2020. When it is appropriate to do so, NHS England and NHS Improvement will work with representatives from the NHS GMCs and GLHs to develop a revised implementation timeline.

NHS England and NHS Improvement will work with Genomics England to develop a communication to notify the 100,000 Genomes Project participants.

The GMS Alliance provider selection process has been suspended at this time. In recognition of the significant work that has already been made to develop the submissions, all areas who wish to do so can still submit their draft proposals using the online portal. We will review and then provide any feedback on the plans so far.

In the meantime, the funding arrangements for the continuation of the NHS GMCs will be in line with all other NHS services, as set out above.

If you have any questions about this guidance, then please do contact us at england.genomics@nhs.net.

The response to COVID19 is rapidly changing and we will provide updates to this guidance when required.
Finally, I would like to take this opportunity to thank all of you for your incredibly hard work. I wish you all well as you and your teams continue to go above and beyond to respond to the unprecedented challenge that COVID19 is bringing and to help ensure genomic testing remains available to those who need it.

With our very best wishes.

Yours sincerely,

[Signature]

Professor Dame Sue Hill  DBE FMedSci FRSB FRCP(Hon) FRCPath (Hon) FHCS
Chief Scientific Officer and SRO for Genomics
NHS England

Annexe 1 – Prioritisation of genomic testing during COVID-19 pandemic

<table>
<thead>
<tr>
<th>Cancer somatic genomic services</th>
<th>RAG rating for pandemic</th>
<th>Rationale for RAG</th>
<th>Further details</th>
</tr>
</thead>
<tbody>
<tr>
<td>All clinically appropriate testing to inform diagnosis</td>
<td>Green</td>
<td>Urgent cancer service</td>
<td></td>
</tr>
<tr>
<td>All clinically appropriate testing to inform therapy choice and patient management</td>
<td>Green</td>
<td>Urgent cancer service</td>
<td></td>
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<tr>
<td>Urgent minimum residual disease monitoring e.g. acute leukaemias</td>
<td>Green</td>
<td>Urgent cancer service</td>
<td></td>
</tr>
<tr>
<td>Other minimum residual disease monitoring e.g. non urgent chronic myeloid leukaemia</td>
<td>Amber</td>
<td>Cancer service</td>
<td>When clinically safe to do so, consider reducing frequency of testing or extending turnaround times</td>
</tr>
<tr>
<td>Chimerism testing for stem cell transplant monitoring</td>
<td>Amber</td>
<td>Cancer service</td>
<td></td>
</tr>
<tr>
<td>Testing for myeloproliferative neoplasms</td>
<td>Amber</td>
<td>Cancer service</td>
<td>When clinically safe to do so, consider extending turnaround times</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rare disease genomic services</th>
<th>RAG rating for pandemic</th>
<th>Rationale for RAG</th>
<th>Further details</th>
</tr>
</thead>
<tbody>
<tr>
<td>All prenatal diagnosis</td>
<td>Green</td>
<td>Urgent diagnostic service</td>
<td></td>
</tr>
<tr>
<td>Service Description</td>
<td>Urgency</td>
<td>Service Type</td>
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<tr>
<td>Urgent carrier testing relating to pregnancy; e.g. cystic fibrosis, thalassaemia etc.</td>
<td>Green</td>
<td>Urgent diagnostic service</td>
<td></td>
</tr>
<tr>
<td>Testing to inform urgent management, transplantation or therapy e.g. neonatal diabetes and congenital hyperinsulinism testing, BRCA testing to inform chemotherapy options etc.</td>
<td>Green</td>
<td>Urgent diagnostic service</td>
<td></td>
</tr>
<tr>
<td>Rapid exome sequencing for NICU/PICU</td>
<td>Green</td>
<td>Urgent diagnostic service</td>
<td></td>
</tr>
<tr>
<td>Genomic testing to support New Born Screening Programme e.g. cystic fibrosis, MCADD</td>
<td>Green</td>
<td>Urgent diagnostic service</td>
<td></td>
</tr>
<tr>
<td>All other rare disease testing</td>
<td>Red</td>
<td>Diagnostic service</td>
<td></td>
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</table>

*Any samples received should be processed and stored appropriately for testing at a later date.*