Performance Guide

iCheck
Iodine
The test kit to measure iodine in salt

BioAnalyt

Performance explained

This Performance Guide is intended to explain the validity of our test kit iCheck Iodine in a nutshell to facilitate your decision making.

Complex language and processes are used during performance evaluation of a test kit, referred to as validation.

To clarify and harmonize this terminology and processes we have summarized how we validate our test kit and what the validation results mean.

We hope you find this material helpful and we are happy to receive your questions and comments! Do not hesitate to contact us at ***support@bioanalyt.com***.

Sincerely,
Your BioAnalyt Support team

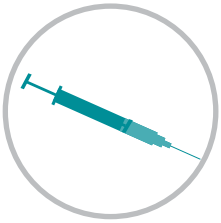
Development, manufacture and sales of all BioAnalyt test kits (devices, reagent vials) are carried out in accor-dance with ISO 9001:2015 and have been certified by TÜV NORD, Germany.

Note:
This material is based on the definitions set by ISO, the International Organization for Standardization in ISO 5725:1994.

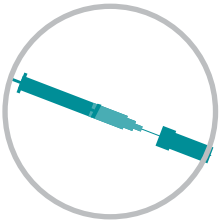
What is iCheck Iodine?

iCheck Iodine is an all-inclusive test kit for rapid on-the-spot measurement of iodine in salt.

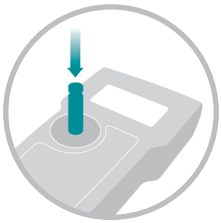
This test kit brings complex laboratory measurements down to a simple three-step process:



- Take up your sample



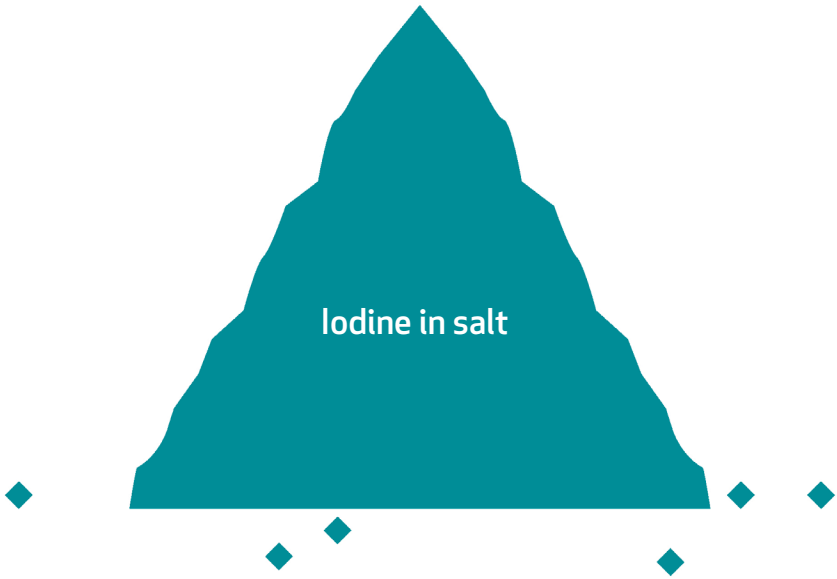
- Inject it into the ready-to-use reagent vial



- Measure the vial in your iCheck

What does iCheck Iodine do?

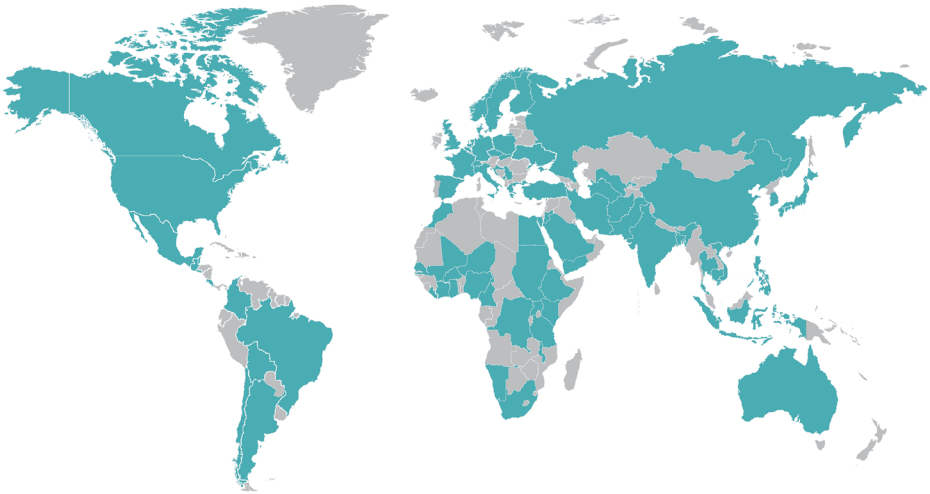
iCheck Iodine measures iodine as potassium iodate in the table salt.



