# Performance Guide

## iCheck
## Chroma 3
The test kit to measure vitamin A in oil

BioAnalyt

# Performance **explained**

This Performance Guide is intended to explain the validity of our test kit iCheck Chroma 3 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***

TOP 100 INNOVATOR 2014

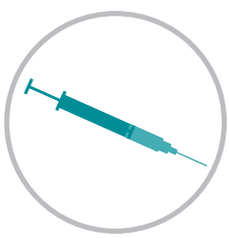
Development, manufacture and sales of all BioAnalyt test kits (devices, reagent vials) are carried out in accordance with ISO 9001:2008 and have been certified by TÜV NORD, Germany.

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

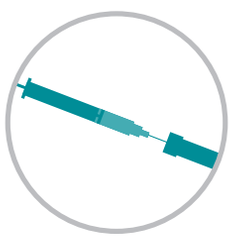
# What is iCheck Chroma 3?

iCheck Chroma 3 is an all-inclusive test kit for rapid on-the-spot measurement of vitamin A in edible oils.

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



- Take up your sample

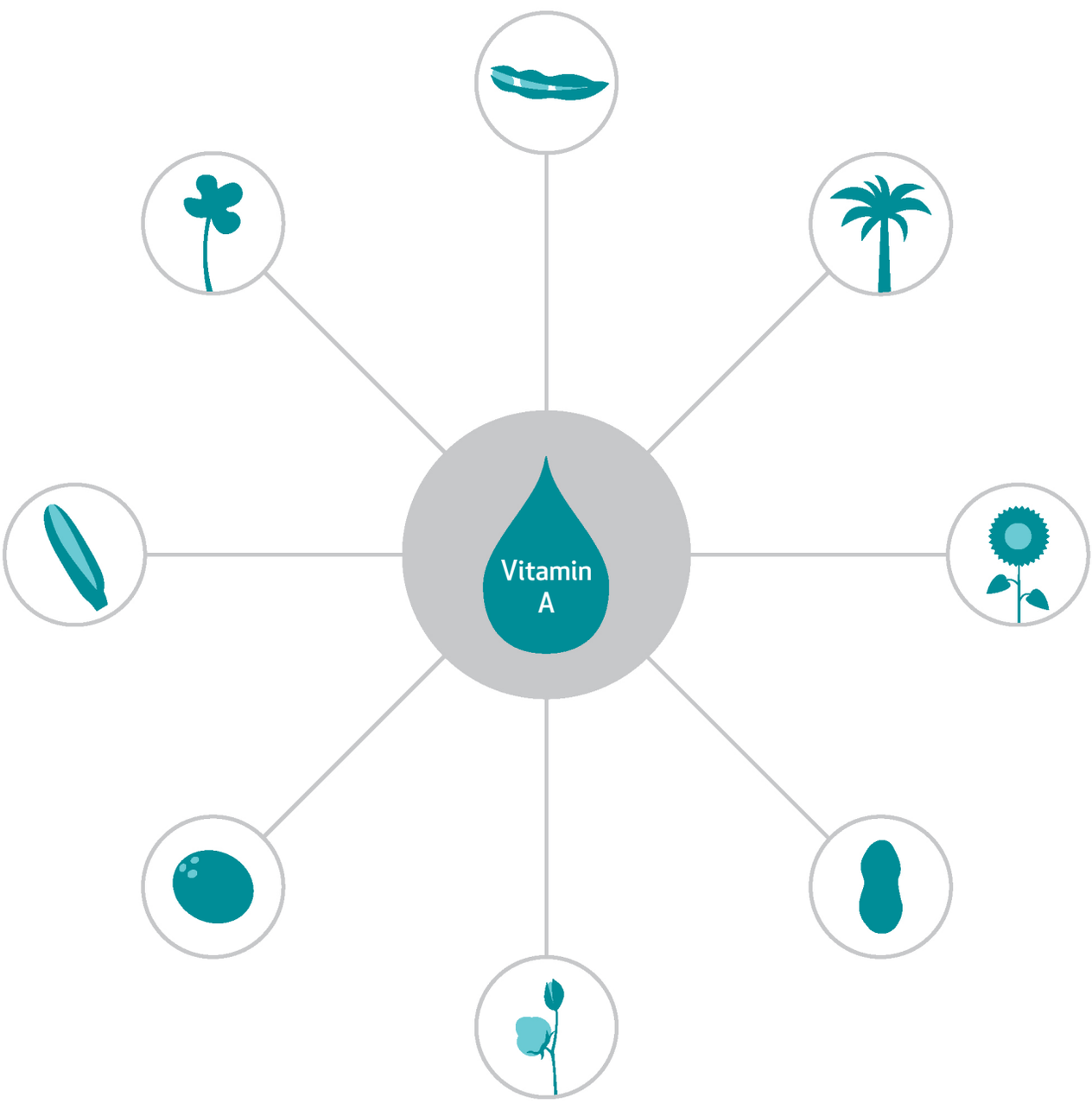


- Inject it into the ready-to-use reagent vial

- Measure the vial in your iCheck

# What does **iCheck Chroma 3** do?

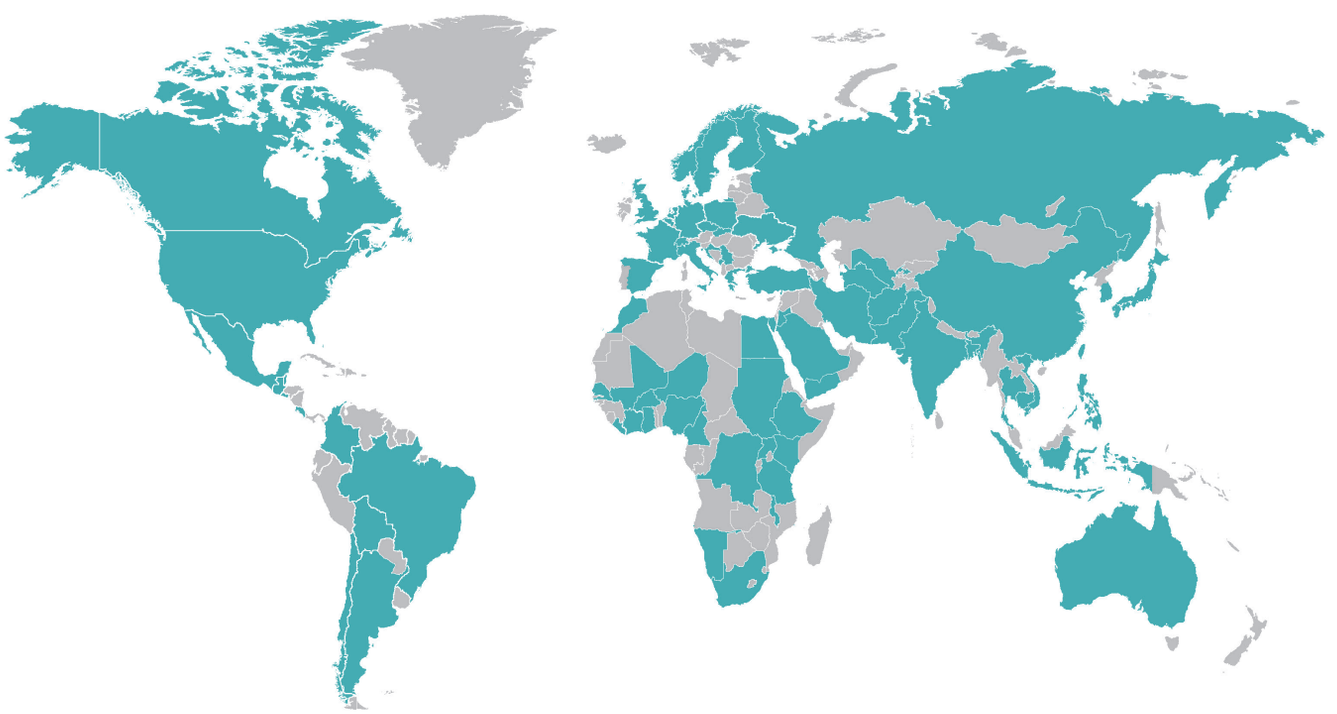
iCheck Chroma 3 measures vitamin A in wide range of refined edible oils such as: soy-bean oil, palm oil, sunflower oil, peanut oil, cottonseed oil, coconut oil, corn oil and rapeseed oil.



