Service Offering and Prices

Quality Labs
BIOMATERIAL TESTING

DAkkS
Deutsche
Akkreditierungsstelle
D-PL-13335-01-00

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-P-520.05.01

QualityLabs BT GmbH is an independent test laboratory that is accredited in accordance to ISO EN 17025 for a test for determining the antimicrobial properties of products and for describing the adhesive or anti-adhesive properties of surfaces. The accreditation includes the lab itself and the testing methods.

Medical device manufacturers can submit QualityLabs BT test reports throughout Europe at notified bodies as recognized test certificates for marketing approval of antimicrobial medical devices.

A) Determination of the antimicrobial properties of material surfaces ➔ Certika proliferation assay

What can be measured with this method?
The ability of material surfaces to inhibit the growth of microorganisms and pathogens on the surface. This measurement can lead to certification.
A detailed description is given starting on page 6.

B) Rapid screening of the antimicrobial properties of material surfaces ➔ QualiScreen

What can be measured with this method?
The ability of material surfaces to inhibit the growth of microorganisms and pathogens on the surface. This is a quick and economical measuring method with a YES or NO answer. A detailed description is given starting on page 14.

C) Determination of the adhesive or anti-adhesive properties of material surfaces ➔ Certika adhesion assay

What can be measured with this method?
The ability of material surfaces to bind fewer or more microorganisms.
A detailed description is given starting on page 19.

With Tests A and C, clients from medical technology are given the opportunity to have the effectiveness of their antimicrobial, adhesive or anti-adhesive medical devices or products assessed.
The information on the tested properties of materials or products can then be submitted to the *notified bodies* as the basis for marketing approval of medical devices.

D) Quantitative determination of the release of silver ions from materials, products and cosmetics ➔ voltammetry

What can be measured with this method?
The amount or concentration of bioavailable (antimicrobial) silver ions. Only silver ions Ag^{+} can kill microorganisms; metallic silver Ag^{0} does not have this property.
A detailed description is given starting on page 26.

1 Short introduction:

1.1 Certika Proliferation assay:

- The assay is performed in micro plates.
- **10** different samples/formulations/concentrations including blank sample(s) can be measured on one micro plate at the same time.
- Each of these samples is tested with 8 replicates.
- The test report of a standard assay (with *Staphylococcus epidermidis* DSM 18857) is a certification that can be submitted to the notified bodies.
- Samples should be as identical as possible (form and area), not longer than 7 mm and no more than 4 mm in diameter

Price per micro plate ➔ **€4,950.-**

A detailed description of the proliferation assay, the results and the pricing is given starting on page 6.

1.2 QualiScreen

- The assay is performed in micro plates
- **20** different samples/formulations/concentrations including blank sample(s) can be measured on one micro plate at the same time.
- Each of these samples is tested with 4 replicates.
- In the test report, the result is presented as **'antibacterial'** or '**not antibacterial'**
- Samples should be as identical as possible (form and area), not longer than 7 mm and no more than 4 mm in diameter

Graduated prices depending on the number of samples ➔ **between € 97.50 and € 165.- per sample**

A detailed description of QualiScreen, the results and the pricing is given starting on page 14.

1.3 Certika Adhesion assay:

- measurement is performed in micro plates
- **10** different samples/formulations/concentrations **including a maximum of one blank sample** can be measured on one micro plate at the same time.
- Each of these samples is tested with 8 replicates.
- The test report of a standard assay (with *Staphylococcus epidermidis* DSM 1798) is a certification that can be submitted to the notified bodies.
- Samples should be as identical as possible (form and area), not longer than 7 mm and no more than 4 mm in diameter

Price per micro plate ➔ **€5,975.-**

A detailed description of the adhesion assay, the results and the pricing is given starting on page 19.

1.4 Voltammetry

Direct quantitative determination of the amount of bioavailable, antimicrobial silver ions in a solution.

→ Determination of release kinetics with 2 to 8 measurements over a period of up to 12 weeks

For further information see page 26.

1.5 Simulation of environmental or ambient conditions/preincubation

For both proliferation and adhesion assays, it is possible to incubate, store or treat client samples before (e.g. 24 h) and during the test in or with substances and solutions. This serves to simulate real-life application conditions.
This means, for example, that catheters can be preincubated in urine, wound dressings in human plasma and dental material in artificial saliva.

Surcharge per preincubation and micro plate ➔ **€ 950.-**

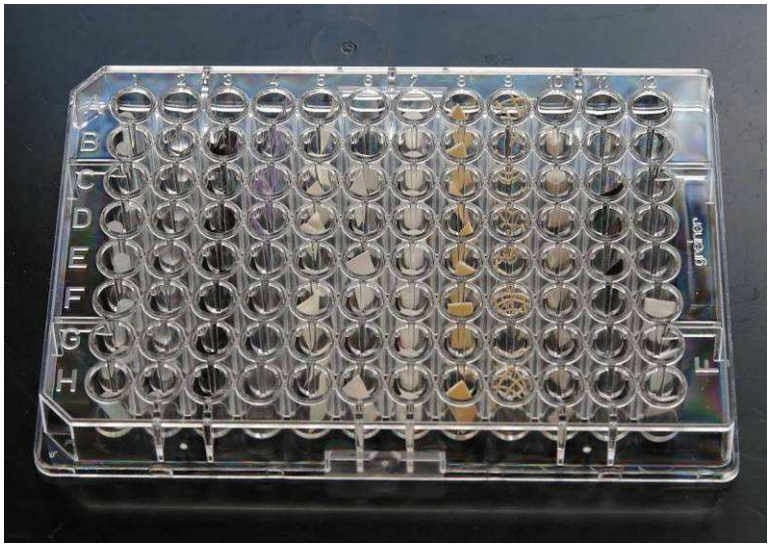
Surcharge for QualiScreen preincubation is about € 490.-

Further information on preincubation possibilities is presented in section 6 on page 25.

All additional work related to sample preparation or extensive sample preincubations are calculated on the basis of time and effort.

