

2022 EQA Schemes for Molecular testing of BRCA genes in Ovarian, Breast, Pancreatic and Prostate Cancers

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 and this EQA scheme is covered within each organisation's accreditation scope. EMQN and GenQA are collaborating to deliver three different EQA schemes for Ovarian, Breast, Pancreatic and Prostate Cancers.

2. Description of the EQA schemes

2.1. Summary of schemes

- Three schemes are provided:
 1. **Ovarian, breast, prostate and pancreatic cancers** (germline testing, PARPi).
 2. **Ovarian and Prostate cancer** (somatic [tissue] testing, PARPi)
 3. **Prostate cancer** (somatic [plasma, ctDNA] testing, PARPi). *This is a pilot EQA scheme.*
- Participant laboratories register for their schemes of interest via EMQN, or GenQA.
- Each scheme will provide 3 samples to test with corresponding mock clinical cases.
- Laboratories have 8-10 weeks to perform mutation analysis of the BRCA 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.
- For detailed information see:
 - <https://www.emqn.org/eqa-scheme-catalogue/>
 - <https://genqa.org/eqa>

2.2. Access to the schemes

- Open to laboratories from ALL countries.
- There are limits on numbers of laboratories that can participate. See table below:

Scheme	Max no. laboratories
1. Ovarian, breast, prostate and pancreatic cancers (germline testing, PARPi).	300
2. Ovarian and Prostate cancer (somatic [tissue] testing, PARPi)	400
3. Prostate cancer (somatic [plasma, ctDNA] testing, PARPi)	50

2.3. Target

- Clinically relevant variants in the *BRCA1* and *BRCA2* genes.

2.4. Sample Material

- **Scheme 1** (Ovarian, breast, prostate and pancreatic cancers): 3 x germline DNA in TE buffer

- **Scheme 2** (Ovarian and prostate cancers): 3 x rolled sections of formalin fixed paraffin embedded artificial reference materials, per scheme. **NOTE** we cannot provide slide mounted materials.
- **Scheme 3** (Prostate cancer): 3 x 4 ml of artificial plasma reference materials.

2.5. Scheme Format

- Suitable for any molecular based assay e.g. PCR, Sanger Sequencing, 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.

2.6. Reporting Language

- Reports accepted in English ONLY

2.7. Performance criteria

- Performance criteria will be applied to the following schemes:
 - **Scheme 1** (Ovarian, breast, prostate and pancreatic cancers): 3 x germline DNA in TE buffer
 - **Scheme 2** (Ovarian and prostate cancers).
- Performance criteria will be NOT apply to the following PILOT scheme:
 - **Scheme 3** (Prostate cancer [plasma]).

2.8. Accreditation

These schemes are covered by the scope of EMQN and GenQA's accreditation (except Scheme 3 which is a pilot for 2022).

3. How to participate

The schemes are a collaboration between both EQA providers and therefore identical. There is NO difference in the cost, or assessment process.

Laboratories are advised to register for the germline and/or somatic schemes via **ONE of the EQA providers only** – please do not register twice via EMQN and GenQA

Laboratories MUST be members of EMQN or GenQA to gain access to the scheme (see section 4.2). Non-members must join one of the providers first to gain access to the scheme.

3.1. 3.1. Already a member of EMQN or GenQA?

- Login to your EQA providers account via www.emqn.org or www.genqa.org
- Goto the "**Purchase**" page and select / register for your schemes.
- Add them to your shopping cart and don't forget to "**Complete**" your purchase to ensure that we receive it.

3.2. 3.2. Not a member of EMQN or GenQA?

- Join your preferred EQA provider by registering via their website (<https://www.emqn.org/joining-emqn/> or <https://www.genqa.org/d/AccountApplication.do>).
- Please allow 5 working days for approval of your new account.
- You will receive an email from the EQA provider once your account has been activated. If you have not had a confirmation email from us after 5 working days, then please contact the EQA providers office office@emqn.org or info@genqa.org.
- Once the EQA provider has approved your account, then please register for the scheme as per the procedure 3.1 above for existing members.

4. Cost of participation

4.1. What is covered



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- The registration costs of your participating in these EQA schemes will be covered by Merck Sharp & Dome (MSD) and AstraZeneca.

4.2. What is NOT covered

- Other costs (beyond the EQA scheme registration fee) including membership fees, customs / importation fees, third party costs etc.
- Costs for any other EQA schemes associated with EQA schemes not covered by the sponsorship provided by Merck Sharp & Dome (MSD) and AstraZeneca.

5. Key Dates and Timelines

The dates below may change and are provided for guidance only. Please consult the EQA providers website for changes.

- Application period: 27th September 2021– 28th February 2022
- Sample dispatch dates: September 2022
- EQA testing period: September – November 2022
- EQA results assessment: December 2022 – January 2023
- Results released to participant laboratories: March 2023

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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