# 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.

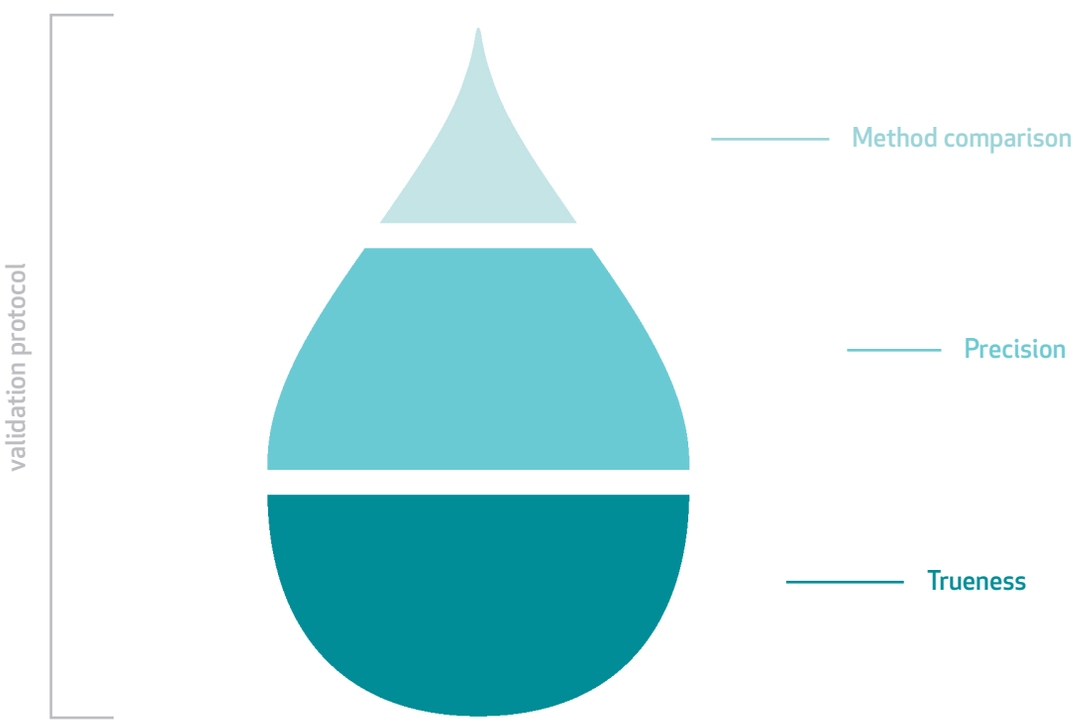


Countries using iCheck

# Is iCheck Chroma 3 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 Chroma 3 validated?

## 1 Assessment of precision

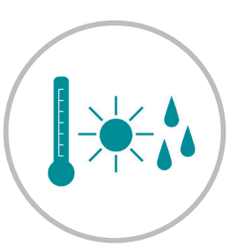
During the validation we assess the precision of the test kit. Precision tells us how similar the repeated measurements of the same sample are.

The difference observed between the repeated measurements 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 different people across all the measurement range of iCheck Chroma 3.

The measurement range of iCheck Chroma 3 is from 3 mg RE/kg to 30 mg RE/kg*.