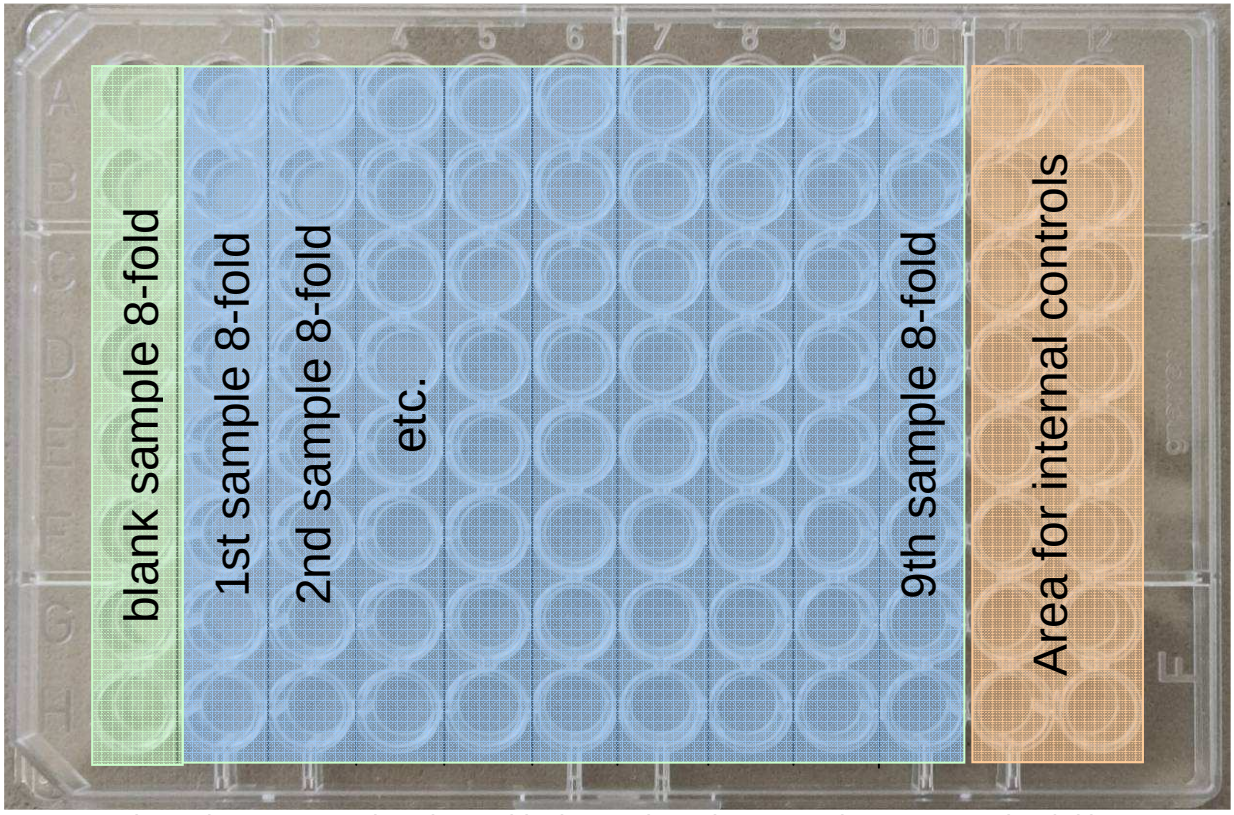
2 Information on the Certika proliferation assay

Proliferation assays are carried out in micro plates (see figure below).

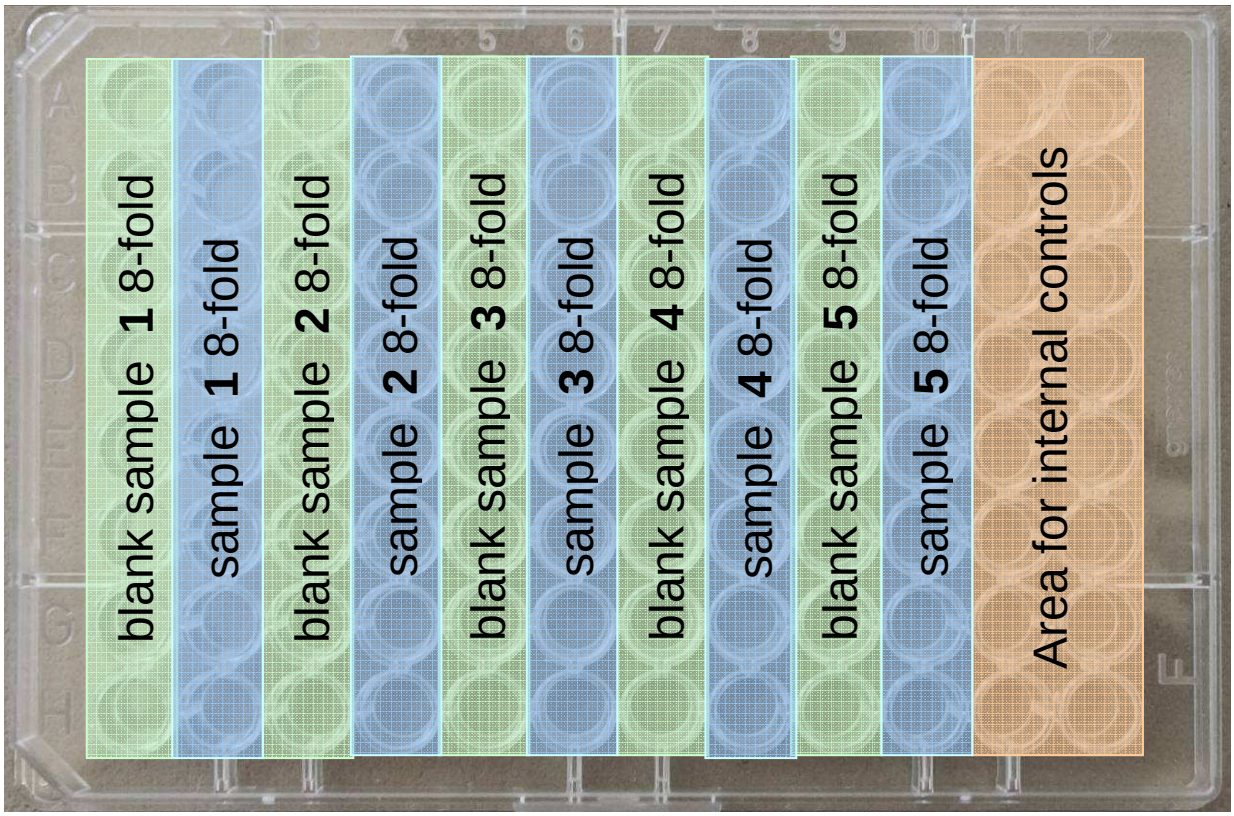


Every sample is processed in one of the 96 ‘miniature test tubes’ and thus has its own reaction space.

➔ One assay plate can contain up to **10** different samples/formulations/concentrations including the blank sample(s); each sample is tested with 8 replicates..



For example, a plate can contain only one blank sample and 9 appropriate test samples (with antimicrobial agent) or variations of this: a total (including blank samples) of no more than 10 samples.

