

Milenia *QuickLine* Total IgE (MQTE) and Milenia POCScan (MSCAN) reader: Clinical Evaluation and Method Comparison

1. Aim of the study

The aim was to show that Total IgE concentrations determined by the rapid test/reader-system (MQTE/MSCAN-system) directly from whole blood are useful for calculating the Xolair dosis in a near patient-setting.

For reference Total IgE concentrations were determined from corresponding serum samples with Phadia UniCAP system. The ImmunCAP system is a well established laboratory method and is the worldwide leading *in vitro*-diagnostic device (IVD) in allergy.

2. In vitro diagnostic devices

In the following table the key features of the two IVDs are compared, i.e. Milenia QuickLine Total IgE and Phadia ImmunoCAP Total IgE..

Feature	Phadia ImmunoCAP Total IgE	<i>Milenia QuickLine Total IgE</i>
Assay type	Enzyme-linked immunoassay	<i>Immunochromatographic assay</i>
Details of test performance	Several incubation and wash steps, performed by a automatic system	<i>Two-step assay: add blood and assay buffer; no wash steps</i>
Sample	Serum, plasma	<i>(Capillary) blood</i>
Sample volume	40 µL	<i>20 µL</i>
Dynamic range	2 – 5,000 U/mL	<i>30 – 2,000 U/mL</i>
Calibration	2 nd International WHO-Standard 75/502	
Overall test time	2.5 hours	<i>7 minutes</i>

3. Patients

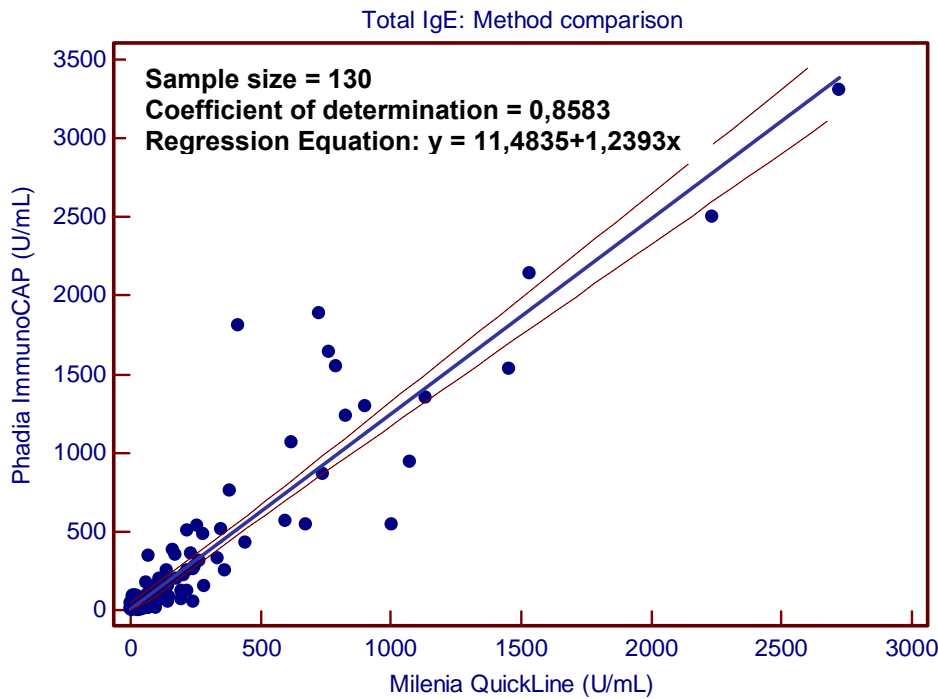
Totally 130 samples has been analyzed in the Milenia QuickLine Total IgE (blood) and the Phadia ImmunoCAP Total IgE (corresponding serum). Additionally actual body weight was measured.

Applying Total IgE concentrations as calculated by the two IVDs and the actual body weight individual Xolair dosis of 95 patients was determined as described in the Xolair package insert. The remaining 35 patients showed Total IgE levels which were outside the Xolair dosis regime, i.e. < 30 U/mL and > 700 U/mL..

