

## QbCheck Technical Manual

## **QbCheck Technical Manual**

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# 1. Introduction

QbCheck is a computer-administered test that objectively measures cognitive performance and activity levels. The test provides data for the core signs of ADHD, that is, hyperactivity, impulsivity and inattention. QbCheck combines a Continuous Performance Test (CPT) with a motion tracking system by use of a web camera. QbCheck is substantially equivalent to another test provided by Qbtech called QbTest. They share the same principle documentation for the ability to be used to aid professionals in the clinical assessment of ADHD and in the evaluation of treatment interventions in patients with ADHD. QbCheck uses an identical test task and stimuli presentation as QbTest and both tests should be interpreted by professionals. In order to simplify the use and installation of the test, QbCheck has been developed as an online test where the test taker uses the spacebar to respond to targets and the test takers motor activity during the test is registered by the web camera. With this online interface, together with a voucher testing functionality, QbCheck has the ability to be performed in as well as outside the clinic setting, including educational and home settings.

The computerized CPT flashes different figures on the screen. There are two versions of the CPT, one for children aged between 6 and 11 years and one for adolescents and adults aged between 12 and 60 years. In the child version, the child is instructed to respond by pressing the spacebar for one figure but not the other (Go/No-Go with a 50 percent Target probability). In the adolescent/ adult version, the responder is instructed to respond when two figures of identical shape and color appears successively (unconditional identical pairs with a 25 percent Target probability).

The results from the test are presented as raw scores as well as Q-Scores and percentiles that are calculated using an age and gender adjusted norm group. The percentile expresses (in percent) the probability of a normative person to score lower than the test person. Consequently, a test-result that ends up in the 93rd percentile shows that 93 percent of the normative group scores lower than that test person. This corresponds to a standard deviation of 1.5 (Q-score).

In addition, QbCheck provides the interpreter of the test with an ADHD Symptom Level Score that represents the likelihood for the test-taker to have a symptom level that resembles a group of individuals with clinically diagnosed ADHD. The method used to calculate this score is logistic regression analysis. The normative data set consists of 1307 normatives of which 576 are children and 731 are adolescents and adults as well as 221 individuals with diagnosed ADHD.

The data from QbCheck is presented as graphs and scores in a two-page report. The first page contains the variable ADHD Total Symptom Score which is also presented as a QbCheck ADHD Total Symptom Level. The page also contains a graphic representation of the test takers result, a graphic representation of a norm group sample result and quantitative measures comparing the test taker's result to an age and gender adjusted norm group. Both the test takers result and the sample result from the norm group are displayed in an Activity Graph and an Attention and Impulse Control-Graph to facilitate visual comparison. The second page of the report contains the QbCheck rating scale result.

## 2. Device Description

### 2.1 System Components

The QbCheck system consists of the following components:

- QbCheck Software, accessed online and used to administer test and access the result
- User Manual
- Technical Manual (this document)
- QbCheck Voucher Testing Instructions
- QbCheck Behavior Observation Form

Access to a remote server that processes QbCheck data and generates test reports QbCheck also requires usage of the user's own computer with web camera.

### 2.2. Intended Use

QbCheck provides qualified professionals with objective measurements of hyperactivity, impulsivity, and inattention to aid in the assessment of ADHD and in the evaluation of treatment interventions in patients with ADHD. QbCheck results should be interpreted only by qualified professionals.

### 2.3. Indications for Use

QbCheck is indicated to be used to aid in the assessment of ADHD and in the evaluation of treatment interventions in patients with ADHD. QbCheck results should be interpreted by qualified professionals.

### 2.4. Limitations

QbCheck shall always be interpreted in combination with other clinically relevant information, such as a clinical interview and/or standard symptom scales.

### 2.5. Contraindications

None known.

### 3. QbCheck Test Design

QbCheck combines a Continuous Performance Test (CPT) with a motion tracking system to provide objective measures of attention, impulsivity and hyperactivity. The CPT design is identical to the well-used and documented QbTest. This section describes the rationale and design of the CPT and the motion tracking system along with the clinical and technical backgrounds for the different test parameters.

#### 3.1. Continuous Performance Test

The aim of the CPT is primarily to measure performance related to attention and impulsivity. QbCheck comes in two separate versions to control for developmental differences in cognitive abilities and performance on the CPT, as follows:

The QbCheck (6-11 years) CPT involves the rapid presentation of two types of stimuli; a grey circle, and a grey circle with a cross over it. A stimulus is defined as a Target if it is a grey circle and it is defined as a Non-target if it is a circle with a cross over it.

The QbCheck (12-60 years) CPT involves the rapid presentation of four types of stimuli; a red circle, a blue circle, a red square, and a blue square. The CPT is based on the unconditional identical pairs principle and a stimulus is defined as a Target if it is identical in shape and color to the stimulus immediately preceding it (thus, the first stimulus cannot be a Target). A stimulus is defined as a Nontarget if it does not match the stimulus immediately preceding it.

The stimuli are presented on a computer screen at a rate of one stimulus every two seconds

(0.5 Hz). In QbCheck (6-11) each stimulus is visible for 100 milliseconds and in QbCheck (12-60) each stimulus is visible for 200 milliseconds (see Figure 1). The total number of stimuli presented in QbCheck (6-11) is 450, with an equal number of Target and Non-Target stimuli. The total number of stimuli presented in QbCheck (12-60) is 600, with a 25 percent Target ratio. The order of the Targets and Non-targets is randomized to prevent practice effects over multiple trials.

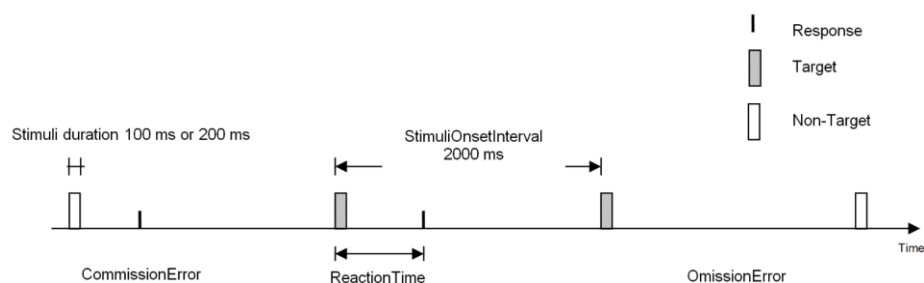


Figure 1. QbCheck timing

In both versions, test takers are instructed to respond to a Target stimulus by pressing the spacebar and to refrain from responding to Non-Target stimuli. The test taker's response profile and any errors are automatically recorded and compared to a normative and clinical database to provide a measure of the test-takers level of inattention and impulsivity as well as the likelihood of having a symptom level that resembles a clinical group with ADHD.

