

PROFICIENCY TESTS 2024

Status 16.01.2024

Quality in Pathology



Legal Disclosure

Qualitätssicherungs-Initiative Pathologie QuIP GmbH
Reinhardtstr. 1
10117 Berlin

Contact:

Phone: +49 30 921 07 17 - 0

Fax: +49 30 921 07 17 - 20

E-Mail: office@quip.eu

Web: www.qualityinpathology.com

Commercial registry number:

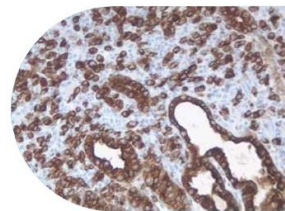
HRB 175419 B

Sales tax-ID:

Sales tax identification number according to §27 of the
German sales tax law: DE306143122

The Qualitätssicherungs-Initiative Pathologie QuIP GmbH
is represented by the managing director:
Thomas Pilz

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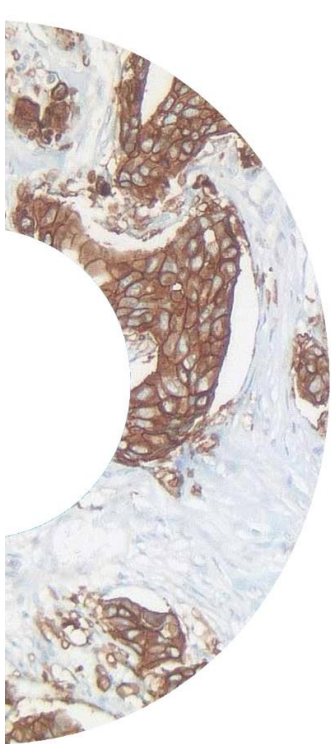
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Overview of QuIP proficiency trials with details sorted by Entity

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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>)

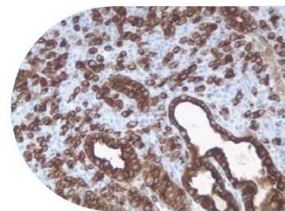
The Quality Assurance Initiative for Pathology, QuIP GmbH, is the service provider for quality assurance in pathology in Germany. QuIP GmbH supports pathologists, pharmaceutical companies as well as diagnostics providers in comparing and optimizing their research results in proficiency tests/EQAs.

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

QuIP is a provider of proficiency testing accredited by DAkkS according to DIN EN ISO/EC 17043: 2010. The accreditation is only valid for the scope of accreditation listed in the certificate attachment D-EP-21450-01-00. The accreditation certificate including the annex can be found on our homepage (https://www.qualityinpathology.com/en_GB/proficiency-tests/accreditation). In the product catalogue, the column "Accreditation" indicates whether the proficiency test is or isn't covered by the scope of accreditation by the DAkkS.

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 posted 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.

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 by DHL.

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.

Evaluation period

Molecular Pathology (recurring): 11 weeks

IHC without review (recurring): 15 weeks

IHC with review (recurring): 23 weeks

IHC with review > 4 markers (recurring): 27 weeks

*Prototypes after approval of the final report

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 DHL Express.

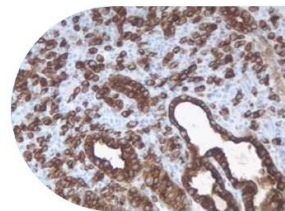
- **EU & European non-EU countries (e.g., Switzerland):** € 60.00 shipping costs will be charged in addition to the cost of the proficiency test.
- **Worldwide:** € 120.00 shipping costs will be charged in addition to the cost of the proficiency test.

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.



Joint ESP Foundation-QuIP Lung EQA Program: Lung Cancer Related Markers

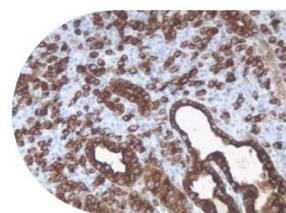
The European Society of Pathology Foundation (ESP Foundation) and the German based Quality Assurance Initiative in Pathology (QuIP GmbH) have decided to cooperate within the scope of the ESP Lung EQA Scheme.

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 11 - 12.

Participants are required to create a user account on the QuIP website to be able to register for the ESP/QuIP Lung Cancer Related Markers Scheme.