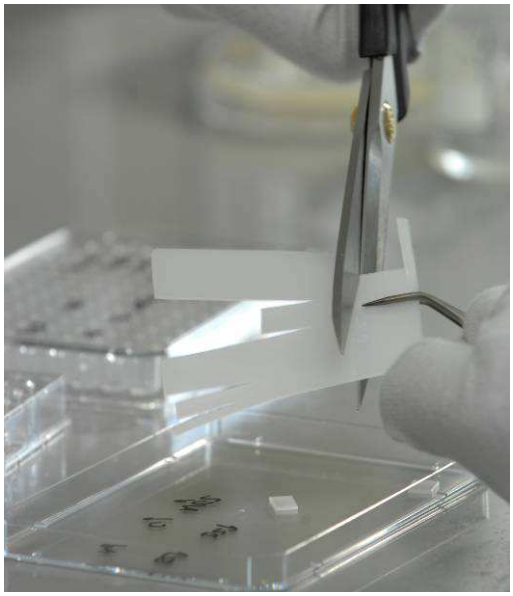


Up to 5 blank samples and 5 appropriate test samples (with antimicrobial agent) can be tested on one plate.

2.1 What are the requirements for proliferation assay test samples?

The samples should be as identical as possible in form and area.
The length should not exceed 7 mm.
The diameter should be a maximum of 4 mm.

Paints and lacquers can also be sent in as liquids. We will then produce the samples in the laboratory.



Cutting sample specimens to size (here, for example, dried lacquer

Please do not label the test samples with organic solvent-containing markers (e.g. Edding) because this can lead to incorrect test results. Pencil markings are neutral.

Do not pack test samples in plastic bags because the bags could contain plasticisers that can diffuse into the samples. Simple paper bags or aluminium foil are completely adequate.

More advice is given in the supplementary document "*Requirements for sample materials*".

Please note: We can prepare very few materials into test specimens. We do not have a mechanical workshop and therefore, have very limited preparation possibilities.

2.2 How does the Certika proliferation assay work?

Cells of the test strain are applied to the test object. Loose cells that do not adhere to the surface are removed in a wash step.

Afterwards, the test material is incubated for a defined time (challenge time) to determine the extent to which the proliferation or growth of the adhering microorganisms is inhibited due to the material's antimicrobial properties.

For non-antimicrobial surfaces, the adhering cells continue to divide on the material's surface and release daughter cells into the surrounding liquid.

Antimicrobial materials affect bacterial growth to different degrees and can even completely prevent cell division.
If all bacteria on the material's surface are prevented from reproducing or dividing, no daughter cells are produced and the test object is said to be bactericidal. But materials can also be antimicrobial, which means that not all of the cells on the test surface are prevented from growing. Some cells on the material surface are able to reproduce and release daughter cells into the surrounding liquid.
Because the number of these released cells is very low after the incubation period, a measurable signal that can be detected by an instrument must be generated through the use of appropriate microbiological methods. The time that the cells need to attain this turbidity is proportional to their number and hence, to the effect of the material surface being tested.
Antimicrobial efficacy is always measured as the difference to an appropriate non-antimicrobial blank sample. Clients provide the blank sample, which is identical to the test object in all aspects except for the presence of the antimicrobial substances.

For both test objects, that is, the blank sample and the actual test sample with antimicrobial additives, the time required for the remaining cells to attain the turbidity described above is measured. The difference between these two times (the time for the blank sample is subtracted from the time for the antimicrobial test sample) is the evaluation criterion for antimicrobial efficacy.
If the time difference is longer than 6 hours, this means that at least ca. 99.9% of all cells on the surface were prevented from proliferating or dividing (i.e. prevented from growing).
In the standardised Certika proliferation assay, antimicrobial efficacy is always measured using *Staphylococcus epidermidis* DSM 18857 as the test strain. This contributes to the uniformity and direct comparability of test results. Measurements performed with different strains or species cannot be directly compared with one another.

The test report from a standard Certika proliferation assay can be submitted to notified bodies throughout Europe as an approved test certification for the marketing authorisation of antimicrobial medical devices.

Further information on the test report is provided on page 10.

2.3 Onset OD in comparison to log_{10} reduction

A test bacteria doubles or divides in a proliferation assay every 30 minutes; this means after 5 hours, the net onset OD (in comparison to a blank sample) yields the following growth inhibition:

300 minutes/30 minutes per doubling = 10 doublings or cell divisions

This is equivalent to a log reduction of 2^{10}:1 (= 1024:1) and corresponds to approximately 0.1% of the daughter cells produced in the blank sample.

➔ Hence, after the inclusion of a margin of safety, 6 net onset OD hours correspond to a 99.9% or 3 log_{10} growth inhibition (in comparison to a blank sample).

2.4 Information on the test report for proliferation assays

After the conclusion of a proliferation assay, you will receive a test report that shows the result for each of the 8 replicates of a sample, for example:

Sample Name	Test result
Sample 1	blank sample
Sample 2	antimicrobial
Sample 3	antimicrobial
etc.	etc.

Furthermore, you will also find the mean of the 8 replicates, the standard deviation and the coefficient of variation:

Sample Name	Sample Code	Onset OD [h] total	Onset OD [h] net	Standard Deviation [h]	CV [%]	Test Result
Sample 1	9991601080001	5.0	-	0.1	2.6%	blank sample
Sample 2	9991601080002	28.0	**23.0**	2.1	10.0%	antimicrobial
Sample 3	9991601080003	>48	**>48**	0.0	0.0%	antimicrobial

It is important to note that the net onset OD value of your samples (with antimicrobial agent) must be at least 6.0 hours to be considered antimicrobial.
If the net time is longer than 6 hours, at least ca. 99.9% of all cells on the surface were not able to proliferate or divide (i.e. grow).

Sample Name
Your designation of the sample

Sample Code.
Work orders are processed anonymously in the laboratory; hence, all samples are tagged with bar codes.

Onset-OD [h] total
Measured total onset OD time (see also section 2.4 Information on the test report, page 10)

Onset-OD [h] net
Calculated net onset OD time; this is the difference between the total onset OD of the test sample (with antimicrobial agent) and the total onset OD of the blank sample.
(see also section 2.4 on page 10)

Standard deviation [h]
Standard deviation (of the 8 replicates)
The standard deviation is a measure of the scattering of the values from the mean.

CV [%]
The coefficient of variation (CV) expresses the standard deviation as a relative standard deviation (independent of units) in per cent values.