To reduce the impact of confounding factors, such as problems with differentiating left from right and dyslexia, the stimuli are presented in the centre of the screen and they consist of shapes rather than numbers or letters. The CPT is designed to be simple with no changes in the complexity during test period since the objective is to measure changes in the test subject's performance over time rather than the reaction to changes in the task. It is the inconsistency of the performance that is important, which is something that seems quite unique to ADHD (27).

### 3.2. Activity Measurement

Activity levels provide important clinical information when discriminating ADHD from other psychiatric disorders or normal controls both in children and adults (1, 28). Children with ADHD have higher activity levels than aged-matched controls. The most pronounced differences have been observed during structured tasks that require the child to sit still and pay attention; the differences are less apparent during various leisure activities (29). The QbCheck test situation simulates a structured context and the process is standardized by combining activity recordings with the CPT measurements.

In QbCheck, the activity is measured using a webcam or other video camera. A motion tracking algorithm is applied to the video feed to track the test taker's head movements during the test. The test taker is not recorded, and no video of the test taker is created. Instead the test taker's head position is sampled and used to calculate his/her activity during QbCheck.

### 3.3. Test Duration

The test duration of QbCheck (6-11) is 15 minutes and data from the whole duration of the test is used to calculate the parameters. The test duration of QbCheck (12-60) is 20 minutes, however, data is only used from the last 15 minutes to calculate the parameters. Nevertheless, data is recorded and presented on the report graphs for the entire 20-minute test duration. The rationale behind excluding the first five minutes from analysis is that many test takers have an inconsistent response style the first few minutes, which is believed to reflect a task-adaptation. This task-adaptation effect is less prominent when test takers are retested, resulting in a relatively poor test-retest correlation for the first five minutes; thus, excluding the first five minutes increases the test-retest reliability. However, qualitative information on test performance can still be gained from all quarters, including the first one, by examining the graphs in the QbCheck report.

## 4. QbCheck Measures and Variables

### 4.1. MicroEventsX

#### *Definition*

*MicroEventsX* occurs when the tracking algorithm detects a position change of the test taker head larger than one millimetre on the x-axis since the last *MicroEventsX*. Movements of less than one millimetre on the x-axis is not register as a *MicroEventsX* (see Figure 2). Movements on the y-axis are disregarded.

#### *Clinical considerations*

A large number of *MicroEventsX* indicate a high degree of activity. *MicroEventsX* quantifies how active the participant is (i.e., the amplitude).

#### *Parameter calculation*

The number of *MicroEventsX* is counted and rounded off to the nearest 100.

### 4.2. Attention and Impulse Control Measures

#### 4.2.1. Reaction Time

#### *Definition*

*Reaction Time* is the average time it takes for the test taker to press the spacebar after the stimuli have been presented. The *Reaction Time* is measured only when a correct button press is registered. The reported time is measured in milliseconds.

#### *Clinical considerations*

*Reaction Time* reflects processing and execution (30, 31, 32, 33). Average response latency is thought to measure the response preparation component of executive functions (34, 35).

#### *Parameter calculation*

If  $r_i$  is the time elapsed between the presentation of a *Target* on the computer screen and the registration of a correct button press, then

$$Reaction\ Time = \frac{1}{N_{Tc}} \sum_{i=1}^{N_{Tc}} r_i \quad [ms]$$

where  $N_{Tc}$  is the number of correct button presses.



## 4.2.2. Reaction Time Variation

### Definition

*Reaction Time Variation* is the standard deviation of the *Reaction Time*.

### Clinical considerations

*Reaction Time Variation* provides a measure of the consistency (or inconsistency) of the *Reaction Time*. A high degree of *Reaction Time Variation* may reflect clinical difficulties with sustaining attention, forgetfulness, disorganization, and careless errors (27).

### Parameter calculation

The *Reaction Time Variation* is measured in milliseconds and computed as:

$$\text{Reaction Time Var} = \sqrt{\frac{1}{N_{Tc} - 1} \sum_{\forall i} (r_i - RT)^2} \quad [\text{ms}]$$

where RT is the average *Reaction Time*, and  $N_{Tc}$  is the number of correct button presses.

## 4.2.3. Normalized Variation

### Definition

*Normalized Variation* or *NormVar* is the *Reaction Time Variation* expressed in terms of *Reaction Time*.

### Clinical considerations

A slow mean *Reaction Time* often produces greater variability (36). *Normalized Variation* corrects for this and should be considered a validity measure of the parameter *Reaction Time Variation*. As such, a normal score on *Normalized Variation* together with a high score of *Reaction Time Variation* indicates that the high *Reaction Time* variability is confounded by a slow mean *Reaction Time*. This parameter is only used to calculate the ADHD Total Symptom Level

### Parameter calculation

The parameter *Normalized Variation* expresses the variation as percent of the mean value.

$$\text{Normalized Variation} = 100 \cdot \frac{\text{ReactionTimeVar}}{\text{ReactionTime}} \quad [\%]$$

## 4.2.4. Omission Error

### Definition

An Omission Error occurs when no response was registered for a Target stimulus (i.e., the spacebar was not pressed when it should have been). An Omission Error is plotted in the 'Attention and

impulsivity graph' as a black marker just above the x-axis at the time when the Target was overlooked.

#### *Clinical considerations*

Omission Errors reflect inattention and inability to remain focused on the task (37). A high level of Omission Errors has been associated with selective attention and deficient arousal (38, 39, 40, 41, 42, 43 and 44).

#### *Parameter calculation*

The result is reported in percent. If NOm is the number of such errors, and NT is the number of Target, then the reported Omission Error rate is:

$$\text{Omission Error} = 100 \cdot \frac{N_{Om}}{N_T} \quad [\%]$$

### 4.2.5. Commission Error

#### *Definition*

A Commission Error occurs when a response is registered when the stimulus was a Non-Target stimulus (i.e., the spacebar is pressed when it should not have been pressed). A Commission Error plotted in the 'Attention and impulsivity graph' as a red circle at the height corresponding to the reaction time, y-axis, and at the time into the test when the response was made, x-axis.

#### *Clinical considerations*

Commission Errors measures impulsive behavior (40, 41, 42, 43, 45, 46, 47, 48, 49, 50, 51, 52) and are believed to result from the anticipatory or incomplete processing of the stimulus (50).

#### *Parameter calculation*

If NCm is the number of incorrect spacebar-presses, and NNT is the number of Non-Targets, then the reported Commission Error rate is:

$$\text{Commission Error} = 100 \cdot \frac{N_{Cm}}{N_{NT}} \quad [\%]$$

## 4.2.6. Normalized Commission

### *Definition*

Normalized Commission or NormCommission is the proportion (ratio) of Commission Errors to correct responses to the Targets. This measure is sensitive to changes in correct responses, that is, it corrects the level of impulsive Commission Errors to different levels of inattention or passive responding (Omission Errors).

This parameter is only used to calculate ADHD Total Symptom Score.