The variability observed between the measurements is defined as coefficient of variation (CV). CV is calculated by dividing the standart daviation with the mean of your repeated measurements.

The maximum CV for repeated measurements with iCheck Chroma 3 is 13%.

**RE: retinol equivalent is a unit for quantifying the vitamin A value of sources of vitamin A. RE is defined as 3.3 International Units (IU) of vitamin A or as 1 microgram of retinol.*

# How is iCheck Chroma 3 validated?

## 2 Assessment of trueness

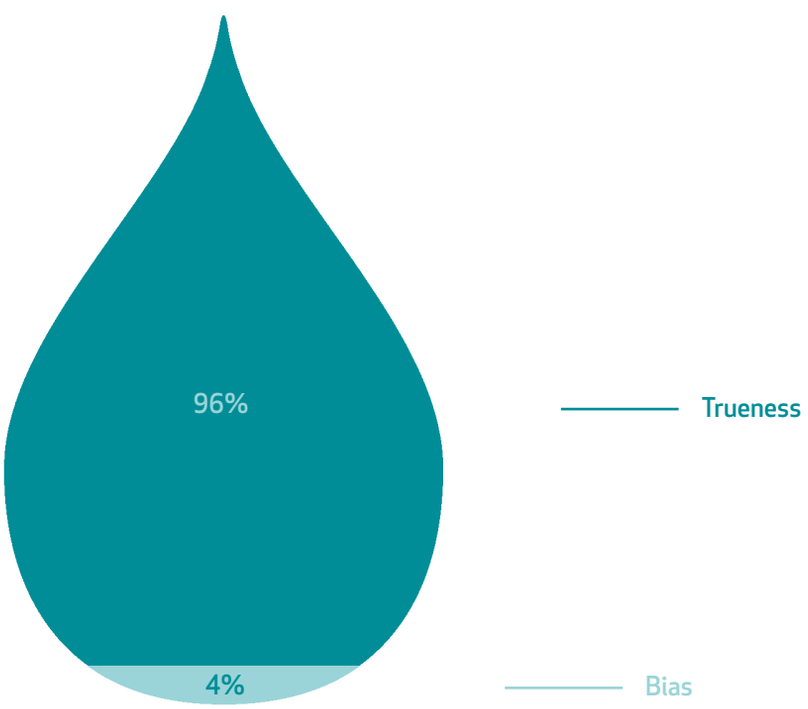
To know how close the measured result is to the real concentration of vitamin A we assess the trueness of the measurement.

To do this we add a known concentration of vitamin A to different types of oil and compare the expected concentration to the measured concentration.

The vitamin A that we use is certified reference material which guarantees that our expected concentration is correct.

The trueness of iCheck Chroma 3 results is 96%. This means that of the expected 100% iCheck Chroma 3 measures 96% of the true vitamin A concentration in the oil sample.

The difference between expected and measured result is called bias and for iCheck Chroma 3 results it is at 4%.



# 3 Method comparison

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

For iCheck Chroma 3 the reference method is HPLC (high performance liquid chromatography). HPLC is a standard laboratory quantitative method for vitamin A measurement in food 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 HPLC and evaluate how do the results agree with one another.

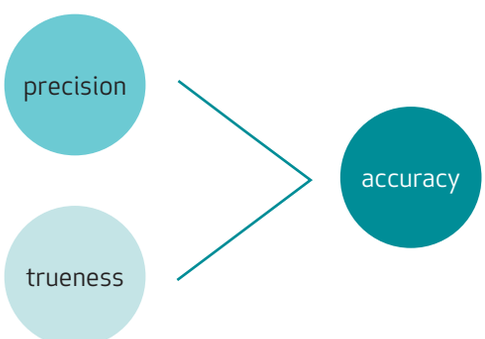
The method comparison shows us that 95% of iCheck Chroma 3 results are in agreement with HPLC results. The results differ by a maximum of 6 mg RE/kg and on average by as low as 0.5 mg RE/kg.

iCheck Chroma 3 HPLC

# How accurate is iCheck Chroma 3 result?

**What is accuracy?**
The assessment of test kit's performance allows us to define how accurate is iCheck Chroma 3 result.