EQA Program 2024

Subscheme	Registration Period	Test Period	Accreditation	Page
February 2024				
EGFR Mutation Analysis Liquid Biopsy (MolPath)	Until 09.02.24	26.02.24 - 08.03.24	Yes	10
March 2024				
MET Exon 14 Skipping Liquid Biopsy (MolPath)	Until 23.02.24	11.03.24 - 22.03.24	Yes	10
April 2024				
ESR1 Mutation Analysis Liquid Biopsy (MolPath)	Until 29.02.24	08.04.24 - 19.04.24	Yes	10

EQA Program 2024

Subscheme	Registration Period	Test Period	Accreditation	Page
June 2024				
Neuroendocrine Markers (IHC)	Until 18.02.24	03.06.24 - 21.06.24	Yes	13
ESP/QuIP Lung Cancer Related Markers - <i>ALK</i> (ISH)	TBA	TBA	Yes	15
ESP/QuIP Lung Cancer Related Markers - <i>ALK</i> (IHC)	TBA	TBA	Yes	15
ESP/QuIP Lung Cancer Related Markers - <i>ROS1</i> (ISH)	TBA	TBA	Yes	15
ESP/QuIP Lung Cancer Related Markers - <i>ROS1</i> (IHC)	TBA	TBA	Yes	15
ESP/QuIP Lung Cancer Related Markers - Mutations: <i>EGFR</i> (MolPath)	TBA	TBA	Yes	14
ESP/QuIP Lung Cancer Related Markers - Mutations: <i>EGFR</i> , <i>KRAS</i> , <i>BRAF</i> (MolPath)	TBA	TBA	Yes	14
<i>BRCA1/2</i> Mutation Analysis (MolPath)	TBA	TBA	Yes	12
<i>TERT</i> Mutation Analysis in Glioma, Meningioma and Bladder Carcinoma (MolPath)	Until 01.04.24	17.06.24 - 05.07.24	Yes	21
Sarcoma (IHC)	TBA	TBA	Yes	20

Blue – Molecular Pathology | Purple – Immunohistochemistry |
Dark blue – Fluorescence In Situ Hybridization | TBA – To be announced

EQA Program 2024

Subscheme	Registration Period	Test Period	Accreditation	Page
September 2024				
HER2 Gastric Carcinoma (IHC/ ISH)	Until 21.06.24	16.09.24 – 04.10.24	Yes	17
October 2024				
PIK3CA Mutation Analysis (MolPath)	TBA	TBA	Yes	18
CD117 (IHC)	Until 12.07.24	07.10.24 – 24.10.24	Yes	11
November 2024				
Keratins/Prostate Carcinoma (IHC)	TBA	11.11.24 - 29.11.24	Yes	19
Deficient DNA Mismatch Repair (IHC)	TBA	TBA	Yes	11

Blue – Molecular Pathology | Purple – Immunohistochemistry |
Dark blue – Fluorescence In Situ Hybridization | TBA – To be announced

Liquid Biopsy

Molecular Pathology

EGFR Mutation Analysis Liquid Biopsy (Liquid Biopsy)		Accredited
Price	Test Material	Description: Marker
950 €	Five samples, each containing 2 ml of human nucleic acid-free plasma spiked with 60 ng of either wild type DNA or a combination of wild type and mutated fragmented DNA in different allele frequencies	Analysis of the <i>EGFR</i> mutation status for exon 19, 20 (exon 20 insertions are NOT included) and 21
Registration Period	Shipping Period	Test Period
Until 09.02.2024	One week prior to the proficiency trial	26.02.2024 - 08.03.2024

ESR1 Mutation Analysis Breast Cancer (Liquid Biopsy)		Not accredited
Price	Test Material	Description: Marker
Please Contact office@quip.eu	10 cases, each containing 2 ml of human nucleic acid-free plasma spiked with 60 ng of either wild type DNA or a combination of wild type and mutated fragmented DNA in different allele frequencies	Analysis of <i>ESR1</i> mutations in exon 5 and 8
Registration Period	Shipping Period	Test Period
Until 29.02.2024	One week prior to the proficiency trial	08.04.2024 - 19.04.2024

MET Exon 14 Skipping (Liquid Biopsy)		Accredited
Price	Test Material	Description: Marker
750,- €	10 cases, each containing 2 ml of human nucleic acid-free plasma spiked with 60 ng of either wild type DNA or a combination of wild type and mutated fragmented DNA in different allele frequencies	Testing for <i>MET</i> mutations in intron 13, intron 14 or in exon 14, which can lead to <i>MET</i> exon 14 skipping
Registration Period	Shipping Period	Test Period
30.10.2023 - 23.02.2024	One week prior to the proficiency trial	11.03.2024 - 22.03.2024