### *Clinical considerations*

This parameter compares the rate of Commission Errors with the rate of correct Targets responses. It provides an additional measure of impulsive performance. A high level of response rate increases the probability to make Commission Errors whereas low level of responding would reduce the risk to make Commission Errors.

The percentage of impulsive Commission Errors as a measure of impulsivity alone may therefore be less sensitive to an underlying clinical problem of impulsivity if the subject at the same time has low response rate to Target due to inattention. Considering the level of correct responses in proportion to the level of Commission Errors may reduce the risk of false negative results on impulsivity when the response rate to Target is low. It may also to some degree reduce the risk of false positive results on impulsivity when the correct response rate is very high.

### *Parameter calculation*

$$NormFact = \max(100 - OmissionError; 0.1)$$

$$NormCommission = 100 \cdot \frac{CommissionError}{NormFact}$$

## 4.3. ADHD Total Symptom Score

QbCheck captures several measures related to the three core symptom areas of ADHD: activity, impulsivity and attention. To predict an individual's likelihood of having typical ADHD symptoms based on these objective measures, the variable ADHD Total Symptom Score was developed. The variable outcome can be found in the text paragraph of the QbCheck Result section on the second page of the QbCheck report.

The ADHD Total Symptom Score is based on a comparison between a group of normally developing individuals and individuals with a clinical diagnosis of ADHD (53) and has been validated in an external validation data set (54, 55). It is expressed as the likelihood for the test-taker to belong to the clinical group. The principle QbCheck variables used in the comparison are MicroEventX,

Omission Errors, Reaction Time, Reaction Time Variation, Normalized Reaction Time Variation, Commission Errors and Normalized Commission. The method used to create the variable ADHD Total Symptom Score is based on logistic regression. This variable can be used in the evaluation of treatment interventions in test taker with ADHD (56).

The ADHD Total Symptom Score is expressed as a value from 0 to 100. A value below 10 indicates a low risk for the test taker to belong to the clinical group. A value between 10 and 50 indicates an elevated risk to belong to the clinical group and a value of 50 and above indicates a high risk to belong to the clinical group with increasing risk at higher values.

It is recommended to categorize the test-results in the “low risk” category versus “elevated/high risk” category. Test-takers in the “elevated/high risk” category should be considered for further assessment. If maximal specificity is needed (low likelihood of false positives) it is recommended to use “high risk” as category for further assessment.

#### 4.4. ADHD Total Symptom Level

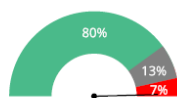
This is a graphic representation of the ADHD Total Symptom Score transformed into a scale representing the approximate prevalence of ADHD symptoms in the general population. Through a mathematical transformation of the QbCheck ADHD Total Symptom Score about 80% of the general population will display low symptom levels (green area), 13 % will display elevated symptom levels (grey area) and 7 % will display high symptom levels (red area). Thus, the green area represents low symptom levels, the grey area elevated symptom levels and the red area high symptom levels. The test-takers symptom level (transformed ADHD Total Symptom Score) is displayed as a black marker.

#### 4.5. Graphic Presentation of Data

Data from QbCheck is presented as graphs and scores in a two-page report. The first page contains the variable ADHD Total Symptom Score that is also presented as a QbCheck ADHD Total Symptom Level. In addition, the report contains a graphic representation of the test takers result, a graphic representation of a norm group sample result and quantitative measures comparing the test taker's result to an age and gender adjusted norm group. Below you can learn more on how variables are graphically presented in the QbCheck report.

## Objective QbCheck Result

The test taker had a **QbCheck ADHD Total Symptom Score of 94**. A score above 50 represents a **high** likelihood for having ADHD-like symptoms.



QbCheck ADHD Total Symptom Level

The test taker's Total Symptom Score equals a **high** ADHD Total Symptom Level. About 7% of the general population display a similar level of ADHD-like symptoms.

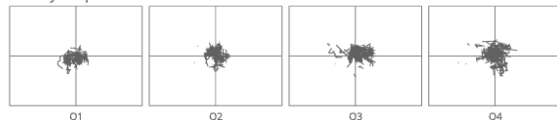
## Objective Measures

The objective measures add valuable information to your interpretation and are expressed in Q-scores and percentiles. The Q-Scores allow for comparison with the performance of an age and gender adjusted norm group. The percentile expresses (in percent) the probability of a normative person to score lower than the test person.

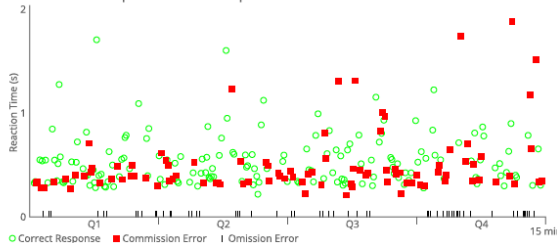
		-3	0	+3	Q-Score	Percentile
Activity	MicroEventsX				1.3	90
Impulsivity	Commission Errors				2.0	97
Inattention	Omission Errors				2.1	98
	Reaction Time				1.1	86
	Reaction Time Variation				2.4	99

## Detailed QbCheck Result

### Activity Graph



### Attention and Impulse Control Graph

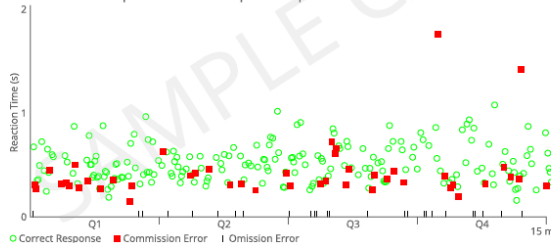


## Sample Case

### Activity Graph - Sample Case



### Attention and Impulse Control Graph - Sample Case



Test Taker ID: 0000000000 Date of Birth: 0000-00-00 Gender: Male Test Details: 0000-00-00 00:00 Age: 8y, 3m.

*First page of the QbCheck report*

## Activity Graph

The Activity Graph illustrates the test-takers head movements during the test. The path of the head is broken down into four diagrams each representing one quartile of the test time duration. These diagrams show the dynamics of activity over time.

## Attention & Impulse Control Graph

The Attention & Impulse Control Graph contains information on several aspects of attention and impulsivity. The horizontal axis (x-axis) is the test-time axis covering the duration of the test. The vertical axis (y-axis) shows the reaction time to both correct and incorrect responses. A correct response to a stimulus results in a green circle and an incorrect response results in a red square (Commission Errors). The position of the green circles and red squares on the y-axis indicates the reaction time for respective response. If the test taker has omitted to respond to a stimulus (Omission Errors) a black bar is shown on the x-axis.

## Quantitative Measure

In addition to the graphs on the first page of the report, the QbCheck result is also expressed as raw scores, Q-Scores and percentiles for the variables MicroEventX, Commission Errors, Omission Errors, Reaction Time and Reaction Time Variation. The Q-Scores and percentiles allow for comparison with

the age and gender adjusted norm group. A Q-Score of 1 is equivalent to 1 standard deviation from norm and a result below 1 Q-Score is considered as a normal performance. The percentile expresses (in percent) the probability of a normative person to score lower than the test taker.

