EQA SCHEME INSTRUCTIONS – 2018
(cfDNA for *EGFR* gene mutation testing)

BACKGROUND

- This scheme is co-ordinated by IQNPath and is a collaboration between five EQA providers (AIOM/SIAPEC, EMQN, ESP QA foundation, Gen&Tiss and GenQA). See Organisation section, page 3 for more details.
- The scheme is designed for laboratories testing cell-free DNA (cfDNA) for *EGFR* gene mutations in Lung Cancer.
- This scheme is delivered by proficiency testing services that are accredited to ISO17043 or laboratories accredited to ISO9001; however, this particular EQA scheme is unaccredited in all instances.

TIMETABLE

- The scheme will run to the following timetable:

Activity	Start	Finish
Sample distribution	10/12/2018	
Reporting period for genotyping	10/12/2018	25/01/2019
Reporting period for clinical report submission	28/01/2019	07/02/2019
Scheme assessments	28/01/2019	11/03/2019
Validated Genotypes published	12/02/2019	
Appeals process	To be advised by your EQA provider	
Final scheme report published	29/03/2019	

GENERAL INFORMATION

- All documents relating to the schemes are available for download from your EQA provider's website.
- Please **read the documentation carefully** and **DO NOT** open any sample tubes until you have read all the scheme documentation.
- Repeat samples for testing are **NOT** available, but if your samples do not arrive or are received damaged then please contact your EQA provider distributing the samples.
- Analysis results of the samples should be kept confidential and should not be disclosed to external parties, including other participating laboratories, other than to report the results to your EQA provider.

SAMPLES

- The number and type of samples sent for this EQA scheme is shown in the table below.

NO. SAMPLES	TYPE / MATRIX	VOLUME (per sample)	GENE(S) (Locus Reference Genomic and / or Ref seq)
5	Artificial reference material[1] / Plasma	3 ml	• *EGFR* (LRG_304t1)

- The samples were sent from the EQA provider with which you registered your participation during the registration period 1st January 2018 to 31st March 2018. Each participating laboratory has been sent an email confirming the exact dispatch date of the samples. Please inform your EQA provider as soon as possible if there are problems regarding delivery.
- The samples are labelled with a random alphanumeric code.
- We have attempted to send enough sample material for a normal diagnostic routine analysis.
- The samples are supplied under the strict condition that they are used for this EQA scheme only. They MUST NOT be used as an internal control in any molecular tests or for any other purpose. If you are unable to test the samples, then you may return them to your EQA provider. For more information please read the terms and conditions available from:

  https://www.emqn.org/participating-in-eqa/terms-conditions/

  http://www.genqa.org/

  http://lung.eqascheme.org/info/public/alk/index.xhtml (after login)

  Or ask your EQA provider.

[1] Engineered from human cell lines

SAMPLE HANDLING

1. Samples are stable at ambient temperature but should be stored at 4-8ºC until testing is performed.
2. To prevent random degradation of cfDNA then please follow these instructions:
    a. The samples should be kept refrigerated until they are ready to be processed.
    b. Extract the cfDNA from each of the five samples following your chosen extraction protocol before proceeding to your genotyping methodology.

REPORTING REQUIREMENTS

THE CLOSING DATE FOR RESULTS SUBMISSION IS 25th January 2019

THE CLOSING DATE FOR CLINICAL REPORT SUBMISSION IS 7th FEBRUARY 2019

- Process the samples as if they were regular clinical cases.
- Please do not include any logos on the report as this would allow identification of your laboratory – the EQA scheme is anonymous to avoid bias during assessment.
- Please keep records of the alphanumeric code you find on the sample tubes until the end of the EQA scheme.
- Reporting times will be rigorously enforced - no submission of results will be allowed after the publication of this data.
- **Reports written in English will only be accepted for GenQA, EMQN and ESP.** You may submit additional supporting information if you wish to.
- **Reports written in Italian will only be accepted for AIOM.** You may submit additional supporting information if you wish to.
- **Reports written in French will only be accepted for Gen&Tiss.** You may submit additional supporting information if you wish to.

RESULTS SUBMISSION

- **Laboratories which have registered for this scheme and received samples are expected to submit the EQA results to their EQA provider in two ways:**
    a. Complete the data form for genotyping through the website of your EQA provider (www.testbiomolecolari.it)
    b. **Once finished the genotype reporting phase,you will receive the mock clinical information related to the samples you analysed. Submit the clinical report in your usual format.** Include your interpretation of the genotype in the context of the mock clinical information supplied for each sample. These written clinical reports (in PDF format) should be submitted to your EQA provider. Further details will be provided.
- Please submit your clinical reports as a single PDF for EACH case.
- DO NOT password protect your documents.
- It is the laboratory's responsibility to ensure that the correct results are submitted to the relevant EQA scheme.
- **Not submitting results?** You must notify us that you will not be submitting results. You can do this either by uploading a short letter to the results submission page, or by contacting your EQA provider **before the results submission deadline**.

POOR PERFORMANCE

- Your EQA provider will contact you with the Poor performance criteria in due course.

ASSESSMENT OF RESULTS

- The reports will be evaluated by a panel of expert assessors in the field of liquid biopsy testing and compared with the expected results. The genotypes will be marked whilst the interpretation will be assessed (but not marked) and comments fed back to each laboratory.
- A report on the results of the scheme as well as your individual scores will be issued after the completion of the assessment period and these documents will be available via your EQA provider's website.
- The identity of individual laboratories will remain confidential – this information will not be shared between the individual EQA providers.
- The Certificates of Participation will be available shortly after the results have been released to the participating laboratories.

ORGANISATION

- This scheme is co-ordinated by IQNPath and is a collaboration between AIOM/SIAPEC, EMQN, ESP QA foundation, Gen&Tiss and GenQA (see below).
- From time to time various aspects of our EQA schemes may be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and each Scheme is responsible for this work.

EQA provider	Contact information
EMQN The European Molecular Genetics Quality Network	EMQN Office, Manchester Centre Genomic Medicine, 6th Floor, St Mary's Hospital, Oxford Road, Manchester M13 9WL, United Kingdom. **Tel:** +44 161 276 6741 **Email:** office@emqn.org
GenQA GENOMICS QUALITY ASSESSMENT	GenQA, Department of Laboratory Medicine, Royal Infirmary of Edinburgh, Edinburgh, EH16 4SA, United Kingdom. **Tel:** +44 131 242 6898 **Email:** info@genqa.org
EQA European Society of Pathology	ESP QA FOUNDATION, **EQA scheme coordination centre**, KU Leuven, Biomedical Quality Assurance Research Unit, Kapucijnenvoer 35 block d, 1st floor, box 7001, 3000 Leuven, Belgium **Tel:** +32 (0)16 33 01 43 **Email:** lung.eqa@kuleuven.be
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SPONSORSHIP

This EQA scheme is supported by an unrestricted educational grant from Astra Zeneca.