NCCP Framework for Decision Making for Cancer Molecular Diagnostic Tests in the Irish Molecular Pathology Service

Appendix 2: Test Proposal Form

This form should be completed by the referring clinical user in partnership with one or more local Molecular Pathology Laboratories where applicable. The form should be submitted to the Cancer Molecular Diagnostics Advisory Group for consideration by emailing completed forms to oncologydrugs@cancercontrol.ie.

1. ADMINISTRATIVE DETAILS of Submitting Individual or Group	
1.1 Date of submission	
1.2 Requesting individual details	**Name:** **Address:** **Email:**
1.3 Supporting laboratory details (*if relevant*)	**Name:** **Address:** **Email:**
1.4 Type of application	☐ **Additional indication for an existing test** ☐ **New test**
2. Details of Test Requested	
2.1 Test Name (*if known*):	
2.2 Estimated incidence/prevalence of condition in the target population to whom the test applies	**The target population is the group of people that meet the minimum criteria for testing. Please provide references to data and relevant research where possible** **Estimated incidence:** **References *(if known)*:**
2.3 What is the indication for the proposed test?	
2.4 What is the clinical utility? Please tick all the relevant purposes of testing. It is helpful when completing the Submission, to consider which of these clinical management areas the test is likely to enhance. These will be considered by the panel in the evaluation of the proposed test.	
2.4.1 Diagnosis	☐ Yes ☐ No
If yes, please provide details: • Can a diagnosis be made for certain by any other method?	

• Will a molecular diagnosis remove the need to do other tests?	
2.4.2 Treatment Is this a predictive test? (will the test affect treatment)	☐ Yes ☐ No
If yes, what is the rationale for this test? **If yes, what is the predictive utility?**	**Test Rationale:** **Predictive utility:**
2.4.3 Prognosis and Management	☐ Yes ☐ No
If yes	
• Is there evidence in this disease that a specific molecular sub-type will affect prognosis and management to a significant extent?	
• Will the result significantly affect the lifestyle choices of the patient or the family	
• Will the additional evidence on prognosis alter subsequent treatment? If so, how?	
2.4.4 Disease monitoring Will molecular diagnosis provide a means to assess disease status in the patient?	☐ Yes ☐ No
2.5 Are testing criteria published? **If yes, please provide details:**	☐ Yes ☐ No
2.6 Will this test be performed as part of a panel **If yes, please provide details**	☐ Yes ☐ No
2.7 What other tests may need to be performed at this point in the pathway? **Please include those predictive for drug uses**	
3. Technical INFORMATION	

To be completed only if submitted in association with a specific lab currently providing or planning to provide this test either in Ireland or internationally	
3.1 Testing information: **Provide details of test required. Include gene, transcript, panel or protein name/testing technology where appropriate and proposed turnaround times**	**Gene:** **Transcript:** **Panel:** **Protein name/testing technology:** **TAT:**
3.2 Does your lab provide an *alternative test* for this gene(s)/disease/condition? If yes, please provide *alternative test* name	☐ Yes ☐ No
3.2.1 Has this *alternative test* been evaluated previously by the Cancer Molecular Diagnostics Advisory Group?	☐ Yes ☐ No
3.2.2 How long have you been providing this *alternative test*?	
3.2.3 Current annual activity (i.e. number for *alternative tests*)	
3.2.4 Are you providing this *alternative test* for other disease condition(s), or are you using the same technology for testing other gene(s)? **If yes, please give details: Name(s) of gene(s)/disorder(s) that this test is provided**	☐ Yes ☐ No
3.3 Has the test for which you make this submission been evaluated by the Cancer Molecular Diagnostics Advisory Group?	☐ Yes ☐ No
If yes, when was the test evaluated and what was the outcome?	
3.4 Current annual activity (i.e. number of tests)	

3.5 Has test been validated	☐ Yes ☐ No
3.6 Has test been included in the scope of laboratory accreditation	☐ Yes ☐ No

4 COST Analysis

4.1 Cost of test

The cost should reflect the resources that will be required to undertake the test e.g. Staffing, consumables, reagents etc.

*Price per test	Staffing requirement	Reagents cost	Validation costs	Expected national activity	Total cost of testing for national activity
€	WTE:	€	€	Total:	€

* *Record the negotiated list price per test as applicable*

4.2 Intellectual property **Are there intellectual property issues related to this test?** **Please provide details of any issues identified.**	☐ **Yes** ☐ **No**
4.3 Are the Irish licensing requirements for the provision of this test met? **Please provide details of any requirements.**	☐ **Yes** ☐ **No**

4.4 If there are cost savings, please provide these below. List the diagnostic tests/procedures/ treatments that would no longer be required with costs.

4.5 List any additional tests/procedures/interventions that will be required due to the introduction of the test. If this test is required to stratify SACT, please state.

4.6 If the test is currently provided from laboratories elsewhere in the Ireland, please state the name of the laboratory if known.

The Cancer Molecular Diagnostics Advisory Group will consider both the information provided in the test proposal form and information provided by each hospital laboratory, taking into account the following key factors:

- How many sites should provide the test; a common test is likely to be appropriate to be provided on multiple sites with each laboratory providing for their catchment population
- A rare test with very low volume is more likely to be cost effective if delivered in one site
- The cost of undertaking the test – are there potential economies of scale, this would point to the test being undertaken on fewer sites
- Local availability of clinical expertise to support testing and reporting
- How this test fits in with other pathways of testing
- Practicalities of transporting the specimen from one site to another – for example a small tissue sample from a lung biopsy