#### *QbCheck ADHD Total Symptom Score*

The ADHD Total Symptom Score, displayed in the text paragraph of the QbCheck Result section, predicts an individual's likelihood of having typical ADHD symptoms. For further description of the variable see chapter 4.3. QbCheck ADHD Total Symptom Score.

#### *ADHD Total Symptom Level*

In order to visually present the test takers results compared to the overall population, the ADHD Total Symptom Score is transformed and inserted into a graph, the ADHD Total Symptom Level. The graph displays the normal distribution of ADHD core symptoms in the general population and how the test takers result compares to this (displayed with a black arrow).

A score within the green area represents a low ADHD Total Symptom Level indicating, a low likelihood that the test taker belongs to the ADHD group. A score within the red area represents a high ADHD Total Symptom Level indicating a high likelihood, that the test taker belongs to the ADHD group. A score within the grey area represents an elevated ADHD Total Symptom Level indicating an uncertain result with about equal likelihood for the test taker to belong to any of the two groups. The areas in the graph correspond to: Low: 80%, Elevated: 13% and High 7% of the total population based on ADHD Symptom Score cut-offs compared to the total population.

#### *QbCheck Rating Scale Score*

The second page of the report contains the QbCheck rating scale result. The QbCheck rating scale adds a subjective perspective to the evaluation process. The scale is developed from the 18 questions in DSM-5, describing patterns of behavior associated with ADHD. Each behavior is graded as Never/ Rarely , Sometimes, Often and Very Often. On the report each behavior is displayed with how the test taker, parent/guardian or teacher rated the test taker.

### About the Rating Scale

The QbCheck Rating Scale adds a subjective perspective to the evaluation process. The scale is developed from the 18 questions in DSM-5, describing patterns of behavior associated with ADHD. Each behavior is rated over the last 6 months and graded as "Never or Rarely", "Sometimes", "Often" or "Very Often".

Children 6-17 years, must present "Often" or "Very Often" on six items in at least one category to display a persistent pattern of ADHD-like symptoms according to the DSM-5 criteria. Test takers 18 years and older must present with five items rated "Often" or "Very Often" in at least one category, in order to display a persistent pattern of ADHD-like symptoms according to the DSM-5 criteria.

### Rating Scale Results

This test taker has 7 items in the Inattentive category and 8 items in the Hyperactive/Impulsive category that are rated as "Often" or "Very Often".

The test taker thus meets the criteria for displaying ADHD-like symptoms according to DSM-5.

### Rating Scale Overview - Reporter: Parent

Inattention	Never or Rarely	Sometimes	Often	Very Often	Hyperactivity/Impulsivity	Never or Rarely	Sometimes	Often	Very Often
Has difficulty paying attention to details or makes careless mistakes unless interested	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Fidgets or squirms	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Has difficulty remaining focused on tasks or play activities unless interested	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Leaves seat when remaining seated is expected	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Does not seem to listen when spoken to directly	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Runs about or climbs when inappropriate or appears restless	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Has difficulty to follow through on tasks	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Has difficulty to engage in play or leisure activities quietly	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Has difficulty organizing and managing tasks	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Seems uncomfortable being still for extended time periods	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Avoids sustained mental effort unless interested	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Talks excessively	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Loses things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Blurts out answers or thoughts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Seems easily distracted by the environment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Has difficulty waiting turn	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Forgetful	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Interrupts or intrudes on others	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Sum of items rated Often or Very Often			3	4	Sum of items rated Often or Very Often			3	5

Test Taker ID: 0000000000 Date of Birth: 0000-00-00 Gender: Male Test Details: 0000-00-00 00:00 Age: 8y. 3m.

### Second page of the report

Children, 6-17 years, must present Often or Very Often on at least six symptoms in one or both categories to display ADHD-like symptoms according to the DSM-5 criteria. Test takers 18 years and older must present with at least five items rated Often or Very Often in one or both categories, to display ADHD-like symptoms according to the DSM-5 criteria.

## 5. Clinical Performance

Studies using the combined measurement of CPT and motion tracking in children and adults have shown that motor hyperactivity can be objectively measured (1, 2) and correlated with both neuroanatomical and neurochemical changes in ADHD (3-5). Validity studies with QbTest have shown between 79 and 96 percent sensitivity (correct classification of participants with ADHD) and between 81 and 94 percent specificity (correct classification of non-clinical participants) with good test-retest reliability (6-11). When being performed outside the clinic setting, QbCheck has shown a similar ability to discriminate between adolescents/adults and controls, with a sensitivity of 82.6% and a specificity of 79.5% (12). A study in children and adolescents (13) showed a significant improvement in diagnostic accuracy of ADHD when the QbTest was added to the clinical process, measured as clinical outcome after one year. In addition, several other studies (14-26) have shown that the QbTest can be used to aid qualified professionals in the evaluation of therapeutic and treatment interventions in ADHD.

Below is a description of the clinical performance for QbTest in the evaluation of treatment interventions specifically. Since QbCheck is substantially equivalent to QbTest, the same documentation and restrictions for use below applies to QbCheck. However, the QbTest Total Score that was used for QbTest to evaluate treatment effects in the registry study is not used in QbCheck. The corresponding variable used in QbCheck is the ADHD Total Symptom Score. The two different methods show high correlations (Pearson correlations >0.8) and equal Effect Sizes (1.04 and 1.06) when used to evaluate treatment in patients with ADHD.

The intended use of QbCheck is to support qualified professional in the evaluation of treatment interventions in ADHD is not based on one specific prospective study. Instead it is based on collated data from seven published clinical studies where QbTest has been used to evaluate different treatment interventions and one registry study, specifically designed to compare QbTest with clinically validated Rating Scales (RS) in the evaluation of treatment interventions. Two of the published clinical studies evaluated the responsiveness of the test after single doses of central stimulants (CS) and two other studies focused on the capacity of the test to measure effects over the day for atomoxetine and CS (20,21,22 and 25)).

Three of the published studies and the registry study evaluated the Effect Size (ES) of different treatment interventions measured by QbTest. Two of these studies included a placebo control group. In the first placebo-controlled study (14), with the objective to evaluate the effect of atomoxetine by means of QbTest and clinical rating scales, 128 children with ADHD (mean age 9.0) were randomized to treatment with atomoxetine or placebo and followed for 8 weeks. The per-protocol ES (Cohens d; small 0.2, moderate 0.5, and large 0.8) for the principal QbTest hyperactivity variables (Time active, Distance, Area and Microevents) varied between 0.85 and 1.49. The



corresponding ES for the principle variables measuring inattention (Reaction Time Variation and Omission Errors) were 1.24 and 0.8 respectively and the principle variable measuring impulsivity (Commission Errors) showed an ES of 0.82. All changes from baseline were statistically significant. In the second placebo-controlled study (6), 36 medication-naïve children aged 9 - 14 years diagnosed with ADHD were treated with methylphenidate, dexamphetamine and placebo for 3 weeks in a cross-over fashion. Group-level analyses revealed a statistically significant overall treatment effect for stimulant treatment compared to placebo with an ES of 0.62 measured by QbTest (partial eta-square; small 0.01, moderate 0.06 and large 0.14).

