Quality in Pathology

PROFICIENCY TESTS 2022

Version: 4 May 2022

Quality in Pathology

Legal Disclosure

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Thomas Pilz

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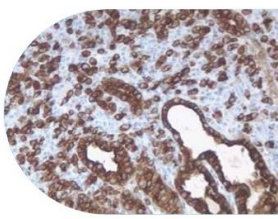

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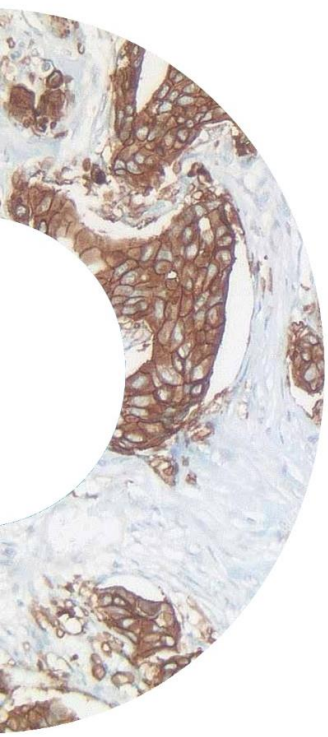


Please pay attention to the **version date** on the cover page. Changes to the program, for example updates to or addition of registration dates, new proficiency tests, etc., will be communicated through the QuIP newsletter and published in the latest program.

Check the newsletter box in your user profile (account) on our website (www.qualityinpathology.com) to receive our newsletter.

About QuIP

Quality in Pathology – QuIP GmbH (https://www.qualityinpathology.com)

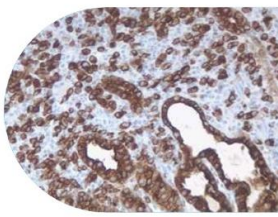
The Quality Assurance Initiative for Pathology, QuIP GmbH, is the service provider for quality assurance in pathology in Germany. QuIP GmbH supports pathologists, pharmaceutical companies as well as diagnostics providers in comparing and optimizing their research results in proficiency tests/EQAs.

QuIP has established itself as a link between science, medical product development and healthcare practice. It provides a platform, on which new findings from science and research as well as experience from healthcare practice are brought together in a transparent manner.

This direct, mutual exchange takes place through the recurring and prototype proficiency tests organized by QuIP and through the recent addition of Digital Readout Tests. Training courses conducted by QuIP and the comprehensive, subject-related information websites also contribute to this mutual transparency.

Ultimately, all participants - scientific institutes at universities and colleges, pharmaceutical companies, pathologists and physicians providing care - would benefit from this endeavor.

QuIP is a joint venture of the German Society for Pathology e.V. (DGP) and the Federal Association of German Pathologists e.V. (BDP).



General Information

The proficiency tests listed in the program can be ordered via our homepage https://www.qualityinpathology.com.

If you (or your institute) do(es) not have a user account with QuIP, please create one, as a user account is needed for registering for/ordering our proficiency tests.

Please make sure you generate the invoice during the registration/ordering process and forward it to your accounting department for payment.

The survey through which you can submit your proficiency test/EQA results will only be available online on our website during the proficiency test period. The survey can be accessed through the personal user area (of the account the EQA was ordered) under 'Enrollments & Invoices'. You will find this under the menu points on the left after you log in.

After the evaluation of the results is completed, you will be informed by email when your certificate is available for download through the personal user area.

News on proficiency tests/EQAs and updated versions of the proficiency test program are post regularly on our homepage and newsletter.

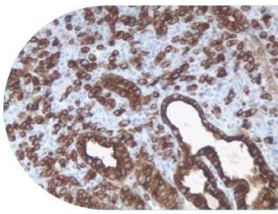
Proficiency test registration periods:
This will be provided when they are available.

Shipping and handling:
QuIP ships the test sets approximately 5 working days before the official start of the respective proficiency test/EQA scheme. Shipping usually takes between 1 to 4 business days. Please inform the project manager or write an email to office@quip.eu if you do not receive your test set before the start of the proficiency test.

Deliveries within Germany:
The shipping of test sets to an address in Germany is included in the proficiency test price. The test sets are usually shipped with GLS Logistics.

Submission of results
The survey is only available online (https://www.qualityinpathology.com) and accessible through your personal user area at the beginning of the evaluation period.

Deadline for appealing your results
You have 6 weeks after receipt of the proficiency test report to appeal the results.



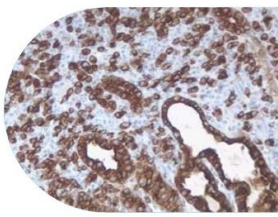
General Information

Deliveries abroad:
The test sets are usually shipped with the logistics company messenger Express GmbH.