Where are iChecks used?

iChecks are in use in over 80 countries around the globe.

Our customers are leading international organizations such as UNICEF, World Food Program, Hellen Keller International , Global Alliance for Improved Nutrition (GAIN), ministries and monitoring agencies, micronutrient premix producers, academic institutions, global and local food producers.

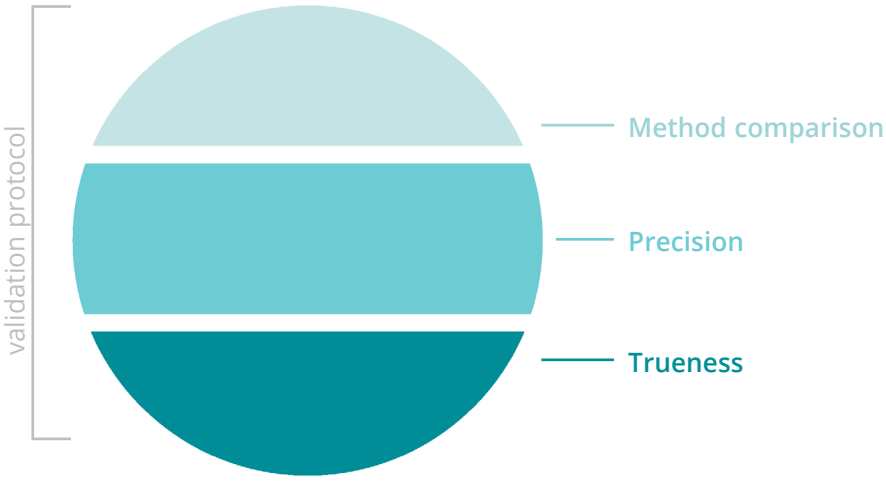


Countries using iCheck

Is iCheck Iodine validated?

We assess the performance of each test kit following a rigorous standardized process. This process is called a validation protocol.

The validation protocol combines assessment of precision, trueness and a comparison to a reference method.



How is iCheck Iodine validated?

1 Assessment of precision

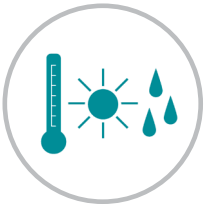
During the validation we assess the precision of the test kit. Precision tells us how similar are the repeated mea-surements of the same sample.

The difference observed between the repeated measure-ments is called variability of the result. The variability is common to all measurement methods and can be smaller or bigger.

Factors that affect the size of the variability of the result are:

- the sample itself

- the analyst



- the environment

- the instrument

We assess the precision by repeated measurements of the same sample under different conditions and by differ-ent people across all the measurement range of iCheck Iodine.

The measurement range of iCheck Iodine is from 1 mg/L to 13 mg/L.

The variability observed between the measurements is defined as coefficient of variation (CV). CV is calculated by dividing the standard deviation with the mean of your repeated measurements. The maximum CV for repeated measurements with iCheck Iodine is 8%.

How is iCheck Iodine validated?