Test result
If the net onset OD is longer than 6.0 h, the sample is designated antimicrobial.

2.5 Additional germs for proliferation assays

For medical devices, the test report is regarded as a certification only if the measurement was performed according to the standard procedure and with *Staphylococcus epidermidis* DSM 18857 as the test strain.
Measurements using other bacteria with the following characteristics are also possible.

Species	Germ properties
Staphylococcus epidermidis	MRSE, gentamycin and tobramycin-resistant, biofilm former
Staphylococcus aureus	MRSA, gentamycin-resistant, highly resistant to tobramycin, produces dermatoxin, is used in DIN 58959-7 and by the FDA, used in European Pharmacopoeia
Enterococcus faecium	Is used in DIN 58959
Enterococcus faecalis	
Listeria monocytogenes	
Salmonella choleraesuis	
Corynebacterium striatum	Foot odor
Citrobacter freundii	Is used in DIN 58959
Klebsiella pneumoniae	
Enterobacter cloacae	Is used DIN 58959
Escherichia coli	Is used DIN 58959-7 and by the FDA
Pseudomonas aeruginosa	Gentamycin and tobramycin-resistant, use in DIN 58959

2.6 Pricing for Certika proliferation assays

One micro plate (regardless of the actual number of samples) costs **€ 4,950**.

For each preincubation there is a surcharge of **€ 950.-**

For example:

One micro plate with 8 samples costs **€ 4,950**

2 samples (8 replicates each) are preincubated in artificial urine → surcharge **€ 950.-**

2 samples (8 replicates each) are preincubated in human plasma → surcharge **€ 950.-**

➔ Total: **4,950 + 950.- + 950.- = € 6,850**

2.7 Graded prices for Certika proliferation assays

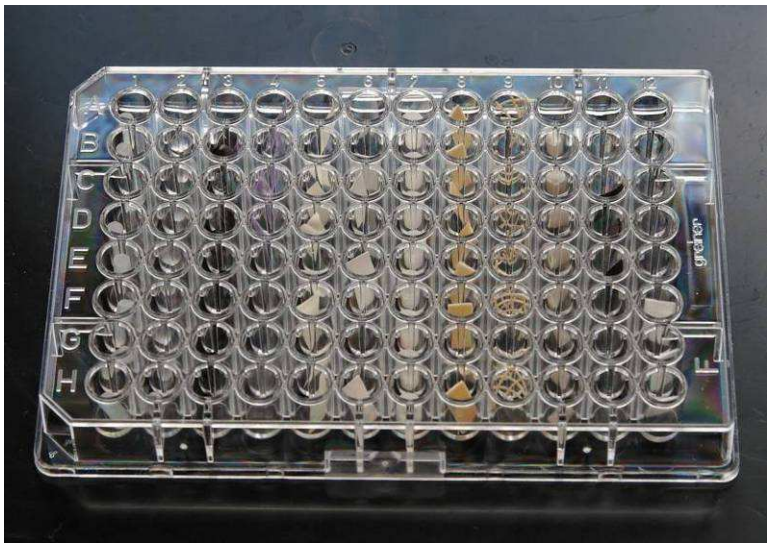
One micro plate (regardless of the actual number of samples) costs **€ 4,950.-**

1 micro plate	**€ 4,950.-**
10 to **19** micro plates	**€ 3,950.-** / micro plate
20 to **34** micro plates	**€ 3,500.-** / micro plate
35 to **49** micro plates	**€ 3,200.-** / micro plate
50 micro plates and more	**€ 2,950.-** / micro plate

Each pre-incubation will be charged separately with **€ 950,-**.
From **20** micro plates and more pre-incubations will be charged separately with concurrently **€ 600.-**

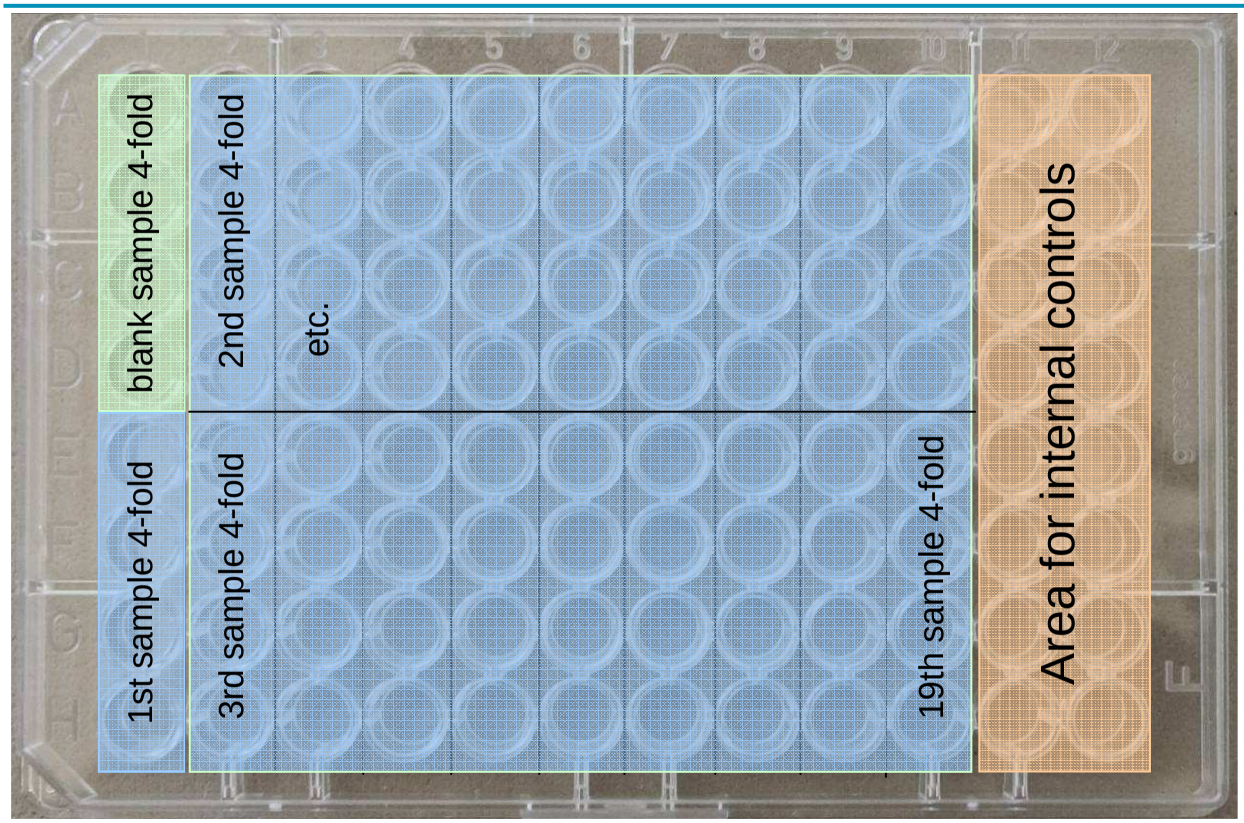
3 Information on QualiScreen

QualiScreen tests are performed in micro plates (see the figure below).