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




**How do we calculate accuracy?**
We express the accuracy of iCheck Chroma 3 in terms of the uncertainty of measurement.

To calculate this uncertainty we take the coefficient of variation (CV) associated with precision and the bias associated with trueness and combine them using 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 Chroma 3 is therefore:

- 4% + (1.96 x 13%) = 30%

**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 vitamin A in oil using the reference method HPLC has the uncertainty between 15% and 30% depending of the laboratory. Similarly, the measurement with iCheck Chroma 3 has uncertainty of 30%.

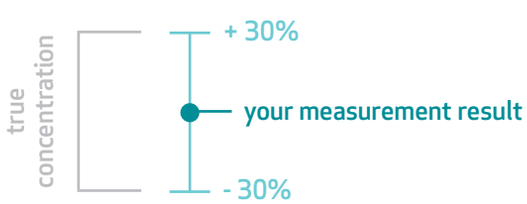
The result you obtain using iCheck Chroma 3 has an accuracy level which enables you to make  a confident decision.

**What does the uncertainty mean to you?**
You have measured your oil sample and the result you have with the iCheck Chroma 3 is 10 mg RE/kg. The uncertainty of the iCheck Chroma 3 measurement is 30%.

This means that the true concentration of vitamin A in your oil sample is in the range of 10 mg RE/kg ±30%.

The result is therefore documented in the following way:
- 10 ± 3 mg RE/kg or
- 7 - 13 mg RE/kg

This range is then controlled against the required concentration.



# Technical Data

The technical specifications for iCheck Chroma 3 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.***

| PARAMETER | DESCRIPTION |
|---|---|
| Analyte | Retinyl palmitate |
| Sample type | Refined edible oils: soybean, palm, sunflower, cottonseed, corn, peanut, rapeseed, coconut |
| Sample preparation | Not required |
| Analysis method | Photometric |
| Units | mg RE/kg and IU/g<br>RE – retinol equivalents<br>IU – international units |
| Linear range | 3 –30 mg RE/kg or 10 –100 IU/g |
| Time per measurement | 2 minutes |
| Optimal temperature for measurement | 20 – 30 °C |
| Uncertainty of measurement | 30% |
| Reference method | HPLC |
| Staff qualification | 1 day training |
| Application | Laboratory and field |
| Energy source | Battery |
| Dimensions | 11 x 4 x 20 cm (W x H x L) |
| Weight | 0.45 kg |

# 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 established 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.* |
| ***HPLC*** | *High Performance Liquid Chromatography. It is one of the standard laboratory quantitative method for vitamin A measurement that involves extraction, separation and detection of the target analyte.* |
| ***ISO*** | *International Organization for Standardization* |
| ***IU*** | *International Unit. It is a unit of measurement for the amount of a substance. One IU of vitamin A equals 0.3 micrograms of retinol.* |
| ***Mean*** | *an average value of a set of values. It is calculated by summing up the values and dividing the sum with the number of values.* |
| ***Precision*** | *the extent to which a measurement procedure gives the same results each time it is repeated under identical conditions (repeatability) and variable conditions (reproducibility).* |
| ***RE*** | *Retinol Equivalent. It is a unit used for quantifying the vitamin A value of sources of vitamin A. RE is defined as 3.3 IU of vitamin A or as 1 microgram of retinol.* |
| ***Retinol*** | *chemical name of vitamin A.* |
| ***Standart deviation*** | *a measure of the amount by which each value deviates from the mean of all values.* |
| ***Trueness*** | *closeness of agreement between the arithmetic mean of a large number of test results and the true or accepted reference value.* |

# Glossary
# of the terms used

| | |
|---|---|
| ***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 analytical 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 9001:2008. 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 Chroma 3 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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