2 Assessment of trueness

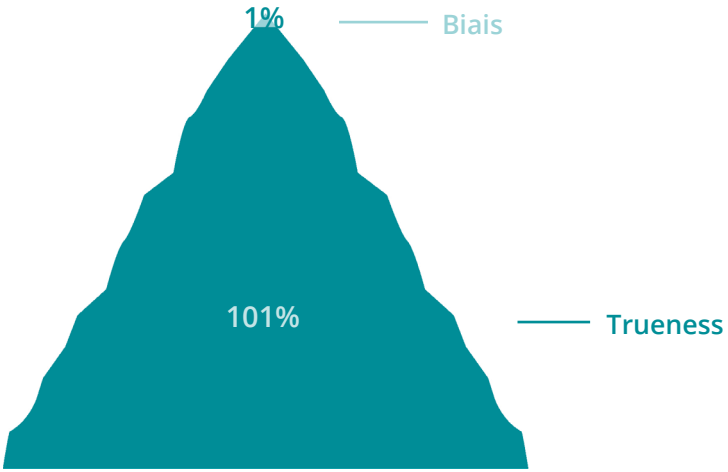
To know how close the measured result is to the real concentration of iodine we assess the trueness of the measurement.

To do this we add a known concentration of iodine to the table salt and compare the expected concentration to the measured concentration.

The iodine (i.e. potassium iodate) that we use is certified reference material which guarantees that our expected concentration is correct.

The trueness of iCheck Iodine results is 101%. This means that of the expected 100% iCheck Iodine measures 101% of the true iodine concentration in the salt sample.

The difference between expected and measured result is called bias and for iCheck Iodine results it is at 1%.



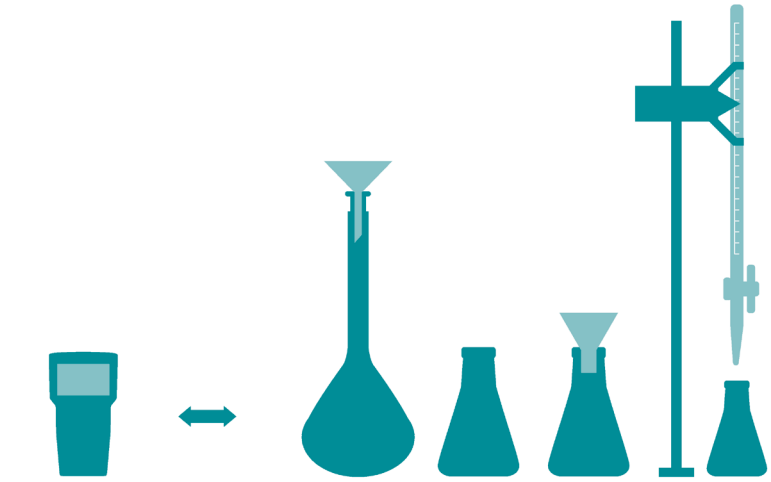
3 Method comparison

We further assess the performance of our test kit against an accepted reference method.

For iCheck Iodine the reference method is iodometric titration. Titration is a standard laboratory quantitative method for iodine measurement in salt as described in Codex Alimentarius issued by World Health Organization and Food & Agriculture Organization.

We measure in parallel the same samples with iCheck and with iodometric titration and evaluate how the results agree with one another.

The method comparison shows us that 97.5% of iCheck Iodine results are in agreement with titration results. The results differ by a maximum of 10 mg/kg and on average by as low as 0.3 mg/kg*.

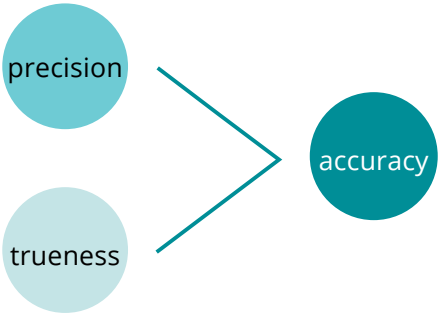


*Reference: Validation of a user-friendly and rapid method for quantifying iodine content of salt. F. Rohner, et al. Food and Nutrition Bulletin, vol. 33, no. 4 (supplement), 2012.

How accurate are iCheck Iodine results?

What is accuracy?
The assessment of the test kit's performance allows us to define how accurate is iCheck Iodine result.

Accuracy combines both the precision and the trueness assessed during validation.



