LABORATORY DETAILS

This questionnaire has been designed to collect information to inform a NICE diagnostic assessment review on KRAS *testing in samples collected from patients with liver metastases from colorectal cancer.*

1. At which laboratory are you based?

KRAS TESTING METHODS

2. What is the *KRAS* mutation testing strategy in your laboratory?

N.B. If your laboratory uses different KRAS *mutation testing methods for different samples (options c or d), please complete the relevant sections of the survey for each method used (to minimise time taken, some questions will be automatically skipped on second and subsequent completions).*

(a) We only use one method of *KRAS* mutation testing

(b) We use more than one *KRAS* mutation testing method in combination on all samples

(c) We use different *KRAS* mutation testing methods depending on sample quality (e.g. % tumour cells)

(d) We sometimes use a single *KRAS* mutation testing method and sometimes multiple methods (e.g. to confirm mutations)

(e) Other (please specify)

3. Which *KRAS* mutation testing method(s) do you currently use in your laboratory?

NB: If you selected options (a) or (b) above, please select all tests used in your laboratory.
If you selected options (c) or (d) above, please select only one test and complete the relevant sections of the survey again for additional tests.

- Sanger sequencing
- Cobas *KRAS* Mutation Test (Roche Molecular Systems)
- Therascreen *KRAS* RGQ PCR Kit (Qiagen)
- Therascreen *KRAS* Pyro Kit (Qiagen)
- *KRAS* LightMix® Kit (TIB MolBiol)
- *KRAS* StripAssay® (ViennaLab)
- High resolution melt analysis
- Pyrosequencing
- MALDI-TOF mass spectrometry
- Next generation sequencing
- Other (please specify)/Comments:

4. What proportion of samples are tested using the indicated method(s)?Cost

- 100%
- Other (please specify)

5. Are you completing this survey for a second or subsequent time?

- Yes
- No

6. How are samples referred to your laboratory for *KRAS* mutation testing?

- All resected primary CRC
- On demand
- Not known
- Other (please specify)

7. Why have you chosen the *KRAS* mutation testing method(s) that you have (please select all that apply):

- Cost
- Sensitivity (Proportion of tumour cells required)
- Mutation coverage
- Ease of use
- Turnaround time
- Other (please specify)

8. If your *KRAS* mutation testing strategy uses more than one method, what is the reason for this? (Please select all that apply)

- NA, we only use one method
- Sensitivity (proportion of tumour cells required)
- Verification of mutations
- Ability to fully characterise detected mutation
- Other (please specify)

9. In which codons does your *KRAS* mutation testing strategy aim to detect mutations and does the strategy aim to detect all mutations or does it target specific mutations? (Please select all that apply)

- Codon 12
- Codon 13
- Codon 61
- All mutations
- Targeted mutations
- Other (please specify)

10. If you use pyrosequencing, which primers do you use?

- Commercial primers
- Self-designed primers
- Details

LOGISTICS

11. In a typical week, how many samples do you screen for *KRAS* mutations?

- ≤5
- 6-10
- 11-15
- 16-20
- >20

12. What is your average batch size for *KRAS* mutation testing?

13. How often do you run *KRAS* mutation testing?

- Daily
- 2-3 times per week
- Weekly
- Other (please specify)

14. Do you wait until you have certain number of samples before running *KRAS* mutation testing?

- No
- Yes
- If yes, how many?

15. On average, how long (in calender days) does it take to receive a sample at the lab once it has been requested?

- <24-hours
- 24-48 hours
- 3-5 days
- 6-7 days
- 8-10 days
- >10 days

Please describe the range of waits experienced by your laboratory (shortest to longest)

16. On average, how long (in calender days) does it take from receiving a sample at the lab to sending a result back to the clinician?

- <24-hours
- 24-48 hours
- 3-5 days
- 6-7 days
- 8-10 days
- >10 days

TECHNICAL PERFORMANCE

Please complete this page only for *KRAS* mutation testing in samples from patients with liver metastases from colorectal cancer.

17. What is the minimum sample requirement of the *KRAS* mutation test in terms of the % tumour cells?

- ≤1%
- 1-5%
- 6-10%
- 11-20%
- 21-30%
- >30%

18. What is the limit of detection of the *KRAS* mutation test in terms of % mutation in extracted DNA?

- ≤1%
- 1-5%
- 6-10%
- >10%

19. How was the limit of detection determined in your laboratory?

20. Do you use microdissection techniques to process samples prior to DNA isolation?

- Yes, always
- No
- Yes, only when tumour content is below a minimum threshold (please specify)

21. We would like to get an idea of the number of samples which could not be analysed and reasons for this. If possible please provide details on the exact number of samples submitted to your laboratory last year with number of rejected samples and reasons for rejection. If you do not have access to the numbers for your lab please provide your best estimate for a hypothetical set of 1000 samples seen in your lab:

Total number of samples submitted to your laboratory for *KRAS* mutation testing (type 1000 if providing an estimate):

22. Number of samples rejected prior to analysis

23. What are the reasons for sample rejection? (Please select all that apply)

- Insufficient tumour cells
- Sample type unsuitable for analysis

Other (please specify)

24. We would also like to get an idea of the number of *KRAS* mutation tests for which no result could be provided (test failures) and reasons for this. If possible please provide details on the exact number of *KRAS* tests undertaken last year with number of failed samples and reasons for failure. If you do not have access to the numbers for your lab please provide your best estimate for a hypothetical set of 1000 samples seen in your lab:

Total number of *KRAS* mutation tests undertaken (type 1000 if providing an estimate):

25. Total number of test failures

26. What are the reasons for failed tests? (Please select all that apply)Insufficient tumour cells

- Insufficient tumour cells in sample
- DNA degradation
- Fixative type
- Other (please specify)

COSTS

27. What is the cost of the test (including purchase costs, personnel, material and overheads)?

28. If you do not have this information, please provide any information on cost that you have available

29. How is *KRAS* mutation testing in your laboratory funded? (please select all that apply)

- NHS
- Merck Serono
- Other (please specify)

30. If applicable, what is the price that you charge to the NHS for the test?

31. If applicable, what is the price that you charge to Merck Serono for the test?

32. Do you have any final comments?

Thank you for taking the time to complete the survey. If you use more than one *KRAS* testing method in your laboratory please could you complete the relevant sections of the survey again for additional testing methods.