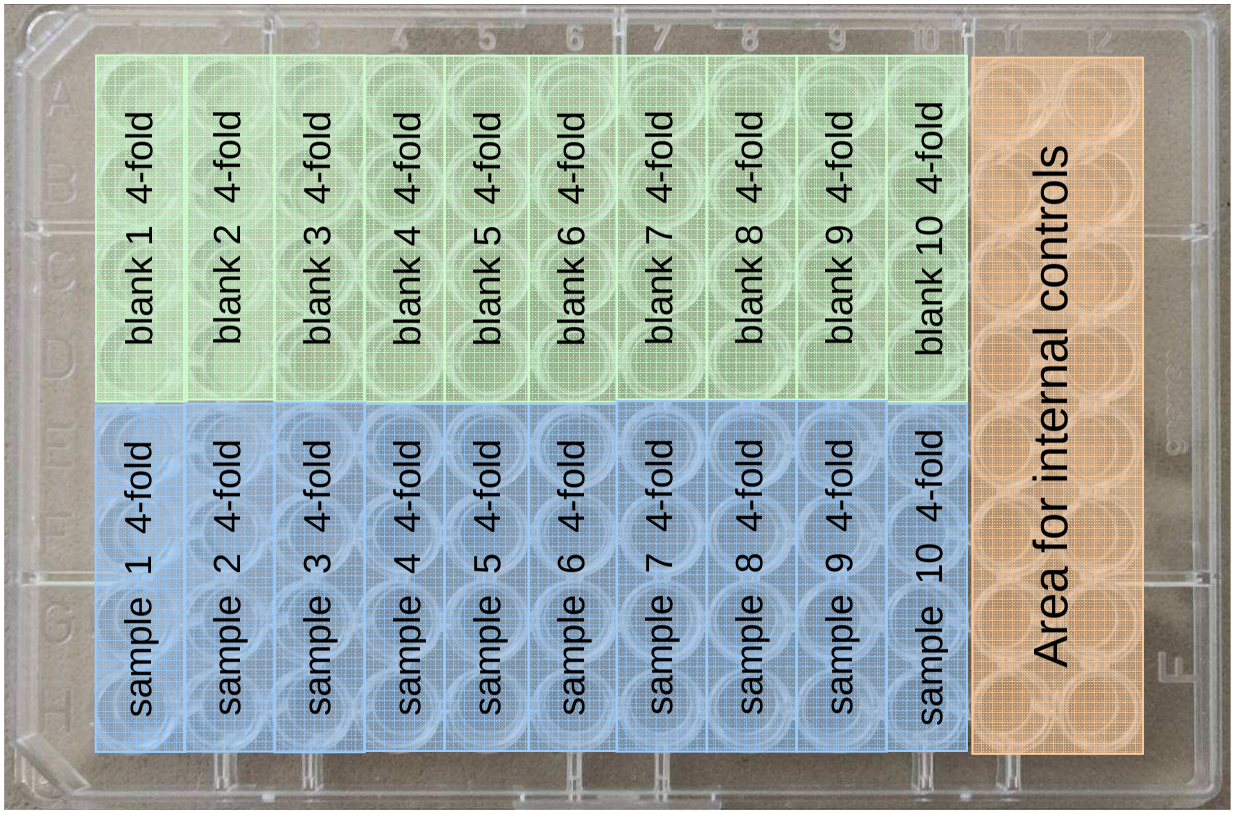


Every sample is processed in one of the 96 ‘miniature test tubes’ and thus has its own reaction space.

➔ One assay plate contains up to **20** different samples/formulations/concentrations including the blank sample(s); each sample is tested with 4 replicates.



For example, a plate can contain only one blank sample and 19 appropriate test samples (with antimicrobial agent) or variations of this: a total (including blank samples) of no more than 20 samples.



Up to 10 blank samples and 10 appropriate samples (with antimicrobial agent) can be tested on one plate.

3.1 What are the requirements for QualiScreen test samples?

Requirements of the samples correspond to that of the proliferation measurements.

➔ see also section 2.1 on page 8.

3.2 How does QualiScreen work?

The test objects are incubated with cells of the test strain. Loose cells are removed through defined wash steps. The material being tested is incubated a defined length of time to determine its effect on the proliferation (growth) of bacteria on the object's surface. For non-antimicrobial surfaces, the adhering bacteria continue to divide on the surface of the material and release daughter cells into the surrounding liquid.
Antimicrobial materials affect bacterial growth to different degrees and can even completely prevent cell division.
Because of the number of these released cells is very low after the incubation period, a measurable signal that can be detected by an instrument must be generated through the use of appropriate microbiological methods.
Antimicrobial efficacy is always measured in comparison to a non-antimicrobial blank sample. Clients provide the blank sample, which is identical to the test object in all aspects except that it is free of antimicrobial additives. Internal controls that are present on all micro plate assays serve as permanent monitors of the measuring process.

The measurement cannot be evaluated if the blank sample has a higher antimicrobial effect than the test object with antimicrobial agent.
For the QualiScreen test, a material is regarded antimicrobial only if it inhibits the formation of at least 99.9% of the daughter cells during the observation period in comparison to the blank sample.

For QualiScreen, all 4 test samples (of a 4-fold measurement) must test as antimicrobial to obtain the designation 'antimicrobial'.

Measurements that are performed with different strains or species cannot be directly compared with one another.

3.3 Information on the test report for QualiScreen

After the conclusion of a QualiScreen, you receive a test report that gives the result for each of the 4 sample replicates, but without statistics and raw data, for example:

Sample Name	Sample Code	Test Result
Sample 1 blank	9991601080001	blank sample
Sample 2	9991601080002	antimicrobial
Sample 3	9991601080003	not antimicrobial

3.4 Other germs for QualiScreen

A QualiScreen test report does not result in certification; hence, the test is not restricted to the standard bacterium *Staphylococcus epidermidis* DSM 18857. However, due to improved comparability, we always recommend performing the test with *Staphylococcus epidermidis* DSM 18857.

For QualiScreen, all bacteria that are available for the proliferation assay can be used.