In a third study (26), QbTest was used to evaluate the effect of 16 and 52 weeks of treatment with methylphenidate in 23 adults. The ES (partial eta-square; small 0.01, moderate 0.06 and large 0.14) for the different QbTest hyperactivity variables (Time active, Distance, Area and Microevents) varied between 0.43 and 0.51. The ES for the variables measuring inattention (Reaction Time Variation and Omission Errors) was 0.51 and 0.46 respectively and the principle variable measuring impulsivity (Commission Errors) showed an ES of 0.28. Repeated measure ANOVAS showed statistically significant changes from baseline for all QbTest variables.

The registry study included consecutive patients, 42 children/adolescents (mean age 11.5) and 73 adults (mean age 35), with QbTest and clinical Rating Scale (RS) data at baseline and after treatment with central stimulants or atomoxetine. Time to follow up varied between 6 days and 10 weeks. The ES (Cohens d; small 0.2, moderate 0.5, and large 0.8) for the QbTest Total Score (QbActivity+ QbInattention + QbImpulsivity)/3 and the RS Total score were 1.06 and 0.98 respectively. Changes from baseline were statistically significant for both methods. Time to follow up after treatment initiation was 5-6 weeks (10 weeks for atomoxetine treated patients) in the child/adolescent cohort and 6 to 65 days in the adult cohort. Of the 42 patients included from the child/adolescent cohort, 35 were male and 7 were female. The mean age was 11.5 years (8.5-15.7). Diagnosis was according the DSM-IV criteria and the baseline ADHD symptoms averaged 1.38 (SD = .36) on the ADHD items with a three step Likert scale ranging from "0- Does not apply" to "2-Definitely applies". This represents an at least moderately severity of ADHD. Of the 73 clinical patients included in the analysis from the adult cohort, 32 were women and 41 were men. The mean age was 35 years (18.6-54.1 years). Fifty-eight patients were diagnosed as ADHD combined subtype and 15 patients as ADHD inattentive subtype. The baseline ADHD symptoms in this cohort had an average of 1.95 (SD = .45) on a four step Likert scale ranging from "0- Never or seldom" to "3- Very often". This represents an at least moderately severity of ADHD. Data on ethnicity and social economic status was not collected in the two cohorts since this is not a routine at these clinical centres.

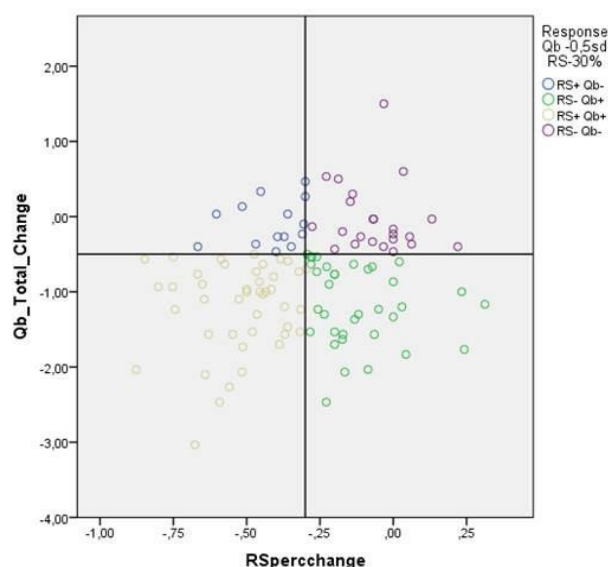
The child cohort consisted of a sample of Swedish children assessed for ADHD and the adult cohort consisted of a sample of Dutch adults assessed for ADHD. It can thus be assumed that most of the included patients were Caucasians.

Frequency of subjects in each cohort:		
Cohort	Frequency	Percent
Adult	73	63.5
Child	42	36.5
Total	115	100.0

Although the ES in the above studies all show large treatment effects they must be interpreted with caution since two of the studies did not include a concurrent control arm.

In addition to the comparison of ES between QbTest and RS, correlations between QbTest based treatment responses and RS based treatment responses were calculated in the registry study. In several studies where rating scales has been used to evaluate treatment effects, a change of -30% in ADHD RS total score has been used as a threshold for a meaningful response to treatment. It should however be pointed out that this threshold has nothing to do with the imprecision of rating scales. Rather, this threshold is based on clinical experience. The same logic can be used for QbTest. Although the imprecision of QbTest has been defined to 0.36 Q-Scores, the Q-Score of - 0.5 is used as a cut-off that defines a meaningful change from baseline. This cut off is based on clinical experience and psychometric conventions. Consequently, the above clinically based thresholds for a meaningful treatment effect were used when the correlation between QbTest and RS was evaluated. The figures and tables below show individual treatment responses, calculated response rates as well as Negative Percent Agreement (NPA) and Positive Percent Agreement (PPA) with Confidence Intervals (CI) for the two methods.

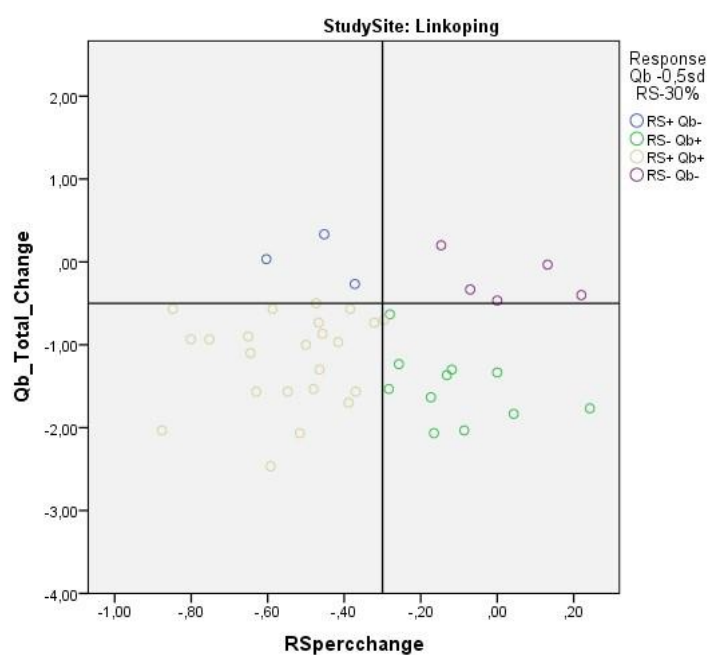
#### Pooled Cohort Analysis:



