Collaboration between UK NEQAS Molecular Genetics and CEQAS
Members of UK NEQAS consortium

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Pilot EQA Scheme for HRR gene testing in Prostate Cancer (2020)

1. Who are EMQN and GenQA?

EMQN CIC and GenQA are both established UK based large, global EQA providers in the field of genomics. Both EQA providers are ISO 17043 accredited. This EQA scheme is not covered within each organisation's accreditation scope because it's a pilot. EMQN and GenQA are collaborating to deliver this pilot EQA scheme for HRR gene testing in Prostate Cancer (2020).

2. Description of the EQA scheme

Participant laboratories will receive 3 samples with corresponding mock clinical cases.

The laboratories have 8-10 weeks to perform mutation analysis of the *BRCA1, BRCA2, ATM* and/or *CDK12* genes using their routine procedures and report their findings. Assessment includes genotyping, and biological and clinical interpretation within the context of the clinical case scenarios provided relating to targeted PARP inhibitor treatment.

All reports are assessed anonymously and independently by at least 2 expert assessors against peer ratified criteria. Participants receive their marks and a final report showing any general take home messages and improvement needs. All laboratories will receive a certificate of participation on completion of the assessment

2.1. Target

- Mutations in the *BRCA1, BRCA2, ATM* and/or *CDK12* genes.

2.2. Sample Material

- Formalin-fixed paraffin embedded (FFPE) rolled sections of artificial reference materials. **NOTE** we cannot provide slide mounted materials.

2.3. Scheme Format

- Suitable for any molecular based assay e.g. PCR, MLPA and/or NGS based testing methodologies.
- Assessment of genotyping, and biological and clinical interpretation. For each case, participants are expected to return a clinical report which includes a complete interpretation of the results.
- We only require clinically relevant pathogenic (disease-causing) mutations to be reported, and not common SNPs / variants.
- Maximum of 30 participant laboratories selected by the EQA providers from the expression of interest applications.
- Open to laboratories from ALL countries.
- 3 mock clinical cases with matching samples (per scheme)

2.4. Reporting Language

- Reports accepted in English ONLY

2.5. Performance criteria

- Performance criteria DO NOT apply.

2.6. Accreditation

This scheme is NOT covered by the scope of EMQN and GenQA's accreditation.

3. How to participate

Laboratories that wish to participate in the pilot EQA are invited to complete an expression of interest by the 31st March 2020. The application form can be accessed via the following online form:

https://www.formdesk.com/EMQN/GenQA_application_Prostate

4. Cost of participation

- The costs of your participating in this pilot EQA scheme will be covered by AstraZeneca.
- **Please note** that labs must cover their own costs for any other EQA schemes they may wish to participate from the EQA providers catalogues. AstraZeneca is only sponsoring participation in the pilot EQA for prostate cancer.

5. Key Dates and Timelines

- Application period: 1st March 2020 – 31st March 2020
- Sample dispatch dates: September 2020
- EQA testing period: September – November 2020
- EQA results assessment: November 2020 – January 2021
- Results released to participant laboratories: February 2021

6. Confidentiality

- The fact that your laboratory participates in the scheme is not confidential. However, the raw data and performance scores are.
- Further information on our terms and conditions and privacy / confidentiality policies can be found on the EQA providers website (www.emqn.org or www.genqa.org).

7. Contact information

- office@emqn.org or info@genqa.org for any queries regarding registration or participation in the scheme.

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