How do we calculate accuracy?
We express the accuracy of iCheck Iodine in terms of the uncertainty of measurement.

To calculate this uncertainty we take the coefficient of variation (CV) associated with precision and the bias associ-ated with trueness and combine them using the following equation:

- Uncertainty = bias + 1.96 x CV

This equation gives us the uncertainty of measurement based on all our observations during the validation.

The uncertainty of measurement gives a range to the result and a 95% confidence level that the true value lies within that range.

The uncertainty of measurement with iCheck Iodine is therefore:

- 1% + (1.96 x 8%) = 17%.

Is this an acceptable accuracy?
It is important to note that the uncertainty does not imply doubt about the validity of a measurement.

On the contrary, the knowledge of the uncertainty implies increased confidence in the validity of a measurement result.

The measurement of iodized salt using the reference method iodometric titration has the uncertainty between 10% and 30%, depending on the laboratory. Similarly, the measurement with iCheck Iodine has uncertainty of 17%.

The result you obtain using iCheck Iodine has an accuracy level which enables you to make a confident decision.

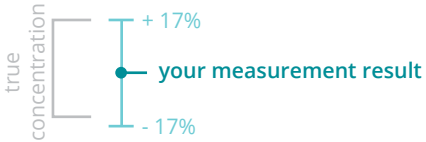
What does the uncertainty mean to you?
You have measured your salt sample and the result you have with the iCheck Iodine is 30 mg/kg, after taking into account the dilution of the salt sample in water.

The uncertainty of the iCheck Iodine measurement is 17%. This means that the true concentration of iodine in your salt sample is in the range of 30 mg/kg ±17%.

The result is therefore documented in the following way:

- 30 ± 5 mg/kg or
- 25 - 35 mg/kg.

This range is then controlled against the required concen-tration.



Technical Data

The technical specifications for iCheck Iodine are listed in the table to the right for your reference. If you would like more detailed information please contact us at **support@bioanalyt.com.**

TECHNICAL DATA	
Sample	
Analyte:	Iodine as potassium iodate
Sample:	Table salt
Sample preparation:	Dilution in distilled or bottled water
Sample volume per analysis:	1.0 mL (1000 µL)
Concentration range:	>3 ppm (mg/kg), samples must be diluted in water; minimum dilution factor is 1:3
Device	
Analytical method:	Photometric determination of iodine concentration using colorimetric reaction
Units displayed:	mg/L
Linear range:	1.0 - 13.0 mg/L
Calibration:	Factory set (standards included for control)
Time per analysis:	< 10 min
Environment:	20 – 30°C, no direct sunlight
Accuracy:	Maximum coefficient of variation is 8%; extended measurement uncertainty at 95% confidence at 25°C is 17%.
Method comparison:	Iodometric titration
User training:	1 day training
Use:	Laboratory and field
Data output:	Sample #, Batch #, Result, Date, Time (in transferred data)
Connectivity and data:	Results are stored in the device and transferred to a PC via USB
Power source:	NiMH rechargeable batteries included; AA 1.2 or 1.5V
Warranty:	2 years
Device weight:	0.45 kg
Device dimensions:	11 x 4 x 20 cm (W x H x L)
Test Kit	
Content:	100 reagent vials and 20 additive vials; 120 syringes - 1.0 mL; 120 needles - 0.8mm x 16mm
Chemical composition:	Starch, potassium iodide, phosphoric acid
Volume per reagent vial:	1.9 mL
Shelf life:	12 months at 20 –30°C, no direct sunlight, upright
Dimension of test kit:	26 x 14.5 x 16.5 cm
Disposal instructions:	Non-hazardous waste
Optional equipment:	50 mL falcons, weighing dishes, reference samples