- EU countries: € 30.00 shipping costs will be charged in addition to the cost of the proficiency test.
- European non-EU countries (e.g., Switzerland): € 40.00 shipping costs will be charged in addition to the cost of the proficiency test.
- Worldwide: Delivery costs outside Europe vary greatly and will therefore be provided individually and invoiced separately.

Return of stained slides
For quality assurance reasons, please return all stained slides (Mol. Path.: H&E slides, if prepared) in their original packaging, i.e., in the blue QuIP container with the set number, to the QuIP office (Qualitätssicherungs-Initiative Pathologie QuIP GmbH; Reinhardtstr. 1; 10117 Berlin) no later than 2 weeks (or 10 working days) after the end of the proficiency test. Please ensure successful delivery by tracking the shipment progress with your logistics partner. For your internal institute documentation, please ensure the digitization of the sections in advance, if necessary. The stained slides will be archived at QuIP for 18 months and will NOT be returned to you.

Prices and invoicing
The prices listed in the program are net prices and do not include VAT. The payment or billing occurs immediately after submission of the order. You can pay by credit card or account transfer. Invoices will not be sent to you or your accounts department by mail - they must be downloaded online through your personal user area.



ESP Lung EQA Scheme: Joint ESP Foundation-QuIP Lung EQA Program

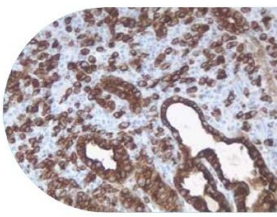
The European Society of Pathology Foundation (ESP Foundation) and the German based Quality Assurance Initiative in Pathology (QuIP GmbH) have decided to cooperate within the scope of the ESP Lung EQA Scheme.

ESP Foundation and QuIP GmbH will bundle and standardize their activities through the joint ESP Foundation-QuIP Lung EQA Program to secure the scientific validity and reliability in European quality assurance for the participating institutes and pathologists.

The goal of this cooperation is to improve the quality and reliability of biomarker testing in routine diagnostics for lung cancer and ensure the determination of optimal treatment for lung cancer patients in Europe.

Details regarding the dates, prices, content and registration of the joint ESP Foundation-QuIP Lung EQA Scheme can be found on pages 8 - 11.

Participants are only required to create a user account on the QuIP website to be able to register for the ESP Lung EQA Scheme: Joint ESP Foundation-QuIP Lung EQA Program.



ESP Lung EQA Scheme 2022: Joint ESP Foundation-QuIP Lung EQA Program

Schedule

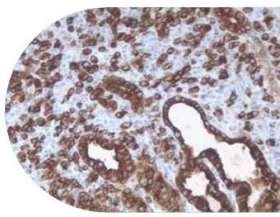
Subscheme	Registration Period	Test Period	Page
September 2022			
NSCLC ALK Fusions (ISH) including a Digital Readout Test (FISH)	04.05.22 – 10.06.22	19.09.22 - 30.09.22	08
NSCLC ALK (IHC)	04.05.22 – 10.06.22	19.09.22 - 30.09.22	08
NSCLC ROS1 Fusions (ISH) including a Digital Readout Test (FISH)	04.05.22 – 10.06.22	19.09.22 - 30.09.22	09
NSCLC ROS1 (IHC)	04.05.22 – 10.06.22	19.09.22 - 30.09.22	09
NSCLC Mutations (molecular pathology): EGFR (mandatory), KRAS (optional), BRAF (optional)	04.05.22 – 10.06.22	19.09.22 - 30.09.22	10
NSCLC Fusions (molecular pathology): ALK (optional), ROS1 (optional), RET (optional)	TBA	TBA	10

ESP Lung EQA Scheme 2022: Joint ESP Foundation-QuIP Lung EQA Program

NSCLC ALK IHC & ALK Fusions ISH

NSCLC ALK (IHC)		
Price	**Test Material**	**Description: Marker**
€400	5 cases (1 whole tissue sample per slide)	Analysis of ALK expression through immunohistochemistry.
Registration Period	**Shipping Period**	**Test Period**
04.05.2022 - 10.06.2022	12.09.2022 – 16.09.2022	19.09.2022 - 30.09.2022

NSCLC ALK Fusions (ISH) including a Digital Readout Test (FISH)		
Price	**Test Material**	**Description: Marker**
€450	5 cases (1 whole tissue sample per slide) 5 digitized cases in the Digital Readout Test (DRT)	Analysis of ALK expression through in situ hybridization.
Registration Period	**Shipping Period**	**Test Period**
04.05.2022 - 10.06.2022	12.09.2022 – 16.09.2022	19.09.2022 - 30.09.2022