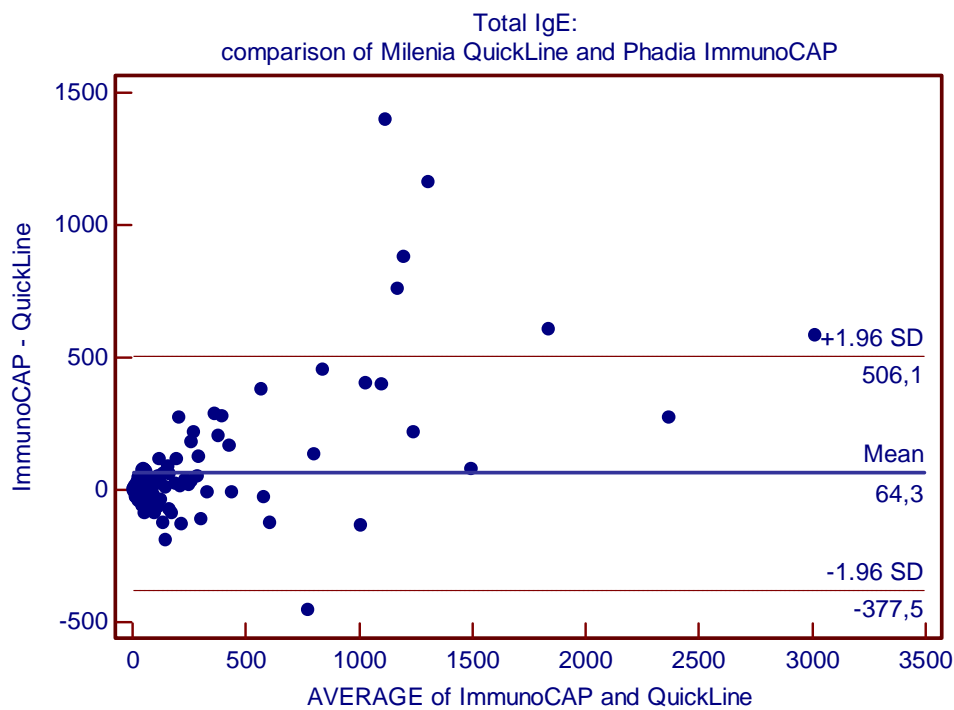
4. Results

4.1. Comparison of the diagnostic tests

Despite the huge differences in all details of the assay format and test performances a good correlation is detected as shown below ($R^2 = 0,8583$; slope 1.2)



In the Bland/Altman-Plot the rational similarity of the results of both assays also is demonstrated.