Glossary
of the terms used

Accuracy	*closeness of an analytic result to an actual result. It is used to refer to both trueness and precision.*
Bias	*difference between expected and measured result due to systematic error of the measurement.*
Codex Alimentarius	*harmonized international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in the food trade. It was estab-lished and is maintained by Food & Agriculture Organization (FAO) and World Health Organization (WHO).*
CV	*Coefficient of Variation. It is calculated by dividing the standard deviation with the mean of your repeated measurements. CV = Standard deviation / Mean x 100%. CV is observed due to random errors of the measurement.*
Dilution	*solubilization of the salt in water to bring the salt sample into the liquid state. The liq-uid sample is then analyzed with iCheck Iodine. To get the concentration of iodine in the dry salt sample the iCheck Iodine result is multiplied with the dilution factor. The dilu-tion factor is calculated by dividing the volume into which the sample was diluted with the weight of the salt sample.*
Iodometric titration	*method of volumetric chemical analysis to determine the amount of iodine in the salt sample. It is a redox titration where the appearance or disappearance of elementary iodine indicates the end point. Also referred to as iodometry.*
ISO	*International Organization for Standardization*
Mean	*an average value of a set of values. It is calculated by summing up the values and divid-ing the sum with the number of values.*
Potassium Iodate	*KIO_3. It is a common form of iodine used for salt iodization. Another common form of iodine used for salt iodization in potassium iodide (KI) but it cannot be measured with iCheck Iodine.*
Precision	*the extent to which a measurement procedure gives the same results each time it is re-peated under identical conditions (repeatability) and variable conditions (reproducibility).*
Standard deviation	*a measure of the amount by which each value deviates from the mean of all values.*

Glossary
of the terms used

Trueness	*refers to the closeness of agreement between the arithmetic mean of a large number of test results and the true or accepted reference value.*
Uncertainty of measurement	*the doubt that exists about the result of any measurement. It combines the random error (CV) and the systematic error (bias) following the equation: uncertainty = bias + 1.96 x CV. The uncertainty of measurement gives the result a range and there is 95% confidence that the true value lies within that range.*
Validation	*an analytical procedure performed with the objective to demonstrate that the analyti-cal method is suitable for its intended purpose. During validation accuracy, precision, trueness, specificity and sensitivity of the analytical method for a certain analyte in a certain matrix is assessed.*
Variability	*a measure of the spread of a set of values from the reference or the mean value.*

Quality Guarantee

iCheck is produced following strict rules of quality assurance according to ISO 9001:2015. This is accomplished by the use of high-grade components and equipment as well as a stream-lined production process. This process includes quality controls for each component and rigorous calibration of the device by trained technicians.

Your iCheck Iodine comes with a 2-year warranty.

If you have any questions, please contact us by calling **+49 (0)33 28 35 15 000** or sending an e-mail to **support@bioanalyt.com**.

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This material has been developed with support from Global Alliance for Improved Nutrition.

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"A partnership to improve the quality of nutritious foods".

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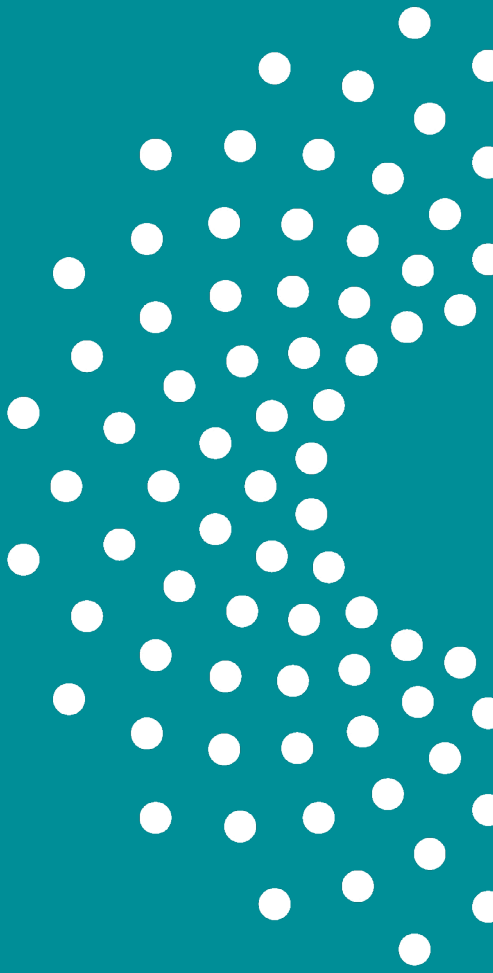

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