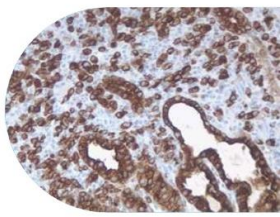


ESP Lung EQA Scheme 2022: Joint ESP Foundation-QuIP Lung EQA Program

NSCLC ROS1 IHC & ROS1 Fusions ISH

NSCLC ROS1 (IHC)		
Price	**Test Material**	**Description: Marker**
€400	5 cases (1 whole tissue sample per slide)	Analysis of ROS1 expression through immunohistochemistry.
Registration Period	**Shipping Period**	**Test Period**
04.05.2022 - 10.06.2022	12.09.2022 – 16.09.2022	19.09.2022 - 30.09.2022

NSCLC ROS1 Fusions (ISH) including a Digital Readout Test (FISH)		
Price	**Test Material**	**Description: Marker**
€450	5 cases (1 whole tissue sample per slide) 5 digitized cases in the Digital Readout Test (DRT)	Analysis of ROS1 expression through in situ hybridization.
Registration Period	**Shipping Period**	**Test Period**
04.05.2022 - 10.06.2022	12.09.2022 – 16.09.2022	19.09.2022 - 30.09.2022



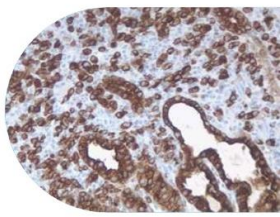
ESP Lung EQA Scheme 2022: Joint ESP Foundation-QuIP Lung EQA Program

Mutations & Fusions NSCLC (Molecular Pathology)

NSCLC Mutations (molecular pathology): EGFR (mandatory)		
Price	**Test Material**	**Description: Marker**
€600	5 cases (2 whole tissue slides/case)	Testing for mutation status of EGFR.
Registration Period	**Shipping Period**	**Test Period**
04.05.2022 - 10.06.2022	12.09.2022 – 16.09.2022	19.09.2022 - 30.09.2022

NSCLC Mutations (molecular pathology): EGFR (mandatory) and/or Supplement 1 - KRAS (optional) and/or Supplement 2 - BRAF (optional)		
Price	**Test Material**	**Description: Marker**
€600	10 cases (2 whole tissue slides/case)	Testing for mutation status of EGFR, and/or KRAS and/or BRAF.
Registration Period	**Shipping Period**	**Test Period**
04.05.2022 - 10.06.2022	12.09.2022 – 16.09.2022	19.09.2022 - 30.09.2022

NSCLC Fusions (molecular pathology): ALK (optional), ROS1 (optional), RET (optional)		
Price	**Test Material**	**Description: Marker**
TBA	5 - 10 cases depending on the number of markers ordered (2 whole tissue slides/case)	Testing for mutation status of ALK and/or ROS1 and/or RET.
Registration Period	**Shipping Period**	**Test Period**
TBA	TBA	TBA



TBA – To be announced

QuIP Molecular Pathology Lung Proficiency Tests

Schedule

Subscheme	Registration Period	Test Period	Page
September 2022			
MET Exon 14 Skipping NSCLC Liquid Biopsy (MolPath)	17.02. - 31.07.22	05.09.2022 – 16.09.2022	12
EGFR Mutation Analysis Liquid Biopsy (Molecular Pathology)	28.02. – 17.06.22	26.09.2022 – 10.10.2022	12

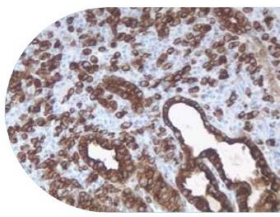
Blue – **Molecular Pathology** | Purple – **Immunohistochemistry** |
Dark blue – **Fluorescence In Situ Hybridization**

QuIP Molecular Pathology Lung Proficiency Tests

MET Exon 14 Skipping NSCLC Liquid Biopsy & EGFR Mutation Analysis Liquid Biopsy

MET Exon 14 Skipping NSCLC Liquid Biopsy (Molecular Pathology)		
Price	**Test Material**	**Description**
€500	10 cases, cfDNA in 2 mL human plasma	Testing for MET mutations in intron 13, intron 14 or exon 14 which could lead to MET exon 14 skipping.
Registration Period	**Shipping Period**	**Test Period**
17.02.2022 – 31.07.2022	31.08.2022 (Express Shipment)	05.09.2022 – 16.09.2022

EGFR Mutation Analysis Liquid Biopsy (Molecular Pathology)		
Price	**Test Material**	**Description**
€950	7 cases, cfDNA in 2 mL human plasma	Detection of EGFR mutations in exon 19, 20 and 21.
Registration Period	**Shipping Period**	**Test Period**
28.02.2022 – 17.06.2022	20.09.2022 (Express Shipment)	26.09.2022 – 10.10.2022



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