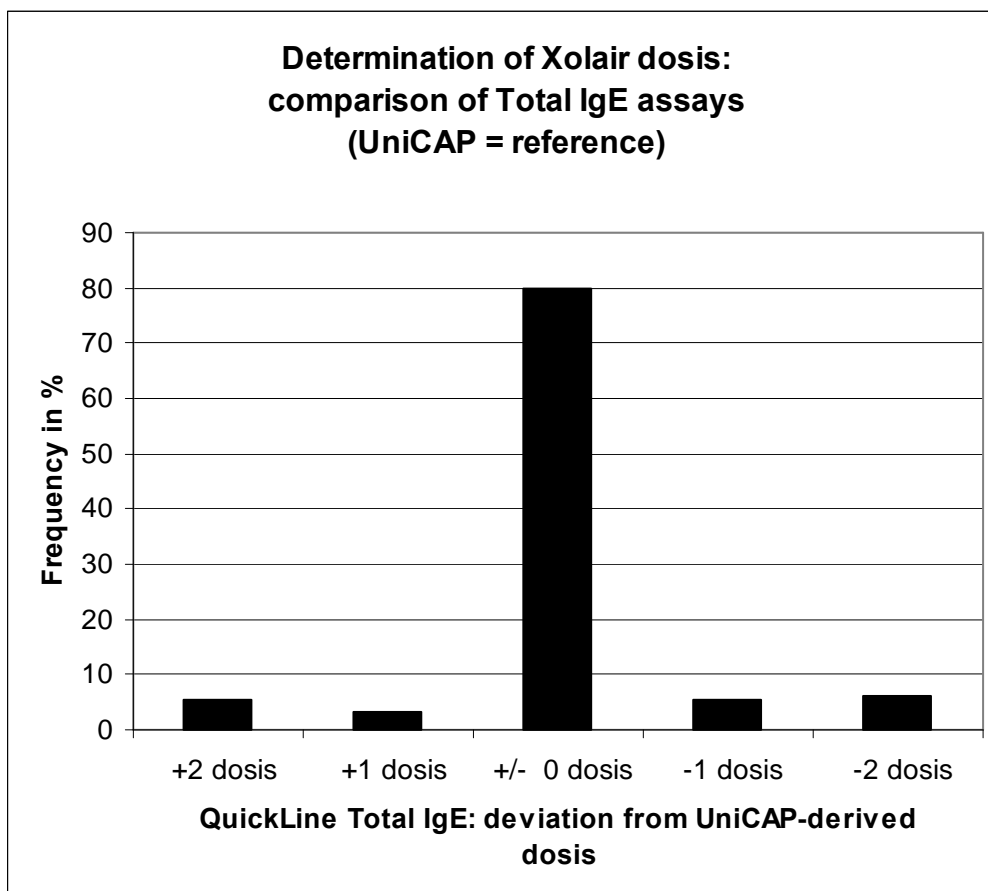
4.2. Xolair dosage calculated with the various IVDs

For 95 patients Xolair dosage has been calculated by applying the IgE concentrations determined with both IVDs, the rapid test Milenia QuickLine Total IgE directly from blood and the enzyme-linked immunoassay Phadia ImmunoCAP Total IgE from serum, resp. .

The results are summarized in the following table:

		Xolair (mg/dosis) calculated from Phadia ImmunoCAP results				N
		150	225	300	375	
Xolair (mg/dosis) calculated from Milenia QuickLine results	150	51	2	4	0	57
	225	1	5	3	2	11
	300	5	2	19	0	26
	375	0	0	0	1	1
	N	57	9	26	3	95

Eighty percent of the samples (76/95) revealed identical Xolair dosage. This result clearly shows the efficacy of the Milenia QuickLine Total IgE for the doctor's office application. The remaining 19 samples showed discrepancies as indicated in the graph below.



Eight samples (8/95; 8,4%) showed one Xolair dosis difference if the Total IgE levels have been determined with the rapid test; 11 samples (11/95; 11,6%) revealed a discrepancy of two Xolair dosis when applied Milenia QuickLine Total IgE as tool for Total IgE measurement.

5. Summary

The Milenia QuickLine Total IgE demonstrated the following features:

- **high correlation** ($R^2 = 0.858$; slope 1.2) with a well established laboratory method for measuring Total IgE (Phadia ImmunoCAP Total IgE) in terms of **IgE concentrations (U/mL)**
- **high correlation** (80%) with the Phadia ImmunoCAP Total IgE in terms of calculated **Xolair dosis**
- **dynamic range** from 30 U/mL to 2,000 U/mL Total IgE
- **short test time** of 7 minutes for determining Total IgE concentrations **directly from whole blood** without further processing
- **good reproducibility** ($CV < 15\%$)
- **simple handling** of both, the rapid test Milenia QuickLine Total IgE and the POCScan Reader
- needs a **very short hands-on time** for test performance
- all items for cleaning the finger tip (**alcohol swab**), finger tip puncture (**lancet**), pick up of calibrated blood volume (**transfer pipet**) and dressing the wound (**adhesive tape**) are **supplied with the test kit**
- can easily be performed at the **point-of-care** in the **doctor's office**