### Pooled Cohort Analysis Continued:

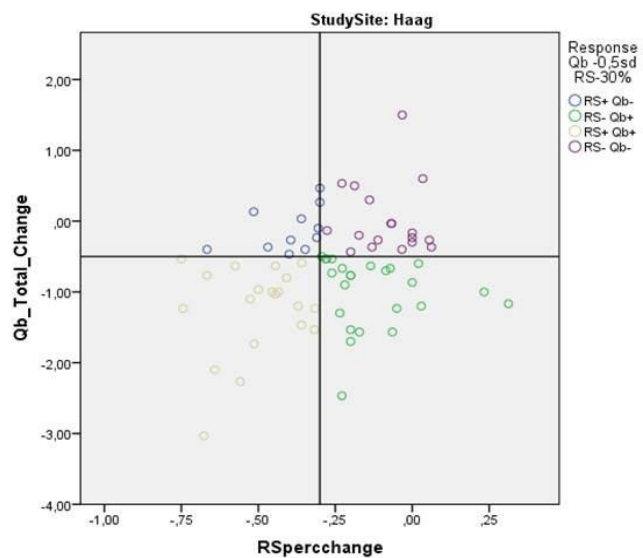
RS Total Score				
	Pooled Cohort	No Improvement	Improvement	Total
QbTest Total Score	No Improvement	23	14	37
	Improvement	35	43	78
	Total	58	57	115
NPA = 40 CI: 28 to 53				
PPA = 75 CI: 63 to 85				

### Child Cohort Analysis:



RS Total Score				
	Child Cohort	No Improvement	Improvement	Total
QbTest Total Score	No Improvement	5	3	8
	Improvement	11	23	34
	Total	16	26	42
NPA = 31 CI: 14 to 56				
PPA = 88 CI: 71 to 96				

#### Adult Cohort Analysis:



RS Total Score				
	Adult Cohort	No Improvement	Improvement	Total
QbTest Total Score	No Improvement	18	11	29
	Improvement	24	20	44
	Total	42	31	73
NPA = 43 CI: 29 to 58				
PPA = 65 CI: 47 to 79				

The registry study showed statistically significant but low correlations between QbTest and the clinically validated rating scales (RS). Therefore and in the absence of a well-defined gold standard for the evaluation of treatment effects in ADHD, QbTest results should be complemented by a clinical evaluation of the treatment effects to avoid the risk that QbTest results should indicate that a treatment is ineffective when it is clinically effective and that QbTest results should indicate that a treatment is effective when it is clinically ineffective.

## 6. Description of the Norm Database

As mentioned earlier, QbCheck is substantially equivalent to another test provided by Qbtech called QbTest. The two tests share the same principle documentation for the ability to be used to aid professionals in the clinical assessment of ADHD and in the evaluation of treatment interventions in patients with ADHD.

### 6.1. Normative Sample

Below is a description of the norm database that is used both for QbTest and QbCheck. A total of 1518 participants aged between six and 75 years were tested between 2003 and 2011 with the objective to be included in the norm database for QbTest. Written or verbal consent was given by all participants according to the existing guidelines for obtaining consent in each region. Written consent from a caregiver was also obtained for all participants under the age of 18. Most participants received either a cinema ticket or a small monetary incentive (5€/test) for taking part. The tests were performed in Sweden and in Germany from nine different regions:

**Uppsala (Sweden):** 460 participants (age range 6-13) were collected by the Department of Psychology, University of Uppsala between 2003 and 2008. The participating children came from six different schools situated in cities of different size and level of urbanization in central Sweden. A structured interview was used to determine the socio-economic status of the children, including the parent ethnicity, parent marital status, possession of car in the household, and the children's leisure activities. Preliminary analyses showed that the sample was representative of Swedish demographics on these measures. Further information about parts of this sample can be found in Brocki, et al. (60).

**Sävsjö (Sweden):** 125 participants (age range 6-7) were collected at eight different schools in a suburban community in the south of Sweden in 2003.

**Aachen (Germany):** 20 participants (age range 8-12) were collected by the Department of Child and Adolescent Psychiatry, University Hospital of the RWTH Aachen in 2009.

**Marburg (Germany):** 60 participants (age range 7-57) were collected by the Department of Clinical Psychology and Psychotherapy at the University of Marburg in 2009. The participants were recruited by word-of-mouth, distribution of flyers, newspaper adverts and notices at pediatrician practices, supermarkets, youth clubs, and pharmacies.

**Karlstad (Sweden):** 322 participants (age-range 13-53) were collected by the Department of Psychology, Karlstad University, Sweden during 2005-2006. This sample consisted of participants

from two primary schools, one high school, and two workplaces in western Sweden and employees/students at Karlstad University.

**Giessen (Germany):** 80 participants (age-range 18-50) were collected by the Centre for Psychiatry, Justus Liebig University in Giessen in 2009. The participants were recruited by flyers, newspaper adverts, fliers at the university, word-of-mouth advertising, and by using an existing database with healthy participants willing to participate in studies.

**Partille (Sweden):** 350 participants (age-range 12-19) were recruited from a Primary and a Secondary school in Partille, located in western Sweden. The tests were collected in 2011. The area was partly selected because of its ethnic and cultural representativeness of Sweden as a whole.

**Kungälv (Sweden):** 46 participants (age-range 21-66) were recruited at a health centre in Kungälv, located in western Sweden. The subjects came from a range of socio-economic backgrounds and had variable physical fitness.

**Mixed group (Sweden):** 55 participants (age range 20-75) from a range of backgrounds and ages were recruited through word-of-mouth advertising in Stockholm, Gothenburg and Partille. They consisted of university students (17 participants), IT engineers (2 participants), employees at a pharmaceutical company (8 participants), health care professionals (4 participants), university teachers (9 participants), and school staff (15 participants).

The same exclusion criteria were used across all the groups. Teacher ratings and self-rating scales were completed by most participants as part of a larger study. However, previous studies have shown high variability between different informants in rating of symptoms and therefore these ratings were not used to exclude individual participants from the norm database (61). Therefore, only tests from participants with a known psychiatric diagnosis were discarded in the first round of exclusions (2 participants). Four additional tests were excluded due to age above 60. Twenty-four tests were excluded due to technical problems with the equipment. In addition, a qualitative review of all tests was performed to identify tests where the subject clearly had misunderstood or malingered on the test. In total, 93 such tests were identified and discarded.

Thereafter, an analysis of extreme outliers was made on the remaining data to prevent extreme cases influencing further statistical analyses. Tests with any variable score  $\geq 3$  times the interquartile range (IQR) for respective age and gender group were excluded. In total, 74 tests were excluded due to such an extreme outlier performance. Since no external exclusion criteria, by means of teacher ratings and self-rating scales, were used to exclude tests, an Anomaly Detection procedure was used to search for unusual cases based on multivariate test scores. Tests with an Anomaly index  $\geq 1.3$  and with at least 6 parameters with Q-scores above 0 were analyzed for multivariate extreme profiles. Of 32 such tests, 14 were discarded due to test profiles with very poor test performance. In total, exclusions for univariate extreme outlier performances and multivariate outlier profile represented 5.8 % of all performed tests.

