

 **Division of Laboratory Medicine**

**Process for changes to the Greater Manchester Immunology Service (GMIS) Test Repertoire**

# Introduction

The Greater Manchester immunology service (GMIS) aims to provide the most appropriate evidence-based test repertoire for our service users. The majority of our tests our performed on site with a small number of specialist tests sent away for analysis. We recognise that our repertoire may need to change to keep up to date with new developments, and in some cases a one off test referral may be needed to confirm results, or to gain additional information in complex cases. We are committed to ensure that any addition or change to our service is evidence based, cost effective and in the best interest of our patients. In order to effectively manage resources and ensure appropriate tests are available, an application will need to be completed for any changes to our repertoire. Three different application types are outlined below. A new test application, a one off referral test application, and an application to changing HCDP flow cytometry panels.

# Process for new test applications

A new test application will need to be submitted for any addition to our current repertoire (in house or referred) that is likely to be requested on more than one occasion. New test applications are approved/ rejected by the DLM new test application review group, and ratified at the DLM board. However there will be a requirement to liaise with specific departments to support your application. Full details can be found in Appendix 1 below, or in the laboratory medicine section of staffnet.

Prior to submission of a new test application for an immunology assay, it is advisable to contact the GMIS management team (mgtteam.immunology@mft.nhs.uk) to discuss clinical utility, required resources, and expected cost per test to support your application. The process is outlined below.

# Process for requesting a one off referral test

A one off referral test application will need to be submitted in cases where a specialist, novel, or confirmatory test is required that is not currently part of our repertoire. This application should only be used for one off requests. If the test is likely to be requested on more than one occasion, a new test application should be completed. See appendix 2 for one off referral test application form. Applications will be reviewed and approved/ rejected by the GMIS management team. The process is outlined below.

Applications for a one off test can be approved/ rejected by e-mail to prevent any delays with test referral. If the assay is not time dependent, applications should be approved/ rejected and ratified at the monthly GMIS management meeting. A minimum of four members of the GMIS management team (including at least one consultant) can approve an application. The ‘changes to GMIS repertoire log’ should be filled in for all applications, and checked for previous same test requests prior to approval. Applications should also be saved in the appropriate folder. The repertoire log and application folders can be found on the immunology shared drive (S:\MedLab\Immunology\GMIS repertoire applications).

# Process for changes to HCDP flow cytometry panels (Duraclone tubes)

Our current Duraclone HCDP panels were agreed in conjunction with consultant haematologist’s to provide a state of the art solution for HCDP flow cytometry testing. Any changes to panels will require production of a new profile that can take up to 1year to develop and verify before acceptance for routine use in the laboratory. Although this can be a lengthy and costly process, we are committed to ensuring that we are providing the most relevant panels to aid the diagnosis of haematological malignancies. Changes to panels will only be considered if there is an evidence based benefit that has been reviewed and approved by the HCDP clinical director. Financial approval for a one off set up fee will also need to be signed off before an application will be considered. Completed applications should be submitted electronically to the GMIS management team (mgtteam.immunology@mft.nhs.uk) for consideration. Applications will be approved/ rejected at the GMIS management meeting where a minimum of 4 members of the GMIS management team (including at least 1 consultant) must be present to approve/ reject the application. Approved applications may take some time to implement due to production processes and accreditation requirements. An application form can be found in appendix 3, and the process is outlined below.

All applications should be saved and the changes to GMIS repertoire log should be updated. Both folders can be found on the immunology shared drive (S:\MedLab\Immunology\GMIS repertoire applications).

# Appendix 1: New test application form



# Appendix 2: One off referral test application form



# Appendix 3: Changes to HCDP flow cytometry panel application form

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