➔ see also section 2.5 on page 12.

3.5 Pricing für QualiScreen

You pay only for the actual number of tested samples.
Because the test sample is always measured against untreated material, **a minimum of 2 and a maximum of 20** samples (4 replicates each) per plate can be tested.

QualityLabs offers the following **graduated prices**:

2 - 7 samples	**€ 165.-** / sample	=	**€ 330.-** to **€ 1,155.-**
8 - 11 samples	**€ 150.-** / sample	=	**€ 1,200.-** to **€ 1,650.-**
12 - 14 samples	**€ 138.-** / sample	=	**€ 1,656.-** to **€ 1,932.-**
15 - 20 samples			**€ 1,950.-**

Hence, for a full plate, the price per sample is **€ 97.50**.

3.6 Graded prices for QualiScreen assays

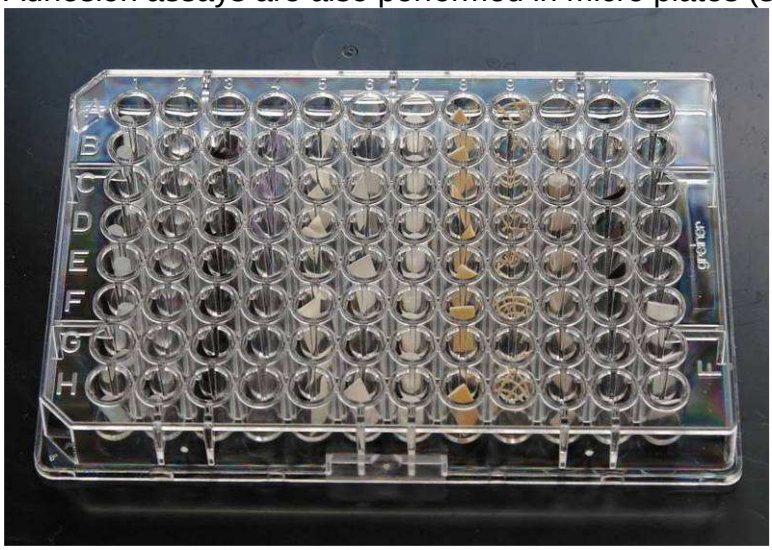
Each pre-incubation will be charged separately with **€ 490.-**.
From **20** plates and more pre-incubations will be charged with **€ 400.-**.

Prices for micro plates with **20** samples (4-fold):

1 micro plate	**€ 1,950.-**
10 to 19 micro plates	**€ 1,900.-** / micro plate
20 to 34 micro plates	**€ 1,850.-** / micro plate
35 to 49 micro plates	**€ 1,750.-** / micro plate
50 micro plates and more	**€ 1,700.-** / micro plate

4 Information on the Certika adhesion assay

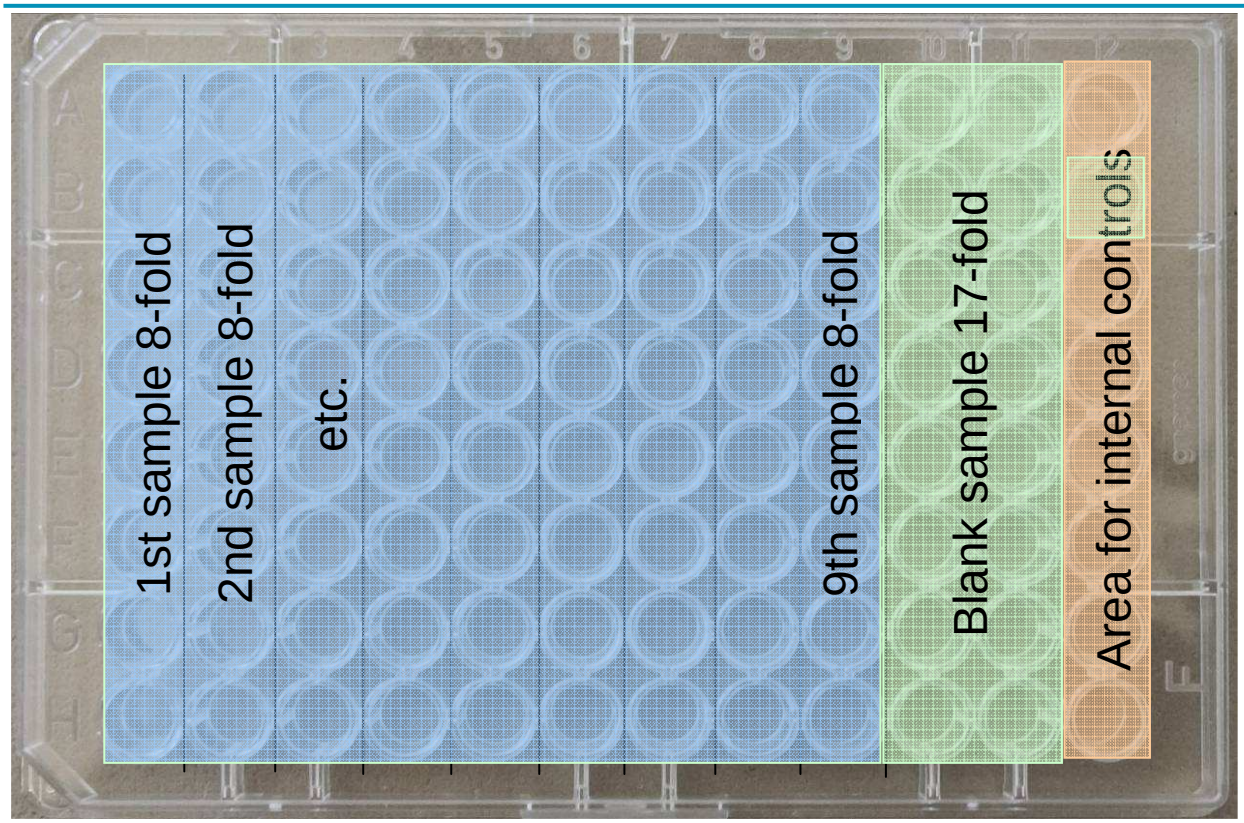
Adhesion assays are also performed in micro plates (see the figure below).



Every sample is processed in one of the 96 ‘miniature test tubes’ and thus has its own reaction space.

➔ One assay plate can hold up to **10** different samples but **includes** only **one blank sample** (17 replicates); each of the samples is tested with 8 replicates.

For one adhesion assay, a maximum of 9 samples and a maximum of 1 blank sample (17 replicates) can be measured.