Multi Entity Schemes

Immunohistochemistry

CD117 (IHC)		Accredited
Price	Test Material	Description: Marker
400,-€	2 TMA slides with 10 cases (2 punches per case)	Immunohistology analysis of CD117 expression
Registration Period	Shipping Period	Test Period
Until 12.07.2024	One week prior to the proficiency trial	07.10.2024 - 25.10.2024

Deficient DNA Mismatch Repair (IHC)		Accredited
Preis	Untersuchungsmaterial	Beschreibung: Marker
TBA	TBA	Immunohistological analysis of MLH1, MSH2, MSH6 and PMS2-Expression and evaluation if a DNA-Mismatch-Repair Deficiency is detectable
Anmeldezeitraum	Versandzeitraum	Versuchszeitraum
TBA	One week prior to the proficiency trial	TBA

Multi Entity Schemes

Molecular Pathology

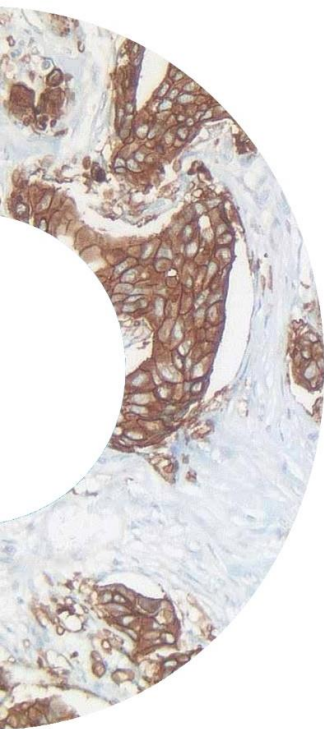
BRCA1/2 Mutation Analysis (MolPath)		Accredited
Price	Test Material	Description: Marker
TBA	Five tissue samples (tissue preparations of ovarian and/or prostate carcinoma); three unstained tissue slides each 5 µm thick are provided per sample	Analysis of the BRCA1/2 mutation status
Registration Period	Shipping Period	Test Period
TBA	One week prior to the proficiency trial	TBA

TERT Mutation Analysis in Glioma, Meningioma and Bladder Carcinoma (MolPath)		Accredited
Price	Test Material	Description: Marker
900 €	10 tissue samples (tissue preparations of gliomas, meningiomas and bladder carcinomas); three unstained tissue slides, each 5 µm thick are provided per sample	Analysis of the TERT promoter mutation status
Registration Period	Shipping Period	Test Period
Until 01.04.2024	One week prior to the proficiency trial	17.06.2024 - 05.07.2024

Neuroendocrine Neoplasia

Immunohistochemistry

Neuroendocrine Markers (IHC)		Accredited
Price	Test Material	Description: Marker
Synaptophysin, Chromogranin, Ki-67 + Calcitonin + Serotonin	1 TMA per marker with 10 cases each and 2 punches per case	The basic package includes the immunohistochemical detection of the markers synaptophysin, chromogranin and Ki-67. In addition, the markers calcitonin and serotonin can be ordered individually. The prerequisite for this is participation in the basic package.
Registration Period	Shipping Period	Test Period
Until 18.02.2024	One week prior to the proficiency trial	03.06.2024 - 21.06.2024



ESP/QuIP Lung Cancer Related Markers Scheme 2024:

Molecular Pathology

ESP/QuIP Lung Cancer Related Markers - Mutations: <i>EGFR</i> (MolPath)			Accredited
Price	Test Material	Description: Marker	
TBA	5 cases (2 whole tissue slides/case)	Testing for mutation status of <i>EGFR</i>	
Registration Period	Shipping Period	Test Period	
TBA	One week prior to the proficiency trial	TBA	

ESP/QuIP Lung Cancer Related Markers – Mutations: <i>EGFR</i> , <i>KRAS</i> , <i>BRAF</i> (MolPath)			Accredited
Price	Test Material	Description: Marker	
TBA	10 cases (2 whole tissue slides/case)	Testing for mutation status of <i>EGFR</i> , <i>KRAS</i> and <i>BRAF</i>	
Registration Period	Shipping Period	Test Period	
TBA	One week prior to the proficiency trial	TBA	