The remaining norm database consists of 1307 tests. Of these tests, 576 were performed with the child version (6-12 years) and 731 with the adolescent/adult version (12-60 years). In total, 371

adult tests ( $\geq 18$  years old) were included in the norm database. For details on gender and age distribution as well as mean and standard deviation for respective standard parameter in the norm database, please see tables below.

Age	#	Male	Female
6	148	62	86
7	57	32	25
8	55	22	33
9	72	31	41
10	65	27	38
11	55	28	27
12	124	60	64
Total	576	262	314

*Table 1. Age and gender distribution in the QbTest (6-12) norm group.*

Age range	#	Male	Female
12-13	129	63	66
14-15	149	76	73
16-17	82	33	49
18-19	63	32	31
20-24	61	37	24
25-29	62	29	33
30-39	71	36	35
40-60	114	54	60
Total	731	360	371

*Table 2. Age and gender distribution in the QbTest (12-60) norm group.*



Gender	Parameter	Mean / std	6	7-8	9-10	11-12
Male	Time Active	Mean	60,5	51,9	32,3	24,7
		Std	23,2	19,1	21,9	18,1
	Distance (m)	Mean	22,8	18,5	12,6	9,6
		Std	13,1	9,3	8,7	5,0
	Area	Mean	86,6	70,6	47,8	37,7
		Std	44,4	33,9	35,8	22,5
	MicroEvents	Mean	13358	11477	7785	6179
		Std	5677	4462	4325	3219
	Motion Simplicity	Mean	48,2	46,4	43,6	43,4
		Std	5,4	6,4	8,8	7,0
	Omission Error	Mean	16,8	9,1	2,5	1,6
		Std	13,1	8,7	3,1	2,1
	Commission Error	Mean	22,2	21,2	15,1	9,8
		Std	13,7	14,1	10,1	7,2
	Error Rate	Mean	21,8	16,6	9,6	6,3
		Std	11,5	11,0	6,5	5,1
	RT, no Outliers	Mean	582,2	519,7	419,6	395,3
		Std	86,8	88,7	67,1	51,8
	RT Var, no Outliers	Mean	214,8	167,9	116,6	102,4
		Std	60,3	49,0	29,4	21,3
Female	Time Active	Mean	46,6	42,3	24,0	14,9
		Std	24,0	22,3	17,2	12,4
	Distance (m)	Mean	17,3	14,5	8,9	6,7
		Std	10,5	7,7	4,9	3,6
	Area	Mean	66,5	55,7	34,2	24,6
		Std	40,1	34,7	23,8	17,0

MicroEvents	Mean	10404	9321	5934	4322
	Std	4882	4189	3022	2412
Motion Simplicity	Mean	45,5	45,8	43,8	41,9
	Std	9,3	7,2	8,6	8,4
Omission Error	Mean	13,6	7,0	1,6	1,0
	Std	11,4	7,2	2,0	1,3
Commission Error	Mean	10,4	15,2	9,8	6,6
	Std	8,0	11,9	8,1	5,5
Error Rate	Mean	12,6	11,8	5,8	3,9
	Std	7,7	9,1	4,5	3,1
RT, no Outliers	Mean	660,7	486,6	445,7	399,2
	Std	102,6	74,6	70,5	50,7
RT Var, no Outliers	Mean	205,5	139,1	111,0	94,2
	Std	48,3	34,3	25,6	24,2
Norm RT Var, noOutliers	Mean	31,0	28,7	25,0	23,5
	Std	5,0	6,0	4,0	4,5

Table 3. Mean and standard deviation for the standard parameters in the QbTest (6-12) norm group.

The parameters Distance, Motion Simplicity, Error rate are used only in QbTest not in QbCheck.

Gender	Parameter	Mean / std	12-13	14-15	16-17	18-19	20-29	30-60
Male	Time Active	Mean	17,2	11,9	7,1	4,6	4,2	4,8
		Std	13,5	12,1	7,1	5,4	4,5	5,7
	Distance (m)	Mean	6,8	6,1	4,5	3,7	3,4	3,3
		Std	3,4	4,1	2,1	1,5	1,4	1,5
	Area	Mean	25,8	23,2	15,0	10,4	8,2	7,9
		Std	18,4	22,3	13,5	7,4	6,9	7,0

	MicroEvents	Mean	4406	3619	2478	1932	1768	1794
		Std	2459	2535	1557	1190	1086	1231
	Motion Simplicity	Mean	41,1	39,4	34,7	32,1	31,2	31,9
		Std	7,9	10,3	11,5	8,0	9,3	9,4
	Omission Error	Mean	13,1	9,5	5,7	4,8	5,3	4,5
		Std	11,1	7,6	5,2	4,2	5,8	5,3
	Commission Error	Mean	1,9	1,9	1,3	,7	,7	,7
		Std	1,4	1,6	1,0	,7	,7	,7
	Error Rate	Mean	4,7	3,8	2,4	1,8	1,8	1,7
		Std	3,4	2,6	1,7	1,3	1,8	1,5
	RT, no Outliers	Mean	594,9	569,8	545,6	512,3	512,0	539,1
		Std	89,9	103,4	105,5	101,5	92,6	97,9
	RT Var, no Outliers	Mean	197,0	182,4	152,5	135,1	132,9	126,7
		Std	45,0	47,0	42,1	38,0	38,2	36,3
	Norm RT Var, noOutliers	Mean	33,2	32,1	27,8	26,2	25,9	23,8
		Std	6,3	6,2	5,1	4,9	5,5	6,2
Female	Time Active	Mean	10,5	9,9	5,0	8,0	3,4	3,7
		Std	9,4	8,5	5,8	7,7	4,8	4,3
	Distance (m)	Mean	5,2	5,1	3,5	4,7	3,1	3,1
		Std	2,4	2,7	1,6	2,3	1,3	1,2
	Area	Mean	18,1	18,7	10,8	16,1	6,6	7,5
		Std	13,3	15,6	9,0	12,1	6,2	5,9
	MicroEvents	Mean	3320	3114	1934	2757	1614	1666
		Std	1834	1829	1273	1675	1118	989
	Motion Simplicity	Mean	40,8	42,3	36,4	40,1	30,5	33,2
		Std	8,8	9,9	9,5	11,2	8,3	9,0
	Omission Error	Mean	9,8	10,6	6,7	7,3	3,6	3,8

	Std	9,1	9,3	5,9	7,4	4,8	4,7
Commission Error	Mean	1,9	1,6	,7	,6	,5	,5
	Std	1,7	1,3	,6	,6	,6	,6
Error Rate	Mean	4,0	3,9	2,2	2,3	1,3	1,3
	Std	2,9	3,0	1,7	2,1	1,4	1,4
RT, no Outliers	Mean	588,7	569,1	557,6	548,1	519,4	569,4
	Std	97,2	103,8	74,7	79,6	98,7	99,4
RT Var, no Outliers	Mean	186,9	175,8	153,8	148,2	123,8	132,5
	Std	48,2	47,6	35,4	35,8	33,7	39,9
Norm RT Var, noOutliers	Mean	31,8	30,9	27,7	27,2	23,9	23,4
	Std	6,4	6,3	5,7	5,6	5,5	6,3

Table 4. Mean and standard deviation for the standard parameters in the QbTest (12-60) norm group.