For one adhesion assay, there must be at least one sample and at the most, 1 blank sample (17 replicates) on the micro plate.

4.1 What are the requirements for adhesion assay test samples?

The samples should be as **identical** as possible in form and area because in adhesion assay differences in the surface size and roughness directly influence the measurements.

The length should not exceed 7 mm.

The diameter should be a maximum of 4 mm.

Further advice is found in the supplementary document "*Requirements for sample materials*".

4.2 How does the Certika adhesion assay work?

The adhesion assay is performed as a relative, semi-quantitative cell count determination. Primary antibodies bind to the cells of the test strain adhering to the test objects. In turn, enzyme-linked secondary antibodies bind to the primary antibodies. After the addition of a chromogenic substrate, the intensity of the resulting colourimetric reaction between the enzyme and the substrate is proportional to the number of adherent cells. The relative adhesion is determined by comparison to the blank sample.

Detailed description of the Certika adhesion assay:

The test objects are incubated with cells of the test strain. Loose cells that are not adhered to the surface are removed in defined wash steps. The adherent bacterial cells on the test object are then detected in an immunoassay through the use of antibodies.

In this assay, adhesion is not determined absolutely, but rather on a relative basis. This means that adhesion is always determined in reference to a starting material that serves as a control. The client provides the material that is to serve as a control sample. Typically, the control samples are made of the same material but have not been rendered adhesive or anti-adhesive. The selection of the control object is ultimately a decisive factor for the test results. The test results apply only to the combination of test and control objects provided by the client. Internal controls that are present on all micro plates serve as permanent monitors of the measurement process.

The result from the test samples is standardised by comparing it to the mean adhesion value determined for the blank samples.

The relative adhesion is the quotient of the mean value from the test sample replicates and that of the control sample replicates. The quotient is multiplied by 100 to yield the relative adhesion in per cent.
Test samples with a relative adhesion of more than 100% show increased adhesion of the test bacteria. Materials with a relative adhesion of less than 100% show reduced adhesion.

Thus, you receive measurements that characterise the ‘adhesive difference’ of your sample to the provided control material. In the interest of obtaining adequate data quality, the variation of the adhesion values obtained from submitted test objects must satisfy a predetermined minimum requirement. If these standards are not met due to large sample heterogeneity, it may be decided that the test results cannot be analysed. Should this be the case, relevant information will be found in the test report under “Interpretation of the results based on the measurements”.

The bacteria *Staphylococcus epidermidis* DSM 1798 is always employed in the standard Certika adhesion assay performed in accordance with the accreditation under ISO/IEC 17025.

The test report of a standard Certika adhesion assay can be submitted to notified bodies throughout Europe as an approved test certification for the marketing authorisation of adhesive or anti-adhesive medical devices.

4.3 Information on the test report for adhesion assays

After the conclusion of an adhesion assay, you will receive a test report that shows the result of each of the 8 replicates of a sample, for example:

Sample	Adhesion Efficacy
Sample 1	blank sample
Sample 2	lowered adhesion
Sample 3	increased adhesion
etc.	

Furthermore, you will also find the mean of the 8 replicates, the standard-deviation and the coefficient of variation:

Sample Name	Sample Code	Relative Adhesion %	Adhesion Efficacy
Sample 1	9991601080001	100	blank sample
Sample 2	9991601080002	45	lowered adhesion
Sample 3	9991601080003	187	increased adhesion

Sample Name
Your designation of the sample

Sample Code
Work orders are processed anonymously in the laboratory; hence, all samples are tagged with bar codes.

Relative Adhesion %
The adhesion behaviour of the respective sample relative to the control sample.
A description of the calculation is given in section 4.2 on page 20.

Adhesion Efficacy
Describes the adhesion behaviour again in understandable language

4.4 Additional bacteria for Certika adhesion assays

Species	Germ properties
Staphylococcus epidermidis	MRSE, gentamycin and tobramycin-resistant, biofilm former
Staphylococcus aureus	MRSA, gentamycin-resistant, highly resistant to tobramycin, produces dermatoxin, is used in DIN 58959-7 and by the FDA, used in European Pharmacopoeia
Escherichia coli	Is used in DIN 58959-7 and by the FDA
Pseudomonas aeruginosa	Gentamycin and tobramycin-resistant, is used in DIN 58959

In principle, almost any microorganism can be used for an adhesion assay. For this, we can order bacteria and fungi from the **German Collection of Microorganisms and Cell Culture** (www.dsmz.de).

Additional charge: **€ 250.-**
Time required: **14 days**

Subsequently, the suitability of the microorganism for the test method however must be first investigated.

Additional charge: **€ 1,000.-**
Time required: **3 – 4 weeks**

Afterwards an antiserum that is specific to this microorganism must be generated.

Additional charge: **€ 1,000.-**
Time required: **6 – 12 weeks**

Please note: The standard adhesion assay in accordance with the accreditation under ISO/IEC 17025 is always performed with the test strain *Staphylococcus epidermidis* DSM 1798.
Only the test report from the standard adhesion assay can be submitted to the notified bodies throughout Europe as an approved test certification for the marketing authorisation of adhesive or anti-adhesive medical devices.

4.5 Pricing for Certika adhesion assay

One micro plate (regardless of the actual number of samples) costs **€ 5,975.-**

For each preincubation there is a surcharge of **€ 950.-**.

For example:

One micro plate with 5 samples costs **€ 5,970.-**

2 samples (8 replicates each) are preincubated in artificial urine → surcharge **€ 950.-**

2 samples (8 replicates each) are preincubated in human plasma → surcharge **€ 950.-**

➔ Total: **5,970.- + 950.- + 950.-** = **€ 7,870.-**

Further information on preincubation possibilities is given under section 6 on page 25.

4.6 Graded prices for Certika adhesion assays

One micro plate (regardless of the actual number of samples) costs **€ 5,975.-**

For each preincubation there is a surcharge of **€ 950.-**.

From **20** micro plates and more pre-incubations will be charged separately with concurrently **€ 600.-**

1 micro plate	**€ 5,975.-**
10 to **19** micro plates	**€ 4,950.-** / micro plate
20 to **34** micro plates	**€ 4,500.-** / micro plate
35 to **49** micro plates	**€ 4,200.-** / micro plate
50 micro plates and more	**€ 3,950.-** / micro plate

5 Certificates

For both proliferation and adhesion assays, certificates for the product properties ‘antimicrobial’, ‘adhesive’ or ‘anti-adhesive’ can be issued.