ESP/QuIP Lung Cancer Related Markers Scheme 2024:

Immunohistochemistry and In Situ Hybridization

ESP/QuIP Lung Cancer Related Markers – ALK (IHC)		Accredited
Price	Test Material	Description: Marker
TBA	5 cases (1 whole tissue sample per slide)	Analysis of ALK expression through immunohistochemistry.
Registration Period	Shipping Period	Test Period
TBA	One week prior to the proficiency trial	TBA

ESP/QuIP Lung Cancer Related Markers - ALK (ISH)		Accredited
Price	Test Material	Description: Marker
TBA	5 cases (1 whole tissue sample per slide)	Analysis of ALK expression through in situ hybridization.
Registration Period	Shipping Period	Test Period
TBA	One week prior to the proficiency trial	TBA

ESP/QuIP Lung Cancer Related Markers - ROS1 (IHC)		Accredited
Price	Test Material	Description: Marker
TBA	5 cases (1 whole tissue sample per slide)	Analysis of ROS1 expression through immunohistochemistry.
Registration Period	Shipping Period	Test Period
TBA	One week prior to the proficiency trial	TBA

ESP/QuIP Lung Cancer Related Markers - ROS1 (ISH)		Accredited
Price	Test Material	Description: Marker
TBA	5 cases (1 whole tissue sample per slide)	Analysis of ROS1 expression through in situ hybridization.
Registration Period	Shipping Period	Test Period
TBA	One week prior to the proficiency trial	TBA

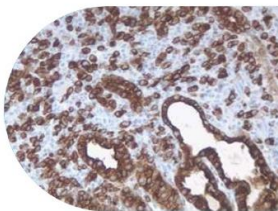


Lung Carcinomas

Molecular Pathology

EGFR Mutation Analysis Liquid Biopsy (MolPath)		Accredited
Price	Test Material	Description: Marker
950 €	5 samples, each containing 2 ml of human nucleic acid-free plasma spiked with 60 ng of either wild type DNA or a combination of wild type and mutated fragmented DNA in different allele frequencies	Analysis of the <i>EGFR</i> mutation status for exon 19, 20 (exon 20 insertions are NOT included) and 21
Registration Period	Shipping Period	Test Period
Until 09.02.24	One week prior to the proficiency trial	26.02.24 – 08.03.24

MET Exon 14 Skipping (Liquid Biopsy)		Accredited
Price	Test Material	Description: Marker
750 €	10 cases , each containing 2 ml of human nucleic acid-free plasma spiked with 60 ng of either wild type DNA or a combination of wild type and mutated fragmented DNA in different allele frequencies	Testing for <i>MET</i> mutations in intron 13, intron 14 or in exon 14, which can lead to <i>MET</i> exon 14 skipping
Registration Period	Shipping Period	Test Period
Until 23.02.2024	One week prior to the proficiency trial	11.03.2024 - 22.03.2024

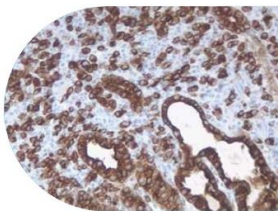


Gastric Carcinoma

Immunohistochemistry and In Situ Hybridization

HER2 Gastric Carcinoma (IHC)		Accredited
Price	Test Material	Description: Marker
450 €	2 TMA sections with approx. 18 cases	Immunohistological analysis according to the modified Hercep score for gastric carcinoma (according to Rüschoff et al. 2010) for biopsies
Registration Period	Shipping Period	Test Period
Until 21.06.2024	One week prior to the proficiency trial	16.09.2024 - 04.10.2024

HER2 Gastric Carcinoma (ISH)		Accredited
Price	Test Material	Description: Marker
500 €	2 TMA sections with approx. 12 cases	Analysis of the HER2 amplification status
Registration Period	Shipping Period	Test Period
Until 21.06.2024	One week prior to the proficiency trial	16.09.2024 - 04.10.2024

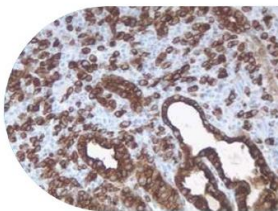


Gynecologic Carcinomas

Molecular Pathology

PIK3CA Mutation Analysis (MolPath)		Accredited
Price	Test Material	Description: Marker
TBA	TBA	Analysis of the <i>PIK3CA</i> mutation status
Registration Period	Shipping Period	Test Period
TBA	TBA	TBA