## 6.2. ADHD Normative Sample

To develop the variable ADHD Total Symptom Score, tests from the normative individuals described above and a clinical sample of individuals diagnosed with ADHD were used. Below is a description of the clinical sample called the ADHD normative population.

The child part of the ADHD normative population consists of 86 children aged 6.9 to 12.9 years, diagnosed with Attention Deficit Hyperactivity Disorder according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, 2004). The ADHD-group had been referred for neuropsychiatric assessment to the Child Neuropsychiatric Clinic (CNC), a regional and national clinic for ADHD and other neuropsychiatric disorders in Gothenburg, Sweden. The patients were included if they were diagnosed with ADHD based on a neuropsychiatric assessment that included examination by child psychiatrist, psychologist and educationalist according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, 2004). Patients with Mental Retardation, Autism Spectrum Disorders or other Pervasive Developmental Disorders as well as patients under medication with central stimulants or atomoxetine at test occasion were excluded.

The adolescent/adult part of the ADHD normative population included 135 adolescents and adults aged 12.5 to 53.3 years diagnosed with Attention Deficit Hyperactivity Disorder according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, 2004). Diagnostic assessments for ADHD were performed at three separate psychiatric clinics; the NU-Health Care in Västra Götaland,

Sweden, the psychiatric division of the County Council of Värmland, Sweden and the Child Neuropsychiatric Clinic (CNC), a regional and national clinic for ADHD and other neuropsychiatric disorders in Gothenburg, Sweden. The CNC included mainly adolescent patients (n=95) with a mean age of 16.7 years. The two other clinics included mainly adult patients (n=55) with a mean age of 33.4. The diagnostic assessments were performed with similar neuropsychological procedures at the different psychiatric clinics and included for example tests of memory, executive functioning and intelligence, interviews, observations and somatic examinations.

Patients from CNC (mainly adolescent group) were included if they were diagnosed with ADHD as an outcome of a neuropsychiatric assessment that included examination by child psychiatrist, psychologist and educationalist. Patients with Mental Retardation, Autism Spectrum Disorders or other Pervasive Developmental Disorders as well as patients under medication with central stimulants or atomoxetine at the test occasion were excluded. For the two adult ADHD-groups, the inclusion criteria were diagnosis of ADHD according to DSM-IV, described chronic course of ADHD symptomatology from childhood to adulthood with some symptoms present before seven years of age and continue to meet DSM-IV criteria at the time of assessment, accepted withdrawal of central stimulant treatment 24 hours before testing. Exclusion criteria for this group were any clinically unstable psychiatric condition including, but not limited to, acute mood disorder, acute bipolar disorder, and acute obsessive-compulsive disorder (OCD) or anti-social personality disorder; central stimulant treatment within 24 hours of participation and not meeting the diagnostic criteria of ADHD in DSM-IV.

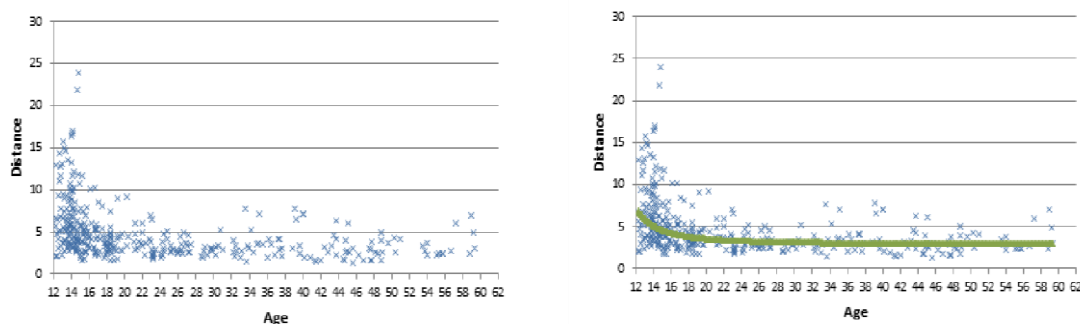
Age	#	Male	Female
6-8	23	16	7
9-11	48	37	11
12-14	39	30	9
15-17	39	25	14
18-30	39	19	20
31-60	33	13	20
Total	221	140	81

*Table 5. Age and gender distribution for the QbCheck ADHD norm group*

## 7. Age and Gender Adjusted Standard Scores

This section describes how raw scores from the normative reference population, described in the previous chapter, have been converted into normalized standard scores. Although QbCheck doesn't utilize the child version of the test in individuals above 11 years old, normative child tests performed by individuals aged 12 have been used in the regression analysis of the child test in order to secure adequate regression curves.

QbTest performance is associated with age and gender (60), though the age effects become less pronounced in adulthood. The association with age is illustrated in the figure 10 showing normative raw-score data plotted against age for the QbTest parameter *Distance* in males.



*Figure 10 (left). Scatter plot for the QbTest parameter Distance in males aged 12-60. Figure 11 (right). Regression line for the parameter Distance in men aged 12-60.*

One commonly used method to standardize a test is to calculate average scores and standard deviations for specific age and gender groups. A disadvantage with that method is that it results in sudden jumps in performance when the subject changes age-group. Also, the age correlation becomes more static. A more elegant way to describe the age dependent differences in performance is regression analysis. This has the advantage that no age spans needs to be defined. Instead the age dependent differences in performance are defined by the regression line so that any expected variable could be calculated given a specific age. Therefore, regression analysis has been used in order to standardize the data in QbTest. The use of a smooth regression line is especially important when multiple tests in a given patient are performed over time. Figure 11 shows the curvilinear regression line for the QbTest parameter *Distance* in males.

In general, performance tests tend to have dispersions from normality which needs to be corrected for. In QbTest, the Box-Cox transformation (62) was used to address this issue since it is a well-established method that for example has been used in the Swedish weight and growth curves (63).

In the test reports, the standard score (Q-Score) shows the difference between the test-persons raw-score and the mean raw-score for the age and gender adjusted normative group expressed as standard deviation. Raw scores that are exactly equal to the mean for the normative group is equivalent with a Q- Score of zero.

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