Certificate seal for the product property ‘antimicrobial’

Tests aiming at a certificate must be performed according to accredited standard procedures (SOPs) (standard bacteria *S. epidermidis* DSM 18857 for proliferation assays and *S. epidermidis* DSM 1798 for adhesion assays). Furthermore, the results must meet specified minimum standards.

6 Preincubation possibilities for assays

Test samples can be pre-treated in specific liquids to simulate special application-specific milieus or ambient conditions. These include:

- ➔ Blood [whole blood or diluted with 0.9% NaCl (physiological saline solution, fresh)]
- ➔ Human blood plasma (1% to 100%, diluted with physiological phosphate buffer)
- ➔ Artificial urine
- ➔ Artificial saliva
- ➔ Artificial perspiration
- ➔ PBS (phosphate buffered saline solution)
- ➔ $NaNO_3$ (sodium nitrate)

Other incubation media are available on request.

7 Voltammetry

7.1 What is voltammetry?

Voltammetry is an electrochemical method for the detection of trace elements in aqueous and nonaqueous media. This method is so sensitive that the concentration of biologically relevant silver ions down to the nanomolar (ppb) range can be determined.

7.2 Applications of voltammetry

Voltammetry permits the direct quantitative detection of bioavailable, antimicrobial silver ions in a solution.

For the **marketing authorisation of silver-releasing medical devices,** notified bodies now demand release or elution profiles that can be obtained through voltammetry.
The migration of the silver ions in certain extraction media (free of organic substances) can also be determined by this method.

Other applications include:

- specific detection of silver ions, also in the presence of other antimicrobial active substances such as for example, triclosan, quaternary ammonium compounds
- correlation with Certika/proliferation assays or QualiScreen tests
- determination of elution profiles for medical devices
- estimation of a product's lifespan by determining the silver ion release kinetics
- determination of the total amount of silver in cosmetic products
- quality control of product homogeneity of silver-containing cosmetics
- accelerated aging (time lapse) models for the simulation of product aging
- determination of silver ion migration in extraction media
- lifecycle assessment
- shelf life analyses

The method can be adapted to the needs and requirements our clients and their samples.

7.3 What are suitable samples for voltammetry?

Voltammetry can be used on a great many substances, for example:

- Cosmetics (from liquids, such as sprays and ointments, to solids, such as soap)
- Silver polymer blends (granulates, pellets)
- Plastic products that contain silver
- Textiles, filaments, fibres, nonwoven and woven materials
- Coatings/paints/lacquers
- Impregnated materials

7.4 How does voltammetry work?

The measurement is based on the detection of redox active substances, meaning substances that can be chemically reduced or oxidised.

The electrical current required for such a redox reaction is measured. The silver redox pair Ag/Ag^+ requires a specific potential to migrate within the reaction space.

The silver ions (Ag^+) released by a silver-containing product are concentrated on a rotating electrode and reduced to metallic silver ($Ag^+ \rightarrow Ag^0$).

During a potential scan, the deposited silver is removed from the electrode. The electrical current that flows during this process is proportional to the concentration of the silver ions.

Every measurement is performed in triplicate.

7.5 Pricing for voltammetry

Release kinetics can be generated from voltammetric measurements. Measurements at several time points must be made for this.
Depending on the product and intended use, different release periods must be tested and hence the number of measurements required varies.

For example:

Release period	Time points of the measurements in days									Number of measurements
12 weeks	1	2	4	8	14	30		60	90	8
6 weeks	1	2	4	8	14	30	45			7
4 weeks	1	2	4	8	14	30				6
2 weeks	1	2	4	8	14					5
1 week	1	2	4		7					4

This means for a 12-week long kinetics test, 8 measurements (3 replicates each) on days 1, 2, 4, 8, 14, 30, 60 and 90 are made.

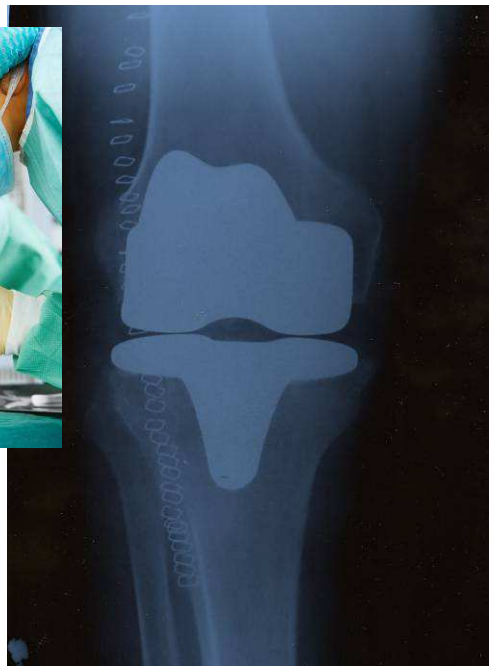
Prices are based on the number of measurements (3 replicates each) made:

Number of measurements	Cost
8	**€ 2,134.-**
7	**€ 1,917.-**
6	**€ 1,700.-**
5	**€ 1,484.-**
4	**€ 1,267.-**

For cosmetics, we also offer single measurements (performed in triplicate) for **€ 417.-**

8 Examples of products that have been tested by QualityLabs BT:

Medical Devices	Consumer Products
intravenous catheters	dental floss, toothbrushes
urine catheters	diapers
brain catheters	forceps
wound dressings	lacquer/paint
metal implants	textiles
dental implants	coatings of piping systems
artificial veins	glass
contact lenses	refrigerator elements
surgery couches	parts from air conditions
surgical gloves	packing foils
seals/valves for medical devices	materials of conveyors
sutures	floor coverings, resins, laminates
bone cement	washing machine parts
	toilet parts
	foams
	seals/valves



Prices are not binding – Last modified on December 1st 2010

Applicable VAT will be added to all prices

The general terms and conditions of business (AGBs) of QualityLabs BT GmbH from 27/10/2004 apply

Contact:
QualityLabs BT GmbH
Dr. Jörg Brünke
Neumeyerstr. 46a
90411 Nuremberg
Germany

Phone: +49 (0) 911 – 25 26 215
Fax: +49 (0) 911 – 25 26 211
E-Mail: joerg.bruenke@qualitylabs-bt.de

Issued by:

QualityLabs BT GmbH
Biomaterial Testing
Neumeyerstr. 46a
90411 Nuremberg
Germany

www.qualitylabs-bt.de

Trade Register: Nürnberg HRB 21092
Legal Domicile: Nürnberg
Tax Office: Finanzamt Nürnberg-Zentral
Tax No.: 11 241 135 50038
Sales tax identification No.: DE 236 963 929

Managing Director:
Dr. Jörg Brünke