ESR1 Mutation Analysis Breast Cancer (Liquid Biopsy)		Not accredited
Price	Test Material	Description: Marker
Please Contact office@quip.eu	10 cases, each containing 2 ml of human nucleic acid-free plasma spiked with 60 ng of either wild type DNA or a combination of wild type and mutated fragmented DNA in different allele frequencies	Analysis of <i>ESR1</i> mutations in exon 5 and 8
Registration Period	Shipping Period	Test Period
Until 29.02.2024	One week prior to the proficiency trial	08.04.2024 - 19.04.2024

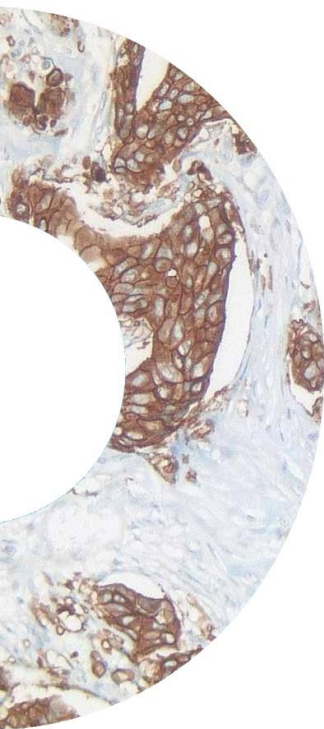


Blue – **Molecular Pathology** | Purple – **Immunohistochemistry** |
Dark blue – **Fluorescence In Situ Hybridization** | TBA – To be announced

Prostate Carcinoma

Immunohistochemistry

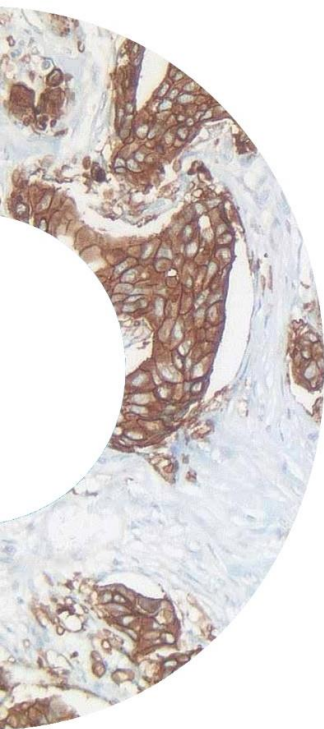
Keratins/Prostate Carcinoma (IHC)		Accredited
Price	Test Material	Description: Marker
500 €	4 cases per marker (TMA with one punch cylinders per case)	The expression of the 6 markers pan-keratin, basal cell marker, keratin 7, keratin 20, racemase and a prostate-specific marker (PSA or PSAP or Prostein or NKX3.1 or PSMA) is analyzed using IHC
Registration Period	Shipping Period	Test Period
TBA	One week prior to the proficiency trial	11.11.2024 - 29.11.2024



Sarcoma

Immunohistochemistry

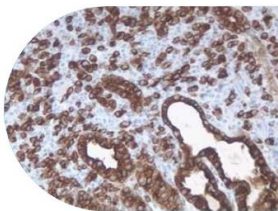
Sarcoma: STAT6, Myogenin (IHC)			Accredited
Price	Test Material	Description: Marker	
500 €	10 cases per marker (TMA with two punch cylinders per case)	Analysis of STAT6 and/or Myogenin expression with IHC	
Registration Period	Shipping Period	Test Period	
TBA	One week prior to the proficiency trial	TBA	



Tumors of the Central Nervous System

Molecular Pathology

TERT Mutation Analysis in Glioma, Meningioma and Bladder Carcinoma (MolPath)		Accredited
Price	Test Material	Description: Marker
900 €	10 tissue samples (tissue preparations of gliomas, meningiomas and bladder carcinomas); three unstained tissue slides, each 5 µm thick are provided per sample	Analysis of the TERT promoter mutation status
Registration Period	Shipping Period	Test Period
Until 01.04.2024	One week prior to the proficiency trial	17.06.2024 - 05.07.2024





📍 Reinhardtstraße 1
10117 Berlin

☎ +49 30 921 07 17 - 0

📠 +49 30 921 07 17 - 20

✉ office@quip.eu

www.qualityinpathology.com